Healthcare Enforcement & Litigation

Contributing editors
Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman

2016

GETTING THE DEAL THROUGH

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Healthcare Enforcement & Litigation 2016

First edition

Getting the Deal Through is delighted to publish the first edition of *Healthcare Enforcement & Litigation*, which is available in print, as an e-book, via the GTDT iPad app, and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured.

Getting the Deal Through titles are published annually in print and online. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman of Skadden, Arps, Slate, Meagher & Flom LLP, the contributing editors, for their assistance in devising and editing this volume.

GETTING THE DEAL THROUGH

London
September 2015

Global Overview

Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman
Skadden, Arps, Slate, Meagher & Flom LLP

Getting the Deal Through's inaugural *Healthcare Enforcement & Litigation* is a practitioner's guide to how government agencies around the world regulate and investigate the healthcare industry, and the unique legal issues presented in the jurisdictions discussed in this edition. The management of cross-border healthcare investigations pose myriad challenges for today's global healthcare corporations. Understanding how the healthcare industry is regulated in different jurisdictions, as well as knowing how such investigations are likely to play out, is crucial to successfully managing business operations in those countries. This book aims to address, on a jurisdiction-by-jurisdiction basis, the questions that arise regarding the way healthcare companies are regulated and the manner in which enforcement of the industry is carried out.

Recent prosecutions of large international healthcare companies underscore the importance of these issues to corporations operating globally today. For more than a decade, the United States Department of Justice has taken an aggressive enforcement stance towards the healthcare industry, and has vowed to continue its zealous enforcement when presented with evidence of wrongdoing. This has resulted in billions of dollars in fines and penalties being paid by healthcare companies, criminal liability and follow-on litigation. Such fines are frequently split between the various law enforcement and regulatory agencies that participate in the investigation. Remedial measures imposed are likewise significant, with companies often required to enter into corporate integrity agreements or, in some cases, to divest of the business that engaged in wrongdoing. As the amount of money the federal government spends on healthcare increases, one can expect that government enforcement of the industry will likewise increase.

The cases brought by the Department of Justice have received widespread international attention, and have prompted law enforcement authorities around the world to increase their own scrutiny of the healthcare industry. Indeed, because the government is a primary payer for healthcare in many countries, there is particular interest in trying to detect and punish perceived misconduct. Toward this end, law enforcement entities around the world are increasingly working collaboratively with one another on these investigations. For example, over the course of six years, Siemens AG reached settlements with government entities in Germany, Greece, Italy, Nigeria and the United States and with the World Bank concerning allegations of bribery and corruption. Moreover, the United States and Germany not only coordinated their investigations but also simultaneously announced their separate settlements with Siemens.

There is every reason to expect aggressive law enforcement and regulatory investigation to continue in the United States for the foreseeable future, as well as for collaboration among international law enforcement entities to continue and to increase. Healthcare entities suspected of wrongdoing, regardless of their size or global reach – and perhaps because of it – are likely to face multiple inquiries from law enforcement and regulatory agencies in different countries. Such investigations are expensive, time-consuming and challenging for management, employees and counsel alike. We hope that this first edition of *Healthcare Enforcement & Litigation* will serve as a valuable introduction to the unique features of law and practice that shape civil and criminal investigations across multiple jurisdictions.

Austria

Rainer Herzig and Michael Heiny

Preslmayr Rechtsanwälte

Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The Austrian jurisdiction provides for a system of mandatory social insurance, which covers almost the entire population.

Delivering healthcare services is considered to be a public task. Hence, more than two-thirds of Austria's healthcare system is funded through social insurance contributions and general tax revenue.

As owners of the hospitals, the provinces are not only responsible for investment and maintenance costs, but also contribute towards the running costs of the hospitals.

According to data from 2014, those who are insured contribute approximately 83.4 per cent (€13.640 billion) to the national health insurance. Earnings from prescription fees for medicines (which currently amounts to €5.55 per pack of pharmaceutical products) contribute 2.3 per cent (€387 million); compensation payments by the federal government contribute 8.7 per cent (€1.418 billion); capital of the equalisation fund of the health insurance agencies contributes 1.7 per cent (€276 million); yield on assets contributes 0.2 per cent (€41 million); and finally another 3.7 per cent of miscellaneous income (€602 million) contributes to the national health insurance agencies' total annual income of €16.364 billion.

The insured are entitled to receive healthcare covering medical care, medicines and medical devices. Healthcare needs to be 'sufficient, appropriate and non-excessive'. Basically, the insured persons make no further payments but have an obligatory contribution to a social security institution. However, there are a variety of exceptions depending on the particular competent health insurance institution, the relevant type of medical treatment and other parameters. For instance, persons insured with the Austrian Insurance Fund for Civil or Public Servants must pay a treatment contribution of 20 per cent of the contractually agreed tariff.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Outpatient healthcare delivery in Austria is characterised by self-employed physicians. Patients also have direct access to outpatient clinics. Additionally, outpatient departments are available in hospitals. The increasing importance of hospital outpatient departments is creating a distinct mix of private and public engagement in primary and ambulant care.

A location plan elaborated by health insurance institutions and medical practitioner associations defines the number and regional distribution of contract doctors (physicians who enter into a contract with health insurance institutions). Contract doctors are paid by the health insurance institutions for the services delivered to patients, whereas patients consulting a non-contracted doctor have to pay for the service and will be refunded only 80 per cent of the fee which would be paid by the health insurance fund to a contract doctor. In addition, the contracted fees are considerably lower than the fees charged by a non-contracted physician.

The group of self-employed health professionals includes midwives, physiotherapists, those with advanced training in health and nursing care, dieticians, ergotherapists, speech therapists, audiologists, psychotherapists, clinical psychologists and health psychologists.

Independent outpatient clinics are basically hospital institutions, but their services are important for primary health care delivery.

Patients can utilise hospital outpatient departments directly by showing a health insurance card. Certain outpatient departments are available for emergency and acute care, as well as for post-treatment and preventive care.

Inpatient health care is delivered in public hospitals, which are mainly operated by the provinces. However, private hospitals are also available. Persons insured with a social health care institution do not have to pay for treatment in public hospitals.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The Medicinal Products Act (AMG) implementing the community code relating to medicinal products for human use (Directive 2001/83/EC) regulates the field of medicines. The Medical Devices Act (MPG) implementing the directives on medicinal products and in vitro diagnostics deals with instruments, equipment and other devices which are designed for certain medical purposes. The Medical Practitioners Act contains provisions on the medical profession, whereas the Pharmacy Act covers pharmacy-related issues. The Hospitals Act provides the framework for the operation of hospitals and sanatoriums on a federal level, whereas the regional laws of the nine provinces provide for the details of these institutions operated in their territory.

The General Social Security Act governs the requirements of healthcare entitlement, the contributions of the insured, the benefits of social insurance and partially even the organisation of healthcare infrastructure. The Public Officers Health and Accident Insurance Act contains special provisions for public officers, the Commercial Social Insurance Act applies to the social insurance of contractors, the Farmers Social Insurance Act applies to the social insurance of farmers and the Social Insurance of Self-employed Persons Act applies to freelance professionals.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Austrian Federal Office for Safety in Health Care (BASG) and the Austrian Medicines and Medical Devices Agency (AGES MEA) supervise the medicinal market and enforce the applicable laws to medicines and medicinal products.

In respect of health insurance benefits, the primarily competent agencies are the health insurance institutions: nine regional health insurance institutions (one in each province), six occupational health insurance institutions and four other health insurance institutions.

All social insurance funds are members of the Association of Austrian Social Security Institutions which has a coordinating function and negotiates agreements with the associations of healthcare providers.

The Austrian Chamber of Physicians (see also questions 21 and 33) is responsible for the education of physicians and quality management in respect of medical professionalism. Austrian dentists are organised in a separate Chamber of Dentists. The Austrian Association for Quality Assurance and Quality Management in Healthcare (ÖQMed) supports the Austrian Chamber of Physicians in its activities relating to quality management.

Pursuant to the Hospitals Act, the district administration authorities and the governor of the particular province are in charge of sanitary surveillance (eg, hygiene, quality assurance in hospitals, documentation,

organisation and technical security). The provincial governments are responsible for the economic governance of hospitals within their territory.

5 What is the scope of their enforcement and regulatory responsibilities?

As the umbrella organisation of the social insurance funds, the Association of Austrian Social Security Institutions is responsible for safeguarding general social security interests and for representing the social insurance institutions in collective matters (ie, concluding contracts with doctors, hospitals, representation abroad, etc).

The major tasks of the particular health insurance institutions are providing services in matters connected with health insurance coverage, assessment and collection of contributions by employers to the social insurance as well as award and payment of benefits from this insurance.

The Chamber of Physicians is legally authorised to issue ordinances concerning, among others, hygiene or education of medical practitioners, to grant and revoke the authorisation to exercise professional practice as well as to elaborate guidelines and codes of conduct.

With regard to sanitary surveillance, district administration authorities or governors may (with or without announcement) inspect hospitals and sanatoria, including the entire site and all facilities or equipment and inspect files and records. In case the district administration authorities notice infringements of sanitary regulations, they file a report with the competent governor who may issue a notice to eliminate the instance of infringement.

Regarding the responsibilities of the BASG, see questions 6 and 7.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The BASG is responsible for the regulation of pharmaceutical products. It is an agency subordinated to the Ministry of Health. AGES MEA is a subunit of the Austrian Agency for Health and Food Safety, owned by the Republic of Austria, which provides the BASG with staff and equipment. The BASG issues ordinances regarding the schedule of fees (www.basg.gv.at/en/about-us/fees/). These ordinances state fees for marketing authorisation, flat-rate annual fees, inspection fees, fees concerning the import of medicinal products and other fees, to finance its activities.

7 What is the scope of their enforcement and regulatory responsibilities?

The BASG is responsible for the enforcement of the Act on Medicinal Products, the Medicinal Products Import Act, the Blood Safety Act, the MPG, the Compulsory Prescription Act and the Human Tissue Safety Act. The activities of the BASG comprise admission of clinical trials; marketing authorisation and life-cycle management of medicinal products; pharmacovigilance; quality of medicinal products (before and after marketing authorisation); inspections; market surveillance of medicinal products (legal and illegal market); market surveillance and vigilance of medical devices; haemovigilance; and tissue vigilance. Furthermore, it is empowered to execute inspections of producers and distributors of pharmaceuticals as well as public pharmacies. Staff and equipment for these tasks is provided to the BASG by AGES MEA, which acts in the name of the BASG.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The task of the Federal Competition Authority (BWB) is to maintain and secure competition in Austria. The Competition Commission is an advisory service to the BWB. It consists of eight members and each of them has one deputy. The Federal Cartel Prosecutor also deals with cartels, abuse of market power and merger control. The Cartel Court is the decision-making body in Austria and employs seven professional judges who are supported by 15 lay judges. The Supreme Cartel Court is comprised of one panel, which is composed of three professional judges and two lay judges. The public prosecutors carry out investigations in case of probable cause for criminal offences (ie, fraud or counterfeiting of drugs). See also question 25.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Principally, only one particular agency is responsible for an investigation of the same legal subject. Indeed, real facts may relate to a variety of legal issues, so that parallel competences in respect of the same real facts are possible. For example, if two pharmaceutical companies agree on an allocation of customers, the federal competition authority is in charge of the enforcement of cartel law, whereas the public prosecutor is in charge of the criminal investigation.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Pharmaceutical products are regulated by the AMG, the Ordinance on Medicinal Production Sites, the Medicinal Products Import Act, the Addictive Drug Act and the Pharmacovigilance Regulation and further laws and ordinances.

Medical devices are regulated by the MPG and ordinances based on this act.

The powers of authorities range from the request for relevant data and documentation to the inspection of sites and facilities. According to section 76 AMG, the BASG or appointed experts are entitled to take samples of drugs and to demand access to the relevant sites. Pursuant to section 68 MPG, companies, institutions and persons dealing professionally or commercially with medical devices are subject to monitoring actions. This monitoring covers all security-related, functionality-related or quality-related aspects of medical devices. If necessary (eg, eminent health risk), authorities are legally obliged to ban pharmaceutical products or medical devices.

11 How long do investigations typically take from initiation to completion? How are investigations started?

The overall duration of investigations depends on many factors, such as priority and cause.

Routine inspections are typically announced three to four weeks in advance. The inspection itself typically takes one or two days. Simultaneous with the inspection report by the authority, the interested party is requested to submit a response regarding the inspection findings detailed in the report within four weeks after receipt of the inspection report for hearing. With the final report the inspection is closed and the document will serve as a basis for any further inspection that may be performed.

The average duration of an administrative criminal procedure (initiation to completion, including appeals and remedies) is approximately four months.

Investigations may be initiated ex officio and upon request.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Subjects of an investigation generally have access to the relevant files of the authority. Nevertheless, there are a few exemptions from access to files. For example, in the event of damages to legitimate interests, threats to the function of the authority or damages to the purpose of the proceedings the authority is entitled to refuse access to particular parts of the records.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Austrian agencies have no power to conduct direct investigations of foreign manufacturing sites or proceedings. They are only authorised to request documents, samples or other evidence that proves that sites and proceedings comply with the applicable regulations.

14 Through what proceedings do agencies enforce the rules?

Generally, the BASG holds its own proceedings, which are governed by the General Administrative Procedure Act (AVG) and the provisions of its Rules of Procedure. Certain infringements fall under the jurisdiction of the criminal courts. In respect of these infringements, the Code of Criminal Procedure (StPO) applies. Besides, the administrative authorities deal with minor criminal law provisions. Their proceedings are governed by

the Administrative Criminal Act (VStG). In the event of sufficiently substantiated suspicion or upon the BASG's request, the competent district administration authority will open an administrative criminal procedure. The appeal against a possible fine leading to the appropriate administrative court must be filed with the district administration authority.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Manufacturers or distributors of drugs and medical devices can be confronted with administrative fines for infringements of the AMG or the MPG ranging from €7,500 to €50,000, or a judiciary prison sentence from one to 15 years. Counterfeit drugs must be confiscated, unless the holder shows a credibly legitimate purpose of use and guarantees that the drugs will not be put into circulation. The BASG is entitled to revoke the marketing authorisation of pharmaceutical products if the marketing authorisation holder has been penalised at least three times for the same particular offence. Furthermore, the BASG can withdraw the authorisation to produce, market and control medicinal products as well as it has the power to bar the practice as a qualified person. The BASG is also obliged to take insecure or insufficient medical devices off the market.

16 Can the authorities pursue actions against employees as well as the company itself?

Administrative actions relate both to the company and to the individual employees in charge. As a rule, the probability of a prosecution concerning an individual employee rises with elevated responsibility or a leading position. Also, with regard to criminal law, employees may be subject to official actions. Usually the criminal liability of the company depends on criminal acts or omissions of its employees.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

In proceedings before the BASG the defendant has access to files, may file statements of defence and has the right to participate in the taking of evidence. The defendant can challenge the authority's decision by an appeal. The competent court of appeal is the Federal Administrative Court. Decisions rendered by the Federal Administration Court can be challenged by means of two appeals (*Revision* or *Beschwerde*). These appeals lead to two different supreme courts. The *Revision* leads to the court of administration, whereas the *Beschwerde* leads to the constitutional court.

Concerning administrative criminal procedure, first instance is the particular district administration authority. Its decisions may be challenged by an appeal which leads to the competent regional administrative court. The appeals against decisions of the regional administrative court are the same as the appeals to challenge the decisions of the Federal Administration Court.

The judicial criminal procedure is ruled by the StPO. Criminal judgments are subject to appeal to the appellate court or the supreme court.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Substantial investments in an effective compliance management system enable companies to avoid enforcement activities. Once enforcement actions are opened, it is strongly recommended to obtain professional advice to develop an effective defence strategy.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Besides the ongoing information on defective medicines, supply shortages, messages and safety warnings (www.basg.gv.at/en/about-us/official-announcements), the BASG has recently dealt with the implementation of online marketing of pharmaceutical products, which has been (partially) legalised by section 59a AMG. Recently, a criminal case about the trafficking of counterfeit drugs has drawn public attention to the issue of drug safety via the internet (among others, english.bmf.gv.at/ministry/press/2013-product-piracy-report.html).

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The Association of the Austrian Pharmaceutical Industry (Pharmig) is a lobby group based on voluntary membership. It has published a Code of Conduct containing provisions on general principles, information or advertisement (www.pharmig.at/uploads/PharmigCodeofConductEN2015_14705_DE.pdf). Pharmig is a member of the International Federation of Pharmaceutical Manufacturers and Associations.

Furthermore, Austromed is an association established to promote the interest of companies manufacturing medical devices. The Code of Conduct of Austromed deals with healthcare-related topics such as collaboration and interaction between stakeholders in the medical devices industry, delivery and ethical standards or cartel law (www.austromed.org).

Physicians and pharmacists are members of the respective professional chambers. In each case there are nine provincial and one federal medical or pharmacist chamber. Their main function is to facilitate and to represent the interests of their members. Nevertheless, they also have disciplinary powers ranging from reprovals and fines to the prohibition to exercise the profession. Such sanctions can only be imposed after a formal disciplinary procedure.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

The main regulatory framework for controlling these financial relationships is provided for by section 55a AMG, section 108 MPG, section 53 Medical Practitioners Act, section 35 of the Dentists Act, the Lobbying and Representation of Interests Transparency Act (LobbyG) and several provisions of the Criminal Code.

It is forbidden to offer, grant or promise gifts or any other inducement to healthcare professionals who have authorisation to prescribe drugs. Not only is the offering prohibited, but also acceptance by a physician. Benefits of low value, which are of interest for medical or pharmaceutical practice, are exempted from this interdiction. The MPG contains similar prohibitions regarding medical devices. In addition, the codes of conduct of various interest groups (ie, Pharmig or Austromed) restrict the financial and non-financial support of events for healthcare professionals, set a certain frame for cooperation, oblige suppliers to transparency provisions (documentation or disclosure) and limit the admissibility of mutual benefits.

22 How are the rules enforced?

Enforcement procedures (or consequences) vary from the civil nullity of illegal agreements to ex officio criminal prosecution. Administrative penalties of up to €25,000, and in the event of recurrence up to €50,000, can be imposed by the administrative authorities. Healthcare professionals may also face suspension or debarment by their chamber.

According to the Pharmig Code of Conduct, the competent decision panel is entitled to impose fines in addition to admonition and a cease-and-desist order. In the event of serious violation, a penalty of not less than €5,000 up to a maximum of €100,000 may be imposed on members. In case of qualified violation of certain provisions, the penalty range is increased to €200,000. The fact of violation can be publicly announced or the violating company may be excluded from Pharmig.

Companies which do not comply with the Code of Conduct of Austromed possibly face exclusion from the association.

Moreover, competitors can sue infringers for cease-and-desist under the Unfair Competition Act. Such proceedings are highly efficient, since the claimant may request an interim injunction.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

According to article 9 of the Pharmig Code of Conduct, as of 2015 pharmaceutical companies that are members to Pharmig are obliged to disclose any and all transfers of value (research, donations, events, etc) granted to healthcare professionals or institutions. The information shall be disclosed in German or English on a publicly available website for a duration of at least three years. Austromed members have to document service

relationships or valuable transfers to employees of healthcare institutions in writing, and request the approval of the relevant employer.

Pursuant to section 9 LobbyG, the Ministry of Justice operates a register in which particular persons and legal entities have to be enlisted. This register contains various information such as personal data, the beginning and termination of recorded occupation or even turnover arising from lobbying activities. Generally the reported data is available to the public, although certain information is explicitly excluded from public accessibility.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Healthcare providers are obliged to carry out a self-evaluation which may be reviewed by the authorities (in particular the ÖQMed) upon request by the Chambers of Physicians, social insurance funds, patient organisations or other administrative authorities. The ÖQMed may conduct site inspections and inspect relevant documents. The proceedings are particularly regulated by the Health Quality Act, sections 118c-f of the Medical Practitioners Act, the Ordinance on Quality Assurance and the Ordinance on Pharmacy Practice.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Quality control is guaranteed by routine examinations. Ordinary inspections of pharmacies and evaluations of physicians are obligatory once every five years. Random re-examinations, as well as controls because of a specific occasion, complete the authorities' competences to monitor and enforce the applicable legal provisions. The particular duration of investigations depends on the individual case. Empirically, routine controls are finalised comparatively fast, provided that no significant deficit is detected. They can be completed within one to three weeks. In the event of serious legal infringements, investigations take more time.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

See question 13.

27 Through what proceedings do agencies enforce the rules?

The proceedings with public authorities are basically ruled by the AVG and the VStG (see question 15). In the event of material infringements, criminal courts may have jurisdiction over healthcare providers. The particular associations usually install disciplinary councils (eg, the Disciplinary Council of the Chamber of Physicians) which hold their own proceedings respecting the limits of their jurisdiction.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

The scope of sanctions and other enforcement measures ranges from monetary fines to reprovals, an instruction to undergo additional professional training, an order to restore legal status and temporary or permanent debarment.

29 What defences and appeals are available to healthcare providers in an enforcement action?

See question 18.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Vocational education and training as well as meticulous self-evaluation, quality control and an effective compliance management system minimise the exposure of healthcare providers to enforcement activities. Once enforcement actions have started, it is strongly recommended to obtain professional advice.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Non-serious infringements typically cause monetary sanctions or reproval. Recently the health insurance institutions focused on 'mystery shopping'. They send healthy persons to healthcare providers (primarily physicians) in order to investigate if the healthcare provider is willing to issue incorrect medical certificates or actually provided the treatments charged to the social insurance fund. In case of such incorrect medical certificates, the health insurance institution terminates its contract with this healthcare provider. On 8 July 2015, the National Council enacted the Anti-Social Fraud Act among others, in order to affirm the admissibility of 'mystery shopping'.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The Austrian Chamber of Physicians is the statutory association of medical practitioners. It represents their professional, social and economic interests, but also constitutes the competent national authority for physicians. The responsibilities of the chamber comprise, among others, the following areas:

- admission to and administration of the medical register;
- involvement in medical training;
- quality assurance of medical practices;
- the conclusion of contracts with social insurance institutions and of collective agreements; and
- the execution of disciplinary legislation and arbitration.

The Austrian Chamber of Pharmacists is the legal professional representation of pharmacists. Membership to this chamber is mandatory.

Moreover, the Dentist Chambers (one federal and nine provincial chambers) represent the interests of dentists and also have partial sovereign power. For instance, the Austrian Dentist Chamber decides on the admission and revocation of authorisation, manages education or conducts negotiations with health insurance agencies.

Apart from statutory chambers, there are interest groups that represent and promote their members' interests, such as the Austrian Federal Association for Psychotherapy.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

General and individual contracts between health insurance institutions and healthcare providers usually specify the healthcare services, which the provider shall undertake, and the remuneration he shall receive, but basically they do not include contractual penalties for improper performance. Nevertheless, eminent poor performance is a breach of contract and the healthcare provider may lose entitlement to the remuneration as agreed. Furthermore, poor performance may even cause the termination of individual contract by act of law or declaration. According to section 59c of the Hospitals Act, the Federal Health Agency may retain financial resources for hospitals or sanatoria if substantial breaches of scheduled plans or substantial quality and documentation deficits are noted.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

The enforcement of healthcare regulation is assigned to the competent public or self-governing authorities. Citizens and other private bodies are only entitled to suggest or encourage the initiation of formal proceedings by the authorities. However, claims for damages because of the infringement of healthcare regulation are possible because, in the field of tortious liability acts, violating protection acts is wrongful. Many provisions of healthcare regulation have the quality of such a protection act. Furthermore, competitors and certain associations of enterprises and consumers may sue for cease-and-desist under the Unfair Competition Act because of infringements of healthcare regulations or law.

Update and trends

Recent developments have intensified the discourse on price-fixing in context of pharmaceutical products. Of primary interest is the question of whether national economic benefits arising from more effective pharmaceutical products shall be taken into consideration in the field of fixing reimbursement prices. On one hand innovative medicines support the maintenance of working capacity, but on the other hand the current system of social security is not organised for such elevated prices. Also the online marketing of medicines promises to be a noteworthy topic in 2015 and 2016.

35 What is the framework for claims of clinical negligence against healthcare providers?

The legal requirements for a successful claim are the existence of protected rights and interests, causation, wrongfulness and fault. The physical and mental integrity is such that a protected right and its damage already indicates wrongfulness. Healthcare providers are considered experts in respect of their profession, hence the standard of fault is strict. They are liable for the care of a common healthcare provider, or in other words they have to expect to pay compensation if their healthcare services are not state of the art. The injured person is entitled to claim compensation for medical costs, the loss of income and for pain and suffering. The compensation for pain and suffering varies between €100 and €330 per day depending on the gravity of pain and suffering. There is no specific reluctance to penalise quasi-public healthcare providers.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

According to the Product Liability Act, the producer is liable for damages caused by a defect in his or her product which has been put into circulation. Fault on the part of the producer is not required. Claims under the Product Liability Act are restricted to loss of property exceeding €500; however, there is no equivalent limitation for personal injury.

The Product Liability Act does not limit the injured person's claims for damages pursuant to other statutory or contractual provisions.

37 Are there any compensation schemes in place?

In the event of slight negligence, the tortfeasor just has to provide compensation for the actual loss. In case of gross negligence or intent, the injured person can claim full compensation. Nevertheless, if the injured person suffered bodily injury, the tortfeasor is liable for compensation for pain and suffering.

With respect to bodily injury, the legal practice has developed certain schemes of compensation. This compensation scheme requires a classification including three categories: heavy pain, medium pain and light pain. For each day of particular pain, the injured person receives a corresponding amount of compensation (currently about €330–€300 per day of heavy pain, €220–€200 per day of medium pain and €110–€100 per day of light pain).

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Austrian law does not provide for class actions. Nevertheless, particular entities, especially consumer organisations (eg, the Austrian Consumers' Association) have already brought claims on behalf of a multitude of persons.

The individual persons assign their claims to one entity, who subsequently brings a common lawsuit over the assigned claims. The monetary benefits are redistributed among the class. This specific tort litigation has occurred in connection with cosmetics (lotion against neurodermatitis contained an aggressive form of cortisone), hepatitis C virus infection because of plasma donation, and magnetic therapy devices.

Since the Austrian jurisdiction lacks specific provisions on class actions, the general rules of civil procedure are applicable. Each party has to prove the facts it is relying on to substantiate its case. Consequently, the entity whom the individual persons have assigned their claims to bears the burden of proof regarding every single assigned claim. However, the admissibility of the prima facie evidence and other exceptions concerning the standard of evidence facilitates the taking of evidence.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Arbitration commissions adjudicate on protests and petitions in the context of general or individual contracts between health insurance institutions and healthcare providers. The Federal Administration Court adjudges complaints in connection with the Reimbursement Code, which is a register enlisting drugs that the health insurance institutions refund. Protests in connection with the termination of individual contracts between health insurance institutions and healthcare providers need to be filed within two weeks after the declaration of termination. Complaints concerning the have to be filed with the Association of Austrian Social Security Institutions within four weeks after receipt. These arbitration commissions and courts of appeal may overrule or approve former decisions as well as decide the case autonomously. Complaints can succeed either on the grounds of improper application of material or procedural law. The arbitration commissions and courts may either decide on the merits or remand the case for re-evaluation.

40 Are there any legal protections for whistle-blowers?

Recent events have accelerated the process of elaborating legal protection for whistle-blowers. However, an extensive whistle-blower law has not been planned or implemented yet.

Currently the Ministry of Justice operates a whistle-blowing website, which allows reporting of suspicious observations to the Public Prosecutor's Office against Corruption and White-Collar Crime anonymously. An amendment that approves the admissibility of this whistle-blowing system, has already passed the competent parliamentary committee and is planned to come into effect in 2016.

41 Does the country have a reward mechanism for whistle-blowers?

Whistle-blowers do not receive any direct financial reward for communicating their observations to the authorities, but if they are involved in criminal cases their cooperation with the law enforcement agency effects certain advantages. These advantages can be mitigation or exemption from punishment (eg, sections 209a and 209b StPO or section 29 of the Financial Criminal Act).

42 Are mechanisms allowing whistle-blowers to report infringements required?

Companies are not obligated by law to install whistle-blowing mechanisms, but it is advisable to implement and maintain sufficient organisational, technical and personnel measures to guarantee compliance with the applicable laws and regulations. According to the Entity Responsibility Act, companies risk punitive fees if criminal actions are made possible or facilitated because of organisational negligence.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Prosecutors and law enforcement authorities cooperate with their foreign counterparts. The intensity of cooperation depends on the particular issue and the state that these counterparts are attributed to. If critical data is concerned (eg, health data of individuals) or the authority is not attributed to an EEA or EU member state and Switzerland, cooperation is only practised to a limited extent.

For instance, the BASG and AGES MEA collaborate with the European Directorate for the Quality of Medicines in order to combat the counterfeiting of drugs or comparable crimes. This cooperation also embraces a network of official medicine control laboratories to effectively allocate limited resources. The collaboration between AGES MEA and the neighbouring DACH-states (Germany, Austria and Switzerland) is particularly well established.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

Investigations will be initiated in Austria as soon as Austrian authorities become aware of foreign investigations that may have an effect on the Austrian market or involve Austrian interests. The agencies which are responsible for the enforcement of the relevant laws and regulation are obliged to open proceedings if they become aware of facts that raise certain suspicion. However, if the case has no sufficient connection to Austrian jurisdiction, proceedings will not be completed.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Apart from rare immunities or miscellaneous exemptions from Austrian jurisdiction, foreign companies and nationals may be pursued for infringements of Austrian healthcare law and regulations if these infringements have an effect on the Austrian market or cause damage to Austrian nationals. However, activities carried out in Austria and domestic property are generally subject to domestic jurisdiction.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

As provided in Brazilian Federal Constitution of 1988, health is a right of all and a duty of the state. It must be guaranteed by means of social and economic policies, with the purpose of reducing the risk of illness and other hazards.

The Federal Constitution of 1988 also allows for the complementary existence of the private sector in health assistance.

The public healthcare system was introduced by the Brazilian Federal Constitution of 1988 and is named the Unified Health System (SUS). The SUS provides for free and universal coverage, and is funded through the social welfare budget of the Union, the states, the Federal District and the municipalities, as well as from other sources such as fines, fees and donations. After a complex judicial dispute, the Supreme Court of Justice ruled that the government has the constitutional duty to provide free medication for those that cannot afford the respective treatment. The federal government, the states and the municipalities are responsible for the free distribution of medicines and medical devices. The Ministry of Health has a programme for the free distribution of essential and specialised medicines; the list of the medicines and health technologies covered is reviewed periodically.

The SUS also provides financial support to philanthropic and not-for-profit organisations, and to private health institutions by financial grants and reimbursement of medical procedures, devices and medicines upon the signature of an agreement between the private entity and the Ministry of Health. The reimbursement values are listed, along with the types of procedure and therapy that are covered.

The private system is funded by out-of-pocket payments made by individuals (users) or by private health insurance. The coverage of health insurances is also defined according to a list of covered therapies and medical procedures issued by the Supplementary Health Agency.

Private healthcare in Brazil used to be restricted to national investments. However, Federal Law No. 13,097/2015 allows the direct or indirect participation of foreign capital in private healthcare companies that operate general or specialised hospitals, polyclinics, and general or specialised clinics.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

In the public sector, healthcare is delivered through programmes and plans that are implemented at federal, state and municipal levels. Actions and services must be organised and executed on a regional basis. The SUS is a complex programme and is organised according to the different federative levels; the Union is primarily involved with the general planning of the system, organisation of health assistance centres in remote regions and to providing financial grants to state, municipal and private health entities that operate in coordination with the SUS. The states are responsible for high and medium complexity health assistance centres, and coordination of the efforts of the municipalities. The municipalities are responsible for primary care and low complexity health assistance institutions.

The private health system operates in parallel with the public healthcare system, with full capacity to provide health assistance to the population, whether through out-of-pocket payments or through health insurance companies.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The key legislation that governs healthcare in Brazil is as follows:

- the Brazilian Federal Constitution of 1988, which provides for principles and guidelines applicable to the delivery of healthcare;
- Federal Law No. 8,080/1990, which rules the SUS. Ordinance No. 2,048/2009 establishes the internal regimen of the SUS;
- Federal Law No. 9,961/2000, which creates the National Regulatory Agency for Private Health Insurance and Plans (ANS);
- Federal Law No. 9,782/1999, which creates the National Health Surveillance Agency (ANVISA).

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

In addition to the Ministry of Health (which governs the SUS at the federal level), the agencies which are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare are the federal health agency (ANVISA); the supplementary health agency (ANS); state and municipal health authorities; and state and municipal health departments. They are funded by the government and by other sources, such as revenue from enforcement activities (ie, the application of fines) and donations, among other things.

5 What is the scope of their enforcement and regulatory responsibilities?

The Ministry of Health is a federal entity and is responsible for outlining public plans and policies and governing the SUS at the federal level. State and municipal health departments perform such governing activities at a local level. The ANS is responsible for regulating, standardising, controlling and inspecting the private health insurance and plans sector in Brazil. ANVISA is responsible for protecting and promoting public health through health surveillance of products and services, among other activities. State and local health authorities enforce ANVISA's regulations.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

ANVISA is the agency that is responsible for regulating pharmaceutical products and medical devices. ANVISA also regulates other products, such as cosmetics and hygiene products, sanitisers, tobacco and foods. It holds administrative independence, financial autonomy and is responsible for the stability of its directors.

ANVISA is funded by:

- revenue from the collection of fees;
- revenue from any services provided to third parties;
- amounts that arise from the collection of fines after enforcement actions;
- the proceeds of the execution of its outstanding debt;
- amounts allocated by the federal budget, special credits, additional credits and transfers;
- revenues arising from agreements or contracts with entities and organisations, both foreign and local;

- donations, legacies, grants and other resources eventually assigned;
- amounts arising from the sale or lease of its properties;
- proceeds from the sale of assets, objects or tools used in illegal activity, as well as assets seized from offenders due to the exercise of police power and incorporated into the assets of ANVISA pursuant to a court order; and
- proceeds arising from investments in the capital markets.

7 What is the scope of their enforcement and regulatory responsibilities?

ANVISA exercises health surveillance over products such as drugs, pharmaceuticals, medical devices, sanitisers, cosmetics, food, tobacco and services such as licensing conditions for health-related companies and healthcare institutions. ANVISA is also responsible for authorising the importation and exportation of the products that are subject to health surveillance, ruling the sanitary aspects of clinical trials and defining health standards for pesticides.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Different agencies may have jurisdiction over healthcare, pharmaceutical and medical devices cases depending on each individual case. For example, whenever a pharmaceutical or medical device case represents a violation of health surveillance rules (ie, the commercialisation of a product without the proper licences or marketing authorisations), ANVISA, and state and local health authorities will have jurisdiction. If this same fact also harms consumers, consumer entities such as the Department of Consumer Protection and Defence (DPDC) and the federal or state prosecution offices may have law enforcement powers.

Whenever pharmaceutical and medical devices cases have a criminal consequence, the police and the public prosecutor office will have jurisdiction.

Some practices of the health assistance, pharmaceutical and medical devices industries may also be subject to review by Brazil's Council for Economic Defence, the entity responsible for competition and antitrust matters.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Yes, multiple government agencies may simultaneously conduct an investigation of the same subject under the competence each agency has over the subject. For example, whenever a pharmaceutical or medical device case represents a violation of health surveillance rules (ie, the commercialisation of a product without the proper licences or marketing authorisations), ANVISA, and state and local health authorities will have jurisdiction. This same fact may be also investigated by police authorities if it characterises a crime, or by consumer authorities such as the DPDC if it represents a violation of consumer rights.

However, there are controversies regarding the possibility of different agencies imposing penalties for the same subject; these are ruled on a case-by-case basis.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

In order to monitor compliance with the rules on drugs and devices, authorities have broad powers and may spontaneously inspect companies, manufacturing sites, documents and products. Depending on the results of the inspections, the authorities may authorise or cancel a company's licences; authorise or cancel marketing authorisations; determine the interdiction or closure of sites such as manufacturing and storage facilities; authorise or deny importation procedures; and determine the suspension of advertising, among other things.

11 How long do investigations typically take from initiation to completion? How are investigations started?

The timing varies according to the complexity of the case and the agency or authority involved. Usually the procedures take years. High exposure cases, or those which involve pressure from the populace, are initiated and completed in shorter periods. However, the authorities may use precautionary measures in case of threat to the population, and issue orders of recall of products or suspension of activities or sales before the conclusion of the investigation.

Investigations usually start after:

- a regular inspection by the authorities (ie, annual inspection for renewing permits);
- a spontaneous inspection by the authorities;
- a denouncement, which may or may not be anonymous; and
- the authorities are informed about a possible fact by other authorities.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Once a subject is formally notified about the investigation, he or she will have access to any files or materials that compose the administrative procedures. This access is mandatory and required in order to guarantee that the subject will be able to enforce its full right of defence.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes, if pharmaceutical products or medical devices are made in a foreign country, the manufacturing plants and processes of the foreign manufacturers will be inspected by ANVISA. Such foreign inspection and the respective good manufacturing certificates are required for the registration of drugs, pharmaceutical active ingredients and some categories of medical devices in Brazil. ANVISA agents personally inspect such foreign manufacturing sites. ANVISA may outsourcing such inspections in the future; and also uses reports prepared by other countries' health agencies to subsidise its analysis.

14 Through what proceedings do agencies enforce the rules?

The agencies have their own proceedings to enforce the rules and do not need to apply to a court in order to execute their legal duties. For example, ANVISA or the Consumer Defence Agency, as federal entities, are bound to and must apply Federal Law No. 9,784/1999 that establishes procedural rules for the Federal Public Administration. ANVISA has also issued specific rules, such as Resolution RDC No. 25/2008, which provides for the submission of administrative appeals before ANVISA. Such proceedings have an administrative nature and may be subject to judicial review.

In parallel, if an infraction is also considered a crime or a civil infraction, then the police and prosecution offices may also start own investigations, which are applied in court.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The main rule applicable to sanctions that may be imposed to drug and device manufacturers and their distributors is Federal Law No. 6,437/1977. This rule defines which practices are considered infractions and which specific penalties will be applied in each case. In general terms, sanitary authorities may impose penalties such as warnings, fines, seizure, destruction, cancellation of a company's permits, suspension of advertising, cancellation of marketing authorisations and interdiction or closure of sites, among other things.

State and municipal health authorities may also issue local rules regarding infractions and sanctions. However, such local rules are usually a reflection of Federal Law No. 6,437/1977.

16 Can the authorities pursue actions against employees as well as the company itself?

Under the sanitary rules, no penalties should be imposed on employees. Therefore, health authorities do not pursue administrative actions against employees and any applied penalty will be imposed to the company.

However, if employees or a professional who undertakes technical responsibility for a company practice any action that causes material or moral damages, they may be held civilly liable. If employees or a professional who undertakes technical responsibility practice any criminal action, they will be held criminally liable. In these scenarios, it is most likely that the company and the employee will be held jointly liable.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The Brazilian legal system provides for a minimum of two levels of defence. Usually drug and device company defendants will be able to present a rebuttal to the authority which rendered the decision for its own review. If the decision is kept, the company may file an appeal to the hierarchically superior authority. It is important to highlight that the rules that provide for administrative procedures (such as Federal Law No. 9,784/1999 and local laws) may contain specific provisions and formalities regarding the preparation of appeals and defences. In addition to administrative defences and appeals, companies may also apply to the judicial courts whenever they consider that agencies' decisions are unlawful.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

As strategies that must be adopted to minimise exposure to enforcement actions and reduce liability, it is advisable that regulated companies:

- prepare standard operational procedures as required by sanitary rules, depending on the activities undertaken by the company;
- prepare internal policies which must be available to all employees;
- provide appropriate training for the employees, considering the activities which will be performed; and
- seek legal advice before attempting any regulated action such as applying for new marketing authorisations; changing a manufacturing site; implementing any corporate transaction such as merge, spin-off and amalgamation; and modifying any aspect of the product (price, labelling, name, place of manufacturing, etc).

Scheduling meetings with authorities may be also helpful in some cases. Once the enforcement action is ongoing, the company must act with transparency, maintain contact with the authorities, be responsive to any requirements made by the authorities and demonstrate interest in remedying the issues and non-conformities.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

To our knowledge, in their recent drugs and devices enforcement activities health authorities have focused on issues related to:

- importation of products subjected to health surveillance;
- operations without the proper permits;
- commercialisation of products which were not registered by ANVISA; and
- improper advertising (especially when related to drugs, which is highly regulated).

The most common penalty is a fine, followed by the penalty of interdiction or closure. Usually, the penalty of interdiction or closure is imposed whenever health authorities understand that manufacturing sites are not compliant with good manufacturing practices and manufactured products may harm public health.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

Yes, there are self-governing bodies from companies that sell pharmaceutical products and medical devices such as the Pharmaceutical Research Industry Association (Interfarma) and the Brazilian Association of High Technology Industry of Medical Devices (ABIMED). Such industry associations require their members to comply with the provisions of published codes of conduct. Although membership is optional, most companies choose to join such self-governing bodies for market competition purposes.

The monitoring of members' conduct is conducted internally. That is, any report of improper conduct can lead to an investigation of the company by the association. Interfarma's Code of Conduct, for example, sets forth that the penalties for the violation of the Code include:

- a fine ranging from 5,000 reais to 220,000 reais;
- suspension of company's membership; and
- expulsion of the company from the association.

The penalty to be applied varies according to the severity of the infraction.

Any penalty will be only applied to the affiliated companies, which are bound to the codes of conduct.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are different rules, such as the following:

- industry group regulations (Interfarma and ABIMED's codes of conduct);
- ANVISA Resolution RDC No. 96/2008, which rules on the advertising of drugs;
- healthcare professionals' codes of ethics (medical, pharmaceutical, etc); and,
- codes of conduct for high-level administration (there are specific provisions to be applied when the healthcare professional is a government official).

Under Interfarma's Code of Conduct, for example, the affiliated companies must:

- reimburse healthcare professionals on an exceptional basis;
- certify that healthcare professionals are backed by fiscal documents and that they do not include any expense or payment made in benefit of third parties; and
- keep a file with all receipts, records and documents related to the expenses made in name of the healthcare professional (at least during the fiscal year).

Under ANVISA's Resolution RDC No. 96/2008:

- any support or sponsorship in favour of healthcare professionals for attending sponsored conferences and scientific events shall not be conditional on the prescription, distribution or advertising of any kind of drug; and
- in scientific events, it is necessary to disclose that the healthcare professional hired as a speaker has a relationship with the company, or to inform about potential conflicts of interest.

22 How are the rules enforced?

The rules given in question 21 are enforced through administrative procedures, in which the investigated company or healthcare professional will have right of defence.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

In Brazil, there are no reporting or transparency obligations for financial relationships, and currently there is no law similar to the Sunshine Act. Companies usually comply with the guidelines of the codes of conduct issued by the self-governing entities (even when companies are not affiliated to such self-governing entities).

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

In order to monitor compliance with the rules on delivery of healthcare, authorities have broad powers and may spontaneously inspect healthcare providers and request the presentation of documents. Depending on the results of the inspections, the authorities may authorise or cancel licences, determine the interdiction or closure of sites such as hospitals and laboratories and determine the suspension of advertising, among other things.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The timing varies according to the complexity of the case and the workload of the authorities involved. In some cases it can take years. Usually, cases which have a high exposure (the facts are disclosed by communication means) are initiated and completed within months. However, in regular cases investigations typically take several months to be completed. The authorities also have powers to determine immediate corrective or precautionary measures, such as suspension of activities. Such measures are imposed in cases where there is an imminent threat to human health.

Investigations usually start after:

- a regular inspection by the authorities (ie, annual inspection for renewing permits);
- a spontaneous inspection by the authorities;
- a denouncement, which may be anonymous or not; and
- the authorities are informed about a possible fact by other authorities.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

Once the subject is formally notified about the investigation, he or she will have access to any files or materials that compose the administrative procedures. This access is mandatory and required in order to guarantee that the subject will be able to enforce his or her right of defence.

27 Through what proceedings do agencies enforce the rules?

The agencies have their own proceedings to enforce the rules and do not need to apply to a court in order to execute their legal duties. For example, the Ministry of Health, as a federal entity, is bound to and must apply Federal Law No. 9,784/1999, which establishes procedural rules for the federal public administration.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Sanctions and measures that can be adopted by authorities against healthcare providers include warning, fine, suspension of professional enrolment before the professional council and debarment. Depending on the situation, authorities may contact other authorities in order to obtain further information and seek enforcement actions against healthcare providers for criminal or civil damages.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare providers are bound to professional codes of ethics issued by the professional council to which they are related (ie, physicians are bound to the code of ethics issued by the Medical Council). Such ethics codes usually contain provisions on possible appeals and defences before the related professional council. This procedure has an administrative nature.

Despite the defences and appeals foreseen in those codes of ethics, healthcare professionals may also seek judicial courts whenever they consider that professional council's decision was unlawful.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

In order to minimise their exposure to enforcement actions and reduce liability, healthcare providers should respect all rules applicable to their professional activities. In case of doubt, legal advice should be sought. It is also possible to consult with the competent authorities or with the professional council in order to obtain clarification on admissible actions and practices. Such consultations should be completed in writing and preferably with the assistance of an attorney. Once the enforcement action is ongoing, the healthcare provider must demonstrate interest in correcting the verified issue and collaborate with the authorities.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In their recent enforcement activities, authorities have focused on the adequate provision of services by healthcare professionals and on the enrolment of such professionals before the professional council. Usually, professional councils impose penalties of debarment, which may be temporary or definitive. Professional councils also impose fines (ie, to a company which provided services through unlicensed technical means).

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare providers are subjected to their professional councils, which work in a similar way to a self-governing body. Furthermore, healthcare professionals may join existing class associations and unions.

These associations and unions usually respond to denouncements and represent their members, but do not police members' activities.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

The government usually contracts healthcare providers (individuals) through examination, in which a healthcare provider's capabilities are evaluated. After approval in the examination, the healthcare provider is considered a civil servant and is bound to the rules that govern the activities of civil servants. According to such rules, a civil servant may be subject to disciplinary sanctions, such as warning, suspension, resignation, forfeiture of retirement and dismissal of commission positions. Penalties are imposed according to the nature and seriousness of the infraction under a disciplinary administrative procedure.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Usually, citizens or other private bodies bring causes of action related to poor performance of services, lack of coverage from insurance plans and damages caused by product issues.

In order to enforce a healthcare regulation or law at an administrative level, citizens or other private bodies may file denouncements (anonymously or not) before different authorities at the same time. Depending on the situation, citizens or other private bodies may file legal measures, accrued or not, with preliminary injunction requests. The public prosecutor office may be also involved in cases which may affect the interests of a community.

35 What is the framework for claims of clinical negligence against healthcare providers?

Healthcare providers (including those who render services in governmental institutions) are bound by their professional codes of ethics and to the rules issued by the respective professional councils. Such codes of ethics and rules provide for ethical guidance and standards that must be adopted by healthcare professionals during the performance of their activities (ie, physicians must use all available diagnostic methods and treatments, scientifically recognised, in favour of the patient, and must treat patient information as confidential). If an ethical standard is breached, the patient and patient's family members may file a denouncement (including before the professional council) and lawsuit against the involved healthcare professional.

A successful claim must contain enough elements to prove the breach of standard guidelines by the healthcare professional and the damage caused. It is necessary to demonstrate a healthcare professional's negligence.

Administratively, the healthcare professional may be punished by the professional council. Depending on the situation, the healthcare professional may be held liable for material and moral damages. Criminal liability is also possible if the breach characterises a criminal offence.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Purchasers or users of pharmaceuticals or devices are end users and, under Brazilian rules, are considered to be consumers. In the event of regulatory and legal infringements, the purchaser or user may file a denouncement (anonymous or not) to consumer protection bodies, health authorities, police authorities or the public prosecutor office. Depending on the situation, they may also file legal measures, accrued or not, with preliminary injunction requests.

37 Are there any compensation schemes in place?

No, there are no compensation schemes in place in Brazil and only direct damages are recoverable (the are no indirect or consequential damages). However, in Brazil loss of profit is considered to be a direct damage. For economic damages, the aggrieved party needs to prove actual damages and will be awarded exactly what was suffered and given in evidence. In general, Brazilian courts are not overly generous in awarding indemnification.

Update and trends

The relationship between industry and healthcare professionals is in the spotlight in 2015, and will remain a focus in 2016 due to a recent scandal involving medical device companies and healthcare professionals. Also, the good clinical practices of health assistance institutions will be on the law enforcement agents' radar.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Yes, class actions are available in cases related to drugs, devices and provision of care and may be used whenever:

- collective interests or rights are held by unidentifiable persons linked by factual circumstances;
- collective interests or rights are held by a group, category or class of persons linked together or to the opposing party by a basic juridical relationship; or
- homogeneous individual interests or rights, understood as resulting from a common origin, are involved.

There are specific public entities that, by law, have attribution and jurisdiction to file such a legal measure.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Any decision or omission in Brazil may be subject to judicial review. Brazilian courts have the constitutional power to review administrative decisions from a constitutional, formal or legal perspective. There are different statutes of limitation and venue provisions depending on the claim and on the involved parties. The success of a complaint will depend on the existence of a lawful request and on the existence of proper evidence. Depending on the situation, it is also possible to request a preliminary injunction.

40 Are there any legal protections for whistle-blowers?

In Brazil there are no specific rules for protecting whistle-blowers. Under the regulatory rules, the main legal protection for whistle-blowers is the possibility of filing an anonymous denouncement or requesting the non-disclosure of a whistle-blowers's personal data.

41 Does the country have a reward mechanism for whistle-blowers?

Brazil does not have a reward mechanism for whistle-blowers. However, the criminal and anti-corruption laws provide for leniency programmes that may benefit a whistle-blower who is also involved in the unlawful act.

42 Are mechanisms allowing whistle-blowers to report infringements required?

There are no specific mechanisms for reporting infringements by whistle-blowers.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes, Brazilian prosecutors and law enforcement authorities may cooperate with foreign authorities whenever necessary, including in healthcare cases. In 2012, ANVISA entered into a Statement of Cooperation with the US Food and Drug Administration for purposes of joint activities, including cooperation involving investigations and other law enforcement actions.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

Enforcement activities by foreign authorities will trigger an investigation in Brazil whenever the investigated matter affects Brazil (ie, when a certain medical device or drug is being investigated abroad for claims related to their quality or safety, if such medical device or drug is imported into and commercialised in Brazil, ANVISA may start its own investigation). ANVISA may also issue specific rules for restricting the importation of products that arise from specific countries (ie, in 2012 ANVISA restricted the importation of foods exported from Japan due to Fukushima's nuclear accident).

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

In theory, the Brazilian health authorities could pursue any company (national or foreign) for infringement of Brazilian healthcare laws. However, is not likely that a foreign company with no representation in Brazil will be pursued by Brazilian health authorities, due to the practical difficulties in imposing penalties.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

Roles and responsibilities for Canada's healthcare system are shared between federal, provincial and territorial governments.

The federal government is primarily responsible for:

- regulating the manufacture, importation and distribution of pharmaceutical products and medical devices;
- providing funding to the provinces and territories for healthcare through cash transfers (referred to as the Canada Health Transfer); and
- delivering healthcare services to certain groups (eg, First Nations, Inuits and veterans).

The provinces and territories have primary responsibility for the delivery of healthcare services. Healthcare delivery is largely funded through provincial tax revenues and supplemented by the Canada Health Transfer. The national Medicare system is composed of 13 interlinked provincial and territorial health insurance plans. These plans vary from province to territory but share similarities in terms of their basic scope of coverage.

Services are delivered by a broad range of healthcare providers, including regulated healthcare professionals, hospitals, long-term care homes and others. Whether services are publicly insured or 'private pay' will depend on what type of healthcare professional is providing the service and in what kind of facility the service is provided.

Generally speaking, healthcare services are delivered and funded as follows.

Primary healthcare

Primary healthcare is delivered by family physicians, nurse practitioners and other healthcare professionals in community clinics. Medically necessary physician services, including primary care services, are paid through provincial and territorial health insurance plans without direct cost to the patient. Other primary care services are delivered on a private-pay basis.

Hospital and long-term care facilities

Patients also receive care at hospitals and long-term care facilities. For the most part, healthcare services provided in hospitals and long-term care facilities are publicly funded without direct cost to the patient. In long-term care facilities, room and board costs are generally paid – in part or in whole – by the patient.

Home and community care

Patients also receive specialised healthcare services in their homes and in the community. These services include a broad range of specialised nursing care, homemaker services, social work, adult day care and others. Home and community care is delivered by regulated healthcare professionals (eg, nurses), non-regulated workers, volunteers, friends and family caregivers. While some home and community care services are publicly funded, many are delivered on a private-pay basis.

Others

To some extent, all provinces and territories extend public insurance coverage to other 'supplemental' services. Additional benefits may include prescription drugs, dental care, vision care, medical devices, paramedical care and others. The extent of coverage varies by province and eligibility is often limited to certain groups (eg, the elderly or children). Many Canadians also have private insurance coverage through group plans (from their employment or purchased privately) to cover the cost of supplementary services that are not covered by the provincial insurance plan.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

See question 1.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Canada is a federal state, and roles and responsibilities for Canada's healthcare system are shared between the federal, provincial and territorial governments.

The Constitution Act, 1867 provides the federal government with constitutional powers in the following areas relating to health: criminal law; spending power; and the ability to pass laws relating to peace, order and good government. The federal government provides oversight for food, drugs, tobacco, controlled drugs and substances under its power to regulate criminal law. The spending power allows the federal government to provide financial contributions to the provinces. It also provides the basis for federal initiatives such as health promotion and health-related research initiatives. The federal government's 'residual power' gives the federal government the ability to make laws for the peace, order and good government of Canada – for example, in the case of a national health emergency, where the emergency can be better managed by the federal government instead of a provincial government.

The provinces have jurisdiction over hospitals, property and civil rights and local and private matters. Provinces have health statutes and regulations governing:

- the establishment of hospitals;
- maintenance of the healthcare system;
- funding for healthcare services;
- healthcare system governance;
- healthcare professional oversight;
- health records;
- privacy and confidentiality; and
- the rights of patients.

Under the provinces' powers for 'property and civil rights,' provinces have the power to regulate healthcare professionals and their practices. Through provincial jurisdiction over 'local or private matters,' provinces administer health insurance regimes, public health and protection and funding for pharmaceutical drugs.

In the 1990s and 2000s, most provinces passed statutes establishing regional health authorities (RHAs) to administer healthcare under delegated authority from the province. The legislated mandate of RHAs vary from province to province, but generally they are responsible for setting priorities for delivery and delivering healthcare services in specified geographical areas (except for primary healthcare services delivered in the community by individual physicians). In Quebec, RHAs also deliver (or oversee the delivery) of various social services. The regional model is not universal. In the mid-to-late 2000s, Alberta and Prince Edward Island

both moved away from regional models and each now operates with a single provincial health authority. Nunavut and the Yukon do not have RHAs. Ontario's Local Health System Integration Networks fund and coordinate but do not directly provide patient care. As a result, Ontario's hospitals and long-term care homes continue to be operated as independent corporations, each with their own governing board.

The Canada Health Act (CHA) governs the funding relationship between the federal, provincial and territorial governments for basic 'insured health services' (namely, medically necessary hospital, physician and surgical-dental services). It entitles provinces and territories to receive the Canada Health Transfer as long as they comply with certain principles and conditions. The five main principles in the CHA are:

- public administration;
- comprehensiveness;
- universality;
- portability; and
- accessibility.

The amount of the Canada Health Transfer that a province or territory is entitled to receive can be reduced if it does not adhere to these principles (and the more detailed conditions associated with each).

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

Self-governing regulatory bodies

Each province and territory has established self-governing healthcare professional regulatory bodies (often known as 'colleges'). These regulatory bodies have a legislated public interest mandate and ensure, among other things, that only individuals who have the proper qualifications practise in the regulated health profession. Regulated healthcare professionals must practise within their legislated 'scope of practice' and must adhere to established professional standards. Where misconduct or other breach is suspected, colleges have the power to investigate and discipline members. Professional regulatory bodies are primarily funded through mandatory membership fees.

Provincial and territorial ministries and agencies

Governments (and their agencies) are often given the power to investigate healthcare providers. The extent of their authority depends on the statute in question. Investigations are generally performed by an inspector appointed by the minister or agency director, and such positions are funded through general tax revenue.

Inquests

Most provinces and territories have a publicly funded coroner's office that investigates unexplained or suspicious deaths and, where appropriate, conducts inquests. Some jurisdictions have a medical examiner's office (instead of a coroner) that conducts an initial investigation where there is an unexplained or suspicious death. The decision to move forward with an inquest, however, falls to another person (usually the minister or a board). Inquests typically occur following an injury or death of:

- an inmate while in custody;
- a resident in a psychiatric facility; or
- an individual or patient in a healthcare institution.

Inquests may include an investigation of healthcare professionals, healthcare facilities and the treatment of patients.

Prosecutors and the courts

Publicly funded prosecutors and courts play a key role in enforcing laws where a healthcare provider has (or is suspected to have) committed an offence, whether under health-specific legislation or other law.

For any of the above-mentioned agencies, courts or other bodies, funding is not dependent on enforcement activities (ie, fines and penalties).

5 What is the scope of their enforcement and regulatory responsibilities?

Self-governing regulatory bodies

If a healthcare professional is investigated by his or her college, the matter usually proceeds to a complaints or disciplinary committee. If a disciplinary committee concludes that there has been professional misconduct or incompetence, the healthcare professional will be subject to penalties that could include a revocation of licence, formal sanction, fines, mandatory education, etc. In most provinces, the decision of a disciplinary committee can be appealed or reviewed, either by a court or a specialised administrative review body.

Provincial and territorial ministries and agencies

If an individual or institution commits an offence by contravening a provincial or territorial statute, that person may be prosecuted and, on conviction, liable for fines or imprisonment.

Prosecutors and the courts

Courts can hear claims brought by the public or by prosecutors. These can be common law tort claims, extra-contractual civil liability claims, criminal prosecutions or constitutional challenges (ie, that the law violates the Charter of Rights and Freedoms (the Charter)). Each case is initially decided in the local provincial or territorial court but the court's decision can be appealed to an appeal court in the province or territory. The final court of appeal is the Supreme Court of Canada. The Supreme Court has reviewed many healthcare-related decisions, especially Charter challenges, that have influenced the delivery of healthcare in Canada.

Inquests

An inquest is quasi-judicial in that it is fact-finding, not fault-finding. The coroner establishes the scope and focus of the inquest and certain parties may also be granted standing (eg, family, institutions, clinicians, special interest groups, etc). Where the jurisdiction has a medical examiner rather than a coroner, a board or a minister has legislative authority to determine whether an inquest will be held. After a hearing and a review of the evidence and submissions, recommendations are provided. Recommendations made as a result of an inquest are influential and often implemented.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The manufacture, importation and distribution of pharmaceutical products and medical devices is regulated at the federal level, under the jurisdiction of Health Canada. As a federal government agency, Health Canada's activities are funded by the federal government (tax receipts) and through licence and other user fee revenue generated from stakeholders. Funding is not dependent on enforcement activities (ie, fines and penalties).

7 What is the scope of their enforcement and regulatory responsibilities?

There are several divisions and subdivisions within Health Canada, each having distinct responsibilities in relation to the regulation of pharmaceutical products and medical devices. The Therapeutic Products Directorate (TPD) is responsible for:

- assessing the safety and efficacy of drugs and medical devices;
- issuing the various market authorisations required under the legislation;
- establishing and implementing standards, policies and guidance; and
- collecting and monitoring post-market information.

There are various divisions within the TPD, each having a specific mandate (eg, the Medical Devices Bureau, the Bureau of Pharmaceutical Sciences and the Office of Clinical Trials). The Health Products and Food Branch Inspectorate (Inspectorate), is responsible for all branch-wide compliance and enforcement activities, its core functions being compliance monitoring, verification and investigation. The scope of the Inspectorate's enforcement powers are set out in the Food and Drugs Act (FDA) and associated regulations, and include a broad power to inspect and compel information, and to suspend or cancel market authorisations or other Health Canada approvals. The financial penalties for non-compliance set out in the FDA can be imposed by the Federal Court of Canada upon conviction.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

There are several Canadian federal and provincial and territorial agencies that have jurisdiction over the various business activities of pharmaceutical and medical device companies operating in Canada (eg, provincial securities regulators, federal tax agencies, the federal Competition Bureau, etc), however, insofar as the manufacture, importation and sale of

pharmaceutical products and medical devices is concerned, Health Canada has primary jurisdiction. In some situations, Health Canada will work closely with other federal agencies in fulfilling its mandate. For example, the Inspectorate works closely with the Canada Border Services Agency in relation to the importation of unauthorised pharmaceutical products and medical devices, and with the Competition Bureau in relation to intellectual property and other issues related to competitive market behaviour.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Simultaneous investigations of the same subject by multiple government agencies are possible where the subject matter involves several issues over which different agencies have jurisdiction. Insofar as pharmaceutical products and medical devices are concerned, it is not uncommon for issues to arise that involve Health Canada, which has jurisdiction over the safety and efficacy of regulated health products, and provincial health ministries, which have general jurisdiction over the delivery of health care services. For example, in Ontario, a recent investigation into the compounding of prescription drugs involved Health Canada, which had an interest in the drug product, and the Ontario Ministry of Health, which has jurisdiction over pharmacists who perform compounding and admixing activity. In general, a completed investigation by one agency does not legally bar another agency from investigating the same facts and circumstances.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Until late 2014, Health Canada's power to monitor compliance was generally limited to:

- the power to inspect facilities under the drug and device establishment licensing regime;
- information collected pursuant to the various mandatory reporting requirements in the regulations; and
- a general power to request information from manufacturers.

In November 2014, the FDA was amended to grant more extensive pre-market and post-market inspection powers to Health Canada. Several of these powers are not yet in force, but will be implemented through the release of new regulations over the next several years. Under these new powers, Health Canada can order:

- any person (ie, not just a manufacturer) to provide information in its control that Health Canada believes is necessary to determine if a product presents a serious risk;
- a manufacturer to conduct an assessment and provide Health Canada with the results; and
- a manufacturer to compile information, conduct tests or studies or monitor experience in order to obtain additional information about a product's effects on health and safety and provide Health Canada with the results.

11 How long do investigations typically take from initiation to completion? How are investigations started?

There is no typical timeline for the completion of an investigation by Health Canada. The length of the investigation depends upon the issues involved, the immediacy and severity of the related risk to health and the cooperation and information provided by the party being investigated. In this regard, an investigation can last anywhere from several weeks to 12 months or more. An investigation can be started in several ways. The FDA provides Health Canada with the power to inspect any business premises without notice and in some cases (although infrequent) a Health Canada inspector will attend a facility and commence an investigation unannounced. Investigations may also be commenced as a result of a non-conformity identified during a regular inspection under the establishment licensing regime. More commonly, an inspection will commence through the issuance of a regulatory letter from Health Canada, advising that a potential violation of the FDA or regulations has come to its attention, and requesting more information or scheduling a time to conduct an on-site inspection.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

The FDA and regulations do not include a specific right of access to Health Canada's investigation files by the subject of the investigation. However, Health Canada will typically provide limited disclosure of information it has collected upon request. Before any enforcement decision is made, Health Canada will provide the grounds upon which a finding of non-compliance was made together with an opportunity for a response, unless the situation presents an immediate risk to health. In relation to the exercise of the broad new inspection powers added to the FDA in November 2014, Health Canada has committed in its published policies to disclosing and explaining the scientific evidence and reasoning used to support a decision to issue an order prior to the order being made. As a matter of procedural fairness, any order issued pursuant to these new powers will be accompanied by a reasoned decision, including the scientific evidence considered and findings on important questions of fact.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

In relation to pharmaceutical products, Health Canada has the ability to inspect foreign sites which supply finished products and active ingredients in Canada for compliance with Canadian good manufacturing practices (GMP) pursuant to the drug establishment licensing regime. In the case of suppliers located in countries with which Canada has entered into a mutual recognition agreement, Health Canada may rely on a Certificate of Compliance issued by the local authority in place of conducting a GMP inspection for establishment licensing purposes. Subject to local laws, post-market investigations of manufacturers located in other countries are not uncommon, and if non-compliance is determined, Health Canada may take steps in Canada to restrict the importation of those products.

In relation to medical devices, Health Canada relies on recognised third party registrars to certify the compliance of manufacturers with the medical device quality management standards in CAN/CSA ISO 13465:2003, no matter where the manufacturer is located. However, Health Canada does have the power to inspect medical device manufacturing facilities and, subject to local laws, does inspect foreign sites in situations of suspected non-compliance with Canadian regulatory requirements. If non-compliance is determined, Health Canada may take steps in Canada to restrict the importation of those products.

14 Through what proceedings do agencies enforce the rules?

Under the FDA and regulations, certain regulatory enforcement actions may be exercised at Health Canada's discretion (eg, the suspension or cancellation of a market authorisation or establishment licence on the basis of non-compliance). In most cases, the regulations provide the stakeholder with an opportunity to be heard prior to the implementation of the enforcement decision, unless the circumstances present an immediate risk to health. Moreover, for most discretionary enforcement decisions, stakeholders are provided with an opportunity to submit a request for reconsideration after the decision has been made. For the most part, these proceedings are informal, and specific procedures are outlined in guidance published by the Health Canada division involved.

Beyond these discretionary enforcement proceedings, a violation of the FDA and regulations is also subject to a fine or imprisonment, or both, upon conviction. These charges are criminal in nature, and must be pursued by the federal government in the Federal Court of Canada.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

With the amendments to the FDA in November 2014, the maximum penalty upon conviction for a violation of the FDA and regulations in relation to pharmaceutical products and medical devices is now $5 million per day, or an unlimited amount at the discretion of the court where the accused knowingly or recklessly caused a serious risk of injury to health, and/or imprisonment for a term not exceeding five years. In addition, if any item was seized by Health Canada in connection with the investigation, the court may order the forfeiture of that item in the event that the accused is convicted of an offence, or otherwise upon an application to the court by Health Canada. These offence and punishment provisions apply to drug

and device manufacturers, distributors and other stakeholders for any violation of the provisions of the FDA or its applicable regulations.

16 Can the authorities pursue actions against employees as well as the company itself?

Any of the company's directors, officers or agents or mandataries who direct, authorise, assent to or acquiesce or participate in the commission of the offence for which the company has been charged are also liable on conviction to the punishment provisions in the FDA, even if the person is not prosecuted for the offence. There have been no proceedings to date in which individuals have been convicted under this enforcement provision (which is new, as of November 2014). However, this provision has been in force for less than a year, and how it will be utilised in the future remains to be seen.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

A violation of the FDA and regulations is a strict liability offence. Other than demonstrating that the violation did not occur, the only statutory defence available to a defendant is due diligence. In other words, liability may be excused if it is shown that the accused took all of the care that a reasonable person might have been expected to take in the circumstances. In terms of sentencing, the Act provides that the court may take into account the harm or risk of harm caused by the commission of the offence, as well as the vulnerability of consumers to the product at issue, which may reduce or increase the severity of the punishment imposed. An appeal is available to the Federal Court of Appeal from a conviction in the Federal Court of Canada.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Ensuring compliance with the law, and having the evidence necessary to demonstrate compliance with the law, is critical to minimising exposure to enforcement actions by Health Canada. In practice, the best method to achieve this is though a comprehensive compliance programme which sets out the company's policies and procedures related to every activity that exposes a pharmaceutical and medical device company to regulatory liability (from GMP to product advertising and promotion). Written policies permit the dissemination of the company's expectations to all employees who engage in a regulated activity, facilitate ongoing training, and create a record of the company's due diligence in the event of a prosecution under the Act. Many pharmaceutical and medical device companies operating in Canada require strict compliance with the company's compliance programme and undertake disciplinary action for incidents of non-compliance.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Health Canada's primary focus in relation to recent drug and device enforcement activity has been related to product quality issues. Although Health Canada does attend to other areas of enforcement, such as drug and device advertising, quality issues present a more immediate risk to the health of Canadian consumers. Commencing in April 2015, Health Canada began posting current enforcement activity for actual or potential drug establishment compliance violations on the Health Canada website (www.hc-sc.gc.ca/dhp-mps/pubs/compli-conform/tracker-suivi-eng.php). To date, all activities cited relate to alleged GMP violations, most of which occur at foreign sites. In most cases, the enforcement activity resulted in the imposition of import restrictions. No prosecutions under the new offence and punishment provisions added to the FDA in November 2014 have been pursued to date.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

There are no independent self-governing bodies for companies that sell pharmaceutical products and medical devices; however, voluntary industry associations are influential in self-policing the conduct of their members. The three largest associations are: Canada's Research-based Pharmaceutical Companies (Rx&D), the Canadian Generic Pharmaceutical Association (CGPA) and Medical Devices Canada (MEDEC).

In addition, Health Canada relies on the independent Pharmaceutical Advertising Advisory Board (PAAB) and Advertising Standards Canada (ASC) as clearance agencies with respect to advertising by drug companies. PAAB regulates advertising intended for healthcare professionals and ASC regulates non-prescription drug advertising directed at consumers.

Each of these associations has adopted a code of conduct with procedures for receiving and investigating complaints. The Rx&D Code of Ethical Practices, for example, sets out rules for the lodging of complaints and investigation of potential breaches and sets out penalties for infractions, which may include monetary fines of up to $100,000 per violation for repeat offenders and publication on the Rx&D website.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There is no general anti-kickback or disclosure legislation governing financial relationships between healthcare professionals and industry in Canada. Instead, the rules come from a variety of sources, including industry codes of conduct; rules of professional conduct for healthcare professionals; and provincial and territorial laws, regulations and policies.

Industry codes of conduct (self-regulation)

Members of Rx&D must comply with the Rx&D Code of Ethical Practices (2012), which contains various restrictions on advertising and commercial practices, including appropriate relationships with healthcare professionals in the context of gift-giving, hospitality, samples, continuing education for professionals, donations and financial support, consulting and advisory board relationships.

The CGPA and MEDEC have adopted similar codes of conduct governing appropriate relations between their members and healthcare professionals.

Rules of professional conduct

Healthcare professionals must comply with professional ethics obligations that strictly limit their ability to engage with and accept benefits from industry as a matter of conflict of interest. The rules come from professional regulatory colleges and associations, as well as from common law fiduciary obligations to patients. Healthcare professionals are generally prohibited from receiving personal gifts, kickbacks or other unlawful benefits from suppliers of medical goods and services.

Healthcare professionals are also limited with respect to the types of investments they can make in suppliers of health-related products or services (such as manufacturers or distributors of pharmaceuticals or providers of therapeutic or diagnostic services). Depending on the province and territory and type of healthcare professional, applicable rules can:

- prohibit such investments entirely;
- prohibit referrals to a facility or supplier in which the professional has a financial interest;
- require prior approval of the investment by the regulator;
- require disclosure of the interest (including to patients, regulators, peers); or
- some combination of the above.

Other restraints

Certain types of healthcare providers are prohibited from engaging in fee-sharing or providing or accepting benefits relating to referrals. For example, licensed laboratories in Ontario are prohibited under the Laboratories and Specimen Collection Centre Licensing Act from providing various types of benefits to healthcare providers that refer samples to the laboratory.

A number of provinces (including Quebec, Ontario and British Columbia) specifically prohibit drug manufacturers and distributors from paying rebates and professional allowances to healthcare professionals (particularly pharmacists). Others, such as Nova Scotia, impose disclosure requirements where such payments are made.

22 How are the rules enforced?

The enforcement mechanisms for the rules vary.

Industry codes of conduct generally contain procedures for receiving and investigating complaints. See question 20 for more details.

Rules of professional conduct are typically enforced by regulatory colleges through disciplinary hearings. Regulators have a range of powers to sanction members, ranging from a reprimand or fine to, in the most serious cases, suspension or revocation of the members' registration (see questions 27 and 28). In Quebec, the Professional Code further provides that every person who knowingly helps or leads a member to contravene a provision of a professional code of ethics is guilty of an offence. As such, there is a risk that a third party (such as a drug manufacturer) could be exposed to fines where its actions place a Quebecois healthcare professional in a conflict of interest.

Where an individual or corporation has contravened a governing statute, the offending party or parties may be charged with an offence and prosecuted in court. On conviction, an offender could be fined or, in extreme cases, imprisoned. A regulator may also be empowered to impose administrative penalties against an offending person, for example, through fines or the suspension or termination of the facility's operating licence.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

There is no general disclosure legislation or reporting obligation relating to financial relationships between healthcare professionals and industry in Canada.

As a matter of professional ethics, healthcare professionals are obliged to clearly disclose relationships with industry where funding has been provided for research studies, whether or not the relevant journal or other publication requires the disclosure. Many regulators require healthcare professionals to disclose other financial relationships with industry or (where permitted) investments in other healthcare facilities. These disclosure requirements vary and may include: oral or written disclosure to the patient, requirements to post signage and obligations to report relationships and investments to the regulatory college.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Healthcare professionals

Self-governing regulatory bodies have extensive powers to investigate whether a member has committed an act of professional misconduct or is incompetent. For example, investigators typically have the power to enter a member's place of practice, and to examine anything relevant. They may seek a search warrant in order to do so. Some professions require members to submit to direct observation (ie, of a patient procedure) during the course of an inspection. In addition, regulators require their members to participate in quality assurance programmes, many of which include peer and practice assessments.

Healthcare facilities and other providers

Regulators of other healthcare facilities, such as long-term care homes; hospitals; laboratories and specimen collection centres; pharmacies; and independent healthcare facilities (non-hospital surgical premises) have similarly broad inspection powers.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

An investigation into the conduct of a healthcare provider is often started as a result of a report (including a media report or a mandatory report), a patient complaint or a poor inspection report.

Where a formal complaint is made against a healthcare professional, the panel that considers the complaint may be required to dispose of it within a certain time period (for example, in British Columbia this period is 120 days), but such time limits may be subject to extension in appropriate circumstances. Otherwise there is no typical or fixed length of an investigation.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

Healthcare professionals

Where a professional regulatory body receives a complaint about the conduct or actions of a member, it must provide notice to the member. If allegations against a member are referred to a discipline hearing, the member will be entitled to full disclosure of the investigation file. Where the regulator takes action short of a referral to discipline, the member may be permitted to seek a review of the decision. In Ontario, for example, such a review is carried out by the Health Professions Appeal and Review Board (HPARB), a quasi-judicial board. In the event of a hearing before a review board, the member is generally entitled to see the reason for the decision and any other documents (in addition to the investigation record) on which the decision was based. This is subject to limited exceptions, for example where disclosure could jeopardise the safety of an individual.

Healthcare facilities and other providers

Some statutes governing healthcare facilities require the disclosure of inspection reports to licensees. Other statutes are silent as to a licensee's right of access. If charges are laid or a hearing is otherwise conducted as a result of an inspection, a court or tribunal will require disclosure as a matter of procedural fairness.

27 Through what proceedings do agencies enforce the rules?

Healthcare professionals

Most self-governing health regulatory bodies have an inquiry committee that is responsible for reviewing complaints and the results of an investigation and determining whether to pursue action against a member. It is generally within the power of an inquiry committee to refer an allegation of professional misconduct or incompetence for a hearing. A disciplinary panel will hear the allegations and determine whether the allegations have been proven on a balance of probabilities and, if so, what penalty to impose. The composition of disciplinary panels varies, but generally includes peer representation. In Quebec, for example, panels are composed of at least three members: the president of the Disciplinary Council, who must be a lawyer appointed by the government, and two physicians designated by the board of the college.

Healthcare facilities and other providers

Under legislation governing healthcare facilities, an inspector or a government official is generally empowered to, among other things, order a licensee who is not in compliance with the statute to do or refrain from doing anything in order to achieve compliance (which may include, in cases of an immediate threat to health or safety, suspending operations entirely). No hearing would be required prior to making such an order, but the order is generally subject to review, either by a court or a specialised administrative review body.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If a disciplinary panel finds that a healthcare professional committed an act of professional misconduct or is incompetent, it usually has the discretion to choose from a variety of potential penalties. These may include:

- revocation of the member's certificate of registration;
- suspending the certificate for a specified period of time;
- imposing terms, conditions and limitations on the member's certificate for a specified or indefinite period of time;
- requiring the member to appear before it to be reprimanded; or
- requiring the member to pay a fine.

Certain types of misconduct attract mandatory penalties. For example, in some provinces and territories if a panel finds that a member has sexually abused a patient, it is required to reprimand the member and to revoke the member's certificate of registration if the sexual abuse was of a serious nature. The panel may also require the member to reimburse the college for funding provided to that patient for therapy and counselling.

A regulator may also revoke or refuse to renew the licence of a healthcare facility that has failed to comply with its regulatory obligations. A decision of this sort is generally subject to administrative review.

Contravention of a health-related (or other) statute may also be a prosecutable offence. In such instances, allegation of a contravention could lead to prosecution. On conviction, an offender could be fined or, in extreme cases, imprisoned. In addition, regulators typically have the power to apply to the courts for an order that directs a person to comply with a provision of the relevant statute, regulations or by-laws, as applicable.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare professionals are entitled to make full answer and defence in the context of a disciplinary proceeding. Possible defences may include:

- a plea that the regulator has failed to prove its case;
- denial of the factual allegations;
- denial that the factual allegations (even if true) rise to the level of professional misconduct or incompetence;
- arguing that defects in the proceeding invalidated it;
- arguing that the provisions under which the member is being prosecuted are unconstitutional; and
- a myriad of others.

A regulated healthcare professional who has been found to have committed an act of professional misconduct or to be incompetent generally has a right of appeal to a court or administrative appeal body. The appeal may be made on questions of law or fact or both. In most cases, an appeal operates as a stay of the order, though there are exceptions to this general rule (eg, cases involving incompetence or sexual abuse of a serious nature).

As noted in question 27, where a government official makes an order against a healthcare facility, or refuses to renew or revokes a licence, the licensee generally has the right to a hearing before an administrative tribunal. In most cases, a further appeal to the courts or other appeal body is also available. Typically, on an appeal the tribunal will consider the fairness of the process that led to the decision as well as the substance of the decision.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

It is important for healthcare providers to comply with (and to maintain records of compliance with) the applicable regulatory requirements. Once an enforcement proceeding is under way, a provider (including a facility or a professional) who cooperates with the investigation and is prepared to admit to wrongdoing (where there has been wrongdoing) may be able to negotiate a less onerous penalty than would otherwise be the case. This is subject to the key proviso that for healthcare professionals in the most serious cases, such as sexual abuse, an early admission will not result in a less strict penalty because the penalty is mandatory. However, an early admission may be beneficial for a member where he or she subsequently seeks reinstatement to the profession.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

It is difficult to generalise; each regulator will have its own priorities.

With respect to healthcare professionals in Ontario, for example, most cases involving physicians involve either allegations of sexual abuse, substandard practice (including poor record keeping) or disgraceful, dishonourable or unprofessional conduct. The regulators of chiropractors and dental hygienists show a high enforcement focus on false insurance claims and falsification of insurance forms. Other regulators focus on such matters as unreasonable or excessive fees, and issuing false or misleading accounts.

Regulators of healthcare providers are also increasingly focused on 'positive' mechanisms for incenting and enforcing quality and efficiency in the delivery of healthcare, including:

- funding incentives for efficient service delivery (eg, activity-based funding for hospitals in Ontario and pay-for-performance schemes for physicians under provincial health insurance fee schedules);
- mandatory pay-at-risk for executives of hospitals (eg, as is required under Ontario's Excellent Care for All Act); and
- mandatory public reporting of quality and patient safety indicators (in Manitoba, Ontario and Nova Scotia).

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare professionals

All provinces and territories have self-governing healthcare professional regulatory bodies. Regulated healthcare professions may, depending on the jurisdiction, include: audiology and speech language pathology; chiropody; chiropractic; dental hygiene; dental technology; dentistry; denturism; homeopathy; kinesiology; massage therapy; medical laboratory technology; medical radiation technology; medicine; midwifery; naturopathy; nursing; occupational therapy; opticianry; optometry; pharmacy; physiotherapy; psychology; psychotherapy; respiratory therapy; and traditional Chinese medicine.

These self-governing regulatory bodies (again known as 'colleges') are governed by councils or boards. The composition of councils or boards vary but generally a majority of the members are elected by members of the profession and a minority are 'public members' selected by the provincial or territorial government to represent the public interest. Other interests (such as university faculties) may also be represented.

College police members conduct through a variety of means, including by developing, establishing and maintaining:

- programmes and standards of practice to assure the quality of the practice of the profession;
- standards of knowledge and skill;
- programmes to promote continuing evaluation, competence and improvement among the members; and
- standards and programmes to promote the ability of the members to respond to changes in practice environments, advances in technology and other emerging issues.

In carrying out their objects, colleges have a statutory duty to serve and protect the public interest. They receive and investigate complaints about members' conduct. They administer mandatory quality assurance programmes and have the power to impose sanctions in the event of an unsatisfactory assessment.

Healthcare facilities and other providers

There are no independent self-governing bodies for healthcare facilities and other types of providers. There are many voluntary industry associations operating at the provincial and national levels, however, these associations tend to focus on advocacy and education rather than on self-policing member conduct.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

In cases of extreme financial mismanagement or misconduct or where there are serious concerns about quality or patient safety, provincial governments generally have the right to revoke a healthcare facility or other provider's licence to operate, to terminate its funding agreement or to otherwise order the provider to cease operation (temporarily or permanently). The governing ministry often has the right to step-in to continue providing the services where it is in the public interest to do so.

In less serious cases of poor performance, governments can terminate a contract or licence (with or without notice), or reduce or reallocate the provider's funding. Smaller financial penalties may be a remedy for less serious breaches. For example, in Ontario, service accountability agreements with providers stipulate that funding may be reduced where reports and other items required under the agreement are not filed or are filed late.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

A private citizen or other private body may seek an order for judicial review in order to compel a statutory power or decision. A person could seek such an order where a statutory decision-maker refuses to exercise its decision-making power. It is available against all forms of administrative inaction, but is a discretionary remedy and various conditions must be met for a court to make such an order. Generally, an order will not be made to compel a decision-maker to exercise his or her discretion in a certain way.

A private citizen or other private body may also seek a declaration with respect to the exercise, refusal to exercise or proposed or purported exercise of a statutory power. A declaration is a judgment of the court that determines the legal position of the parties or the law applicable to them. Declarations are not coercive in nature, and there is no penalty or sanction imposed on the defendant for failing to act on a declaration. If a decision-maker continues to act in a manner that is inconsistent with the court's declaration, the applicant may seek to restrain the decision-maker through other means. It is within the discretion of the court to recognise public interest standing in a particular case. The jurisdiction of a court to grant

declaratory relief may not be available where the authority to deal with a particular question or issue is delegated to a particular statutory body.

35 What is the framework for claims of clinical negligence against healthcare providers?

An individual who has suffered from clinical negligence may seek redress from the courts. In order to succeed in a negligence action, a plaintiff must establish that:

- the defendant owed him or her a duty of care;
- the defendant breached that duty by falling below the standard of practice that is applicable in the circumstances;
- the plaintiff suffered damages that are recognised at law; and
- there is a causal connection between the damages and the negligence.

Healthcare professionals owe a duty of care to their patients. Over the years this duty has grown to encompass a widening sphere of obligation, including the duty to obtain informed consent, to provide referrals when necessary, to warn patients of inherent dangers in products and not to abandon patients.

Not all medical errors will result in a successful negligence action. The standard of care owed by healthcare professionals is not one of perfection but that of a normal and prudent professional of similar experience and standing. The baseline standard is objectively determined according to the specific health profession. Recognised damages may include costs incurred by a patient as a result of the negligence (eg, home care bills), general damages for pain and suffering, loss of past and future income and the cost of future care. Close family members may be entitled to compensation for services they have provided to the plaintiff, as well as for loss of care and companionship.

Causation is proven by establishing, on a balance of probabilities, that the injury would not have occurred 'but for' (in the absence of) the defendant's negligence. Generally speaking if it can be shown that the patient's trajectory was worsened by the act or omission, causation will be demonstrated.

Hospitals and other healthcare facilities can be held directly liable for negligent administration or management of the facility, such as failure to hire competent staff, to properly sterilise equipment, or to provide a safe environment, where that causes or contributes to damages to the plaintiff. Hospitals can also be held vicariously liable for the negligence of their employees. Generally speaking, hospitals are not liable for the negligence of staff physicians who have privileges because, typically, these individuals are independent contractors rather than employees of the institution.

With that said, bringing claims against healthcare providers that operate within the public sector or the broader public sector (eg, RHAs and public hospitals) can be challenging. Most have robust statutory protections against claims alleging negligence or a default in the performance or good faith exercise of a statutory duty or power. Even where statutory protections are not a barrier, the plaintiff must establish the existence of a sufficiently proximate relationship between the health service provider and the plaintiff. The courts will also consider whether there are public policy reasons that justify limiting the duty of care owed to a plaintiff.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

A purchaser or user of pharmaceuticals or medical devices may seek recourse for legal infringement (typically, an alleged defect in the drug or device, or an alleged failure to warn of an adverse side effect, or a failure of the drug or device to achieve its intended purpose) by commencing a legal proceeding against the manufacturer or seller of the drug or device on the basis of contract or tort law principles, or for breach of a consumer protection statute in some of the provinces and territories. For contractual liability to be established, the consumer must establish that there was an enforceable contract between the consumer and the manufacturer or seller, the manufacturer or seller breached a term of the contract, and the damages claimed were a reasonably foreseeable consequence of the breach. In tort law, the typical tort used in these types of cases is that of negligence. To prove negligence on the part of the manufacturer or seller, the consumer must establish that the manufacturer or seller owed a duty of care to the consumer, the manufacturer or seller's conduct fell below the standard of reasonable care, and the manufacturer or seller's breach of the standard of care caused or contributed to the consumer's loss.

Purchasers or users of pharmaceuticals or medical devices cannot seek a remedy against a manufacturer or seller of a drug or device simply on the basis of regulatory infringement (typically, a failure of the drug or device to meet regulatory requirements such as those imposed by the regulations under the FDA). Instead, the failure to comply with regulatory requirements may be offered by consumers as evidence of negligence or evidence of conduct that falls below the standard of reasonable care in the context of legal proceedings for the tort of negligence as described above.

37 Are there any compensation schemes in place?

Canada has a public health system that provides government-funded medical care for most illnesses and adverse conditions. However, with the exception of a couple of extraordinary illness-specific programmes, generally there are no widespread compensation programmes for people suffering from a given medical condition or incurring the adverse effects of allegedly defective medical products. One exception is the recently announced federal compensation programme for victims of thalidomide. Moreover, Quebec has a programme that compensates victims of vaccination pursuant to the Public Health Act and the Regulation under the Public Health Act.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Class actions are available as a form of collective recourse in all provinces and territories in Canada. The fundamental components of a class action proceeding in Canada are: certification to proceed as a class action, a trial of common issues, and (if the common issues are resolved in favour of the class of plaintiffs) adjudication of individual issues and damages. The test for certification as a class action comprises five elements that are generally consistent across Canada:

- the pleading discloses a cause of action;
- there is an identifiable class of two or more persons;
- the claims of the class members raise one or more issues that are common among all of the class members;
- there is no other procedure preferable to a class proceeding for the resolution of the common issues; and
- the representative plaintiff will fairly represent the interests of the class. Once a legal action has been certified as a class action, the fact of certification is communicated to people falling within the definition of the class either by publication of a notice of certification or direct contact to the class members if that is feasible.

Members of the class may then elect to participate in the class action lawsuit and be bound by its result, or to opt out of participating in the class action. While some types of claim are better suited to being litigated as a class action than others, generally no types of claim are automatically excluded from potentially forming the substantive basis of a class action.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Generally speaking, private institutions are not subject to judicial review because they do not exercise statutory powers of decision.

The acts, omissions and decisions of public officials and bodies, on the other hand, are typically subject to review. In particular, unless a decision or decision-maker is protected from review by statute, Canadian courts have the inherent common law power to review an administrative decision. In some cases, specialised boards have been established to review certain types of health-related administrative decisions. In Ontario, for example, HPARB is empowered to review various types of decisions made by health profession regulatory bodies as well as decisions of public hospitals relating to physician privileges.

A complaint may be made on the basis of: an error of law by the decision-maker (although generally speaking decisions of specialised tribunals are subject to a high degree of deference); lack of jurisdiction by the decision-maker; a failure to adhere to principles of procedural fairness; the decision-maker unduly fettered its discretion; or proceedings based on improper considerations. The remedies available to a court or review body vary but may include the orders in the nature of *mandamus* (ie, ordering the decision-maker to do something), prohibition (ie, ordering the decision-maker to refrain from doing something), and *certiorari* (essentially, quashing the decision).

Update and trends

Drugs and medical devices
The amendments to the FDA in November 2014 represent the first substantial changes to Canada's drug and device legislation in 50 years. The new extensive investigation and enforcement powers granted to Health Canada, as well as the substantial increase in the potential consequences for non-compliance, are major developments in Canada. Over the next year (and beyond) we can expect to see increased enforcement activities by Health Canada using its newly enhanced powers (eg, the power to require product testing, the power to require labelling changes and the power to recall products).

Enhanced scrutiny of foreign drug manufacturing plants is also expected to continue. Finally, we may see Health Canada take a position on the regulation of e-cigarettes, currently regulated in Canada as drugs. Since Health Canada cannot act unilaterally in this regard, any change in regulatory classification will be contingent on legislative reform.

Healthcare professionals
Across the country, there is an increasing emphasis on regulators showing 'zero tolerance' for sexual misconduct of any kind by professionals toward their patients. One can expect to see more such cases referred to disciplinary hearings and fewer 'plea bargains' on those that are referred.

Time limits for requesting a review of a decision vary depending on the province and body from which the review is sought (for example, a request to HPARB must be made within 30 days, although the Board may extend the time limit by 60 days). Generally anyone who is affected by the decision can request a review of the decision. In some cases, public interest standing may also be recognised.

40 Are there any legal protections for whistle-blowers?

Healthcare professionals
Under the legislation governing regulated healthcare professionals, in certain circumstances healthcare professionals and institutions are required to report matters to the regulator. In Quebec, a healthcare professional must report to their college any member whom he or she believes to be unfit to practise, incompetent or dishonest. The legislation prohibits any actions or conduct relating to another person's employment or service contract in retaliation for that person filing a report or making a complaint, as long as the report was filed or the complaint was made in good faith. A contravention of that prohibition is an offence, and on conviction the person who contravened it is liable, in the case of an individual, to a fine of up to $25,000 for a first offence and up to $50,000 for a second or subsequent offence. In the case of a corporation the maximum fines are $50,000 and $200,000, respectively. Another section of the legislation says that no action or other proceeding shall be instituted against a person for filing such a report in good faith.

Healthcare facilities and other providers
The Criminal Code of Canada further affords protection to whistle-blowers who report an offence that is being committed contrary to federal or provincial legislation. It is a criminal offence for an employer to take disciplinary action against an employee who has reported an offence that the employee believes is being committed by the employer contrary to any federal or provincial Act or regulation.

The provinces also regulate in this area. Ontario, for example, provides legal protection against reprisals to employees (under the Occupational Health and Safety Act) who make complaints against their employers where their health is at risk, as well as to healthcare providers under the Long-Term Care Act and the Retirement Homes Act when they file a mandatory report of misconduct where they suspect that a resident has suffered or is at risk of harm. Other statutes in specific areas provide protection from threats, retaliation, dismissal, penalties or intimidation to whistle-blowers where they have disclosed anything to a designated official.

41 Does the country have a reward mechanism for whistle-blowers?

There are currently no reward mechanisms for whistle-blowers in Canada in the area of healthcare.

42 Are mechanisms allowing whistle-blowers to report infringements required?

See question 40.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Drugs and medical devices
There have been no prosecutions under the FDA for drug or device violations, so this question does not apply with respect to drugs and medical devices.

Healthcare professionals
There is cooperation among regulators of health professions in various provinces and across international borders, although the degree of cooperation varies with the sophistication and resources of the regulator. Under the legislation governing regulated healthcare professionals in Ontario, a panel of the disciplinary committee is required to find that a member committed an act of professional misconduct where the governing body of a health profession in a jurisdiction other than Ontario has found that the member committed an act of professional misconduct that would, in the opinion of the disciplinary committee, be an act of professional misconduct as defined in Ontario. Regulators are increasingly sharing information about regulatory action taken against individual members in order to protect the public against disgraced members going outside the jurisdiction and seeking a licence to practise without disclosing their history.

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44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

Drugs and medical devices

Health Canada regularly communicates with several of its foreign counterparts in relation to drug and medical device safety. For example, in 2003, Health Canada and the United States Food and Drug Administration entered into a formal Memorandum of Understanding under which both agencies agreed to share, among other things, post-marketing information that could have an impact on public health, information on quality defects, clinical trial information, inspection reports, and information related to enforcement activities and investigations in their jurisdiction. Where a compliance investigation or enforcement activity in another jurisdiction involves a drug or medical device product that is also marketed in Canada, it is not uncommon for Health Canada to commence its own investigation. Whether or not an investigation occurs in Canada depends on whether the issue under investigation in the foreign jurisdiction also involves a violation of Canadian laws and regulations, or otherwise presents a risk to health of Canadian consumers.

Healthcare professionals

If a regulator becomes aware that a regulatory body in another jurisdiction has taken action against a member, the regulator will generally commence an investigation. Most colleges will require their members to provide details of any such proceedings on their annual renewal forms. If a healthcare professional has been found guilty of an offence (this is undefined but likely means criminal or quasi-criminal offence), then the member is required to file a report in writing with the college. This requirement applies regardless of the jurisdiction in which the finding was made. Such a report may also trigger an investigation by the college.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Drugs and medical devices

Foreign drug and device manufacturers that market products in Canada are required to comply with the FDA and its regulations, and are subject to enforcement action by Health Canada. Although there have been few prosecutions under the FDA, Health Canada does use other discretionary enforcement tools (such as the suspension or cancellation of market authorisation and establishment licences, import restrictions) against foreign companies when violations have occurred.

Healthcare professionals

The nationality of the person who is alleged to have violated the law in Canada is irrelevant. Generally, however, regulators only have jurisdiction over their members. Whether foreign companies and foreign nationals are pursued in court will depend on whether the conduct in which they were engaged occurred in the jurisdiction or otherwise in a manner connected with the jurisdiction.

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China

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The sources of medical funding in China include:

- government budget expenditure, which is mainly used to support state-owned medical institutions;
- social healthcare expenditure, which mainly refers to social medical insurance, including expenditure from administrative institutions and enterprises; and
- individual citizens' personal medical and healthcare expenditure.

According to published statistics from 2014, the percentage of government budget expenditure, social healthcare expenditure, and individual citizens' personal medical and healthcare expenditure compared to the total amount of medical and healthcare expenditure is approximately 30 per cent government, 35 per cent social and 35 per cent individual citizens.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare services in China are provided by medical institutions that engage in medical and disease diagnosis and treatment. Medical institutions mainly include hospitals and health centres, as well as other institutions such as sanatoriums, outpatient departments, etc.

According to statistics from 2014, up to 90 per cent of outpatient treatment is provided by public hospitals. Approximately 55 per cent of hospitals are public and 45 per cent are private.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

General legislation includes the Criminal Law of the People's Republic of China (Criminal Law), the Product Quality Law of the People's Republic of China (Product Quality Law), the Administrative Coercion Law of the People's Republic of China (Administrative Coercion Law) and the Law of the People's Republic of China on Administrative Penalties.

Healthcare related legislation includes the Administrative Regulations on Medical Institutions, Detailed Implementation Rules of the Administrative Regulations on Medical Institutions and the Regulations on the Supervision and Administration over Medical Devices.

Drug related legislation includes the Drug Administration Law of the People's Republic of China (Drug Administration Law) and the Provisions on the Procedures for Drug Administrative Penalties.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The National Health and Family Planning Commission of the People's Republic of China (NHFPC) and its subordinate agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare.

Funding for healthcare administration authorities, including the NHFPC, is primarily derived from government financial allocations and additional non-budgeted income. By law, income from administrative enforcement by healthcare administration authorities cannot be directly classified as funding for the administration authorities.

5 What is the scope of their enforcement and regulatory responsibilities?

The NHFPC and its subordinate agencies are responsible for formulating relevant policies and regulations, permits and access in the field of medical treatment and supervising law enforcement.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The China Food and Drug Administration (CFDA) and its subordinate agencies are principally responsible for the regulation of pharmaceutical products and medical devices.

The funding of the drug administration authorities is primarily derived from government financial allocations and additional non-budgeted income. According to the relevant laws, income from administrative enforcement drug administration authorities cannot directly be classified as funding for the administration authorities.

7 What is the scope of their enforcement and regulatory responsibilities?

The responsibilities of the CFDA and its local agencies include formulating relevant policies and regulations and implementing drug supervision and administration.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Administration for Industry and Commerce (AIC) is responsible for violations of AIC rules in relation to drugs, medical devices, etc during the production and distribution processes, and for penalising such violations by revoking business licences.

The public security bureau (PSB) is responsible for violations of laws relating to public security administration and the Criminal Law in relation to drugs, medical devices, etc during the production and distribution processes, and for penalising violations by imposing fines, detention and in serious cases, referring matters to prosecutors for prosecution.

In addition, where drugs or medical devices-related projects or cases are suspected of constituting a monopoly, or involving anti-competitive activities, the Ministry of Commerce (for M&A projects), the National Development and Reform Commission (for pricing-related cases) and the State Administration for Industry and Commerce (SAIC, for all other cases) will have jurisdiction.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Based on our experience, government agencies in China frequently conduct cross-agency investigations, especially where a significant medical incident has occurred.

A completed investigation does not bar another agency from investigating the same facts and circumstances. Where the same facts or circumstances constitute a violation of different regulations, investigations may

be conducted by the different enforcement agencies who have jurisdiction for those regulations.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Drugs

According to the Drug Administration Law, the CFDA has administrative powers including:

- regulating drug development, production and distribution, and the use of drugs by medical institutions;
- selectively examining and testing drug quality; and
- follow-up examinations of drug production enterprises and drug distribution enterprises.

Medical devices

There are also administrative regulations related to medical devices. According to the Regulations on the Supervision and Administration over Medical Devices, the CFDA has administrative powers including:

- supervising and examining the registration, filing, production, operation and use of medical devices;
- conducting on-site inspections and extracting samples;
- accessing, copying, sealing up or confiscating relevant contracts, bills, books and other materials;
- sealing up or confiscating medical devices that do not conform to legal requirements, or parts, accessories and raw materials that are used in the violation of laws or regulations, and tools and devices used for the illegal production of medical devices; and
- sealing up premises that are used for the production and operation of medical devices in violation of relevant laws and regulations.

11 How long do investigations typically take from initiation to completion? How are investigations started?

It normally takes the CFDA a number of weeks from the initiation of an investigation to completion.

CFDA investigations are primarily initiated in the following four circumstances:

- they are identified during the course of supervision and inspection;
- they are identified during inspection by another inspection authority;
- they are reported by citizens, legal persons and other organisations; or
- they are assigned by superior authorities, reported by subordinate authorities, transferred from other relevant authorities or disclosed through other means or approaches.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Administrative authorities will hold a hearing upon the request of the relevant parties prior to determining the relevant penalty. Penalties include ordering suspension of production and business, revoking a licence or permit and imposing large fines. During the hearing, investigators will present the facts, evidence and recommendations for the administrative penalties.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Generally, the CFDA has no right to investigate abroad, and can only conduct domestic regulatory examinations and investigations in relation to imported drugs or medical devices.

14 Through what proceedings do agencies enforce the rules?

The CFDA and its local branches generally enforce the rules through two forms of proceedings, including the following.

Administrative proceedings

The CFDA primarily has the authority to enforce administrative regulations through administrative measures and penalty proceedings.

Criminal proceedings

In serious matters that are suspected of involving a criminal offence, the CFDA may submit the case to the PSB or the prosecutor for investigation and prosecution through criminal proceedings in court.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

In administrative proceedings, in accordance with the laws and regulations of the relevant authorities, punitive measures include imposing fines, banning or revoking business licences and permits, confiscating drugs produced and sold in violation of laws and the disgorgement of illegal gains, etc.

In criminal proceedings for serious violations, sanctions include imposing fines and imprisonment.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes. The relevant authorities can impose administrative or criminal liability on the person in charge and other persons who are directly responsible, as well as on the company itself. The authorities typically do this in cases involving serious violations.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

Defences

Defences may vary in different cases. For example, the defendants may claim that the CFDA's investigation process involved errors, or that there were errors of fact and that the investigation is therefore invalid.

Appeals

For administrative enforcement proceedings, defendants may apply to a higher authority for administrative reconsideration where they are dissatisfied with the administrative measures imposed by the administrative authorities. Defendants may also appeal to a court when they are dissatisfied with administrative appeal decisions or serious administrative measures ordered, such as detention.

For criminal enforcement proceedings, companies may appeal to a higher court.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Given that the legislation in relation to drugs and medical devices evolves quickly in China, companies are advised to pay close attention to updates to all relevant legislation, ensure corporate compliance and maintain strict control of the quality and security of drugs and medical devices.

During the enforcement process, companies may seek professional legal advice to avoid any abuses in the proceedings, to negotiate with the authorities and to identify and collect evidence that may be relevant. It is also advisable for companies to cooperate with the administrative authorities investigating the violation, which may lead to lesser or mitigated punishment or penalties. In addition, companies may actively seek to compensate any victims in an effort to settle potential claims by such victims before any formal investigation is initiated by the authorities.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Lately, the CFDA has been focusing on anti-bribery issues in their enforcement activity. For example, in the recent GlaxoSmithKline (GSK) bribery case, GSK was alleged to have paid large sums of money to doctors to encourage them to promote the sales of its drugs. Serious sanctions were imposed on GSK in this case including fines and imprisonment sentences for some of its senior executives. In China, any drug must first obtain the CFDA's approval before it can be released to the market. It has been reported that certain CFDA officials had improper relationships with GSK, which created wide public concern about CFDA's fairness and impartiality.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

Yes, there are many industry associations for companies that sell pharmaceutical products and medical devices in China, including the China Association of Pharmaceutical Commerce (CAPC), which is supervised by the state-owned Assets Supervision and Administration Commission. The main task of CAPC is to enhance the compliance standards in the

industry and raise awareness of the law, and regulate enterprises' actions by requiring them to follow the articles of association of their respective associations. The members may be dismissed by the association in cases of serious violation of the articles of association and where approved by the board.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

Professional codes published by the NHFPC prohibit any relationship of improper interests between healthcare professionals and enterprises or persons that produce or sell drugs and medical devices.

General provisions against commercial bribery are set out in the relevant administrative regulations of the SAIC.

Certain serious actions may constitute a violation of the Criminal Law.

22 How are the rules enforced?

The professional code of the NHFPC is implemented by the NHFPC itself and its subordinate authorities.

The regulations of the SAIC are supervised and inspected by the AIC and its local branches.

The provisions of the Criminal Law are enforced by the PSB, the prosecutor and the People's Court.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

For violations of any of the above rules, persons and entities should report to the relevant authorities when they are aware of such actions.

Where no violation has occurred, there is no authority in China that is responsible for the collection and processing of such information. Some companies may have internal rules on the recording of such information, but it is unlikely that there are requirements to be make such disclosures public.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

According to the relevant laws, the healthcare authorities have broad powers to monitor medical institutions, including to:

- approve the establishment, practice registration and verification of medical institutions;
- examine and guide the practice activities of medical institutions;
- organise evaluations of medical institutions; and
- impose penalties for acts in violation of the relevant laws and regulations.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

It normally takes weeks from the initiation of an investigation to the determination of administrative decisions. Pursuant to the relevant laws, investigations of healthcare administrative authorities are primarily initiated under the following circumstances:

- during the course of supervising, inspecting or guiding the implementation of relevant laws, regulations, rules and standards by medical institutions;
- during the course of supervising, examining or guiding the practice activities of medical institutions; and
- during investigation and evidence collection in cases where medical institutions are in violation of relevant laws and regulations.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

See question 12.

27 Through what proceedings do agencies enforce the rules?

The NHFPC and its local branches generally enforce the rules through two proceedings, including the following.

Administrative proceedings

The NHFPC primarily has the authority to enforce administrative regulations through administrative measures and penalty proceedings.

Criminal proceedings

In serious matters that are suspected of involving a criminal offence, the NHFPC may submit the case to the PSB or the prosecutor for investigation and prosecution in accordance with criminal proceedings in court.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

There are many sanctions and other measures that the authorities may impose. Such measures include ordering rectification, issuing a warning, confiscating illegal gains, imposing fines and revoking business licences. These can be imposed or sought by healthcare administration authorities in accordance with the Administrative Regulations on Medical Institutions, or by product quality administration authorities in accordance with the Product Quality Law. Where a criminal offence is suspected, a criminal investigation will be conducted.

29 What defences and appeals are available to healthcare providers in an enforcement action?

The same defences are available as set out in question 17.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

The same strategies are available as set out in question 18.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Recently, the NHFPC has focused on two issues: anti-bribery and illegal practices.

Sanctions such as fines, revoking business licences, confiscating medical devices and imprisonment have been imposed on practitioners operating illegally.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Yes, there are many self-governing bodies for healthcare providers in China. One of the most prominent associations is the Chinese Medical Association (CMA), which is supervised directly by the NHFPC. The main task of the CMA is to enhance the development of medical technology and protect health practitioners' interests. The members may be dismissed by the CMA in cases of serious violation of the articles of association and where approved by the board.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

In China, the health insurance management centres (HIMCs) in each city, which are managed by the Ministry of Human Resources and Social Security of the PRC and its local branches, enter into service agreements with every medical institution which treats patients that are insured by public health insurance. Such service agreements usually provide that the HIMC may terminate payments to the medical institution or terminate the service agreement if such medical institution violates the agreement due to poor performance.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

In accordance with relevant provisions of the Tort Law of the People's Republic of China (Tort Law), citizens and other private organisations are entitled to request that measures be taken against medical institutions in any of the following circumstances:

- when any such institution fails to explain to patients their state of illness and medical treatment measures;
- when healthcare professionals fail to conform with the current standard (discussed further below) of medical treatment during diagnosis and treatment;

Update and trends

The authorities' enforcement priorities in the coming year are likely to be anti-bribery issues in the healthcare industry.

The noteworthy cases mainly focus on medical companies and officials in positions of authority. For medical companies, for example, Siemens has been reported as being involved in investigations relating to bribing hospitals to promote their medical devices in China. For officials in positions of authority, one noteworthy case is that of Mr Tong Min, the director of the Medical Devices Department in the CFDA, who is being investigated in relation to alleged bribery issues.

The Drug Administration Law (2015) and the Regulations on the Supervision and Administration over Medical Devices (2014) have been revised recently. The People's Congress has also been preparing the Basic Health Law, which aims to guarantee basic medical services for Chinese people.

- when any injury is caused to patients due to a defect in drugs, disinfectants or medical devices, or due to the transfusion of contaminated blood;
- when a patient's privacy is breached or a patient's medical record is publicised without consent; or
- when medical institutions and their healthcare professionals conduct unnecessary examinations in violation of diagnosis and treatment norms.

35 What is the framework for claims of clinical negligence against healthcare providers?

The standard of care the health provider must meet is the 'current standard'. In other words, if a medical professional fails to perform the diagnosis and treatment according to current standards, resulting in damage suffered by the patient, then this will constitute a breach.

Generally, to hold the medical institution liable to pay compensation for any claim, the victim needs to show that:

- damage was caused in the course of the medical treatment; and
- the medical institution (or one of its medical professionals) is at fault.

If any damage is caused to the patient under any of the following circumstances, the medical institution will be deemed to be at fault:

- its medical professionals have violated laws, administrative regulations, rules or other relevant requirements on diagnostic and treatment practices;
- its medical professionals have concealed or refused to provide medical records relating to the dispute; or
- its medical professionals have forged, tampered with or destroyed medical records.

The courts will not distinguish public or quasi-public healthcare providers from private health providers when hearing cases and determining penalties.

As to damages, health providers can be ordered to pay compensation for losses suffered by the victim, including reasonable expenses incurred for treatment and recovery such as medical expenses, nursing expenses and transportation expenses, as well as for any loss of income due to absence from work.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

According to Chinese law, purchasers and users of pharmaceuticals or devices can seek compensation from either the medical institutions who provided the product or the manufacturers for any damages caused by such defective products. If the victim chooses to seek compensation from the medical institution, the medical institution may, after paying compensation, claim damages from the manufacturer.

37 Are there any compensation schemes in place?

At present, there are no general compensation schemes in place. Medical institutions or manufacturers will compensate victims on a case-by-case basis for all reasonable expenses incurred for treatment and recovery such as medical expenses, nursing expenses and transportation expenses, as well as for loss of income due to absence from work.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Yes, joint actions can be commenced in China.

The requirements for joint or collective claims include:

- the cause of actions are the same or fall within the same category;
- the court considers that the actions can be combined as a joint action; and
- the parties have consented to the proceedings being joined.

In cases where individual plaintiffs have commenced separate actions, if the court thinks that the actions can be joined, the court will seek consent from the parties. The actions can be combined into one joint action if all the parties consent.

Healthcare-related claims are not excluded from the joint action scheme.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Acts, omissions or decisions of public and private institutions in the healthcare sphere are subject to judicial and administrative review if there is a complaint from interested parties.

The NHPFC and other authorities may initiate administrative review following a complaint. Courts may conduct further judicial review over the acts or decision of the administrative authorities.

There are strict rules regarding the time limits for judicial review. For example, if an interested party is not satisfied with specific conduct of the authority, then it must initiate court proceedings within six months of the relevant conduct. If an interested party is not satisfied with a decision following an administrative appeal, then it must initiate court proceedings within 15 days after receiving the decision.

The grounds on which complaints can succeed vary on a case-by-case basis. For example, in a medical accident case, if there is a dispute between the complainant and the medical institution, then the complainant may submit the case to the NHPFC's local subsidiaries or to a court for review. A technical identification will usually be organised to determine the responsibilities of the doctor and the medical institution. The result of such technical identification will usually be the key ground for the complaint to succeed in such case.

The remedies that the adjudicator can order also depend on provisions of relevant laws and regulations. For example, in a medical accident case, the NHPFC's local subsidiaries may give a warning according to the grade and situation of the medical accident. If the circumstances are serious, the NHPFC's local subsidiaries may order the medical institution to suspend business for rectification within the specified time limit or the original licence-issuing department shall revoke the licence of the practice, and the medical workers responsible will be investigated for criminal liability in accordance with the provisions of the criminal law on the crime of medical accidents. If their acts are not serious enough for criminal punishment, administrative or disciplinary sanctions will be administered according to law.

40 Are there any legal protections for whistle-blowers?

Yes, generally speaking, all authorities are required to provide certain protection to whistle-blowers, such as adopting confidentiality measures including retaining whistle-blower information in dedicated computers by designated persons, maintaining whistle-blower information and materials in confidential premises, and so on.

41 Does the country have a reward mechanism for whistle-blowers?

There is no unified reward mechanism for whistle-blowers. Many authorities have set up their own reward mechanisms for whistle-blowers. In particular, if certain infringements are a current enforcement priority, the authorities usually set up a special reward or incentive system for whistle-blowers for reporting such infringements.

42 Are mechanisms allowing whistle-blowers to report infringements required?

Yes, generally speaking, all authorities are required to set up their own reporting mechanisms allowing whistle-blowers to report infringements.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

With respect to criminal proceedings, China has signed many treaties and conventions relating to judicial assistance between cross-border authorities. With respect to administrative proceedings, the authorities may cooperate with their counterparts on a case-by-case basis.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

Enforcement activities by foreign authorities may trigger an investigation in China if:

- the Chinese authorities are made aware of such enforcement activities; and
- they present persuasive evidence or materials to show a violation of Chinese law.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Under the following circumstances, foreign companies and foreign nationals may be pursued in China for infringements.

Where the infringement has an effect on a Chinese national

If a Chinese national suffers any damage in China from any drug or medical device produced by a foreign company or foreign national, then the foreign company and the foreign national may be pursued in China.

Where the infringement has occurred domestically

If a foreign company or a foreign national infringes China's healthcare laws in China, then the foreign company and the foreign national may be pursued in China.

Where the foreign company is registered in, or a foreign national is domiciled in China

If a foreign company is registered in China or a foreign national is domiciled in China when the infringement occurs, then the foreign company or the foreign national may be pursued in China.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

In Germany every citizen is, in principle, subject to compulsory health insurance. Therefore, approximately 90 per cent of the population is insured by one of the several public health insurance companies. In these cases, the insurer directly pays the healthcare providers, including costs for medical treatment, drugs and medical devices. The public health insurance companies are financed by contributions from employers and employees. The amount of contribution depends on the employee's income. Persons who are self-employed or who earn in excess of around €55,000 per year can opt for private health insurance. They pay their medical bills themselves and submit them to the health insurance company, which then reimburses them. Holders of private insurance pay premiums to their private health insurance company. The amount depends on the contractual agreement and is generally based on the individual's age and health status. Private health insurance can also be taken to complement the coverage of the public health insurance.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is mainly delivered by doctors in private practice and doctors who are employed in hospitals. In 2013, out of 1,996 hospitals, 896 were state-owned, 706 were private non-profit and 694 had private owners.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

There are a large number of laws and regulations that govern the healthcare sector, some of which are regulated on the federal level, others on the state level. Most notable among the federal laws is the Social Security Code (SGB), which contains provisions regarding health insurance coverage, statutory pension insurance and nursing insurance. The production and sale of pharmaceuticals are governed by the German Medicinal Products Act (AMG). Its counterpart for medical products is the German Medical Devices Act (MPG). The contractual relationship between doctor and patient is regulated by the German Civil Code. Hospital planning is a responsibility of the states. The details are therefore regulated in the hospital laws of the individual states. At times, European law might come into play. According to Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities. Therefore, numerous relevant European regulations and directives must be observed in this context.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

In relation to doctors, self-governing bodies called medical chambers and the health authorities are primarily responsible for the enforcement of applicable laws and rules. The Federal Joint Committee, a joint self-government of physicians, dentists, hospitals and health insurance funds, is responsible for quality assurance (cf section 137 et seq SGB V).

Regarding hospitals, some states have enacted hospital laws whereby the state authorities are responsible for legal supervision. According to section 113 SGB V, supervisory responsibility also lies with the associations of the health insurance providers in each state, substitute health insurance providers and the associations of private health insurance companies in each state.

In terms of criminal offences committed in the context of the delivery of healthcare, such as maltreatment or fraud, the competent prosecutor's office is responsible. The prosecutor's offices are organised on a state and regional level. Their territorial jurisdiction corresponds with that of the courts of law and they are subject to directives by the respective Ministry of Justice.

5 What is the scope of their enforcement and regulatory responsibilities?

The administrative bodies are generally responsible for the assurance of quality and profitability as well as for monitoring compliance with regulations on hygiene and professional duties. The prosecutor's offices investigate and enforce criminal offences.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

According to section 77 AMG (and respectively section 32 MPG), the competent higher federal authority is the Federal Institute for Drugs and Medical Devices (BfArM) unless the Paul Ehrlich Institute (the Federal Agency for Sera and Vaccines (PEI)) is competent. The PEI is competent for sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, tissues, allergens, advanced therapy medicinal products, xenogenic medicinal products and blood components manufactured using genetic engineering. Their revenue mainly results from fees charged for official acts, such as marketing authorisations and batch testing. Additional revenues are generated by mandates assigned by the European Medicines Agency (EMA) and other healthcare institutions. If pharmaceutical products are not only sold in Germany but also in other member states, the EMA is generally responsible for the scientific evaluation.

7 What is the scope of their enforcement and regulatory responsibilities?

The regulatory responsibilities of the PEI comprise authorising marketing, providing scientific advice on the development of medicinal products, approving clinical trials, experimental product testing and the official testing and release of batches as well as the assessment of adverse reactions to medicinal products. A focus of the work of the BfArM is the authorisation of proprietary medicinal products according to the provisions of the AMG. In this conjunction the health benefit, in other words the effectiveness and the pharmaceutical quality, is assessed. It further collects and assesses reports on the adverse effects of medicinal products and takes the necessary steps to protect patients.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Other agencies may have jurisdiction over healthcare related cases, in particular the prosecutor's office and antitrust authorities.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Different government agencies may conduct investigations simultaneously and independently. For instance, the BfArM may lead an investigation into activities of a pharmaceutical company while the prosecutor's office investigates the employees of the same company that were involved in the process. The authorities can and are likely to coordinate their investigations, but the completion of investigations by one agency does not necessarily bar another agency from investigating further as the subject and the potential sanctions of the investigations may differ. For example, the BfArM may prohibit the marketing of medicinal products, whereas criminal sanctions against the person involved can only be imposed by a court where criminal behaviour has been proven to the conviction of the competent court.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

According to section 64 AMG, the authorities have very broad powers in monitoring compliance with the rules on pharmaceuticals. Pursuant to sub-section 4, the persons in charge of the supervision are inter alia authorised to:

- enter and inspect properties and office premises;
- take pictures for documentation purposes;
- review the relevant documentation on the development, manufacture, testing, clinical trial or residue testing, acquisition, storing, packaging, marketing and other whereabouts of the medicinal products;
- prepare or request transcripts or photocopies of documents or printouts or copies of data storage media on which documents are stored in so far as personal data from patients are not concerned;
- demand from natural and legal persons and associations without legal capacity all the necessary information, in particular on the company operations; and
- issue provisional orders also on the closing of the company or facility, in so far as this is deemed necessary for the prevention of imminent danger to public order and safety.

With regard to medical devices, sections 26, 27 and 28 MPG provide corresponding powers.

In the process of pharmacovigilance, section 62(6) AMG authorises the authorities to inspect the collection and evaluation of medicinal product risks and the coordination of necessary measures in enterprises and facilities that manufacture, place on the market or clinically test medicinal products. For this purpose they can take the necessary measures like entering the production site and business premises.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Pursuant to section 64(3) AMG, the competent authority, on the basis of a surveillance system and paying special attention to possible risks, shall carry out inspections at appropriate intervals, to an appropriate extent and, if necessary, also unannounced and shall stipulate effective follow-up measures. Therefore, the decision of when to initiate an investigation is at the discretion of the authority. The inspections can also be carried out at the request of another member state, the European Commission or the European Medicines Agency. Enterprises and facilities requiring a manufacture or import authorisation are to be inspected every two years according to section 64(3a) AMG.

The duration of the investigations differs and depends on the measures taken and the necessity to issue provisional orders.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Specifically for pharmaceuticals, according to section 64(3d) AMG, the competent authority is obliged to draft a report on the inspection and to inform the inspected enterprises, facilities or persons of the content of the draft report. They have to be granted an opportunity to comment on the draft before it is completed. In criminal proceedings, in principle only, the defence lawyer of the incriminated individual is entitled to inspect the files and materials held by the prosecutor's office (section 147 of the German Code of Criminal Procedure (StPO)). While the investigation is pending, such request for inspection of the files or some parts of the files by the defence lawyer may be denied if his or her knowledge of the files may endanger the purpose of the investigation. The accused has no right to inspect the files. In some cases, even though there is no concept of corporate criminal liability, a juridical person is also considered to be a participant of the criminal proceedings when a fine may be levied against it (as is usually the case in corruption and cartel cases). The defence lawyer of the juridical person is then also entitled to inspect the files.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

In some cases such extraterritorial investigations are possible when pharmaceutical products are intended for import into Germany. For products that are manufactured in another member state of the EU and the European Economic Area (EEA) it is sufficient for the authorisation of the import that the manufacturer proves that it is entitled to manufacture medicinal products in accordance with the legal regulations laid down by the country of manufacture (cf section 22(5) AMG).

For products from other countries, import is only possible without inspection in the respective originating country where certificates on the proper manufacturing process are mutually recognised. Such mutual recognition is in place for all member states of the Pharmaceutical Inspection Convention and the Mutual Recognition Agreements which the EU has concluded with some states, most notably Japan and the United States. For all other states, the necessary certificate can only be received after a competent authority from Germany or the EU or EEA has satisfied itself through inspections in the country of manufacture that the relevant requirements are being observed in the manufacturing process according to section 72a(1) sentence 2 AMG.

14 Through what proceedings do agencies enforce the rules?

According to section 69 AMG (respectively section 28 MPG), the competent authorities shall issue the necessary directives to rectify any violations that have been identified and to prevent future offences. The agencies therefore enforce the rules through administrative proceedings; in other words they hold their own proceedings without having to take recourse to a court. Only in the event that a company intends to quash such directive will it have to initiate proceedings before the competent administrative court.

Criminal proceedings are only initiated for proceedings against individuals.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The authorities have wide discretion regarding the choice of adequate measures. According to section 30 AMG, a withdrawal, revocation or suspension of a marketing authorisation is possible. Furthermore, pursuant to section 69(1) AMG, the competent authorities shall issue the necessary directives to rectify any offences which have been identified and to prevent offences in the future. Under certain conditions they may, in particular, prohibit the marketing of medicinal products or active substances and order their recall from the market and seize them (respectively sections 22 b, 27 and 28 MPG).

In criminal proceedings, in particular in cases of corruption (eg, when doctors are incentivised to prescribe certain drugs), fines of up to €10 million (and more depending on the profit derived from the illegal act) may also be levied against the company for which the respective individual acted (sections 30 and 130 of the Law on Regulatory Offences).

16 Can the authorities pursue actions against employees as well as the company itself?

Generally the authorities can only pursue actions against the company. However the behaviour of an employee may become criminally relevant according to sections 95 et seq AMG (respectively sections 40 et seq MPG). In case of a suspicion of individual guilt, the prosecutor's office will initiate investigations against the employee.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

Defendants may file a formal objection to any administrative deed directly with the acting authority according to section 68(1) Administrative Court

Procedures Code (VwGO). If the authority refuses to amend or revoke its order, the defendant can bring a claim before the competent administrative court to have the order quashed according to section 42(1) VwGO.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Once an enforcement action is under way, it is pivotal for a healthcare provider to immediately initiate its own investigation of the matter. This will allow it to better assess the risk it faces and also to revise or discontinue certain activities or procedures, if necessary. It is generally advisable to seek to reach an agreement with the authorities before they issue their directive to the effect that the least burdensome measure is taken. In most cases there is room for negotiation, provided that the alleged violations are not too grave.

For incriminated individuals and equally for companies involved in criminal proceedings like an incriminated individual (see question 12), the correspondence with the law firm in charge of the internal investigation will be privileged and thus not subject to seizure (section 97 StPO). In contrast, any correspondence within the organisation with in-house lawyers is generally not understood to be privileged. In criminal proceedings, it is also usual and advisable for a company to engage advisers on criminal law and to see to it that all charged employees are represented by defence counsel.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

The authorities are permanently concerned with counterfeits of medical drugs and devices and risk assessment processes. In the latter case, the suspension of marketing authorisations according to section 30 AMG has usually been the imposed sanction.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The German Association of Researching Pharmaceutical Manufacturers (VFA) is a self-governing body for pharmaceutical companies. It acts mainly on the basis of the code of conduct of the organisation 'Voluntary Self-regulation for the Pharmaceutical Industry' (FSA), which also contains provisions regarding inspections and sanctions. The implementation of these provisions is provided through an arbitration board. Approximately 60 pharmaceutical companies have committed themselves to the VFA and FSA.

With regard to pharmacies, the chambers of pharmacists are the relevant self-governing bodies that regulate the monitoring of the activities of pharmacists. They can generally impose a fine or in cases of serious violations bar the pharmacist from practice.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

According to sections 30 et seq of the Model Professional Code of Conduct (MBO-Ä), doctors have to be independent. In particular, they must not accept presents or other kinds of advantages if this may create the impression that the doctor's independence is affected. If a doctor acts against this principle, the authorities may revoke his or her licence to practice medicine (cf sections 5(2), 3(1) sentence 1 No. 2 of the Federal Medicines Code).

According to section 331(1) of the German Criminal Code (StGB), a public official or a person entrusted with special public service functions who demands, allows himself or herself to be promised or accepts a benefit for himself or herself or for a third person for the discharge of an official duty shall be liable to imprisonment of up to three years or a financial penalty. The same applies to a person who offers, promises or grants such benefit. Doctors who work at a state-owned hospital are regarded as public officials or persons entrusted with special public service functions and thus may be prosecuted, for example for taking bribes or improper incentives from pharmaceutical companies in return for prescribing their drugs rather than comparable, cheaper products from competitors. However, under current legislation, doctors who work at a privately owned hospital or in private practice (even if working under contract with the public health insurance companies) are neither regarded as public officials nor as agents of a business (cf section 299 StGB) and can therefore not be criminally charged for the same actions. Equally, suppliers who offer bribes to such doctors cannot be criminally charged.

22 How are the rules enforced?

Regarding the alleged breach of the MBO-Ä provisions, the authorities can impose mandatory administrative deeds against the doctor. In case of criminally relevant conduct, the prosecutor's office may initiate criminal proceedings.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

As yet, unlike in the United States, there is no mandatory reporting system in place. However the FSA has issued a Code of Transparency, which imposes strict duties on its members to report different kinds of financial relationships between pharmaceutical companies and healthcare providers. As of 2016, the companies will be obliged to publish relevant information on their websites. However, Germany has very strict data protection rules which require the consent of the healthcare provider (eg, the doctor) prior to the publication of his or her personal data.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The authorities monitoring hospitals usually have the power to ask for certain pieces of information and to enter the premises without a search warrant. In some federal states, the supervising authorities are also explicitly entitled to request access to all hospital records. The authorities supervising the conduct of doctors are more limited in their powers. Doctors are obliged to respond to requests for information from the medical chamber and the chambers can also question witnesses. However, as the chambers usually have neither the right nor the resources to conduct wider-ranging investigations, they often depend on information discovered by the prosecutor's office. The prosecutor's office principally has wide-ranging powers, for example it can conduct a search within the premises of a doctor's office albeit only with a search warrant. Search warrants are granted if it can be assumed that the search will lead to the discovery of evidence, which is usually the case. When the prosecutor's office intends to make a search in a hospital rather than on the premises of a sole practitioner, the prerequisites for a search warrant are stricter because usually not the hospital itself but individual doctors are the subject of the investigations and such third persons are granted greater protection under German law (cf section 103 of the StPO).

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The length of investigations varies greatly, from weeks to years, depending on the complexity of the case and the severity of the offence. The prosecutor's office is obliged to start an investigation if there is an initial suspicion that a criminal act has been committed (section 152(2) StPO). For the administrative bodies overseeing the conduct of doctors and hospitals, there are no formal rules for the initiation of an investigation. Usually they will do so if they have gained knowledge of facts, through a complaint, the prosecutor's office or otherwise, that support the assumption that a specific rule has been breached. The first step in the investigatory process of the administrative bodies will usually be a request to the doctor or hospital while the prosecutor's office is more likely to covertly investigate before seeking to catch a suspect by surprise in order to find incriminating material.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

For criminal proceedings, see question 12. In administrative proceedings, the affected person can generally request access to the files if such access is necessary in exercising legitimate interests.

27 Through what proceedings do agencies enforce the rules?

The respective supervisory authorities of hospitals and doctors enforce their rules by way of administrative proceedings. They make their

decisions by way of administrative deeds that are binding upon the hospitals or doctors against which they are directed. These proceedings are neither criminal nor civil. In Germany the concept is that the relationship between an individual, whether private person or legal entity, and governmental bodies is governed by administrative law. Criminal law is generally understood to be a specific and clearly separated part of administrative law. Proceedings initiated by the prosecutor's office are criminal in nature and the prosecutor's office must apply to a court by way of an indictment.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

There is a wide range of sanctions and measures. Administrative bodies may, for example, request changes of certain practices, impose administrative fines or revoke licences to practice. The prosecutor's office will seek the imposition of financial penalties or imprisonment.

29 What defences and appeals are available to healthcare providers in an enforcement action?

There are formal and informal defences. In criminal proceedings, a healthcare provider can, for example, appeal against a search warrant or object to the seizure of certain privileged documents. In administrative proceedings, when administrative deeds have been imposed, the affected healthcare provider generally needs to formally object to the deed. When the authority fails to amend or revoke the administrative deeds, the affected healthcare provider can then turn to the competent administrative court to have the deed quashed. Informally, communication by various means with the respective authorities is possible.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 18.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In the past years, many directors of large hospital groups and doctors have been investigated for fraud, namely for submitting false claims to the insurers or patients. Typical sanctions have been financial penalties or prison sentences (mostly on probation, at least for first-time offenders) and loss of medical licence.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

All doctors have to be members of medical chambers in the respective states where they are practising. Each chamber has a set of rules concerning the conduct to be observed by the doctors. There are also specialised medical courts that can order disciplinary measures, including a declaration that the incriminated individual is not suitable for the medical profession. These specialised courts act in parallel to the ordinary courts of law so that a doctor who is, for example, accused of negligent homicide is likely to face proceedings before the criminal courts, the civil courts (if the bereaved or his or her insurance company claim damages) and the specialised medical court. However, proceedings before the medical courts and the civil court are often suspended until the criminal proceedings have been concluded.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

The most important contracts between the government and healthcare providers are contracts whereby public health insurance companies grant hospitals the right to treat patients that are insured by public health insurance companies. Such contracts can be terminated by the public health insurance companies if the hospital can no longer ensure efficient and economic treatment.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Most relevant enforcement actions are conducted by either administrative bodies or the prosecutor's office, both of which are not only entitled but also obliged to act in case of any infringements of relevant regulations or laws. Citizens may only invoke a breach of the relevant legislation if they themselves have been negatively affected by it; in other words if they have a personal interest in the enforcement. In particular these are cases of medical malpractice or pharmaceuticals with unwanted harmful effects.

35 What is the framework for claims of clinical negligence against healthcare providers?

A patient can bring claims against the respective doctor, or, where the doctor has practised in a hospital, also against the hospital. Liability can be based on both a breach of the respective contract governing the medical treatment and tort law. The applicable standards are essentially the same. The patient needs to show that the doctor has culpably failed to meet a standard of care that can reasonably be expected of a doctor who is an expert in that specific field of medicine. In principle, the patient has to prove that a medical error was committed, that this error caused the purported damage to his or her health and that the doctor acted culpably. However, over the years the courts have made some exceptions from that rule to allow for a level playing field, taking into consideration that the patient generally is in a weaker position in terms of the ability to provide evidence. There is no general principle to rule in favour of hospitals, even if they are state-owned. The damages to be awarded primarily serve to cover all costs incurred due to the purported malpractice, namely all costs for treatments, care and rehabilitation. In addition, a reasonable compensation in money may be demanded for any damage that is not a pecuniary loss: a 'money for pain'. The amount of compensation depends on the severity of the pain suffered and will exceed €100,000 only in exceptional cases. There is no concept of punitive damages under German law.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

If the user of a pharmaceutical product suffers damages to his or her health, he or she can directly claim damages from the manufacturer if the drug has had harmful effects in excess of what can reasonably be expected according to the current scientific standard, or if labelling or manuals have been insufficient (section 84 AMG). It is not necessary for the user to show that the manufacturer acted culpably. The burden of proof in terms of causation is shifted to the manufacturer. Similar standards apply in case of medical devices (section 1 Product Liability Law).

37 Are there any compensation schemes in place?

There are no specific compensation schemes in place. In the past such schemes were only set up in cases where a high number of people were affected.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Neither class actions nor other collective claims are permissible in Germany. Under German law, several persons can only bring claims jointly under strict prerequisites that are usually not given in cases related to drugs, devices and the provision of care. In addition, any costs for treatment, care and rehabilitation will usually have been borne by the health insurance companies. Any claims by the insured against the doctor or hospital are then automatically subrogated to the extent that they have been paid by the insurance company. Therefore, in practice most proceedings initiated by individuals concern claims for non-pecuniary losses.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Under German law, only persons that are directly affected can bring claims against certain acts, omissions or decisions.

Update and trends

Corruption in the healthcare system is at the forefront of the public interest at the moment. As seen in question 21, under the current German anti-corruption laws, private practitioners under contract with the public health insurance companies, unlike their counterparts working in state-owned hospitals, are in principle not criminally liable under the corruption laws because they are not considered to be public servants. This was perceived to be a gap in the law. A draft bill was presented in January 2015 and is currently being considered. The draft bill envisages two new sections to the German Criminal Code dealing with corruption in the health sector in order to allow for criminal charges against both the doctors who are bribed and the employees of the pharmaceutical companies that bribe or attempt to do so. The maximum sentence in severe cases is five years of imprisonment.

40 Are there any legal protections for whistle-blowers?

There is no specific legislation for the protection of whistle-blowers in place, even though this has been debated over the last few years. However, whistle-blowers are generally understood to be protected from any discriminatory or retaliatory actions by their employer through existing labour law.

41 Does the country have a reward mechanism for whistle-blowers?

No reward mechanism exists. In case of criminal proceedings where the whistle-blower itself has been involved in a criminal act, the general rule applies that if the perpetrator has substantially contributed to the discovery of an offence, the court may reduce the sentence or, in some cases, order a discharge.

42 Are mechanisms allowing whistle-blowers to report infringements required?

There are no legal requirements for the implementation of such mechanisms under the applicable laws. However, there is an obligation to implement a Critical Incident Reporting System whereby employees can notify certain errors on a voluntary and anonymous basis and without any risk of criminal prosecution unless a grave criminal offence has been committed (section 137 (1)(d) SGB V).

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes, they generally cooperate with their foreign counterparts. Formal cooperation takes place by way of mutual assistance. Where no specific bilateral or multilateral treaty exists, this is governed by the Act on International Mutual Assistance in Criminal Matters.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

In criminal cases, any competent German prosecutor's office is obliged to start an investigation if there is an initial suspicion that a criminal act has been committed. Therefore, it will have to initiate investigations if it learns of any enforcement activities by foreign authorities that give rise to the suspicion that criminal acts have also been committed on German territory.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

German Criminal Law (and with it all provisions on criminal liability contained in other laws such as the Medicinal Products Act) will be applied to all acts committed in Germany, whether by German or foreign nationals. Such criminal investigations can only be directed against foreign individuals, not against companies as there is no concept of corporate criminal liability.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

There is a two-tier health service in Ireland, comprising the public healthcare system and the private healthcare system. The public healthcare system is funded by the state. The private healthcare system is funded by private funds and private insurance.

Healthcare policy and expenditure in Ireland is determined by the Department of Health. Public healthcare services are provided by the Health Service Executive (HSE). The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, receive state funding but are owned by religious orders or similar institutions.

In Ireland, every citizen is entitled to free or subsidised medicines and certain medical and surgical aids and appliances. The prices paid by the HSE for medicines are maintained on an official reimbursement list, and are set by reference to the Health (Pricing and Supply of Medical Goods) Act 2013.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is mainly delivered by way of primary or secondary care. Primary healthcare services are provided outside of hospitals to people living in the community, for example by general practitioners, nurses, health clinics, etc. Secondary healthcare is delivered in hospitals to patients normally living at home, for example outpatient clinics, accident and emergency clinics, etc. In recent years, more health insurers have provided secondary care such as 'home nursing' or 'treat at home' schemes.

Most medical treatment is available free of charge or subject to a subsidised charge under the public health system. In addition to private hospitals, a limited number of private beds in public hospitals facilitate the treatment of patients who opt for private health insurance. The most recent statistics indicate that approximately 44 per cent of the Irish population hold private health insurance, a key benefit of which is avoiding lengthy public waiting lists for elective procedures.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

A wide variety of legislation governs the delivery of healthcare, including:

- the Health Acts 1947–2011: the statutory framework governing the national healthcare system;
- the Health Act 2007: this established the Health and Information Quality Authority (HIQA); and
- the Medical Practitioners Act 2007: this established the Medical Council.

Other legislation governs healthcare professions such as the Dentists Act 1985, the Nurses and Midwives Act 2011 and the Pharmacy Act 2007.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

A number of bodies are responsible for the enforcement of laws and rules applicable to the delivery of healthcare. For example:

- The HIQA is responsible for setting standards for the safety and quality of public or publicly funded hospitals and healthcare services, and social care and residential services. The HIQA is responsible for the registration, oversight and scrutiny of designated health and social care services, which include public and private residential facilities for children and adults with disabilities and nursing homes (called designated centres). The HIQA is funded by the Irish government. The HIQA does not currently regulate private hospitals, though its scope is due to be extended imminently.
- The Medical Council is responsible for regulating doctors in Ireland. It is funded by the registration fees of medical practitioners.

Numerous other statutory bodies regulate other healthcare professionals, such as the Dental Council of Ireland, the Irish Nursing Board, the Pharmaceutical Society of Ireland and the Health and Social Care Professionals Council.

Many statutory bodies have the power to prosecute summary offences under applicable legislation. In Ireland, a summary offence is one that can only be dealt with by a judge in the lower courts sitting without a jury. Summary proceedings carry lower fines and penalties. Indictable offences are more serious and are heard in the higher courts and, in certain circumstances, must be tried before a judge and jury. The Director of Public Prosecutions (DPP) directs and supervises public prosecutions on indictment.

5 What is the scope of their enforcement and regulatory responsibilities?

The HIQA sets standards for safety and quality in healthcare. It has a monitoring function and carries out investigations as to the safety, quality and standards of healthcare and social care services under its remit. Designated centres under its remit can be deregistered for failure to comply with safety and quality standards. The HIQA can also bring summary proceedings for offences under the Health Act 2007, which carry penalties of:

- on summary conviction, a fine not exceeding €5,000, or imprisonment for up to one year, or both; or
- on conviction or indictment, a fine up to €70,000, or imprisonment for up to two years, or both.

The Medical Council investigates complaints against doctors and can impose sanctions (see question 24).

Other regulators, including those named in question 4, have investigative and enforcement powers.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The Health Products Regulatory Authority (HPRA) is responsible for regulating medicinal products, medical devices, controlled drugs and cosmetic products. The HPRA was established under the Irish Medicines Board Act 1995 (as amended) (the IMB Act). Before 1 July 2014, the HPRA was called the Irish Medicines Board.

In relation to medicinal products, the HPRA is self-funded through the collection of fees. In relation to the regulation of the medical devices, the HPRA's funding has been predominantly provided by the Department of Health, with a small contribution from self-collected fees. However, the HPRA aims to introduce a fee-based self-funding model to support the conduct of medical device regulatory activities.

The National Standards Authority of Ireland (NSAI) is the notified body in Ireland responsible for performing conformity assessments to ensure compliance with medical device legislation and for awarding CE marks.

7 What is the scope of their enforcement and regulatory responsibilities?

The HPRA is the regulatory authority responsible for authorisations for manufacturing, marketing, importing, exporting or distributing medicinal products, and for the assessment of clinical trials. The HPRA is also responsible for monitoring the safety and quality of medicinal products placed on the Irish market. The HPRA is the competent authority for monitoring the safety of medical devices.

The HPRA investigates activities associated with the illegal supply, manufacture or advertising of health products. Where significant risk to public health has been detected, or where compliance cannot be achieved, or other aggravating factors exist, the HPRA will prosecute the offender. The HPRA can prosecute certain summary offences. Indictable offences are prosecuted by the DPP (see questions 4 and 5).

Summary offences under the NSAI Act 1996 (as amended) may be prosecuted by the Minister for Jobs, Enterprise and Innovation. Indictable offences are prosecuted by the DPP.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Other agencies that have jurisdiction over healthcare, pharmaceutical and medical device cases include:

- the Data Protection Commissioner, responsible for the enforcement of data protection laws;
- the Director of Corporate Enforcement, responsible for the enforcement of company laws;
- the Competition and Consumer Protection Commission, responsible for the enforcement of competition and consumer laws;
- the Health and Safety Authority, responsible for the enforcement of occupational health and safety laws; and
- the Revenue Commissioners, responsible for the assessment and collection of taxes and duties.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct investigations. However, agencies are usually obliged to ensure that their investigations do not interfere with another investigation.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The HPRA (and its authorised officers) have wide-ranging powers to investigate regulatory breaches. For example, authorised officers can enter premises to carry out inspections, investigations, tests or examinations and can inspect, copy, remove and detain records, documents or samples for review and testing.

An authorised officer of the NSAI may, on request, obtain access to the place of manufacture or storage of medical devices and make such examinations, tests, or inspections as it considers appropriate. An authorised officer may also apply to the District Court for a warrant to seize medical devices that are not in compliance with the regulations, or to compel information from a person in relation to that device.

11 How long do investigations typically take from initiation to completion? How are investigations started?

The HPRA has an inspection programme for carrying out proactive and reactive inspections and auditing. In 2013, the HPRA carried out 279 national inspections and audits and 34 foreign inspections and audits. Of the total number of inspections and audits carried out, 63 per cent were completed within 90 days. On average, in 2013, an inspection and audit took 103 days to close out.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

In the context of a prosecution, the accused is entitled to certain evidence. For prosecutions on indictment, the prosecution has a statutory duty to provide the accused with the Book of Evidence intended to be given at trial. In summary prosecutions, there is no general duty on the prosecution to provide the accused with the statements of witnesses or documents. However, a District Court judge may order that statements and documents are handed over to the defence if it is deemed necessary in the interests of justice. The criteria used to determine a judge's decision include the seriousness of the charge, the importance of the statements or documents, whether the accused had been adequately informed of the nature and substance of the accusation, and the likelihood of risk of injustice in failing to furnish the statements or documents to the accused. This Order is commonly known as a '*Gary Doyle*' Order.

Ireland's data protection and freedom of information laws contain exceptions that allow a body to decline access to data or records kept for the purpose of investigating offences.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes; this is generally done with the cooperation of the local, national or EU regulatory authority. The HPRA has carried out inspections of manufacturing sites and clinical trial sites in many countries in recent years.

14 Through what proceedings do agencies enforce the rules?

Depending on the severity of the offence, a regulator may try to work with an offender to correct non-compliances in a non-adversarial manner. For example, the HPRA typically notifies the offender that they are in breach and affords them an opportunity to cease the offending practice before more serious action is taken. The HPRA's policy on enforcement is to:

> *...prosecute where significant risk to public health has been detected, or where compliance cannot be achieved, or other aggravating factors exist.*

Generally speaking, the HPRA and other entities have the authority to initiate proceedings to prosecute summary offences through the Irish criminal justice system. More serious indictable offences are prosecuted by the DPP.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Any person found guilty of an offence under the IMB Act is liable:

- on summary conviction to a fine not exceeding €2,000, or imprisonment for up to one year, or both; or
- on conviction on indictment to a fine up to €300,000 and, or imprisonment up to 10 years, or both.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes. When an offence under the IMB Act has been committed by a company, the directors, managers or other officers of the company may also be prosecuted when the offence is proved to be committed by the company with consent, connivance or attributable neglect on the part of the particular individual. A company does not have to be charged with, or convicted of, an offence for a director, manager or other officer to be charged or convicted.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The defences available will typically depend on the nature of the allegations.

An appeal of a prosecution for breaches of pharmaceutical products and medical devices laws is taken through the criminal justice system. For criminal cases, the Circuit Criminal Court hears appeals of decisions from the District Court and the Court of Appeal hears appeals against convictions or sentences imposed by the Circuit Criminal Court, the Central Criminal Court (High Court) and the Special Criminal Court.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Once an enforcement action is under way, the company should immediately seek to remedy any breach and cooperate fully with the investigation by complying with all directions and recommendations of the investigating body. The company should also seek legal advice.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

A key focus for the authorities has been on falsified medicines that pose a health risk to the public. Operation Pangea VIII, a cross-border coordinated effort targeting the sale of falsified medicines, was conducted in June 2015. It resulted in the detention of medicines including sedatives, anabolic steroids and weight loss units. Recent efforts by the Irish authorities have also focused on the online sale of weight loss substances due to high-profile media reports of adverse reactions.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

There are a number of self-governing bodies in Ireland representing companies that manufacture and sell medicinal products and medical devices.

The Irish Pharmaceutical Healthcare Association (IPHA) is the industry association that represents the international research-based pharmaceutical industry in Ireland. Its member companies include manufacturers of prescription and non-prescription medicines. The IPHA is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and has published a Code of Practice for the Pharmaceutical Industry Edition 8.1 (IPHA Code) which reflects the standards of the June 2013 edition of the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals. The IPHA Code also provides practical guidance on implementing the Medicinal Products (Control of Advertising) Regulations 2007.

Although the IPHA Code is a self-regulatory code and is only binding on members of the IPHA, it reflects best practice in Ireland. The IPHA has a Code of Practice Panel, a Code Council who hear complaints in the first instance, and an appeals board. The Code Council have the authority to impose a number of sanctions including reprimanding a company, ordering the recovery of material or correction of inaccurate information, publishing a decision, referring a matter to the Minister for Health (in the case of difficult or persistent breaches) and recommending the suspension or expulsion of the offending party to the IPHA board of directors.

The Association of Pharmaceutical Manufacturers of Ireland (APMI) is an industry body representing manufacturers of generics. It has published the APMI Code of Practice on Advertising of Medicinal Products.

The Irish Medical Device Association and the Irish Medical and Surgical Trade Association have published codes of ethical business practice. These codes reflect the Eucomed Code of Ethical Business Practice. There are no formal complaints procedures or sanctions contained in these codes.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

The IPHA Code aims to bring greater transparency to the interaction between pharmaceutical companies, healthcare professionals (HCPs) and healthcare organisations (HCOs). It contains a set of industry rules relating to the disclosure of transfers of value from pharmaceutical companies to HCPs and HCOs.

The disclosure rules oblige every member company to document and publicly disclose all transfers of value (subject to certain exceptions) it makes to HCPs or HCOs. These include items such as donations; grants; consultancy or speaking fees; and hospitality, sponsorship or funding for attendance at medical meetings, conferences or symposiums.

The IPHA Code provides that contractual provisions consenting to disclosure must be incorporated into contracts with HCPs and HCOs.

22 How are the rules enforced?

See question 20.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

Since January 2015, the disclosure of transfers of value must be made on annual basis within six months of the end of the reporting period. A reporting period is a full calendar year. The first reporting period is 2015. Disclosures may be made on a company's website, provided that they are unrestricted and publicly available. The information must remain in the public domain for three years.

The IPHA Code provides for two forms of disclosure: individual and aggregate. Individual disclosure is where the monetary amounts attributed to all transfers of value to each clearly identifiable HCP or HCO are disclosed. The IPHA Code provides that, as a preference, individual disclosure should be used, except where certain information cannot be disclosed on an individual basis for valid legal reasons. In those circumstances, the transfers of value can be disclosed on an aggregate basis. Aggregate disclosure is where a company discloses the aggregate amounts attributable to transfers of value under specific categories.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The HIQA has powers of entry and inspection of premises under its remit. Authorised officers have broad powers, including the power to take copies and remove documents and records, inspect computers, and interview patients and staff.

The Medical Council is responsible for investigating complaints about doctors. If a complaint against a doctor is upheld, the Medical Council has the power to impose sanctions such as:

- advice, admonishment or censure in writing;
- fines of up to €5,000;
- to attach conditions to a doctor's registration; or
- to suspend or cancel a doctor's registration.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The length of an investigation can vary, depending on the complexity of the issue.

The HIQA is responsible for undertaking investigations as to the safety, quality and standards of services if it believes there is a serious risk to the health or welfare of a person receiving those services. The Minister for Health may require the HIQA to undertake an investigation.

Medical Council investigations of complaints can last a number of months or years, depending on the issues being considered. Any person can complain to the Medical Council about a doctor.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

See question 12.

In the case of complaints to the Medical Council, a doctor is provided with the core evidence during the investigation process, including witness statements and expert reports, and is allowed an opportunity to comment on new evidence.

27 Through what proceedings do agencies enforce the rules?

The HIQA inspectors engage directly with service providers under its remit to address non-compliance with standards and regulations, including through issuing safety notices. The HIQA can prosecute certain summary offences.

The Fitness to Practise Committee of the Medical Council conducts inquiries of complaints about doctors. Hearings are generally held in public. For most types of sanction, the Medical Council must apply to the High Court to affirm its decision.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

See questions 5 and 24.

29 What defences and appeals are available to healthcare providers in an enforcement action?

In relation to the HIQA, an appeal of a prosecution for breach of the Health Act 2007 can be brought through the criminal justice system (see question 17). Designated centres for children or adults with disabilities, or the elderly, that are refused registration or are deregistered can appeal the HIQA's decision to the District Court.

When the Medical Council imposes sanctions such as advice, admonishment or censure in writing, there is no statutory right of appeal, and the only option available is judicial review (see question 39). If the Medical Council imposes sanctions such as conditions, suspension or cancellation of a doctor's registration, there is a statutory right of appeal to the High Court.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Healthcare providers should familiarise themselves with all applicable rules and guidelines applicable to their activities. Once an enforcement action is underway, the healthcare provider should attempt to remedy the breach and cooperate with the body bringing the action. The healthcare provider should also seek legal advice.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

The HIQA has recently focused on investigations into the safety, quality and standards provided by the HSE in various hospitals. For example, the HIQA carried out 52 unannounced inspections of public acute hospitals in 2013, with a focus on the prevention and control of healthcare-associated infections.

The Medical Council must investigate all of the complaints it receives.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The Medical Council is the self-governing body for medical practitioners. See question 24 in relation to policing members' conduct.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Typically, government contracts contain performance issue procedures that give contractors multiple opportunities to correct non-compliances. However, where non-compliances persist, this can result in the contractor having to undergo mandatory training, the withholding of funding, the suspension of certain services or termination of the agreement.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

The enforcement of healthcare regulations or laws is generally undertaken by the appropriate regulatory body or a state prosecutor. However, there are some instances where citizens may bring private enforcement actions when they are directly affected by the breach or infringement of that regulation or law; for example, in the case of personal injuries arising out of medical or clinical negligence (malpractice) by a healthcare professional or out of a defective pharmaceutical product or medical device.

35 What is the framework for claims of clinical negligence against healthcare providers?

In Ireland, the framework for clinical negligence claims is governed by the law of tort. In order to succeed in a clinical negligence action, the plaintiff must prove that a duty of care exists between the plaintiff and a healthcare provider, and that there has been a breach of that duty, which was causative of the plaintiff's injuries.

The principles for establishing breach of duty against a healthcare provider are set out in the seminal case of *Dunne v National Maternity Hospital*. The test is the 'reasonable standard of care', in other words, whether a healthcare practitioner is guilty of such failure as no practitioner of equal status and skill would be guilty if acting with ordinary care. Provided that the practitioner acted in accordance with a practice accepted as proper by a body of responsible opinion within his or her profession, it does not make him or her negligent if a separate body would have adopted a different practice. The test acknowledges that there may be a variance of medical opinion within a particular field. However, the practice followed by the practitioner must have been free of any inherent and obvious defects.

The plaintiff must then prove that this breach of duty caused or made a material contribution to the plaintiff's injury. The standard of proof is 'on the balance of probabilities'. However, in certain circumstances the doctrine of *res ipsa loquitur* may be applied. This means that negligence is presumed on the part of the defendant since the object causing injury was under his or her control. It reverses the burden of proof and places the onus on the healthcare provider to disprove an allegation of negligence.

The Irish courts are not reluctant to penalise public or quasi-public healthcare providers.

In Ireland, damages are awarded in order to put the plaintiff as far as possible back in the position he or she would have been had the wrong not occurred. There are two main categories of damages available: general and special damages. General damages compensate for non-pecuniary losses suffered by the plaintiff as a result of the wrongdoing. Such losses include pain and suffering, loss of amenity and loss of expectation of life. Special damages may also be awarded for any financial loss suffered, and expense incurred by a plaintiff as a result of the wrongdoing. A claim for special damages is usually formulated on the basis of expenses and liabilities incurred up to the date of trial and future loss, being the estimated anticipated loss, usually based on actuarial evidence. In exceptional circumstances, exemplary or punitive or aggravated damages may also be awarded.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The purchaser or a user of pharmaceuticals or devices can seek recourse for regulatory and legal infringements through the Irish courts, for example under product liability rules. In Ireland, liability for defective products falls under four main headings: statute, tort, contract and criminal. The principal product liability statute in Ireland is the Liability for Defective Products Act 1991. This Act supplements the remedies in tort and contract and provides for a strict liability regime, making a producer of the defective product liable in damages in tort for damage caused wholly or partly by a defect in the product. A purchaser or user may also sue in tort for any reasonably foreseeable damage caused to them, or in contract where the pharmaceutical or device was not of merchantable quality.

It is also open to the purchaser or user of a pharmaceutical product or a device to make a complaint to the HPRA.

37 Are there any compensation schemes in place?

In Ireland, compensation schemes have been set up in circumstances where an organ of the state may have liability. Such schemes are ad hoc, rather than statutorily required.

The State Claims Agency manages these schemes. Examples of compensation schemes include the Hepatitis C Compensation Tribunal, which was set up in 1997 to compensate women who had become infected with hepatitis C, having been transfused with infected blood products during pregnancy. In July 2013, the government approved the establishment of the Lourdes Hospital Redress Scheme, to compensate former patients of an obstetrician who performed unnecessary surgeries. More recently, a state compensation scheme was set up for women seeking damages in respect of symphysiotomy operations carried out between 1945 and 1982.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

There is no specific Irish legislative provision dealing with class actions. Litigation is conducted by individually named parties. However, in situations where there are numerous separate claims arising from the same circumstances, it is not uncommon for a representative test case to be taken, where an agreement is reached between the parties that the balance of the cases would be stayed pending the outcome of the representative action. The judgment in the representative action can become the benchmark by which the remaining cases are managed, by virtue of the doctrine of precedent. Subsequent litigation is often resolved by agreement on the basis of the outcome of the representative action.

The Law Reform Commission published a report in 2005 on multiparty litigation. It recommended that a procedure called a multiparty action (MPA) be introduced to deal collectively with cases that are sufficiently similar. The Commission recommended that the procedure operate

Update and trends

New legislation is expected to be published imminently which will allow the HIQA to investigate private healthcare institutions, and which will pave the way for a full licensing system for public and private hospitals. The HIQA will also oversee research ethics committees in respect of clinical trials.

A recent Supreme Court decision in relation to Medical Council investigations has implications for the meaning of 'poor professional performance' for medical practitioners. It confirmed that a threshold of seriousness must be met in order to satisfy the definition of poor professional performance. The decision has important implications far beyond the regulation of doctors as the concept of poor professional performance is also used in legislation governing the regulation of dentists, pharmacists, health and social care professionals.

on the basis of an opt-in system whereby individual litigants would only be included in the group where they decided to join. A single legal representative would be nominated by the MPA members to deal with the common issues arising within the MPA. To date, the recommendation has not been implemented.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Judicial review proceedings are heard in the High Court. Judicial review in Ireland is a two-stage process, comprising:

- an application to the High Court for permission to bring judicial review proceedings; and
- the substantive hearing.

The time limit for commencing judicial review proceedings can vary depending on the applicable legislation; however, typically, an application for leave to apply for judicial review must be made within three months from the date when the grounds for the application first arose. The Irish courts apply a 'sufficient interest' test to determine whether a party bringing judicial review proceedings has the requisite standing to litigate; however, the courts apply this test liberally. In judicial review the High Court's primary focus is not whether the public entity made the right decision, but to see that the decision was made in the proper manner. The common grounds for judicial review include that there has been an error of law, a procedural error, lack of fair procedures, an error of fact, or, in limited circumstances, that the decision is manifestly unreasonable. The High Court can quash the decision, or remit the decision back to the public entity to be re-decided.

40 Are there any legal protections for whistle-blowers?

While Irish legislation contains a number of provisions for whistle-blower protection in relation to discrete offences, the principal protections are contained in the Protected Disclosures Act 2014 (Protected Disclosures Act), which protects workers in circumstances where they report suspicions of illegal activity.

Where a worker makes a protected disclosure, the employer in question is prevented from dismissing or penalising the worker; taking an action for damages or an action arising under criminal law; or disclosing any information that might identify the person who made the disclosure. The Protected Disclosures Act also makes provision for a cause of action in tort for the worker for detriment suffered as a result of making a protected disclosure.

However, a disclosure will only be considered to be a 'protected disclosure' when it is a disclosure of information, made by a worker, which in their reasonable belief tends to show a 'relevant wrongdoing' and which came to their attention in connection with their employment. A relevant wrongdoing is broadly defined as relating to the commission of an offence; non-compliance with a legal obligation (except one arising under the worker's employment contract); a miscarriage of justice; endangerment of health and safety; damage to the environment; misuse of public funds; mismanagement by a public body; or concealing or destroying information relating to any of the above. The definition of worker is very broad and covers employees (including temporary and former employees), interns, trainees, contractors, agency staff, and consultants.

If the protected disclosure is part of an unfair dismissals claim by the worker, and a Rights Commissioner of the Labour Relations Commission finds in favour of the worker, it can require the employer to pay compensation of up to 260 weeks remuneration to the worker.

While the motivation for making the disclosure is irrelevant, these protections are not available to those who deliberately make false disclosures, as these are not considered to meet the test for having a 'reasonable belief' that a wrongdoing has occurred.

41 Does the country have a reward mechanism for whistle-blowers?

The purpose of the Protected Disclosures Act is to protect workers who make protected disclosures, from penalisation. Consequently, there is no reward mechanism for whistle-blowers in the Protected Disclosures Act. However, in relation to competition law, the Irish Competition and Consumer Protection Commission operates an immunity programme for members of a cartel who confess their involvement in breaches of the Competition Act 2002 (as amended). In order to benefit from this immunity, a number of requirements must be met, most notably that the whistle-blower is the first member of the given cartel to have satisfied the requirements.

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42 Are mechanisms allowing whistle-blowers to report infringements required?

Under the Protected Disclosures Act, public sector bodies must put whistle-blowing policies in place. While there is no such requirement for private sector businesses, we strongly recommend policies be put in place. Where a policy already exists, we recommend that the policy be reviewed to ensure it is in line with the provisions of the Protected Disclosures Act.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. For example, as noted above, the HPRA, the Irish Revenue Commissioner's Customs Service and the Irish police took part in Operation Pangea, which is an international week that targets the sale of falsified medicines online.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

This is determined on a case-by-case basis. The HPRA will take enforcement activities by foreign authorities into account when deciding whether an investigation is required.

A complaint can be made to the Medical Council about a medical practitioner on the grounds of a conviction outside of Ireland that would constitute an indictable offence in Ireland.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Enforcement of Irish healthcare laws is applied to offences committed in Ireland, and whether or not foreign companies or nationals are pursued will depend on who is the offender. If the entity does not have an establishment in Ireland, prosecution can be more difficult.

Italy

Alberto Mocchi, Elena Cappellaro and Francesca Libanori

Avvocati Associati Franzosi Dal Negro Setti

Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

In general terms the National Healthcare Service (NHS) is exclusively funded by the national income tax system, with the following exceptions:

- 'tickets': regions can impose a fee ticket on reimbursable healthcare service in general and on particular products (Class A medicine products); and
- fees for any non-reimbursable healthcare service.

Private financing of healthcare is based on direct payment for rendered services and insurance payments.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The local delivery of healthcare services is organised through Local Health Authority Services (ASLs). ASLs are public entities involved in the administration, accounting and management of healthcare services. Services are supplied through public structures, private accredited structures or private qualified structures. Public structures include hospitals directly managed by an ASL and *presidi ospedalieri* which are independent structures, generally with a regional or inter-regional catchment area, independently managed and with purchasing power (research hospitals are included within this category).

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The key legislation which regulates the delivery of healthcare has, as a reference point, article 32 of the Constitution, which provides that:

> *The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person.*

Law No. 833/1978 founded the NHS. Among other principles it:

- provides that the production and marketing of medicinal products must be regulated according to criteria consistent with the objectives of the NHS; and
- introduces the principles according to which patients have the right to choose the provider and place of treatment.

Other important laws are:

- Decrees 502/1992 and 517/1993 that reshaped the public healthcare system through three major changes: devolution of powers to regions, managerialism and competition in health service provision; and
- Legislative Decree No. 229/1999 that attributed full responsibility and management of public healthcare to the regions.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The NHS is made up of several institutional bodies, at national and territorial level, which mutually coordinate their activities within their specific areas of competence. At national level, the most important institution is the Ministry of Health (MoH) which directs and leads the policies of healthcare related in Italy. The territorial level comprises the regions, the self-governing provinces of Trento and Bolzano, local health units, hospitals and university institutions. Regions have, among other things, the power to approve the local healthcare plan (in conformity with the national one) and to grant wholesalers with authorisation for distribution.

Institutions, authorities and agencies contained within the NHS are funded by public expenditure; the funding does not depend on enforcement activities.

5 What is the scope of their enforcement and regulatory responsibilities?

The scope is strictly related to the powers conferred on them by law, and depends on the provisions of the complex legal framework. For example, for medicinal products such a scope is designed by Legislative Decree No. 219/2006; and for medical devices it is defined by Legislative Decree No. 46/1997. All the regulatory sanctions may be challenged before the administrative courts.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The main institution, responsible for the regulation of pharmaceutical products and medical devices, is the MoH. The MoH also has the power to monitor the activities performed by the Italian Agency of Medicines (AIFA), which has a wide responsibility on drugs.

They are both funded by public expenditure; the funding does not depend on enforcement activities.

7 What is the scope of their enforcement and regulatory responsibilities?

The MoH commits the management of pharmaceutical products to AIFA, which has relevant powers in different fields, including granting marketing and manufacturing authorisations and negotiating the prices of medicinal products reimbursed by the NHS.

The regions and the self-governing provinces of Trento and Bolzano also have responsibilities; for example, regions grant distribution authorisation to the wholesalers.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Competition Authority (Antitrust) or Data Protection Authority have jurisdiction, as long as their competence is involved in unlawful cases. Public prosecutors may also investigate such cases.

Ordinary courts have jurisdiction regarding medical malpractice and product liability cases.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Yes they can, without barring each other.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

In Italy the responsibility to monitor compliance with rules on drugs and medical devices is distributed between two different authorities:

- AIFA has wide powers and responsibilities on drugs in general (eg, clinical trials, marketing authorisation and manufacturing); and
- the MoH is responsible for medical devices.

As far as drugs are concerned, in cooperation with the European Medicines Agency (EMA), AIFA shall ensure through inspections (announced or otherwise) that all the legal requirements governing medicinal products are complied with. In particular, pursuant to Legislative Decree No. 219 of 24 April 2006, AIFA:

- is responsible for the monitoring of all safety information and adverse reactions of medicines;
- can perform inspections of manufacturing-authorisation holders to ensure that they are adhering to the principles and guidelines of good manufacturing practice;
- can inspect the plants of importer or distributor; and
- can take samples of medicinal products or ingredients.

The costs of the inspections are paid by the subject of the investigation.

The MoH is responsible for monitoring compliance with the rules provided by Legislative Decree No. 46 of 24 February 1997 (implementing Directive 93/42/CEE), regarding medical devices.

Among other powers, the MoH may audit and inspect production plants, warehouses, importers and distributors.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Both AIFA and the MoH can conduct an unannounced inspection or dawn raid.

Investigations usually comprise the following steps:

- start of the investigation;
- report of the outcome of the investigation (see below); and
- reply, comments and a remedy plan (if needed and required) by the subject of the investigation.

The whole proceeding takes from two to four months.

AIFA issues a conformity certificate within 90 days following the inspections if it ascertains the manufacturer's compliance with good manufacturing practices (GMP) and any applicable law.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

AIFA provides the subject of an investigation with a report of the activities carried out and the outcome of the investigation. Before taking any further decisions and before imposing any sanctions AIFA must allow the subject of the investigation to submit comments and remarks.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

AIFA cooperates with both EU member states and the EMA in order to coordinate inspections in foreign countries.

Unless the foreign country has negotiated an appropriate agreement with the EU establishing mutual recognition of GMP inspections, AIFA conducts investigations of the manufacturing processes in foreign countries on a regular basis.

14 Through what proceedings do agencies enforce the rules?

AIFA can revoke, vary or suspend an authorisation when a statutory condition of the authorisation is no longer complied with. AIFA notifies the authorisation holder of its proposed action and its reasoning. The authorisation holder then has 15 days to respond. Where public safety is at risk, AIFA can suspend an authorisation with immediate effect.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Both AIFA and the MoH have the power to impose:

- pecuniary sanctions; and
- interdictory sanctions (see question 5).

16 Can the authorities pursue actions against employees as well as the company itself?

AIFA can sanction with administrative fine:

- the qualified persons that must be appointed by every marketing authorisation holder, who are responsible for ensuring that each batch of the medicinal product has been manufactured or assembled under the relevant legal requirements; and
- the person responsible for the establishment and maintenance of the marketing authorisation holder's pharmacovigilance system.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

All final administrative acts of regulatory bodies that have a direct impact on identified or identifiable natural entities (ie, individuals) or legal entities (ie, undertakings) may be challenged either before the same administrative body which adopted the act in question or before the relevant administrative court.

An administrative act can be challenged by filing a claim before the competent administrative regional tribunal (TAR). The competent TAR for decisions adopted by the Italian Ministry of Health or AIFA is the TAR of Lazio, which is located in Rome. The relevant claim must be filed (ie, notified to the administration that adopted the act in question) within 60 days of notification or knowledge of the act in question. Alternatively, an administrative act can be challenged by filing a claim before the President of the Italian Republic within 120 days of notification or of knowledge of the act.

The subject challenging an administrative act must have an actual and direct interest in the administrative act being annulled, or be otherwise adequately modified.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies can adopt and implement compliance programmes and protocols. If an investigation is under way a prompt and effective remediation plan will avoid higher sanctions.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

According to an AIFA report, between 2012 and 2014 GMP deviations have represented the vast majority of the investigation activities performed by AIFA.

The three major areas involved in GMP deviations are related to buildings and facilities; process equipment; and documentation and records.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

Farmindustria and Assobiomedica are the two associations of pharmaceutical companies and medical devices companies, respectively.

They can carry out investigations and fact-finding activities on the premises of companies who are members of the associations, within the framework of their statutory scope and on a voluntary basis.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

It is banned as a specific form of bribery to give or promise money or another utility to healthcare professionals (HCPs). HCPs are punished, in their turn, when they accept such a utility to the purpose of easing in any

way the availability of medicinal products, unless the utility is of negligible value (eg, gadgets whose worth is not higher than €25).

In any other hypothesis, financial relationships between HCPs and suppliers of products and services are allowed and regulated.

HCPs may provide such suppliers with consultancy – asking their hospital for authorisation beforehand, should they work as employees and should they not be academics. Moreover, they may be invited to congresses or symposia, even as speakers, with reimbursement of expenses and payment of fees. In such cases, top hospitality may not be offered for more than 12 hours prior the event and 12 hours following the conclusion, and the technical and scientific purposes of the event may not be overshadowed. No hospitality of any kind or form may be offered to companions of the person invited. The companies may only offer economy-class air travel to Italian health operators invited to an event abroad, while the category of the hotel accommodation must not exceed four stars.

As to the grant, an express pecuniary ceiling does not exist. In any case, the consideration paid for the consultancy provided must meet cost-performance criteria and reflect the market value of such services, whereas the initiative must guarantee coherence and appropriateness in respect of the objectives pursued and be capable of being fully documented.

22 How are the rules enforced?

These rules are enforced either by criminal sanctions when punishing bribery conducts, or by regulatory sanctions (fines) able to be challenged before the administrative courts.

Sanctions are also provided for under the codes of conduct of the associations of pharmaceutical companies. They go from the written warning, including the order to cease the unlawful conduct, until the exclusion from the association.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

Since 2015, reporting is required by the European Federation of Pharmaceutical Industries and Associations' rules on transparency. This is implemented in the national codes of conduct and imposes disclosure of transfers of value to healthcare professionals.

The disclosure is to be made each calendar year (in 2016 for pecuniary benefits granted in 2015), in principle on an individual basis, giving the name and business address of the recipient, the benefit category (consultancy or other services, conference fees, travel and accommodation expenses, etc) and the pecuniary benefits granted during the period under review.

The contractor's payments in respect of agreed consultancy or other services and the related costs are to be disclosed separately. Should the contractor deny or revoke the consent to a disclosure of the aforementioned data, pecuniary benefits should be disclosed in summary form (on aggregate) by stating the total annual sum per recipient in each benefit category, or in aggregate form by stating for each healthcare organisation the pecuniary benefits that the professionals, working in the healthcare organisation concerned, have received directly or indirectly.

The information shall remain in the public domain (eg, on the company website) for a period of at least three years from the moment of disclosure. Moreover, the companies shall conserve the documentation to support the data disclosed for a period of at least five years and also make it available in detailed form to any requests from the healthcare professionals involved.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Controls on the healthcare services are performed both at national and local level. At primary level, the MoH establishes minimum essential levels of healthcare services that must be guaranteed across the country, and performs a general activity of supervision and vigilance. At a local level, each region must ensure the quality and efficiency standards of the healthcare services delivered in the regional territory, and they are entrusted with monitoring and vigilance powers, exercised with the support of the network of the Local Health Units (LHUs). In order to enforce such vigilance powers, Regions have investigational and sanctioning powers. Besides controls over quality and efficiency, regions also perform financial control over healthcare expenditure at a regional level.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Investigation procedures differ from authority to authority, and it is difficult to provide for a standard rule. In general, investigations might be either routine or initiated following a specific complaint by a private citizen, or upon the initiative of the competent authority. Investigations carried out by the prosecutor within criminal proceedings are a different matter.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

This depends on the type of investigation. During checks and inspections carried out by the police body specialising in health-related matters (NAS) or the LHU (see answer 27) concerning the quality of healthcare services, the investigated party does not have proper standing during the investigation phase, and only once the sanction is issued will he or she have the right of appeal. Disciplinary investigations are a different matter (see question 32) as are judiciary proceedings, where the defendant has the right to be formally involved and specific procedural rules must be followed.

27 Through what proceedings do agencies enforce the rules?

The Ministry of Health and Regions enforces its investigative powers on HCPs or healthcare organisations (HCOs) through the NAS or the LHU. These are usually administrative proceedings carried out in accordance with the internal rules of the proceeding authority. However, courts have competence typically in cases of malpractice, which may either trigger the civil liability of the HCPs and HCOs under the tort law or, in the worst-case scenario, might amount to a criminal offence

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Competent authorities mainly issue sanctions of an administrative nature, which ranges from pecuniary fines up to suspension or revocation of the authorisation or the capacity to provide healthcare services. Sanctions issued by the courts in case of civil or criminal proceedings are a different matter.

29 What defences and appeals are available to healthcare providers in an enforcement action?

HCPs may challenge administrative sanctions issued by the NAS or LHU before either the prefect or the LHU itself, depending on the nature of the sanction.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

HCPs can pay a reduced pecuniary fine (equal to one third of the maximum penalty applied to the violation committed or, if more favourable and if it is established the minimum sanction prescribed by law, equal to twice the amount in addition to the costs of the proceeding) within a period of 60 days from the notification of the violation.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In recent enforcement activity, the authorities have imposed over 12,000 administrative and criminal penalties on HCPs. The most common violations concern fraud against the NHS, abusive exercise of the healthcare profession, marketing of medicinal products without licence and marketing of counterfeited or stolen drugs. In 2014, about 350 structures (pharmacies, stores, medical offices and health clinics) have been closed or seized.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

In Italy, doctors must be registered with the professional association competent for the territory where they exercise their activity. The professional association has disciplinary powers over their members. It may start an investigation following the complaint of a patient or another HCP. If the complaint is grounded, a formal disciplinary proceeding is set up before

the association committee and a broad range of sanctions may be applied, from warning to temporary suspension and up to debarment.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

From a contractual standpoint, a distinction should be made between individual HCPs and HCOs. Regions stipulate framework agreements with the local HCOs (hospitals, clinics, etc) whereby quality, performance and volume requirements are set for the provision of healthcare services in affiliation with the regional health system. HCOs that do not meet such contractual standards might be, in the worst case, disqualified from their affiliation with the regional health system. As to individual HCPs, since they are usually employees, they might be sanctioned for poor performance in accordance with the applicable employment rules (depending on whether they are public employees, as the vast majority is, or not).

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Within the general category of civil liability, there are three different private causes of action:

- for breach of contract, article 1,218 of the Italian Civil Code, which follows the breach of a contractual obligation (hospital liability for employees' negligence and a hospital's own negligence);
- for intentional or negligent act or omission, article 2,043 of the Italian Civil Code, which derives from an unjustified injury caused by an intentional or negligent act or omission (medical malpractice cases); and
- for strict liability, article 2,050 of the Italian Civil code and Legislative Decree 06/2005, which is prominent in tort law (product liability or ultra-hazardous activities).

These private causes of action are different because of:

- the burden of proof (see question 35);
- the damage assessment; and
- the limitation period (five or three years instead of the general term of 10 years).

35 What is the framework for claims of clinical negligence against healthcare providers?

Healthcare professionals may be held civilly liable for their negligent or culpable behaviour, in particular if their conduct fails to meet the standard of care provided under similar circumstances and is not compliant with the guidelines and the good clinical practices accredited by the scientific community.

Therefore, the claim against medical malpractices must show:

- the suffered injury;
- that the malpractices are imputed to the healthcare professionals (lack of diligence, lack of prudence); and
- the existence of a causal link between the negligent conduct and the harmful act.

According to article 3 of Law 189/2012, the healthcare professionals can be held liable by a criminal court in case of gross fault only.

On the other hand, hospitals are generally ascribed of a contractual liability. This means that after the hospitalisation a patient is assumed to be entering into a contract with the hospital.

In this case, a successful claim must prove:

- the existence of a contract;
- the aggravation or appearance of a pathological situation; and
- the causal link with the medical act or omission.

The defendant has to prove that:

- the health service was diligently performed and that there was no fault in the medical treatment; and
- the event that occurred is unlikely (on a 51 per cent basis) to be a consequence of the relevant medical treatment or that the event was the result of a natural condition not attributable to the doctor or hospital.

The number of medical malpractice cases has recently increased. In general, Italian courts do not seem to be reluctant to sentence public or quasi-public healthcare providers.

In 2008 the Court of Cassation, which is the highest court in Italy, delivered a fundamental judgment which stated that the claim for damages can be divided in two main categories: pecuniary damages (such as the emerging damage and the loss of profits) and non-pecuniary damages (biological, moral or existential damage should be included under this unique item).

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The Italian Consumer Code (Legislative Decree 06/2005) sets the manufacturer's strict liability, regardless of fault (except for cases in which the liability is specifically excluded). Moreover, the agreement that excludes or limits this manufacturer liability is invalid, while the consumer who suffered damages is always entitled to obtain a compensation.

There are three different types of damage:

- death or personal injury;
- detriment or destruction of property other than the defective product; and
- defect of one or more parts.

The product is defective when it does not provide the safety as generally expected by the public.

In residual cases, if the purchaser is not a consumer but a company, contractual liability criteria apply.

37 Are there any compensation schemes in place?

There are two types of compensation schemes for personal injuries.

In case of minor personal injuries, the Italian Code of Insurances applies. This sets that a Decree of the President of the Republic (recently updated) establishes the amount of compensation.

For major injuries, the most commonly applied criteria is the one provided by the Tribunal of Milan, although some other tribunals have created their own. The Tribunal of Milan has drawn up a scheme that is useful to determine the compensation for:

- biological damages (ie, physical, mental and social damages); and
- moral damages (ie, moral harms, anxiety, distress and offences to a person's general wellbeing).

The quantification of moral damages depends on the biological damages percentage.

The judge may adapt the compensation's amount to the specific case.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

According to article 140-bis of the Consumer Code, the class action may be filed by each class component, singularly or through the consumer's associations or committees which he or she is part of, and only in three cases:

- to protect a plurality of consumers' contractual rights against the same company;
- to protect the rights of a specific product's consumers against its producer; and
- to obtain compensation for damages suffered because of unfair business practice.

When the class action has been filed before the competent court, the judge decides whether it is admissible and sets the limits to make it public. In this way, other consumers may adhere to the same class action and ascertain producer liability and compensation for damages (both pecuniary and non-pecuniary).

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

In Italy, appeals of administrative decisions are brought before the administrative judge according to Legislative Decree 104/2010 (the new administrative procedure code). A common law judge does not have the power to annul the decision of a public institution.

The administrative judge examines whether the exercise of public power was legal, and looks for the presence of a lack of legitimacy, such as:

- lack of incompetence;
- violation of law (misinterpretation of the law, formal defeats, lack of motivation, etc); and
- misuse of power (distortion of the facts, illogical or contradictory motivation, unequal treatment, etc).

In the case of an action for annulment, the compensation claim could be made during the proceeding or within a time limit of 120 days after the decision has become definitive.

The ordinary judiciary system and rules are applied to review acts, omissions or decisions of private institutions.

On the other hand, for issues related to services provided by the national healthcare system, a citizen is entitled to file a legal suit before the common law court (pursuant to article 442 of the Italian Civil Procedure Code).

40 Are there any legal protections for whistle-blowers?

In Italy, there are only a few rules for the protection of whistle-blowers who are public servants.

Article 54-bis of Legislative Decree No. 165 of 30 March 2001 (recently updated) sets forth that a public servant who reports unlawful behaviours may not be subject to sanctions, dismissal or undergo any discriminatory measure, either direct or indirect, having an impact on work conditions for reasons related to the complaint. The rule sets also specific provisions for the protection of the whistle-blower's identity: considering the risk of retaliation from the person to whom the complaint relates, the whistle-blower's identity shall not be revealed without his or her consent (unless it is necessary for the accused's defence). It is obvious that the employee's protection is subject to his or her good faith. The complaint that reports false information and wilful misconduct are subject to disciplinary, civil or even criminal sanctions.

41 Does the country have a reward mechanism for whistle-blowers?

No. Italy has not provided any reward mechanism in favour of whistle-blowers. Currently, the only provisions introduced in their favour are intended to protect them from any form of retaliation or revenge that they may incur because of the complaint. As seen above, there is no possibility of dismissal; there is protection against any form of discrimination; and the whistle-blower's identity is kept secret).

42 Are mechanisms allowing whistle-blowers to report infringements required?

The Anticorruption Law (Law No. 190 of 6 November 2012) sets that each public administration must adopt a triennial plan for the prevention of corruption where they identify the areas where there is a higher risk of corruption, adopt the necessary measures to minimise this risk and, finally, regulate the complaints procedure. The plan must be drawn up by 'those responsible for the prevention of corruption', who verify its implementation, receive public servants' complaints and carry out an initial investigation about the reported facts. The complaint contains:

- the whistle-blower's personal details;
- the date and place of the event;
- the reasons why the accused behaviour is considered unlawful; and
- the fact's description and its author.

If the claim is non-manifestly unfounded, 'those responsible for the prevention of corruption' will convey the complaint to the competent authorities for the implementation of all necessary measures.

Those authorities are:

- the public servant's superior (in order to obtain preliminary elements);
- the department of disciplinary proceedings (if there is also a disciplinary liability);
- the Judicial Authority or the Court of Auditors or the Italian National Anti-corruption Authority (for questions within their respective competence); and
- the Department of Public Service.

The whistle-blower's identity will be kept secret in each procedure's phase.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

The organisation and delivery of healthcare in Italy falls under Italian jurisdiction.

However, law enforcement authorities (such as AIFA and the MoH) collaborate at an international and European level on a wide range of matters related to healthcare.

At European level cooperation exists, among other thing, with regard to:

- patient's rights in cross-border healthcare: where Directive 2011/24/EU ensures cooperation through the creation of a network of national contact points that provide information on cross-border healthcare; and
- the pharmacovigilance system, which operates with the management and involvement of regulatory authorities in member states (AIFA in Italy), the European Commission and the European Medicines Agency.

At an international level cooperation also exists with regard to issues related to counterfeit and stolen medicines.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

An investigation could be triggered in case of international fraud or abuse involving Italian subjects or territory, or in case of issues related to the

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safety of the healthcare products (ie, post-marketing surveillance of pharmaceutical products).

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

In simple terms, they will be pursued as long as the Italian jurisdiction and legislation applies to them.

As a rule, if a foreigner (health care company or individual) operates in the Italian territory, then he or she must observe Italian legislation.

This is an expression of the territoriality principle, which applies in the event of a criminal or administrative offence. The infringement of healthcare laws entails a criminal or an administrative sanction.

Consequently, as long as the act or omission which constitutes the infringement, or the related damage, takes place within Italian boundaries, a foreigner can be pursued in Italy.

Moreover, in some circumstances Italian law (article 7, 8, 9 and 10 of the Italian Penal Code and, with regard to companies, article 4 of Legislative Decree No. 231/2001) provides the terms and conditions under which criminal prosecution can be brought against foreign individuals or foreign companies for crimes committed in a foreign country against the Italian state, against an Italian national or against the EC or a third country.

Korea

Hwa Soo Chung and Kyungsun Kyle Choi
Kim & Chang

Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

South Korea operates a compulsory national health insurance (NHI) system that provides coverage for all residents.

The NHI is funded primarily by mandatory contributions from all residents, as well as government subsidies. The insurance premium is paid by the individual's employer (workplace health insurance) unless the individual is self-employed (community insurance). For employees, half of their total contribution is deducted from their salary, and the remaining half is paid by their employer. Individuals who are self-employed or ineligible for workplace insurance can apply for self-employed health insurance. In this case, an individual's contribution amount, which is put into a community insurance pool, is calculated based on income and assets, gender and age. The medical aid programme is fully funded by government subsidies and provides full coverage for low-income families. Approximately 3 per cent of the population is enrolled in the medical aid programme.

Although NHI premiums have steadily increased from year to year, the funds are insufficient to cover the relevant year's budget, and reserves set aside for future usage have been used, which is why the government continues to search for ways to contain healthcare costs.

Private health insurance is restricted by law. Although the majority of Korean families subscribe to some form of private health insurance, this is supplemental to the NHI system, as private health insurance does not duplicate or replace the NHI system.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is mostly delivered by healthcare professionals (HCPs) working at private sector hospitals, private clinics and pharmacies that are contracted to the National Health Insurance Service (NHIS), which is supervised by the Ministry of Health and Welfare and responsible for operating the NHI system. Healthcare is also delivered by public sector or government-run hospitals, but to a much lesser extent.

Patients can seek treatment at any clinic, small hospital or medium-sized general hospital. In order for patients to present at one of 44 tertiary hospitals (ie, large, specialised general hospitals), they must have a referral letter from an HCP at a small or medium-sized hospital or the NHI will not reimburse the medical costs. However, in the following exceptional cases, patients may go directly to a tertiary hospital without a referral letter: childbirth, emergency (ie, visits to the emergency room), dental care, haemophilia, rehabilitation and certain 'diseases to be treated by a doctor in the department of family medicine'.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The National Health Insurance Act (NHIA) and the Medical Services Act (MSA) primarily govern the delivery of healthcare in South Korea.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Ministry of Health and Welfare (MOHW), NHIS and the Health Insurance Review and Assessment Service (HIRA) are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare. The MOHW, the NHIS and the HIRA are mostly funded by the national annual budget. Although the law allows for these entities to impose administrative sanctions including monetary fines, such fines do not directly fund these entities as they are paid to the national treasury and put into the national budget.

5 What is the scope of their enforcement and regulatory responsibilities?

The MOHW oversees the NHI system and is responsible for setting and enforcing healthcare policy. The MOHW also supervises the NHIS and the HIRA. The NHIS operates the NHI system and serves as the insurer. In operating the NHI, the NHIS:

- manages the enrolment of the insured and their dependents;
- collects the mandatory NHI contribution;
- contracts with healthcare service providers; and
- reimburses medical institutions for healthcare costs.

The HIRA determines which products and medical services will be reimbursed by the NHI, and is also responsible for assessing reimbursement claims submitted by medical institutions.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The Ministry of Food and Drug Safety (MFDS) and the MOHW are principally responsible for the regulation of pharmaceutical products and medical devices. The MFDS and the MOHW are mostly funded by the national annual budget. Although the law allows for these entities to impose administrative sanctions including monetary fines, such fines do not directly fund these entities as they are paid to the national treasury and put into the national budget.

7 What is the scope of their enforcement and regulatory responsibilities?

With respect to the regulation of pharmaceutical products and medical devices, the MOHW is chiefly responsible for the following activities:

- establishing and amending laws and regulations governing the reimbursement, pricing, distribution and delivery of pharmaceutical products and medical devices;
- making decisions regarding the pricing of pharmaceutical products and medical devices and whether they can be reimbursed; and
- conducting enforcement activities to ensure the orderly distribution of pharmaceuticals and medical devices, and in particular regulations governing the proper interactions between pharmaceutical and medical device companies and HCPs.

Similar to the US Food and Drug Administration and the European Medicines Agency, in terms of function and oversight authority, the MFDS is primarily responsible for the following activities:

- establishing and amending laws, regulations, standards and specifications to ensure the safety and quality control of pharmaceutical products and medical devices in the Korean market;
- evaluating and granting product approval (marketing authorisation) for the manufacture, importation and sale of pharmaceutical products and medical devices;
- conducting post-marketing surveillance of approved pharmaceutical products and medical devices (including ordering recalls); and
- regulating the advertising of pharmaceutical products and medical devices.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Numerous other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases. They include, among others:

- the Korea Fair Trade Commission;
- the National Tax Service;
- the National Customs Service;
- the public prosecutor's office (a joint task force to eradicate improper economic benefits established within the Seoul Central Prosecutor's Office); and
- the police.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct an investigation of the same subject. A completed investigation does not bar another agency from investigating the same facts and circumstances.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The MFDS and the MOHW have the authority to:

- make information and document requests; and
- enter the grounds (including but not limited to offices and manufacturing and other facilities) of the pharmaceutical and medical device companies in order to inspect the premises, objects, company books, accounts and other documents, and question or interview employees.

The authority can also collect samples of products for quality, safety and other testing and order product testing. If the authorities find that there may be a criminal violation of the law, they may refer the case to the criminal authorities who may start their own investigation.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Investigation times vary depending on the nature of the violation. Many cases involving a regulatory infraction will take one to two months from the start of the investigation to the imposition of administrative sanctions. Other cases take several months. Many investigations are started as a result of complaints filed by competitors, private citizens or employees (in recent years, we have seen an increase in whistle-blowing). Often, a particular issue will garner the attention of the media, including developments outside Korea, and prompt the authorities to investigate. The health authorities also investigate as part of a planned agenda to investigate or review certain areas or products.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Generally, the subject of an investigation does not have the right to access the files relating to a pending investigation. However, if a hearing takes place before a disposition or decision is made, the subject of an investigation (individuals or companies) may request the relevant government authority to review or copy the files unless there are statutes or regulations stating to the contrary. For pending criminal investigations, those under investigation may review or copy the files after indictment but not before.

In matters where the administrative disposition or the court's ruling in a criminal trial has been finalised, the subject of the investigation may request to review or copy the relevant files unless there are statutes or regulations prohibiting such review or copying.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

When approving pharmaceuticals or medical devices that are manufactured overseas and imported into Korea, the MFDS will ordinarily conduct a document-based review of compliance with relevant quality requirements. If deemed necessary, however, the MFDS may conduct an on-site inspection of the overseas manufacturing plant and check for the manufacturer's compliance with quality standards (this process is called 'the overseas Current Good Manufacturing Practice' (CGMP) review). The MFDS may also engage in overseas CGMP review in cases where there is reason to believe there has been a violation of CGMP by the overseas manufacturer.

14 Through what proceedings do agencies enforce the rules?

The agencies may hold their own proceedings for the purpose of determining whether to impose administrative sanctions. They may also refer the matter to the public prosecutor's office for a criminal investigation, if the relevant statute stipulates that such referral may be made.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The health authorities may take various administrative actions (eg, order to test, recall, dispose, make public notice of or cease using relevant products; revocation of business or product licence; order to cease relevant operations), impose an administrative fine or make a criminal referral. The authorities may also decide to impose an administrative fine in lieu of an order on suspension of sales, manufacturing or import, as the case may be (ie, convert a suspension order into a fine) in order to alleviate the detrimental effects that a sales suspension might have on a business, assuming that the suspension order was not predicated by a safety-related violation.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes. In many instances, actions are pursued against executive officers of the company or management as well as against the company itself.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

Companies are granted an opportunity to submit position papers pending the outcome of an administrative proceeding, and may challenge an administrative action (fine, corrective order, etc) through litigation. Companies against whom criminal charges are found may avail of the criminal trial process to present various defences.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Once an investigation is underway, it is important to maintain control over any on-site investigation, manage what kind of evidence is submitted (keep a detailed inventory of documents and materials that have been submitted or collected by the investigators) and maintain dialogue with investigators. In most cases, it is important for the company to conduct thorough fact gathering early on so that it is in possession of all the relevant facts and is able to respond to the investigators in a consistent manner.

It may also be helpful for the company to take voluntary corrective action even as the investigation is ongoing, and adopt and implement compliance programmes for longer term mitigation. While it is unlikely that taking such corrective action will prevent the company from being sanctioned for violations, the authorities may take such actions into account when determining the level of sanctions. Companies are also recommended to have crisis management plans in place for dealing with investigations, and especially dawn raids ex ante.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

The main areas of focus have been the giving of kickbacks and production issues that affect product quality. Typically, monetary fines are imposed together with other types of dispositions, such as a corrective order, a business licence suspension or order to suspend sales of the relevant product.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The Korea Pharmaceutical Manufacturers Association (KPMA) and the Korean Research-based Pharmaceutical Industry Association (KRPIA) are the two major industry organisations for pharmaceutical companies, while the Korea Medical Device Industry Association (KMDIA) is the main industry association for medical device companies. These associations have issued various industry codes of conduct, most prominently on anti-bribery issues, and require member companies to report certain kinds of interactions with HCPs.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

The Pharmaceutical Affairs Law (PAL), Medical Devices Law (MDL) and MSA contain the Dual Punishment System provisions that punish both the giver and recipient of economic benefits provided in the context of interactions between pharmaceutical and device companies and HCPs for the purpose of increasing sales of such companies' products. Similarly, the Monopoly Regulation and Fair Trade Law (FTL) prohibits the provision of valuables to customers (eg, HCPs and medical institutions) in order to unfairly procure business from them as a type of unfair trade practice. The Criminal Code generally prohibits official and commercial bribery, while the recently enacted Act on the Prohibition of Improper Requests and Provision/Receipt of Money and Valuables (widely referred to as the 'Kim Young-ran Law') proscribes the giving and receipt of valuables to and by government officials (in the present context, mainly HCPs employed by public hospitals).

22 How are the rules enforced?

The rules are primarily enforced through government investigation. Notably, a Joint Task Force on Rebates in the Pharmaceutical Industry (composed of members from the public prosecutor's office, the police, the MOHW, the MFDS, the NHIS and the HIRA) has been actively investigating the provision of kickbacks to HCPs and medical institutions by pharmaceutical companies since its formation in 2011.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

There are no statutes comparable to the US Sunshine Act that require device and pharmaceutical companies to make regular disclosures to government authorities on all financial relationships (the provision of anything of value). Many companies are members of the KPMA, the KRPIA or the KMDIA and are required as part of their obligations as members to report certain conduct to the respective organisation. However, the information that is so reported is not publicly available.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The regulatory authorities, including the MOHW, may order medical institutions and HCPs to submit materials to ensure medical services are provided in compliance with the MSA. The MOHW is also empowered to enter the premises of medical institutions, inspect the facility, records and other materials, and question and interview employees and staff. In addition, in accordance with the NHIA, the regulatory authorities can order medical institutions to submit reports or relevant documents concerning insurance benefits, such as the medical services that were provided or drugs that were prescribed. Moreover, a staff official from, for example, HIRA may question the hospital administrators to ensure that medical services were provided in accordance with the NHIA. If the authorities find that medical institutions have submitted improper or false claims, and as a result received an inaccurate amount of reimbursement from the NHI, they may order the medical institutions to pay back the reimbursed amounts and impose administrative sanctions, such as temporary suspension of business.

The MSA and NHIA also provide for criminal sanctions, and therefore the regulatory authorities may, in certain egregious cases, refer the violation to the relevant criminal authorities.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

See question 11.

For healthcare providers, investigations are often initiated by patients (including families), patient groups, and media. However, investigations are also initiated because different groups of HCPs submit complaints against members of another group (eg, physicians versus practitioners of oriental medicine versus pharmacists) for improperly encroaching on such group's sphere of practice.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

See question 12.

27 Through what proceedings do agencies enforce the rules?

See question 14.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If there has been a violation of law, the regulatory authorities may revoke a medical institution's operational licence, cancel any accreditations as well as suspend (or cancel) an HCP's medical licence or impose administrative fines. In addition, violations of the MSA carry criminal penalties including imprisonment and criminal fines. Where medical institutions or HCPs received improper economic benefits, the value of the unjust economic benefit may be confiscated.

In addition, as outlined in question 24, if medical institutions submit false claims for reimbursement under the NHI, the authorities may order the medical institution to pay back the reimbursement amount or temporarily suspend the medical institution from conducting its business. If a business suspension is ordered, patients may present at such medical institution to receive medical services; however, the medical institution may not claim for reimbursement during the suspension period.

29 What defences and appeals are available to healthcare providers in an enforcement action?

See question 17.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 18.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

As outlined in question 19, over the past few years the authorities have focused their enforcement activities on kickbacks to medical institutions and HCPs. The PAL, MDL and MSA were amended, effective 20 November 2010 (with the introduction of the Dual Punishment System) and now prohibit and criminally penalise givers and recipients of economic benefits for the purpose of promoting sales (see question 21). According to the PAL and MDL, the MOHW may impose administrative sanctions (eg, licence suspension, disgorgement of the economic benefits, etc) and the public prosecutor's office may impose criminal sanctions, including imprisonment and fines.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

There are various trade associations for physicians, dentists, pharmacists, hospitals, nurses and other groups of healthcare providers. These associations have guidelines and rules governing the conduct of their members (eg, code of conduct, charter documents, etc). For example, the Korean Medical Association (KMA) may impose sanctions, such as suspension of the physician's membership with the association, fines, etc, as well as conduct investigations of members and affiliated organisations that are suspected to have violated medical ethics or the KMA's articles of association. The Korean Dental Association (KDA) may investigate and take disciplinary measures (eg, membership suspension) against individuals who have violated the KDA's ethical guidelines, articles of association or the MSA. The Korean Pharmaceutical Association may also impose sanctions for violating their organisational documents and ethical guidelines as well as the PAL. These types of medical trade associations have an ethics committee and a board of directors who deliberate, find violations and impose sanctions.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Once a medical institution has been established in Korea, such medical institution is, absent a special reason, automatically enrolled as a medical care institution under the NHI (ie, it is not necessary to enter into any contract with the government). Therefore, the government's remedies for poor performance are also set forth in the law rather than in a contract. Medical institutions have a duty under the law to provide optimal medical care to patients, and after providing medical services they file claims for reimbursement of the cost under the NHI. The HIRA reviews claims filed by the medical institutions, and has the authority to revise the reimbursement amount or deny the claim altogether. In addition, the MOHW is authorised under law to suspend the business of the medical institutions and suspend or cancel HCPs' licences.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Individuals or private bodies (such as consumer organisations and other civic groups) may lodge a criminal complaint with the investigative authorities for HCPs' violation of healthcare-related laws and regulations.

35 What is the framework for claims of clinical negligence against healthcare providers?

In order to prevail in a civil claim for negligence against a defendant who is a healthcare provider, the plaintiff must show the existence of negligence on the part of the healthcare provider in rendering medical services. However, in cases involving medical malpractice, the courts have relaxed the burden of proof on the plaintiff by allowing for the assumption that causation is presumed between the healthcare provider's actions and the harm to the patient if the patient can show the following:

- the existence of medical negligence based on a reasonable person standard; and
- that there was no intervening event to break the chain of causation (eg, there was no pre-existing medical condition).

Once causation is established, the burden of proof shifts to the healthcare provider. He or she must show that the damage is not attributable to his or her medical services.

In addition to the civil claim, the patient can file a criminal complaint for the crime of 'occupational negligence causing injuries or death'. Patients generally file a criminal complaint concurrently, not only for the purpose of seeking criminal sanctions against the healthcare provider but also so that they may use evidence and information compiled by the investigative authorities to support their civil claims.

The Korean Civil Code applies to patients' civil claims. However, considering the uniqueness of medical malpractice cases, upon a party's request, the court may appoint an independent expert as a witness. The court mandates this individual to investigate and make a determination on whether there was in fact negligence. Also, ex officio or at the request of a party, the court may appoint an individual as an 'expert officer of the court'. This individual is someone with professional or specialised knowledge, who may participate in the litigation process and provide his or her input, which the court will consider.

In addition to filing a civil or criminal claim, patients may request for mediation or arbitration with the Korea Medical Dispute Mediation and Arbitration Agency (KMDMA). Both parties must submit to the mediation (ie, either party may reject and proceed with litigation). If the parties reach an agreement through mediation, such agreement shall have the effect of a settlement administered by the court. Arbitration with the KMDMA is subject to the Arbitration Act and therefore, the decision by the KMDMA and any arbitral award is binding under the law. Mediation or arbitration with the KMDMA does not bar patients from pursuing a civil claim with the courts.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Purchasers or users of pharmaceuticals or medical devices may seek compensation under the Civil Code or the Product Liability Act. In order to prevail in a civil claim, the plaintiff must prove negligent or intentional conduct, which caused damage to the plaintiff. In a product liability claim, the plaintiff is only required to prove causation between the damages and the defect in the relevant product (ie, not required to prove the manufacturer's negligence or intent).

37 Are there any compensation schemes in place?

The Korean health authorities have implemented a social compensation scheme for adverse drug reactions (the Compensation Scheme), which took effect on 19 December 2014. The Compensation Scheme is funded by contributions from manufacturers or importers of pharmaceuticals and is aimed at providing compensation to victims and families for death, injury, disease or illness and other types of damages caused by adverse drug reaction. Patients do not need to demonstrate a defect in order to be eligible (ie, patients are compensated for harm from adverse reactions when they have properly used the drug according to instructions). The scope of compensation under the Compensation Scheme is being expanded in stages; currently, compensation is only provided in case of death. By 2017, compensation will be paid for injuries, expenses for medical treatment and funerals.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Class actions or other forms of collective action are not available in Korea for such cases. However, plaintiffs with the same cause of action may file a claim as co-plaintiffs.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Any person affected by actions (including decisions) or omissions of administrative agencies that have a direct influence on a person's rights (a Disposition) can file an administrative claim within 90 days from the date on which the Disposition became known or within one year from the date of the Disposition with the court. Plaintiffs can file for a revocation of the Disposition (for affirmative actions) or a confirmation of illegality (for omissions). Individuals who have been affected by the Disposition or parties with a vested legal interest have standing to file an administrative claim. In order to prevail in an administrative claim, the complainant must show that there was a violation of law or an abuse of authority.

Unlike administrative claims against a Disposition, an individual seeking compensation against private institutions must file a civil complaint in order to challenge acts or omission of the private institutions. In such case, the plaintiff must show that an act or omission of the private institution has caused damages to the plaintiff.

40 Are there any legal protections for whistle-blowers?

The Act on the Protection of Public Interest Whistle-blowers (the Whistleblower Act) provides general protection for individuals who report violations of law involving the 'public interest'. Violations involving public interest are defined as acts which have harmed or are expected to harm the health and safety of the public, the environment, consumer interests or fair

Update and trends

New anti-bribery legislation passes the National Assembly (scheduled to take effect in September 2016)

New anti-bribery legislation entitled the Act on the Prohibition of Improper Solicitation and Provision/Receipt of Money and Valuables, commonly referred to as the 'Kim Young-ran Law' (named after the then head of the Anti-Corruption & Civil Rights Commission who led the preparation of the original bill), was passed by the National Assembly on 3 March 2015 after undergoing numerous revisions over a period of several years.

The bill, which was first introduced in August 2012, gained significant traction in the last year or so in the wake of the Sewol ferry incident. After passing the National Policy Committee on 12 January 2015, the bill was submitted for deliberation by the Legislation and Judiciary Committee in February 2015.

As a whole, the new legislation contains several noteworthy features that represent significant departures from the existing anti-bribery regime in Korea, including the following:

Corporate criminal liability for a payment or benefit provided to a public official by employees

While the anti-bribery provisions under the Criminal Code do not impose liability on corporations for bribes made by employees, under the new legislation corporate criminal liability may be imposed for the provision of a payment or benefit by employees unless the corporation exerted due care and supervision to prevent such provision.

Criminal liability for payment or benefits provided to a public official exceeding 1 million won in a single instance or exceeding 3 million won per year in aggregate, regardless of whether such payment or benefits were linked to the recipient's official duties

Contrary to the anti-bribery provisions in the Criminal Code which require the crime of official bribery to include a showing that a payment or benefit was provided or received 'in connection with the receiving official's duties' in order for liability to attach, under the new law, criminal liability would be imposed without showing such link to the public official's duties, as long as the value of benefits received by the public official exceeds 1 million won in a single instance or the aggregate value of benefits in a one-year period exceeds 3 million won. If the value of a payment or benefit provided to and received by a public official is below 1 million won in one instance, and the sum of benefits given to the same public official in a one-year period is less than 3 million won, and there is a link to the public official's duties, administrative fines would be imposed by the court rather than criminal penalties.

Criminal liability for a public official who knew of but failed to report a payment or benefit provided to his or her spouse in connection with official duties

Another significant provision provides that criminal sanctions would be imposed on a public official if a payment or benefit is provided to the public official's spouse in connection with the public official's duties, and the public official knowingly fails to report such provision to the authorities.

Expanded scope of application

While the public bribery prohibition under the Criminal Code applies to provision of bribes to public officials and deemed public officials (eg, employees of state-owned enterprises and state-invested corporations), the new legislation applies not only to public officials but also to employees of private schools and kindergartens, members of the media which are registered under Korean law and 'civilians who perform public functions according to relevant laws.'

Prohibition against improper solicitation with respect to public officials

The new law prohibits 'improper solicitation' (ie, causing public officials to violate laws or to abuse their position or authority), irrespective of whether such solicitation involves any payment or provision of benefits. The law, which illustrates 15 types of acts which constitute improper solicitation, specifically excludes seven types of requests made to public officials from the scope of improper solicitation, including:

- open requests to commit a certain act;
- requests of elected officials, political parties or civil groups for public interest purposes;
- requests to protect rights that are infringed upon, pursuant to legal procedures; and
- other requests that are within the bounds of social custom.

Further details such as provision of courtesy payments and benefits that may be allowed in light of social custom will be established through the Presidential Decree before the new legislation takes effect.

Some commentators have remarked that this legislation amounts to a change in legal paradigm in terms of governing public official misconduct. Until now, the Korean anti-corruption regime was not been known to impose particularly stricter standards as compared to other developed countries, and adherence to 'global anti-corruption standards' had been deemed sufficient to avoid running afoul of Korean anti-corruption laws. However, this new legislation will impose much stricter requirements regarding interactions with public officials than do other jurisdictions.

Although details will be prescribed by the Presidential Decree, which has yet to be issued, and the new law will not take effect until September 2016, a point of interest for the pharmaceutical and medical device industries will be how this new legislation will interact with the existing laws and regulations governing the benefits provided to healthcare professionals and medical institutions.

competition. The protections for whistle-blowers stipulated in the Whistle-blower Act include, among others, the following:

- investigative authorities may omit information concerning the identify of the whistle-blower in their official reports;
- the personal information of whistle-blowers must not be disclosed or leaked;
- whistle-blowers may request protection of their persons (personal safety);
- whistle-blowers must not be subjected to retaliation (eg, termination of employment); and
- the person against whom the whistle has been blown is barred from suing the whistle-blower for damages.

Individuals who violate the Whistle-blower Act may be subject to criminal sanctions or administrative fines.

In addition, the FTL prohibits the Korea Fair Trade Commission (KFTC) and relevant government officials from disclosing information relating to a person who voluntarily reported violations or otherwise cooperated in a KFTC investigation.

41 Does the country have a reward mechanism for whistle-blowers?

Under the Whistle-blower Act, a whistle-blower may request compensation from the Anti-Corruption and Civil Rights Commission (ACRC) if his or her report leads to a recovery of unjust profits (ie, the information provided by the whistle-blower resulted in a disgorgement of unjust profits). The ACRC's Compensation Deliberation Committee may decide to provide the whistle-blower with a reward based on the following guidelines.

If the amount recovered by the government is:

- 100 million won or less – the reward will be 20 per cent of the recovered amount;
- over 100 million won but not more than 500 million won – the reward will be 20 million won plus 14 per cent of the amount exceeding 100 million won;
- over 500 million won but not more than 2 billion won – the reward will be 76 million won plus 10 per cent of the amount exceeding 500 million won;
- over 2 billion won but not more than 4 billion won – the reward will be 226 million won plus 6 per cent of the amount exceeding 2 billion won; and
- over 4 billion won – the reward will be 346 million won plus 4 per cent of the amount exceeding 4 billion won.

In addition to receiving a reward, the whistle-blower may also be entitled to compensation if he or she has been subject to retaliatory action for whistle-blowing (eg, lost wages, expenses to cover treatment for mental and physical harm, litigation costs if the whistle-blower sued his or her employer for unjust termination, etc).

42 Are mechanisms allowing whistle-blowers to report infringements required?

Under the Whistle-blower Act, any person believing that conduct detrimental to public interest has been, or is likely to be, committed may make a public interest report. The Whistle-blower Act prohibits any person from taking retaliatory action against the whistle-blower (eg, termination, salary reduction, restrictions on advancement, etc) for submitting such report. The law also prohibits any person from attempting to stop the whistle-blower from submitting the report or forcibly compelling the whistle-blower to retract his or her report. Both actions are criminally punishable under the Whistle-blower Act. Finally, if there is a request from the whistle-blower for the employer to take measures concerning his or her personal safety or management (eg, change of position, transfer to or from another office, etc), the employer must give priority to the whistle-blower's request.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

There have been cases of cooperation between the Korean law enforcement authorities and their foreign counterparts. For example, the MFDS and the US Food and Drug Administration have signed a memorandum of understanding. Rather than jointly conducting investigations into potential violations, the two agencies share investigation reports and materials.

With regard to criminal proceedings, Korea cooperates with foreign countries in accordance with the International Judicial Mutual Assistance in Criminal Matters Act (IJMACM Act) and the Extradition Act. According to the IJMACM Act, under the principle of reciprocity, in the case where a mutual assistance treaty has been concluded or even when a mutual assistance treaty is not concluded, if a requesting country guarantees to comply with a request by Korea for mutual assistance with respect to the same or similar matters, mutual assistance should be provided.

The scope of the mutual assistance is as follows:

- investigation into the whereabouts of a person or object;
- provision of documents and records;
- service of documents, etc;
- gathering of evidence, seizure, search and verification;
- transfer of objects, such as evidence; and
- hearing of statements, and other measures to make any person testify or cooperate with an investigation in the requesting country.

The Extradition Act also adheres to the principle of reciprocity, in which cooperation concerning extradition is provided where an extradition treaty has been concluded or if a requesting country guarantees that it will grant extradition for offences of the same or similar kind as those for which it requests extradition.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

It is possible for enforcement activities by foreign authorities to trigger an investigation in Korea. For example, there have been several cases where a collusion investigation initiated from abroad triggered an investigation in Korea.

In addition, when safety issues concerning pharmaceuticals or medical devices occurred causing foreign supervisory authorities to take measures, there have been several cases where the Korean supervisor authority initiated follow-up investigations to take corrective measures.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

If the offence had been committed within Korea, or if the offence committed abroad caused damages to a Korean business or person, the foreign company or the foreign national may be subjected to Korean law.

For example, in the case of a violation of the Monopoly Regulation and FTL, the FTL applies to foreign companies and foreign nationals if:

- the target for the act of violation includes the domestic market;
- thereby directly affecting the domestic market; and
- it is not unrelated to competition in the domestic market.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The Mexican healthcare system comprises public (social security institutions) and private institutions, insurers and independent professionals.

The private sector is funded by individuals and private insurers. Private health insurance generally covers professional, executive and higher levels of the private sector. Enrolment in private health insurance has increased considerably over the last five years. According to official figures, up to 50 per cent of annual health spending in Mexico comes from out-of-pocket expenses related to private doctors, insurance and drug acquisitions.

The public sector comprises:

- social security institutions exclusively directed to formal workers, in which the funding comes from contributions by the federal government, the employer and the employee; and
- public institutions exclusively directed to attend people not covered by social security, in which the funding comes from the federal government, states and patients.

The public health sector normally faces financial problems and implements measures to limit costs, for example by pressing for price reductions in consolidating public bids (involving the most important health institutions) and encouraging competition.

In the public sector, medicines are provided by the social security or public institution. However, if the medicine is not available when required, it can be dispensed in a private registered drugstore.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The public sector comprises:

- social security institutions exclusively directed to formal workers such as the Mexican Institute of Social Security, the Institute of Social Security for State Workers and other specialised public institutions such as the Mexican Navy Force, Naval Secretariat and Mexican Petroleum Workers; and
- public institutions exclusively directed to attend people not covered by social security, such as the People's Insurance and state health institutions.

The private sector comprises private institutions, insurers and independent professionals in which the beneficiaries are not restricted.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Key legislation includes the following:

- the General Health Law;
- the General Health Law Regulations;
- the Health Supplies Regulation;
- the Official Mexican Standards (NOMs); and
- the Mexican Pharmacopoeia.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Federal Commission for Protection against Sanitary Risks (COFEPRIS), which is an administrative agency depending of the Ministry of Health and is funded by the federal government. The General Health Law entitles COFEPRIS to recover income derived from insurance rescue and other exceptional incomes.

5 What is the scope of their enforcement and regulatory responsibilities?

In accordance with the General Health Law, COFEPRIS is in charge of the following:

- the sanitary regulation, surveillance and control of public social security institutions and private institutions;
- the sanitary control of products and services, and its importation and exportation;
- the sanitary control of the process, use, maintenance, import, export and disposal of medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, supplies of dental use, surgical materials, healing and hygienic products;
- preparing and issuing NOMs relating to health facilities, products and services;
- evaluating, issuing or revoking sanitary authorisations;
- exercising control and sanitary surveillance of drugs and other health supplies;
- disposal of organs, tissues, human cells and their components, toxic or dangerous substances, biotechnological products and raw materials;
- exercising control and surveillance of the advertising of sanitary activities, products and services; and
- imposing sanctions and implementing security measures.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The General Health Council is an agency controlled by the Executive Cabinet of Mexico and funded by the federal government. COFEPRIS is an administrative agency controlled by the Ministry of Health and funded by the federal government. The General Health Law entitles COFEPRIS to recover incomes derived from insurance rescue and other exceptional incomes.

7 What is the scope of their enforcement and regulatory responsibilities?

The General Health Council is in charge of the following:

- preparing, updating and circulating the National Formulary of Basic Drugs;
- preparing and updating the Guidelines for the Evaluation of Health Supplies; and
- preparing the Guidelines for Interchangeability Tests of medicines that will be submitted before COFEPRIS for the granting of marketing authorisation as generics.

For more on COFEPRIS, see question 5.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The following agencies have jurisdiction over healthcare, pharmaceutical and medical device cases:

- the Mexican Institute of Industrial Property (IMPI);
- the Office of the Federal Prosecutor for the Consumer (PROFECO);
- the Antitrust Commission (COFECE); and
- the Federal District Attorney's office (PGR).

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct an investigation on the same subject provided that the corresponding actions are independent from each other and intended for different purposes.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Pharmaceutical products

Pharmaceutical products are subject to the following provisions.

New molecules

Essentially, applicants for marketing authorisations must prove the safety and efficacy of their products through standard clinical trials, according to the rules set out by the General Health Law, its regulations and NOMs of good manufacturing of medicines and active ingredients. Concurrently, they have to request approval of their products as new molecules by the New Molecules Committee of COFEPRIS. According to the Health Law Regulations article 2 section XV, a new molecule is:

- an active ingredient or drug not approved worldwide (a new molecular entity);
- an active ingredient or drug already available in other countries but with limited clinical experience or disputed information, without approval in Mexico;
- a drug which is a non-marketed combination of two or more active ingredients; or
- an active ingredient or drug already available on the market, but to be marketed for a new therapeutic indication.

R&D companies benefit from a special procedure for drugs that have been previously approved by a regulatory authority abroad to be approved for the first time in Mexico.

Generics

Applicants for marketing authorisations have to prove that their products are bioequivalent to the innovator product. They have to provide information concerning dissolution profiles or bioavailability studies regarding the reference product. COFEPRIS periodically issues a reference list of medicinal products.

Recently, the NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated (NOM-177-SSA1-2013). Legally, COFEPRIS should not grant marketing authorisation for generics breaching exclusivity rights.

There is a linkage system between COFEPRIS and IMPI, which aims to prevent the granting of marketing authorisations in violation of patent rights. According to the Intellectual Properties Regulations, every six months IMPI must publish a gazette that includes patents covering allopathic medicines (Linkage Gazette). The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use patents). On 31 July 2012, for the first time the IMPI included formulation patents in the Linkage Gazette, in accordance with a 2010 ruling of the Mexican Supreme Court (Jurisprudence No. 2a/J7/2010, Federal Judicial Gazette, No. XXXI, page 135).

Usage patents are included in the Linkage Gazette by a court order, since IMPI considers that they should not be included in the linkage system.

Under the linkage regulations, at the filing of the application, the applicant must prove that he or she is the owner or licensee of the patent of the active ingredient of the product (recorded before IMPI), or state under oath that their application does not violate the list of products published in the Linkage Gazette and observes patent law.

Biologics

Amendments to the legal framework to regulate the approval of biologics are recent and being tested. Under the General Health Law, applicants have to prove the quality, safety and efficacy of their products, its regulations and applicable NOMs, particularly those for good manufacturing practices for medicinal products (NOM-059-SSA1-2013) and for active ingredients (NOM-164-SSA1-2013).

In accordance with the recent NOM-257-SS1-2014, all biologicals drugs that were authorised before the legal reform and are still on the market must enter a regularisation process in order to comply with the new standard for biologics.

NOM 257 emphasises that key points to ensure the safety, efficacy and quality of biologics are already regulated in other NOMs currently in effect, such as those for clinical trials and pharmacovigilance. NOM 257 empowers the Assessment Subcommittee on Biotech Products (SEPB) to assess technical and scientific data in connection with clinical trials, approval or renewal of innovator biologics or follow-on biologics (biocomparables) and to issue opinions to characterise biologics as innovators, reference products or biocomparables.

NOM 257 provides transitional provisions for the renewal of those marketing authorisations of biologics granted before the amendments to the Health Law Regulations for Biologics issued in 2011 came into force. These provisions establish that:

- COFEPRIS will assess whether biologics refer to innovators or biocomparables;
- renewal applications for innovators will not require assessment by the SEPB; and
- renewal applications for biocomparables will require prior assessment by SEPB to identify the product of reference in order for applicants to submit the corresponding tests.

These provisions will be applicable only for those renewal applications submitted before 31 December 2015.

COFEPRIS, however, missed an opportunity to address the current uncertainty in respect of Regulatory Data Protection for Biologics, as NOM 257 does not provide for guidelines in this regard.

Biocomparables

Applicants must submit clinical tests, and when appropriate in-vitro tests, to prove the safety, efficacy and quality of this product comparable (similar) to those of the reference biologic.

The pre-clinical and clinical test used by an applicant for a biocomparable must use the corresponding reference biologic to perform comparative and physico-chemical studies. For this, the applicant must submit:

- in vitro studies;
- the report of a comparative pharmacokinetic test, if determined by the Ministry of Health, to show pharmacokinetic comparability on key parameters between both the follow-on and the reference biologic;
- pharmacodynamics test reports; and
- comparative efficacy and safety clinical test to show the similarity between both the follow-on and the reference biologic.

Although industry participants have welcomed amendments to the approval of biologics, specific rules to approve follow-ons have caused debate. There is currently no indication of a data protection period for biologics. The recognition of data package exclusivity rights for biologics can only currently be achieved through litigation. Accordingly, there are also concerns regarding the accurate application by COFEPRIS of linkage provisions.

Orphan drugs

Orphan drugs were recently introduced into the General Health Law and the Mexican Pharmacopeia. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate. Specific rules are still pending. The draft of an NOM compiling requirements for granting marketing authorisations includes orphan drugs.

Medical devices

Medical devices are subject to the following provisions.

In general, it would be fair to say that regulation regarding medical devices is lighter than that for drugs and other substances. According to their use, the General Health Law classifies medical devices into:

- medical equipment;
- prosthetics, orthotics and functional supports;
- diagnostic agents;
- dental supplies;
- surgical and healing materials; and
- hygiene products.

Marketing authorisation requirements for these devices depend on the level of risk involved in their use, according to a threefold classification:

- Class I. Products which are well known in medical practice and for which safety and efficacy have been proven. They are not usually introduced into a patient's body.
- Class II. Products which are well known in medical practice, but may have material or strength modifications. If introduced, they remain in a patient's body for less than 30 days.
- Class III. Products either recently accepted in medical practice or which remain in a patient's body for more than 30 days.

COFEPRIS analyses both medical devices and, if applicable, software that enables them to work. Conversely, mobile medical applications are a new area that COFEPRIS may address in future by particular regulations, especially if they represent health risks.

As an incentive, applicants can benefit from a special procedure for certain devices to be approved in Mexico, which has been previously approved by the US Drug and Food Administration and Health Canada. This procedure is essentially based on a dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 30 working days. Industry participants have welcomed these new rules, but they are still being tested.

Powers to monitor compliance

COFEPRIS can request reports from marketing authorisation holders, and make on-site inspection visits in the manufacturing, distribution or storage facilities, essentially to verify that their products meet the approved specifications and do not represent a risk for the public health and to ensure that good manufacturing practices, stability, pharmacovigilance and labelling standards are complied with.

COFEPRIS can initiate ex officio legal proceedings to sanction noncompliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

COFEPRIS is also entitled to implement measures on behalf of public health, such as:

- seizure of products; and
- ordering partial or total suspension of activities, services or adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

Administrative infringements can incur penalties ranging from a fine up to 20,000 times the minimum wage to final closure of the establishment. Repeated infringement is also considered a criminal offence.

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The manufacturing and sales of counterfeiting or falsified medicines is classified as a crime by the General Health Law. In addition, COFEPRIS commonly enters into collaboration agreements with the PGR and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Investigations conducted by COFEPRIS can be initiated either by the complaint of an individual or by COFEPRIS itself. However, the duration of the investigation varies depending on the complexity of the case. Certain investigations related to counterfeit and commercialisation of illegal medicines are generally conducted in a matter of a few days.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Access to files and materials submitted before COFEPRIS by companies or individuals during the prosecution of administrative proceedings are usually restricted to third parties.

However, in most contentious administrative and judicial proceedings the subject of an investigation has full access to the files and materials, except for the information expressly classified as confidential upon request of the authority or another individual.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

No, but to hold a marketing authorisation foreign applicants must have either:

- an approval from COFEPRIS for a manufacturing facility or laboratory for medicines or biologic products for human use in Mexico; or
- an equivalent approval (a licence, certificate or other permit document) for any of these facilities abroad from the competent authority in the country of origin.

14 Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, and the possibility to later apply to a court remains available.

COFEPRIS is entitled to revoke sanitary authorisations in the following cases:

- when the corresponding products or activities constitute a risk of harm to human health;
- when the exercise of an authorised activity exceeds the limits set in the respective authorisation;
- when the authorisation is used for different purposes;
- for noncompliance with the Health Law or Regulations;
- when the product covered by the authorisation does not meet or no longer meets specifications or requirements established by the Health Law, NOMs and other general provisions;
- when the information or documents provided by the applicant are false;
- when the reports provided by authorised third parties are false; and
- when the products no longer possess the attributes or characteristics under which they were authorised or lose their preventive or therapeutic properties.

There is also an available action called *accion popular*, whereby any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks in a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to cease a health risk and not to obtain compensation.

For additional information regarding COFEPRIS see question 10.

In coordination with COFEPRIS, the PGR is entitled to investigate and prevent the commercialisation of illegal medicines and also to implement measures on behalf of public health, such as the seizure of products.

PROFECO can initiate infringement proceedings in relation to violations of the NOMs. Individuals are entitled to file complaints against the providers of a service or manufacturers of a product. PROFECO, nonprofit associations and a common representative of a group of at least 30 members can now pursue class actions. The federal procedural laws have been amended to allow class actions before the federal courts.

COFECE itself and individuals can request investigations and inspection visits. Once the investigation stage is concluded, the authority will determine whether the case is closed or if it is applicable to initiate an administrative trial. In both cases, COFECE is entitled to impose preliminary injunctions. The affected party can claim damages before a court. Follow-on private litigation against manufacturers is possible, but has not been as widely spread as in other jurisdictions, such as the United States. Additionally, COFECE can file a criminal complaint.

Individuals can file patent infringement and unfair competition claims before the IMPI, which is entitled to implement preliminary measures while investigating the infringement, which includes:

- the recall of infringing goods, or preventing their circulation;
- infringing articles to be withdrawn from circulation, including tools used in the manufacture, production or obtaining of infringing articles;

- the alleged transgressor or third parties to suspend or cease all acts that violate the law; and
- suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Once an infringement has been declared and cannot be appealed, the claimant can bring an additional civil action for damages and lost profit, accruing from the date on which the existence of the infringement can be proved. The civil courts impose a tariff scheme specifying the costs that can be claimed for reasonable attorneys' fees, regardless of whether this reflects the actual fees charged.

The imposition of administrative sanctions does not exclude civil and criminal liability.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

See questions 10 and 14.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes, the General Health Code includes a chapter (VI) of specific offenses in which both individuals and the responsible legal entity may be the subject of an enforcement action.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

Company defendants are entitled to file a non-conformity recourse against the decisions issued by COFEPRIS within 15 working days following the issuance of the decision.

Likewise, a decision issued by an administrative authority can be appealed through a review recourse before the corresponding authority, within 15 working days following the issuance of the decision. The decision issued in the review recourse can be challenged by means of a nullity trial before an administrative court (the Federal Court for Tax and Administrative Affairs) and lastly before an administrative Federal Circuit Court.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should focus on the diagnosis of the problem and its resolution through institutional proceedings, appealing adverse decisions when applicable.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

In the past years, COFEPRIS' enforcement activities have been focused on the seizure of illegal medicines, which has resulted in the closure of the establishment and suspension of activities.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The National Chamber of the Pharmaceutical Industry (CANIFARMA) exercises institutional representation of the pharmaceutical industry before the Mexican authorities. Affiliate members are required to comply with the codes issued by the organisation.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and healthcare professionals, such as the Health Law and Health Law Regulations (including those that concern the sanitary control of activities, establishments, products and services). Industry Codes of Practice complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments:

- the Code of Ethics and Transparency of the Pharmaceutical Industry (Code of Ethics & Transparency);
- the Code of Good Practices of Promotion (Code of GPP); and
- the Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations (Code of GPI).

The latest versions of these Codes have been in force since 1 April 2013. Affiliate members of CANIFARMA are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance.

22 How are the rules enforced?

Scientific and educational events

The Code of GPP states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by pharmaceutical companies or any other third party must have, as a main purpose:

- scientific exchange;
- medical education; and/or
- information about medicines.

Whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws. They must have a strict scientific content sustained, if required, on clinical evidence; and, most importantly, they must be accredited and certified by the corresponding academic authorities.

Under no circumstances will support be offered in order to influence the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

Samples

According to the Code of GPP, samples are provided directly, in fair amounts and without cost to healthcare professionals, so that they may get to know and be familiar with the products or in order to initiate a treatment. According to article 49 of the Health Law Regulations concerning advertising, providing samples of products for free does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with a smaller number of units than the approved product. The Code of GPP establishes guidelines for sampling. It prohibits members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples. Members are required to have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians. We always recommend that our clients have strict control of product samples as there have been cases of resale of said samples.

Gifts and donations

The Code of GPP essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value or incentives of any kind may be offered to healthcare professionals as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study. No gifts, bonuses, pecuniary advantages, benefits in kind or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to the practice of medicine or pharmaceutical activities. The Code delineates an inexpensive promotional aid as that one that does not exceed the equivalent of 10 times the minimum wage (around US$50). Concerning healthcare professionals in government institutions, article 47 of the Federal Law of Responsibilities for Government Officers expressly forbids these officers from requesting, accepting or receiving any gifts or donations from persons whose commercial or industrial activities are directly linked, regulated or supervised by government officers.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The Code of GPP establishes that collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place that includes:

- activities to be undertaken, cost, source and destination of funding; and
- direct and indirect support and any other relevant non-financial aid.

In these agreements, members must follow their applicable guidelines and codes of ethics and conduct, have transparent practices and use deontological instruments approved by CETIFARMA and CANIFARMA. The Code requires members to set forth criteria and procedures for the approval and implementation of these kinds of collaborations. Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

In coordination with the educational authorities, the Ministry of Health and the governments of the states are in charge of monitoring health professionals when providing the following services:

- conducting sanitary evaluations and verification visits and, as a result, issuing an official report which states whether the subject of the investigation complied with laws, regulations and NOMs. In case of non-compliance, the health authority in charge of the investigation will initiate the corresponding administrative proceeding; and
- applying sanctions and safety measures when appropriate, and verifying compliance.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The duration of the investigation varies depending on the complexity of the case.

The establishment or site requiring an evaluation or verification visit is determined by any of the following:

- by random selection;
- due to a previous contingency or health emergency;
- by programmes determined by the health authority;
- due to a claim by a third party;
- at the request of the owner; and
- as follow-up to an administrative procedure initiated by the health authority.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

The subject of an investigation has full access to the files and materials, except for information that is expressly classified as confidential upon request of the authority or another individual.

27 Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, while the possibility to later apply to a court remains available. The Ministry of Health and the governments of the states are in charge of performing regular sanitary evaluations and verification visits to public and private institutions which, depending on the results, can lead to the application of sanctions and safety measures. The imposition of administrative sanctions does not exclude civil and criminal liability.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If the sanitary conditions of the establishment, raw materials, process, procedure or product present a significant risk to health or lack the essential requirements of the law and other applicable provisions, verifiers should take immediate security measures with the approval or consent of the health authority on which they depend.

The competent health authorities may order the application of the following security measures:

- isolation;
- quarantine;
- personal observation;
- vaccination of persons;
- vaccination of animals;
- destroying or controlling of insects or other vermin;
- the suspension of work or services;
- the suspension of advertising in health;
- the issue of advertising messages that warn of potential damage to health;
- the seizure and destruction of objects, products or substances;
- eviction from houses, buildings, facilities and any property in general; and
- other health measures as determined by the competent health authorities.

The sanitary authority has statutory powers to impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare providers are entitled to file administrative, civil and criminal complaints against sanctions or adverse decisions. The National Commission of Medical Arbitration (CONAMED) provides guidance and assistance to healthcare providers during the process of a complaint filed against them for medical negligence and during the medical arbitration proceeding.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 19.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Enforcement activity has been focused on the inspection of private clinics. This has resulted in the closure of establishments and suspension of activities due to a significant risk to health, lack of essential requirements for the establishments' operation and uncertified medical personnel.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare providers in Mexico are grouped and represented by different private associations depending on their specialisation and field of work.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Contracts for the acquisition of health supplies and health services provisions usually include the following sanctions:

- Penalties for delays in compliance with agreed dates of delivery or service provision, which shall not exceed the amount of the guarantee of compliance of the contract, and will be determined according to the goods or services not delivered or rendered on time.
- When a supplier totally or partially breaches any of the obligations expressly established in a contract, government entities can terminate the contract in advance without liability and without any judicial resolution.

Contracts for the acquisition of medicines or health supplies provide that the government institution may request that the supplier exchange goods with defects or the total devolution of the goods, where after delivering the new batches, the same defect is detected.

The supplier of the goods is obliged to respond at its own risk regarding claims that failure or negligence on their part have caused problems for government institutions or third parties.

Update and trends

Medicine and health supplies
The Supreme Court of Justice recently solved a case in which an individual appealed the denial of supply of a medicine that was prescribed by its physician but not included in the national formulary of basic drugs of the health public institution to which the patient was affiliated. The Court determined that the denial of supply of the prescribed medication violated the patient's human right to health where basic health services are considered, among others, the availability of medicine and other health supplies. This decision also established that the obligation to provide appropriate health services is not exclusive to the state, but is shared with other members of the society such as private health institutions. The criteria applied in this decision will certainly increase the number and diversity of actions filed by individuals against public and private health institutions, which will eventually impact the attention of healthcare as we know it.

Advertising
Several amendments to the Industry Codes of Practices by CETIFARMA were approved last year. As a consequence of compliance practices, there is an expectation that the rules governing pharmaceutical advertisements will be strengthened by both industry associations and regulatory authorities.

In February 2014 COFEPRIS issued detailed guidelines regarding the approval of adverts for non-prescription medicinal products. Most of these guidelines are in line with the Codes. As a development, we would highlight the non-approval of an advert providing disease awareness if it is followed by another advert of a medicinal product related to that disease, unless both adverts are approved jointly.

Trans-Pacific Partnership
In November 2011, during the Asia Pacific Economic Cooperation meeting, Mexico showed interest in initiating consultations to participate in the Trans-Pacific Partnership (TPP). On 18 June 2012 during the G20 meeting in Los Cabos, Mexico, the countries participating in the TPP decided to invite Mexico to participate.

Regarding intellectual property, the TPP partners remain confident that copyrights, patents and trademarks will be enforced. There appears to be a general consensus that the standard of protection for intellectual property should go beyond the Trade-Related Aspects of Intellectual Property Rights agreement.

The terms, conditions and wording of the TPP remain confidential. However, it has been made public that the main topics regarding intellectual property include effective customs measures, pharmaceutical patents, and agrochemical patents.

In the case of pharmaceutical patents and regulation, the main topics appear to be that the countries commit to have additional mechanisms of intellectual property protection such as:
- patent linkage;
- extensions or compensation for the life term of patents due to regulatory delays; and
- data package exclusivity for new chemical compounds and formulation and second uses.

Mexico has implemented the first steps towards TPP, since the World Intellectual Property Organization Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol) entered into force in Mexico at the beginning of 2013. The rushed approval of this, without a full review of the trademark system (and assuming IMPI is prepared to properly adopt the Madrid Protocol system) is a good indication that the Mexican government is willing to fulfil the standards of the TPP and replicate the enactment of IP Law 1991, when the North America Free Trade Agreement started to be discussed.

Due to the negotiations and eventual integration of Mexico into the TPP, Mexico has a new and valuable opportunity to review and change its entire intellectual property system and adopt higher and, importantly, more efficient standards of intellectual property protection.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Besides civil and criminal actions, in order to enforce a healthcare regulation or law, citizens or other private bodies can file an innovative constitutional action against a particular act or omission of the authority, grounding their legal standing in article 4 of the Mexican Constitution which provides the human right of due access to health.

35 What is the framework for claims of clinical negligence against healthcare providers?

Patients or relatives of patients who have received medical, public or private care that potentially caused them harm because of malpractice are entitled to file complaints against healthcare providers.

CONAMED provides guidance and expert advice to patients and healthcare providers about their rights and obligations. It also receives and investigates cases related to irregularity or denial in providing justified or urgent medical services by public institutions.

Patients are entitled to file a complaint before CONAMED, in which case such authority will be a mediator between the patient and the healthcare provider with the purpose of achieving a settlement agreement. If this is not the case, the patient can chose between submitting to a medical arbitration proceeding before CONAMED or filing a civil action.

Decisions issued by CONAMED can have the following effects:
- ordering the provision of adequate medical care; and
- ordering reimbursement, compensation or both to the patient.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Individuals are entitled to file complaints against the providers of a service or manufacturers of a product before PROFECO on the grounds that the product of interest does not comply with the essential requirements provided by the applicable regulations and NOMs or the advertised characteristics and functionality.

37 Are there any compensation schemes in place?

The State Liability Law aims to establish the bases and proceedings for recognising the right to compensation of those who, without any legal judicial obligation, suffer damages to their property and rights as result of irregular administrative activity of the state.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The federal procedural laws have been amended to allow class actions before the federal courts. PROFECO, the Attorney General's Office, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. These amendments are subject to testing in the courts, and apparently there are no precedents of class actions for product liability.

Accion popular allows that any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks in a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to cease a health risk and not to obtain compensation.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Acts, omissions and decisions of both public and private institutions are the subject of administrative, civil and criminal complaints from interested parties before courts. Actions should be filed as soon as possible in order to duly attend and repair the claimed act or omission. In these type of cases the legal standing of the complainant is grounded in the human right of due access to health. In relevant cases it has been decided that the state will always be responsible for appropriate health attention, even if the claimed act or omission derives from a private institution.

40 Are there any legal protections for whistle-blowers?

No, in Mexico we do not have a figure equivalent to a 'whistle-blower'. The Federal Law on the Administrative Responsibilities of Public Servants

provides that public servants must inform their superiors in writing about any conclusive doubts that arise from the origin of the orders they receive that could constitute an infringement of any legal or administrative provision. However, such Law fails to consider the protection that should eventually be granted to the public servant or the process that should be implemented in order to preserve the confidentiality of the denouncement.

41 Does the country have a reward mechanism for whistle-blowers?

No.

42 Are mechanisms allowing whistle-blowers to report infringements required?

Yes. The Ministry of Public Administration is the authority in charge of verifying that public servants act in accordance to the applicable laws during the exercise of their functions, and is the authority in charge of implementing the corresponding sanctions.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. In accordance with the Health Law, its Regulations and the international treaties subscribed by Mexico, the Ministry of Health is in charge of institutional relationships with the health dependencies of other governments and international organisations in order to facilitate the provision of technical advice, information and assistance in everything related to the sanitary regulation, control and health promotion.

Additionally, the Ministry of Health notifies the World Health Organization of all the measures it has taken, temporarily or permanently, in international health, as well as of any case that is of interest in the surveillance of the diseases listed in the International Health Regulations.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

When the Ministry of Health receives an international communication, alert or requirement on health matters, in coordination with the corresponding administrative entities (Ministry of Foreign Affairs and Ministry of the Interior) it will conduct inspection visits in order to verify compliance or noncompliance with international sanitation rules.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Mexican healthcare laws, regulations and official standards are equally enforceable against foreign companies and nationals.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

Access to most medicines and medical devices is arranged through the Health Insurance Act. It is mandatory for all residents of the Netherlands to take out basic health insurance, which consists of a standard package of insured services. The healthcare system in the Netherlands is one of private health insurance with public social conditions. The system is operated by private health insurance companies that must accept all Dutch citizens, regardless of their age or condition of health. A system of risk equalisation enables the acceptance obligation and prevents direct or indirect risk selection. All people pay the same nominal insurance premium to their health insurer for the basic health insurance. The Health Insurance Act also provides for an income-related contribution to be paid by the insured. Employers contribute by making a compulsory payment towards the income-related insurance contribution of their employees. In summary, funding is arranged as follows:

- a premium paid by the insured (approximately €1,162 in 2015). People who cannot pay the fixed premium due to low income can apply for a care allowance;
- a compulsory deductible sum (€375 in 2015);
- an income-related contribution to be paid by the insured;
- compulsory employer payment towards the income-related contribution of the employee;
- funding by the government through the Health Insurance Fund.

In addition to the mandatory basic package of insured healthcare, patients can take out additional insurance at their own costs.

In addition to the mandatory healthcare insurance, Dutch citizens may also be entitled to other (long-term) forms of healthcare through:

- the Long-Term Care Act which is funded by the government and personal contributions; or
- the Social Support Act, which is funded by the government.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is delivered by healthcare providers through both public and private practices (ie, hospitals, general practitioners, therapists, etc).

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The Public Health Act and the Social Support Act arrange for the regulatory framework regarding the execution of public healthcare and social support. Municipalities are responsible for the execution of these laws.

The Health Insurance Act and the Long-Term Care Act are insurance laws that arrange for the regulatory framework regarding the financing and content of curative and long-term care. These laws are executed by health insurance companies and healthcare providers.

The Health Care (Market Regulation) Act provides for the development, organisation and supervision of the Dutch healthcare markets in order to ensure an efficient and effective system of healthcare.

The Care Institutions (Quality) Act, the Medical Treatment Contracts Act and the Individual Health Care Professions Act are directly related to the delivery of healthcare and provide for conditions for healthcare institutions and healthcare providers.

The Medicines Act and the Medical Devices Act contain the regulatory framework and provisions regarding the manufacturing, marketing and distribution of drugs and medical devices.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The following agencies are responsible:

- the Ministry of Health, Welfare and Sport;
- the Healthcare Inspectorate; and
- the Dutch Healthcare Authority.

These agencies are funded by public funds. None of the abovementioned agencies are dependent on enforcement activities for funding.

5 What is the scope of their enforcement and regulatory responsibilities?

The Ministry of Health, Welfare and Sport is principally responsible for the enforcement of laws and rules applicable to delivery of healthcare, and these enforcement tasks are generally executed by the Healthcare Inspectorate.

The Dutch Healthcare Authority is the competent authority regarding the organisation and supervision of the Dutch health care markets, including health insurance companies and healthcare providers, and it may set rules regarding delivery of healthcare and maximum tariffs that healthcare providers are allowed to charge for their services.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The following agencies are responsible:

- The Dutch Medicines Evaluation Board;
- the Healthcare Inspectorate; and
- the Ministry of Health, Welfare and Sport and its Farmatec department.

These agencies are funded by public funds, charges or both. None of the abovementioned agencies are dependent on enforcement activities for funding.

7 What is the scope of their enforcement and regulatory responsibilities?

The Dutch Medicines Evaluation Board grants, rejects, suspends and revokes marketing authorisations, and is responsible for pharmacovigilance and the supply status of medicinal products.

The Healthcare Inspectorate supervises and enforces pharmaceutical and medical device legislation. It may, for example, conduct investigations and impose financial penalties on behalf of the Ministry of Health, Welfare and Sport.

The Ministry of Health, Welfare and Sport is responsible for healthcare legislation and policy. The Farmatec department grants manufacturing, import and wholesale authorisations relating to medicinal products, and deals with notifications and exemptions relating to medical devices.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Netherlands Authority for Consumers and Markets is the general competition authority and is involved in general competition matters, including healthcare, pharmaceutical and medical device cases.

The Fiscal Intelligence and Investigation Service and Economic Investigation Service may conduct investigations in respect of suspected fraud.

Disciplinary courts and the medical supervision board may – after disciplinary proceedings have been initiated – impose sanctions on individual healthcare practitioners.

The Public Prosecution Service is authorised in certain cases of serious violations of healthcare, pharmaceutical and medical device laws and regulations to initiate criminal investigations and to demand criminal sanctions to be imposed by the criminal courts.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

When multiple government agencies are authorised to conduct an investigation, such agencies will generally work together in one investigation, will generally inform each other of such investigations and/or will agree that the investigation shall be performed by one agency. Pursuant to the *ne bis in idem* principle that applies in the Netherlands, a criminal or administrative penalty cannot be imposed twice for the same cause of action.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The Healthcare Inspectorate and other public authorities have general administrative enforcement authorities as set out in the General Administrative Law Act, which also applies to monitor compliance with the rules on drugs and devices:

- enter into and search premises, including site inspections, excluding houses if no permission of the occupant has been obtained;
- demand information;
- demand inspection of business documents and records;
- investigate objects and means of transport, including the power to open packaged products and to draw samples; and
- any person has the general obligation to cooperate with the competent authority.

If there is suspicion of a criminal sanction, the public attorney may have various powers to undertake a criminal investigation, which is specifically relevant in cases that concern products that fall within the scope of the Narcotics Act.

11 How long do investigations typically take from initiation to completion? How are investigations started?

There is no general rule for the length of an investigation; this will depend on the type of investigation. An investigation is generally started with a letter in which the investigation is formally announced. However, an investigation may also start by means of an unannounced dawn raid.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

An interested party will – at its own request – be informed as soon as possible regarding the outcome of the investigation and inspection of objects and samples.

If a site inspection has been performed pursuant to the Dutch Medicines Act, a report will be drafted which will be provided to the person or entity that owns the inspected site. This person or entity will then be allowed to provide comments to such report.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

The Healthcare Inspectorate is not authorised to conduct inspections outside the Netherlands. For inspections that are required to take place in other countries, requests for assistance will be made to the competent authorities of such other countries.

14 Through what proceedings do agencies enforce the rules?

Agencies enforce their rules through administrative procedures. Legal proceedings regarding enforcement measures are administrative law proceedings that may eventually end up before the administrative courts.

Government agencies are bound by general administrative law provisions when enforcing the rules. Such provisions entail, inter alia, that an agency should act pursuant to the principle of proportionality, the principle of due care, the principle of legal certainty and that the agency may not misuse its powers.

In addition to such general rules, the Ministry of Health, Welfare and Sport has published guidelines regarding the imposing of an administrative fine for healthcare-related violations. These provide for guidance on when an administrative fine is imposed and how the amount is calculated. The Healthcare Inspectorate has published various documents in which their enforcement policy is further detailed.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The following sanctions and measures can be imposed:

- administrative fines up to €450,000 for violation of the Medicines Act and up to €900,000 for violation of the Medical Device Act;
- restorative administrative measures may be taken;
- measures in respect of drugs:
  - the order to stop or suspend the manufacturing, distribution, marketing, import, export or dispensing of drugs or substances used to manufacture a drug;
  - the order to withdraw drugs or a substance intended to manufacture a drug from the market;
  - the order to close a pharmacy; and
  - the power to confiscate certain substances and products and to order that such substances and products are withdrawn from the market, destroyed or made unfit for use; and
- measures in respect of medical devices aimed at prevention of damage to public health:
  - the order to stop or suspend the marketing, import, export or delivery of medical devices; and
  - the order to withdraw medical devices from the market.

16 Can the authorities pursue actions against employees as well as the company itself?

Actions can only be pursued against an employee if such employee has violated any applicable law or regulation. Actions cannot be pursued against employees if the violation was committed by the company.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

If administrative enforcement measures are taken, the company or person against whom such measures were taken can appeal such measures by filing objections. During such objections proceedings, the company or person that filed the objections is generally heard during a formal hearing. If the objections are dismissed, appeal can be initiated before the administrative court.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies can try to limit their exposure to enforcement actions by having internal written procedures in place in order to ensure compliance with the applicable laws and regulations, setting up training programmes for employees to ensure better compliance, holding mock inspections and consulting with the competent authorities regarding questions of how to interpret specific provisions or how to best comply with the applicable laws and regulations. Competent authorities are, however, generally reluctant in providing detailed advice. All these actions may also help to reduce liability or reduce the amount of an administrative fine.

Strategies that may help to reduce liability and the amount of an administrative fine include cooperating with competent authorities during

inspections and stopping the alleged infringement of laws and regulations immediately upon becoming aware of them.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Recent drug and devices enforcement activities by the Healthcare Inspectorate were focused on trade in counterfeit drugs, infringement of provisions regarding inducement of healthcare professionals by pharmaceutical companies, safety of certain injection needles and qualification of products as drug or medical device. The Healthcare Inspectorate has imposed various administrative fines in relation to such enforcement activities.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

There are several self-regulatory bodies:

- The Foundation for the Code for Pharmaceutical Advertising (CGR), which focuses on prescription-only drugs;
- the Inspection Board for the Public Promotion of Medicines and Health Products, which focuses on over the counter drugs and self-care medical devices and other health products; and
- the Foundation for the Code of Conduct Medical Devices, which formulates self-regulatory medical device advertising and inducement rules.

Members of the self-regulatory bodies are bound by the applicable codes of conduct, and complaint procedures apply and can be initiated if a member infringes such self-regulatory code. Such complaint procedures may lead to sanctions, for example an order to stop certain behaviour, publication of the outcome of the complaint procedure, etc.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

Drugs

The Medicines Act contains a general prohibition in respect of inducement of a healthcare professional. The Medicines Act provides for four exceptions to this general ban:

- reasonable payment for delivery of services;
- offering hospitality during a scientific or other meeting to the extent strictly necessary to participate in such meeting;
- providing a 'gift' if of insignificant value and relevant to the practice of medicine or pharmacy; and
- bonuses and discounts in relation to the sale of medicinal products to the extent this is transparent.

These forms of permitted inducement are further elaborated in policy rules of the Ministry of Health, Welfare and Sport and in the Code for Pharmaceutical Advertising of the CGR. The latter Code also provides for the possibility of sponsoring, where a pharmaceutical company is allowed to provide sponsoring for a project, meeting, study or otherwise to the extent the support is for:

- innovative or quality enhancing activities:
- the support is intended to achieve a direct or indirect improvement of patient care or to advance medical science; and
- such activity is not funded or not fully funded via regular sources of funding.

Medical devices

The Medical Devices Act does not provide for rules on inducement; however such rules are included in the self-regulatory Code of Conduct Medical Devices (GMH Code). These rules are similar to the rules that apply in respect of drugs as set out above.

22 How are the rules enforced?

The inducement rules for drugs are enforced by the Healthcare Inspectorate and by the following self-regulatory bodies: the CGR and the Inspection Board for the Public Promotion of Medicines and Health Products. To this extent the Healthcare Inspectorate, the CGR and the Inspection Board for the Public Promotion of Medicines and Health Products have agreed on what issues will be handled by whom through written working arrangements. Generally the Healthcare Inspectorate handles more serious violations of the Medicines Act whereas the less serious matters are handled by the self-regulatory bodies. Enforcement of rules regarding the disclosure of financial relations is handled by the CGR, as the Healthcare Inspectorate has no enforcement powers in this respect.

The Healthcare Inspectorate enforces rules by an administrative procedure, which is generally initiated by an investigation. The self-regulatory bodies generally enforce rules by initiating a complaint procedure.

The inducement rules for medical devices are enforced by the self-regulatory body GMH throughout complaint procedures.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

As of 2013, financial relationships relating to sponsoring and services/consultancy agreements between pharmaceutical companies and healthcare professionals should be disclosed in the central Healthcare Transparency Register. As of 2015, financial relations regarding hospitality offered to individual healthcare professionals should also be included in the central Healthcare Transparency Register.

As of 2015, certain financial relationships relating to sponsoring and or services/consultancy agreements between medical device companies and healthcare professionals should be disclosed in the central Healthcare Transparency Register. The obligation to disclose financial relations applies to services and sponsoring of projects and activities in 2015, between:

- physicians that are included in the Dutch public register of healthcare professionals (HCPs) (BIG-register) with the title 'cardiology' or 'orthopaedics'; and
- suppliers of the following implantable medical devices:
  - implantable cardioverter defibrillators;
  - pacemakers, stents; and
  - hip and knee prostheses.

The obligation to disclose payments applies if the total amount exceeds €500 per calendar year. The central Healthcare Transparency Register is publicly available and the following information is made available:

- amount paid;
- type of agreement (sponsoring or services) or hospitality;
- data regarding the supplier or pharmaceutical company; and
- the HCP's details (ie, name and address).

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The Healthcare Inspectorate and other public authorities have general administrative enforcement authorities as set out in the General Administrative Law Act, which also applies to monitoring compliance with the rules on drugs and devices:

- they may enter into and search premises, including site inspections and excluding houses if no permission of the occupant has been obtained;
- they may demand information;
- they may demand inspection of business documents and records;
- they may investigate objects and means of transport, including the power to open packaged products and to draw samples; and
- any person has the general obligation to cooperate with the competent authority.

If there is suspicion of a criminal sanction, the public attorney may have various criminal powers to undertake a criminal investigation.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

There is no general rule for the length of an investigation; this will depend on the type of investigation. An investigation is generally started with a letter in which the investigation is formally announced. However, an investigation may also start by means of an unannounced dawn raid.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

An interested party will – at its own request – be informed as soon as possible regarding the outcome of the investigation and inspection of objects and samples.

27 Through what proceedings do agencies enforce the rules?

Agencies enforce their rules through administrative procedures. Legal proceedings regarding enforcement measures are administrative law proceedings that may eventually end up before the administrative courts.

Government agencies are bound by general administrative law provisions when enforcing the rules. Such provisions entail, inter alia, that an agency should act pursuant to the principle of proportionality, the principle of due care, the principle of legal certainty and that the agency may not misuse its powers.

In addition to such general rules, the Ministry of Health, Welfare and Sport has published guidelines regarding the imposing of an administrative fine for healthcare-related violations that provide for guidance on when an administrative fine is imposed and how the amount is calculated. The Healthcare Inspectorate has published various documents in which their enforcement policy is further detailed. Likewise, the Dutch Healthcare Authority has published guidelines concerning administrative fines.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

The following measures can be imposed:

- criminal penalties can be imposed, depending on the law or regulation that is violated. For example, if a healthcare provider delivers healthcare outside his or her competence, they may face a criminal penalty of up to €4,050 or may face imprisonment of up to three months;
- administrative fines can be imposed, depending on the law or regulation that is violated;
- restorative administrative measures may be taken; and
- disciplinary courts may impose the following measures:
  - warning;
  - reprimand;
  - a monetary fine up to €4,500;
  - suspension of a relevant healthcare professional from the professional register, for a period of up to one year;
  - partial removal from the authority to practise the profession as included in the professional register; and
  - cancellation of registration in the professional register.

29 What defences and appeals are available to healthcare providers in an enforcement action?

If administrative enforcement measures are taken, the healthcare provider against whom such measures were taken can appeal such measures by filing objections. During such objections proceedings the healthcare provider that filed the objections is generally heard during a formal hearing. If the objections are dismissed, an appeal can be initiated against such dismissal decision with the administrative court.

Disciplinary measures can be appealed before the disciplinary court of appeal. Criminal sanctions can be appealed before the criminal court of appeal.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Healthcare institutions can try to limit their exposure to enforcement actions by:

- having internal written procedures in place in order to ensure compliance with the applicable laws and regulations;
- setting up training programmes for employees to ensure better compliance; and
- holding mock inspections and consulting with the competent authorities regarding questions of how to interpret specific provisions or how best to comply with the applicable laws and regulations.

Strategies that may help to reduce liability and the amount of an administrative fine include cooperating with competent authorities during inspections and stopping the alleged infringements of laws and regulations immediately when becoming aware of them.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Examples of enforcement activities by the Healthcare Inspectorate relate to the quality of healthcare in healthcare institutions and unlawful inducement from pharmaceutical companies to healthcare providers.

The Dutch Healthcare Authority has imposed several financial penalties upon hospitals that committed healthcare fraud by unlawfully charging healthcare costs from health insurance companies.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

There are disciplinary courts in the Netherlands that may impose disciplinary measures upon healthcare providers on the basis of statutory law.

The self-regulatory body in respect of pharmaceutical advertising, the CGR, is competent to receive complaints regarding healthcare providers' conduct in the area of pharmaceutical advertising and the request of or receipt of unlawful inducements.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

The government does not typically enter into contracts with healthcare providers. Rather, health insurance companies, which are private companies, enter into agreements with healthcare providers. Such agreements would typically contain provisions concerning the quality of the healthcare provided by the healthcare provider to the patients who have taken out health insurance from the health insurance company.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Citizens or private bodies may submit a request for enforcement to the competent authorities. If the competent authorities subsequently identify a violation of a healthcare law or regulation, they should in principle take enforcement measures.

Citizens or private bodies may also initiate civil proceedings against the company, healthcare institution or healthcare provider. Such civil proceedings would be based on the argument that the violation of the healthcare law or regulation constitutes a tort with regards to the citizen or private body, as a consequence of which the citizen or private body suffers damage.

Competitors may also initiate such civil proceedings against other competitors, but this is generally difficult as the courts may consider that the healthcare regulation or law aims to protect the interest of public health rather than the interests of competitors. However, it may be successfully argued that one competitor acted unlawfully specifically against the other competitor by violating a healthcare law or regulation.

Patients may also file complaints against individual healthcare providers before the disciplinary courts.

35 What is the framework for claims of clinical negligence against healthcare providers?

Patients can initiate legal proceedings before the civil courts against healthcare providers if they have suffered damage. The healthcare provider has to apply a standard of good professional healthcare. The patient would have to demonstrate that the healthcare provider has not conducted due care as may be expected from a professional good healthcare provider. This duty of care is assessed on a case-by-case basis. Professional standards such as treatment guidelines may generally provide guidance as to what constitutes due care in a specific case. The healthcare professional cannot exclude or limit his or her professional liability.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Pharmaceuticals and medical devices are generally purchased by healthcare institutions, pharmacists and patients. If a drug or medical device is defective, it may be possible to submit product liability claims. If the seller

Update and trends

The Healthcare Inspectorate has identified five priorities for its enforcement activities for 2015:
- changes in the healthcare sector;
- governance;
- medication safety;
- inpatient care for the elderly; and
- healthcare providers who do not function well.

From a policy perspective, the Minister of Health, Welfare and Sport has informed that she intends to include enforcement authority for the Healthcare Inspectorate in the Medical Devices Act in respect of advertising and inducement of healthcare practitioners.

With regards to transparency, it may be decided in the future that the obligation to disclose financial relations between suppliers and healthcare practitioners in respect of medical devices will be extended to cover other medical devices and healthcare practitioners as well.

of a drug or medical device infringes any healthcare laws or regulations, purchasers may, depending on the contract, be able to seek recourse on the basis of breach of contract. If the seller of a drug or medical device infringes any healthcare laws or regulations, the purchaser may also be able to initiate civil proceedings on the basis of tort (see question 34).

37 Are there any compensation schemes in place?

There are no specific compensation schemes in place.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Dutch law does not provide for an 'American-style' class action. Instead, Dutch law provides for two formal litigation mechanisms to settle collective mass damage claims, namely:
- the Dutch Collective Settlements Act (WCAM); and
- the collective action based on article 3:305a of the Dutch Civil Code (DCC).

Firstly, the WCAM enables the collective settlement of mass damages claims. Pursuant to the WCAM, the collective settlement has to be concluded between, on the one hand, one or more associations or foundations representing the interests of a group of injured parties who suffered damages and, on the other hand, the party or parties allegedly causing the damages. Once such settlement is reached, the parties can submit a joint application to the Amsterdam Court of Appeal (that has sole jurisdiction), requesting this Court of Appeal to declare the collective settlement binding. If the Court of Appeal indeed declares the collective settlement binding, the settlement agreement will in principle bind all injured parties falling within the scope of the settlement agreement, whether known or unknown and whether residing in the Netherlands or abroad. Those injured parties who do not wish to be bound by the settlement agreement have the option to opt out, but they must do so within a limited period of time.

Secondly, Dutch law provides for a collective action based on article 3:305a DCC. This article stipulates that a collective action can be instituted by a foundation or association whose statutory goal is to represent the interests of groups of injured parties having similar damage claims and having a similar interest in holding a third party liable for the damages suffered by such group of injured parties. The foundation or association initiating the collective action must also have full legal capacity. However, a foundation or association shall have no course of action if, in the circumstances, it has not made a sufficient attempt to achieve the objective of the collective action through consultations. The collective action can only be used to seek a declaratory judgment against the third party that the third party acted wrongfully. Thus, current Dutch law does not provide for a collective action for damages. Despite the fact that no damages can be claimed through an action based on article 3:305a DCC, such collective actions have been successfully employed to obtain declaratory judgments in which it is confirmed that one or more defendants acted wrongfully and are liable to pay damages. Although individual claimants still need to file follow-on suits to obtain damages, they can rely on the findings of the court that heard the collective action on common issues such as, for example, wrongfulness and duty of care. However, on 7 July 2014 the Dutch Minister of Security and Justice submitted a draft bill that aims to amend the collective action based on article 3:305a DCC. This draft bill intends to facilitate claims for monetary damages in such collective actions. The draft bill is under the attention of the Dutch Minister, and at this stage it is not known whether it will be amended, and if so to what extent.

In principle, cases related to drugs, devices and provision of care be subject to the two formal litigation mechanisms as set out above. It should be noted, however, that some cases may be difficult to deal with by way of these litigation mechanisms given the uniqueness of each case and the individual circumstances of each injured party involved.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

There is no specific mechanism in the Netherlands that subjects acts, omissions or decisions of healthcare institutions to judicial or administrative review.

Pursuant to the Clients' Right of Complaint Act, healthcare institutions should implement an internal complaints procedure and there should be a committee to whom complaints can be submitted. Complaints can be submitted by patients, in other words individuals to whom the healthcare institution has provided healthcare.

Complaints against individual healthcare providers can be submitted to the disciplinary courts. Such complaints can be submitted by patients, patients' relatives, the person who provided instruction to the healthcare provider, the healthcare provider's employee or the healthcare inspector.

40 Are there any legal protections for whistle-blowers?

In 2012, Members of Parliament submitted a draft bill to protect whistle-blowers. The draft bill ensures that employees can, upon reasonable grounds, submit complaints to an independent government body concerning, for example, violations of laws or regulations or risks for public health. The draft bill has not yet been adopted. The Minister of Internal Affairs has expressed the view that he is in favour of a better level of legal protection for whistle-blowers. The Minister of Internal Affairs has also expressed the view that the most benefit could likely be obtained by internal policy within companies.

In the healthcare sector, there is a self-regulatory Governance Code that requires healthcare institutions to ensure that employees can freely and securely report any serious malpractice to the board of directors or to a person specifically appointed for that purpose.

41 Does the country have a reward mechanism for whistle-blowers?

At present, there is no reward mechanism for whistle-blowers. There is a draft bill (see question 40) that proposes to set up a financial fund for the purpose of paying costs or damages to whistle-blowers. These payments would relate to costs made for legal proceedings, costs made for social-psychological assistance and for loss in income. The financial fund for whistle-blowers would be managed by a new specific government agency.

42 Are mechanisms allowing whistle-blowers to report infringements required?

See question 40.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

The competent authorities have their own powers based on the laws of the Netherlands. In practice, competent authorities may discuss cross-border matters with each other. In particular when enforcing healthcare laws or regulations that are based upon EU law, the Dutch competent authorities may consult with their counterparts in other EU member states.

For example, in May and June 2015 the Dutch authorities participated in a cross-border investigation into illegal internet trade in pharmaceuticals.

For example, in the area of pharmacovigilance, inspections are in practice not carried out by the European Medicines Agency (EMA) but by the

competent authorities of the EU member states, who cooperate with each other and with the EMA.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

If activities by foreign authorities give rise to the suspicion that illegal activities may take place in the Netherlands, this may trigger an investigation in the Netherlands.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Foreign companies and foreign nationals must comply with the laws of the Netherlands if they conduct their business (for example, market a pharmaceutical or a medical device) or if they provide healthcare in the Netherlands. If they infringe Dutch healthcare laws while operating in the Netherlands, they risk being confronted with enforcement activities from the Dutch authorities.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

In Nigeria, healthcare is generally funded by:
- the public sector;
- the private sector; and
- diverse public-private partnerships.

Under the public sector, the respective tiers of government provide annual budgetary allocations to cater to the provision of healthcare, access to medicine and medical devices. In addition, the Nigerian National Health Act 2014 allows for a basic healthcare provision fund that is used in the provision of basic healthcare and access to medicines.

The private sector provides funding into the provision of healthcare and access to medicines, as well as being an alternate source of healthcare delivery. It provides funding by setting up various alternate health management schemes or health insurance services. Reports indicate that the private sector currently accounts for at least half of the healthcare service provision, and this has the potential to expand access to health services, improve the quality of care, and contribute to job creation and the country's gross domestic product.

There is also an increasing amount of public-private participation in healthcare funding in terms of the development of hospitals and specialist centres.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

In Nigeria, healthcare is generally delivered by:
- the public sector;
- the private sector; and
- diverse public-private partnerships.

In the public sector, the respective tiers of government provide the regulatory framework for healthcare delivery and access to medicines in Nigeria. The government is also a primary healthcare provider. There is an array of teaching hospitals, public hospitals, specialised health centres and other health facilities that are created as government initiatives aimed at subsidising health care delivery to the general populace. There is also the National Health Insurance Scheme that provides free healthcare service to children, women and the elderly.

Furthermore, there is growing participation from private health care providers in the industry, albeit closely regulated and monitored by the federal and state Ministries of Health as the case may be.

In recent times, there has been a growing trend of collaboration between both sectors. Public-private partnership initiatives have seen the establishment of state of the art health care facilities that dispatch hitherto non-existent health services.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The key legislation governing the delivery of healthcare in Nigeria is as follows:
- the Constitution of the Federal Republic of Nigeria 1999 as amended;
- the National Health Act 2014; and
- the National Health Insurance Scheme Act Cap 42, 2004.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The agencies responsible for the enforcement of laws and rules applicable to the delivery of healthcare are as follows:
- The Federal Ministry of Health;
- the respective State Ministries of Health;
- the Medical and Dental Council of Nigeria;
- the Nursing and Midwifery Council of Nigeria;
- the Pharmacists Council of Nigeria; and
- the respective federal and state university teaching hospital management boards, among others.

These agencies are largely funded by annual budgetary allocations by the government, with no portion of funding dependent on their enforcement activities. The agencies are, however, permitted to generate additional income internally.

5 What is the scope of their enforcement and regulatory responsibilities?

The scope of their enforcement and regulatory responsibilities include:
- ensuring compliance with regulations by routine inspection and monitoring of healthcare providers;
- registration and deregistration of medical professionals;
- licensing and accreditation of healthcare delivery centres;
- levying of fines and penalties;
- closure of the premises of healthcare delivery centres, and
- initiating criminal proceedings under grievous circumstances.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The agencies that are primarily responsible for the regulation of pharmaceutical products and medical devices in Nigeria are:
- the National Agency for Food and Drug Administration and Control (NAFDAC); and
- the Standards Organisation of Nigeria (SON).

These agencies' funding is not dependent on their enforcement activities. NAFDAC sources of funding include:
- subventions and extra budgetary allocations from the federal government;
- fees charged from services rendered by NAFDAC;
- foreign aid and assistance from bilateral agencies; and
- sums given as gifts, endowments, bequests or other voluntary contributions by persons and organisations.

SON sources of funding include:
- budgetary allocations from the federal government (SON is a federal government agency and hence it is primarily funded by the federal government of Nigeria);
- fees charged from services rendered by NAFDAC; and
- sums given as gifts, endowments, bequests or other voluntary contributions by persons and organisations.

7 What is the scope of their enforcement and regulatory responsibilities?

NAFDAC's enforcement and regulatory responsibilities include:
- registration of medical devices and pharmaceutical products that comply with its designated standards;
- imposition of bans on medical devices and pharmaceutical products that are not safe for human consumption;
- regulation and control of the importation, exportation, manufacture, advertisement and distribution of pharmaceutical products, medical devices and drugs; and
- carrying out investigations and routine inspections on laboratories, sites and premises used in the production of pharmaceutical products and medical devices.

SON's enforcement and regulatory responsibilities include:
- preparation of standards relating to products, measurements, materials, processes and services among others, and promotion of these standards at national, regional and international levels;
- certification of products and assistance in the production of quality goods and services;
- prosecution of fraudulent importers; and
- informing the public of defective and injurious products.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Other agencies that have jurisdiction over healthcare, pharmaceutical and medical device cases include:
- the courts;
- the Corporate Affairs Commission (for registered companies);
- the Nigeria Police Force; and
- the Securities and Exchange Commission (for quoted and public companies).

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Yes, multiple government agencies can simultaneously conduct investigations of the same subject. This would be determined by the nature of the offence.

In addition, a completed investigation does not bar another agency from investigating the same facts and circumstances as a secondary investigation can only be estopped by a final judgment of court.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

NAFDAC exercises the following functions in monitoring compliance with its rules on drugs and devices:
- undertaking inspection of product sites and certification of regulated products;
- conducting routine tests on regulated products in its laboratories; and
- carrying out investigation exercises on production processes in factories where the products are made.

11 How long do investigations typically take from initiation to completion? How are investigations started?

It is not currently possible to accurately estimate the timeline. However, investigations can be kickstarted through information obtained from anonymous tips, whistle-blowers or through information obtained from random checks on production sites of pharmaceutical devices producers.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

The Nigeria Freedom of Information Act 2011 guarantees unhindered access to public records and information in the custody of government institutions. Hence, a subject of investigation is entitled to access the investigation files subject to the limitations prescribed under the Act and on the condition that the access given would not prejudice the ongoing investigation.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes, the authorities can conduct their investigations in foreign countries. This authority is exercised as a precondition to certifying the products, in accordance with guidelines which state that the production or manufacturing site must be inspected even when such site is situated in another country.

14 Through what proceedings do agencies enforce the rules?

The proceedings adopted would largely be determined by the nature of the rules breached.

In some cases, infringement of regulations would be met by administrative sanctions from the relevant authorities without making recourse to court.

The contravention of any rule or regulation made by NAFDAC is an offence by virtue of section 25(2) of the NAFDAC Act 2004; hence proceedings against offenders for rules breached are enforced in court. The proceedings are usually criminal in nature and are instituted by NAFDAC with the consent of the Attorney General of the Federation.

There are, however, occasions where agencies can conduct their own quasi-judicial proceedings. These decisions are enforceable by law. The proceedings are usually in the form of civil proceedings.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

There are a variety of punitive measures and sanctions that can be imposed against drug and device manufacturers in enforcement actions. They include:
- levying of fines;
- sealing of production sites;
- delisting of offenders;
- confiscation of infringing medical devices and pharmaceutical products; and
- petitioning for the winding-up of infringing companies, especially in cases where such infringement has led to fatalities. The assets of the infringing companies are thereafter acquired by the federal government.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes, the authorities can and usually do pursue actions against employees in circumstance of gross negligence or fraud.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The available defences would be dependent on the facts of each individual case. In terms of an appeal, NAFDAC is a federal government agency, hence the appropriate forum is the Federal High Court and appeal from its decision lies to the Court of Appeal by virtue of section 240 of the Constitution.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Generally speaking, companies should adopt the following strategies to minimise their exposure to enforcement actions:
- maintain standards and good practice;
- ensure that regulations are adhered to;
- train and retrain all personnel;
- ensure that all staff have the requisite licence to practice and that all renewals are up to date; and
- have a comprehensive medical indemnity scheme.

This will go a long way towards minimising exposure to enforcement actions. Where an enforcement action is under way, showing willingness to cooperate with the enforcement agency is always a good step.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Recent enforcement activities have focused on customer protection. Sanctions have included closure of businesses and restriction on the production of dry gin.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

Yes. The Pharmaceutical Society of Nigeria and its parent body, the Pharmaceutical Council of Nigeria, are self-governing bodies that regulate their members' conduct. The code of ethics enacted by the Pharmaceutical Council of Nigeria prescribes regulations that must be adhered to and sanctions for non-compliance.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are no specific rules governing the financial relationship between healthcare professionals and suppliers of products and services. However, the basic principles of companies would be applicable.

22 How are the rules enforced?

The rules are enforced by the aforementioned agencies, NAFDAC and SON.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

There are no specific rules stipulating reporting requirements of the financial relationship between healthcare professionals and suppliers of products and services.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The authorities ensure compliance with the rules on healthcare delivery by carrying out routine inspections of healthcare facilities to ensure adherence with their prescribed standards. The authorities also ensure compliance with their rules by conducting an annual registration of medical professionals; and the annual renewal of licences and accreditation of healthcare delivery centres.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

It is not currently possible to accurately estimate the timeline. However, investigations can be kick-started upon information obtained from anonymous tips, whistle-blowers and routine checks on healthcare centres to ascertain compliance with guidelines and regulations.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

See question 12.

27 Through what proceedings do agencies enforce the rules?

The proceedings adopted will be determined largely by the nature of the rules breached.

In some cases, infringement of regulations by healthcare providers would be met by administrative sanctions from the relevant authorities without making recourse to court.

Generally, agencies do not try offenders as the proper forum for prosecution of severe violation of the rules is before a court of competent jurisdiction. Under such circumstances, proceedings are usually criminal in nature.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Sanctions imposed by the authorities include:

- imposition of fines;
- closure of healthcare facilities;
- disbarment of practitioners; and
- prosecution of healthcare providers in serious cases when an infringement involves allegations of crime.

29 What defences and appeals are available to healthcare providers in an enforcement action?

The available defences will be dependent on the facts of each case. Being matters prosecuted by a federal government agency, the appropriate forum is the Federal High Court and appeal from its decision lies to the Court of Appeal by virtue of section 240 of the Constitution of the Federal Republic of Nigeria 1999 (as amended).

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 18.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Authorities have focused on ensuring healthcare providers are properly licensed. Sanctions have included closure of healthcare delivery centres and imposition of fines.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Yes. Bodies like the Nigeria Medical Association, The Nursing Council and the Medical and Dental Council of Nigeria fall within this category. They ensure compliance with the standards of practice as evinced in the rules and regulations, and mete out relevant sanctions for non-adherence to such rules.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

A typical remedial provision often included in such contracts is an indemnity clause obligating the healthcare provider to make good the losses incurred by the government as a result of the latter's default in carrying out its undertaking. The right to unilaterally terminate the contract can also be provisioned for in the event the healthcare provider fails to comply with the key performance indexes in the contract.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

As a general rule, a private person or body is precluded from seeking to enforce the infringement of a healthcare regulation or law as the prerogative to do so often lies with the regulatory authority. However, when the infringement proceeds to adversely affect the personal rights of a person, an action may be initiated in a private capacity. However, in criminal cases a private person may institute proceedings subject to securing a fiat from the prosecutorial authority as the case may be.

35 What is the framework for claims of clinical negligence against healthcare providers?

The standard of care varies and is dependent on the field of medicine in which the provider professes competence and the skill set expected of the individual practitioner.

To be successful in a claim for breach, the following must be exhibited in a claimant's pleadings:

- the provider's duty of care;
- explicit actions evidenced with proof of the breach of the duty of care;
- damages or harm occasioned to the claimant arising from the actions of the defendant; and
- the claimant must prove on a balance of probabilities that harm was so caused.

Update and trends

In terms of the authorities' enforcement priorities in the coming year, we believe that the recently enacted National Health Act 2014 that established a regulatory framework for the Nigeria health sector will be expounded, as much attention will be devoted to ensuring its provisions are effectively implemented.

To our knowledge, there are no significant pending cases. However, in May 2015 the National Food Safety Management Committee was inaugurated in line with national food safety policy developed by the Federal Ministry of Health. It is made up of five technical committees with the following responsibilities:

- the Technical Committee on Regulatory Framework: modernising Nigeria's food safety regulatory framework in line with international best practices;
- the Technical Committee on Risk Analysis: minimising the incidence of risk associated with physical, chemical and biological hazards in foods and water;
- the Technical Committee on Capacity Building: strengthening institutional capacity for food safety;
- the Technical Committee on Information, Education and Communication: establishing an effective information and communication mechanism for the food safety system; and
- the Technical Committee on Monitoring and Evaluation: monitoring and evaluating the national food safety system.

The courts are neither reluctant nor keen to penalise public or quasi-public healthcare providers. Each case must be proven on the merits. Furthermore, damages can be either general or special damages. The damages to be awarded by the court would depend on the facts of the case and the discretion of the judge.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The users and purchasers of pharmaceutical devices may seek recourse for regulatory and legal infringements by:

- instituting personal actions against the infringing company in the courts;
- petitioning the regulatory body to mete out the necessary sanctions against the infringing company; or by
- instituting a class action against the company where the infringement affects a wide range of users.

The grounds for such actions depend on the particular infringement.

37 Are there any compensation schemes in place?

Healthcare delivery centres are required to maintain a medical indemnity scheme or medical insurance covering the premises of the healthcare delivery centre and the staff therein.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Yes, the procedural rules of court make general provisions for class actions, especially when the wrong complained of by the claimants arose from the same transaction. A party seeking to join an action has to bring an application on notice (accompanied by an affidavit and a written address) stating that he or she has similar interests to the claimants and is entitled to benefit from the same reliefs sought.

The following claims are excluded from collective actions:

- declaration of rights in land matters; and
- fundamental human rights actions.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes, they are.

Generally speaking, all actions, decisions and omissions of private or public institutions are subject to judicial review by virtue of section 6 of the Constitution of the Federal Republic of Nigeria 1999 (as amended).

Hence the courts will be the competent forum for hearing such complaints. Where the decision complained of is that of a public or government institution, a pre-action notice must be given to the concerned institution before such matter is brought before the court for review, and it is advisable for the complaint be brought to the court after the expiration of the served notice.

The question of standing can be answered from two perspectives or approaches adopted by the courts. First, a litigant is said to be seised of the requisite standing if he or she is adversely affected by the action which is complained about. The second approach is peculiar to public interest litigation and human rights cases where the personal connection with the reliefs sought is dispensed with.

The complainant may succeed in such actions on the following grounds:

- the public institution has exceeded its jurisdiction by the decision complained of; or
- the actions of the public or private institution have infringed the fundamental rights of the complainant; and
- such decision was not reached in accordance with due process of law where there are rules and procedures to be followed.

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The following remedies can be ordered:

- an injunction restraining the concerned body from carrying out certain actions;
- an order compelling the completion of obligations owed to the complainant;
- declarations of right; and
- general and special damages upon sufficient proof of entitlement by the complainant.

40 Are there any legal protections for whistle-blowers?

There are none at this time. Anonymity may be the best way to proceed.

41 Does the country have a reward mechanism for whistle-blowers?

No.

42 Are mechanisms allowing whistle-blowers to report infringements required?

Yes, such mechanisms are required. The Federal Ministry of Health and the respective state ministries should put in place policies that ensure protection for whistle-blowers.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

Enforcement activities spearheaded by foreign authorities will trigger a local investigation in Nigeria when the object or subject of investigation by the foreign authorities involves an infringement of Nigerian domestic laws.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

As a general rule, foreign companies and foreigners are not exempted from the provisions of domestic law unless such nationals are subjects of diplomatic immunity. Infringements of domestic healthcare laws by foreign nationals and companies within the jurisdiction will be visited with the appropriate sanctions from the regulatory bodies, and where such infringements are criminal in nature they will be prosecuted by the relevant authorities.

Poland

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare in Poland is delivered through a publicly funded health care system, which is free for all citizens. Free medical care is provided within the range of guaranteed benefits. Detailed conditions for granting those benefits have been included in the Act on Publicly Funded Healthcare Benefits and a series of decree acts. An entity established to carry out the above tasks is the National Health Fund (NHF), which is also the payer of these benefits.

In the system of guaranteed benefits, an increasingly significant role is played by private entities. They are smaller, better managed and therefore more competitive than the public entities with whom they compete while under observation from the NHF.

With regard to drugs and medical devices, patients have access to reimbursed medicines; in other words, this aspect is partly or entirely publicly funded.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Access to healthcare is provided by the NHF by allowing free-market competition in order to grant specific health benefits.

Contests are announced separately on a top-down basis, according to the type and range of services. Patients may receive benefits from institutions that have entered into an agreement with the payer.

Benefits are granted in order of request, taking into account the date of filing and the health of the patient. Public and private entities use identical rules for granting benefits.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The most significant acts that regulate the functioning of the healthcare system in Poland are:

- the Act of 15 April 2011 on Medical Activity;
- the Act of 27 August 2004 on Publicly Funded Healthcare Benefits;
- the Act of 12 May 2011 on Reimbursement; and
- the Act of 6 November 2008 on Patient Rights.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The NHF oversees the providers of healthcare services that are financed from public funds. The NHF is also involved in the execution of duties against these providers. In addition, specific powers are granted to the Ministry of Health and to civil and administrative courts.

5 What is the scope of their enforcement and regulatory responsibilities?

Within the law, the NHF defines the conditions applied to healthcare providers, and establishes standard form contracts.

Then, by audit, the NHF verifies the correct implementation of these agreements. If any irregularities are found, depending on their nature the NHF may exact the reimbursement of improperly granted benefits. The NHF may also impose penalties on the provider or may terminate their contract with immediate effect.

The NHF has tools to independently enforce these financial sanctions. Any disputes between the NHF and healthcare providers are subject to the administration of the courts of general jurisdiction.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

Regulation in the field of medicinal products is a matter for the legislature and, when required, the Minister of Health.

Executive powers of supervision and control over medical devices are entrusted to the Office for Registration of Medicinal Products, Medical Devices and Biocides. When it comes to control over the quality of medicinal products, special powers are granted to the State Pharmaceutical Inspectorate.

Insofar as the medicinal products and medical devices are financed or co-financed using public funds, special powers are granted to the NHF, which supervises the fiscal issues associated with refund.

7 What is the scope of their enforcement and regulatory responsibilities?

The legislature lays down the principles and procedures for the marketing authorisation of medicinal products, including requirements for quality; safety and efficacy of use; conditions for conducting clinical trials; production; and trade.

The Minister of Health has the power to decide the principles of individual refunds of medicinal products and medical devices. Proper implementation of these principles has been assured by specialised institutions such as the State Pharmaceutical Inspectorate and the Office for Registration of Medicinal Products, Medical Devices and Biocides which has, among other things, the power to authorise individual medicinal products on the market.

When it comes to financing medicinal products or medical devices, the NHF oversees the appropriate execution of the applicable rules.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Office of Competition and Consumer Protection is the authority that has jurisdiction in matters relating to medicinal products or medical devices within the framework of oversight practices which restrict competition. The President of the Competition Office may render decisions that require the termination of competition that causes infringement for both producers and distributors of medicinal products and medical devices.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

It is possible that several independent agencies may lead proceedings concerning the same facts and the same entities. Each of them, within the limits of its own powers, examines another aspect of the case and evaluates it in the context of compliance with various laws. For example, the NHF may assess the correct execution of the agreement and possibly impose

financial sanctions while enforcement authorities simultaneously investigate whether any crime existed during the execution of the agreement.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The most significant legal act that regulates aspects of production and marketing of medicinal products and medical devices is the Pharmaceutical Law of 6 September 2001, and subsequent acts.

In addition, there are:

- the Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Use and Medical Devices; and
- the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocides.

There are three levels of control exercised by the competent authorities:

- supervision of the quality of medicinal products and the process of their distribution in the retail market falls under the competence of pharmaceutical inspectors;
- the pharmacovigilance system falls under the supervision of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocides (President of the Office); and
- supervision of the quality of veterinary medicinal products and the process of their distribution falls under the competence of the Chief Veterinary Officer.

The medical devices area is also under the control of the President of the Office. Regulation is performed regarding manufacture; marketing and use; and performance evaluation.

Supervision over medical devices is based on collecting and analysing information on the safety of products and control of all entities that have a direct or indirect impact on the shape of a medical device (such as manufacturers, authorised representatives, importers, distributors or subcontractors). Control of these entities covers all stages – from design and manufacture of medical devices to their placing on the market or use. It may also include the presentation of the product at trade fairs, exhibitions, demonstrations and scientific and technical symposia.

In some situations, justified by the need to protect the life or health of patients or to protect public health, the President of the Office may inspect the device, its documentation and conditions of use.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Anyone who has information about the occurrence of a medical incident may report that event to the President of the Office.

In case of an occurrence of a medical incident, the healthcare provider is obliged to report it immediately to the manufacturer or an authorised representative, and to send a copy of such report to the President of the Office. The obligation of such notification also applies to any manufacturer who has been informed of an incident related to the product they have produced.

A similar procedure is provided for medicinal products. In the case of justified suspicion of any irregularities causing a threat to the safety or quality of the medicinal products, the Chief Pharmaceutical Inspector (PCI) may order the immediate inspection of the manufacturer of the active substance, and any distributors established in a third country.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Any procedural acts concerning control or inspection of medicinal products or medical devices are carried out in the presence of a controller or a person authorised by a controller. The controller may waive the right to participate in these proceedings. In such cases, control proceedings are performed in the presence of an appointed witness. The witness does not have to be present during acts related to obtaining evidence from books, records or other documents.

Following the correct procedures, various parties' involvement in the production process is established. After the proceedings are complete, a protocol of control is drawn up.

The controlled entity can file reasonable objections, which are subject to examination by the inspection body.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

The PCI may also inspect the manufacturing conditions of medicinal products that are manufactured abroad. Such inspection is carried out by the Inspector of Producing Affairs.

Inspection of the manufacturing conditions of a medicinal product in a third country is intended to confirm the compliance of these conditions with the requirements of good manufacturing practice (GMP) within the meaning of EU pharmaceutical law.

The PCI also considers as equivalent inspections carried out by:

- a competent authority of a member state of the European Union or member states of the European Free Trade Association (EFTA) (parties to the European Economic Area or a state which has an agreement on mutual recognition of inspections of EU member states or is a member state of EFTA);
- a party to the Agreement on the European Economic Area; and
- countries with the equivalent of the European Union GMP requirements and an equivalent inspection system.

In such cases, the foreign inspection is not carried out.

The PCI may request that a producer established in a non-member state or a non-EFTA state submit to inspection of manufacturing conditions.

However, unlike manufacturers of medicinal products or manufacturers of active substances established in the Polish territory, the third-country manufacturer has no obligation to submit to such an inspection.

The PCI does not have any legal instruments that would oblige producers outside the EU or EFTA to submit to an inspection.

In addition, under the regulation of good distribution practice, if there is justified suspicion that irregularities are causing a threat to the safety or quality of an active substance, the PCI may order the immediate inspection of the active substance manufacturer or distributor of the active substance who is established in a third country.

Regarding the medical devices area, the President of the Office has no authority to inspect third-country producers. In such cases, control may be exercised only towards the manufacturers, authorised representatives of the importers, distributors and subcontractors who are domiciled or established in Polish territory.

14 Through what proceedings do agencies enforce the rules?

The Pharmaceutical Law and the Law on Medical Devices Acts contain detailed regulations concerning audit and inspection procedures within the competence of the PCI and the President of the Office.

They may impose appropriate sanctions on producers. This proceeding is administrative in nature. Controlling authorities may also impose subsidiary criminal sanctions.

The Pharmaceutical Law Act and the Act on Medical Devices contain provisions that specify the punitive sanctions imposed in criminal proceedings. In addition, the Pharmaceutical Law Act provides certain administrative sanctions.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

As part of its administrative sanctions, the PCI has the authority to give or remove permission to produce or import a medicinal product when the producer or importer of the medicinal product has ceased to fulfil their duties as required. If there is any question that a medicinal product or active substance does not meet established quality requirements, the PCI gives a decision regarding a ban on its introduction, or regarding withdrawing the medicinal product or active substance from the market. After examining the circumstances, the PCI:

- orders that the responsible entity or parallel importer destroy the medicinal product or active substance; or
- allows circulation of the medicinal product or active substance to continue.

The legislature recognises that measures and non-penalty sanctions are not sufficient for enforcing correct standards regarding medicinal products. Pharmaceutical law also contains penal provisions, where the following sanctions are recommended:

- restriction of liberty and imprisonment; and
- fines of an administrative-disciplinary character.

In the Act on Medicinal Products, it is indicated that the President of the Office can give an administrative resolution regarding forbidding, stopping or introducing restrictions for the use of a medicinal product or group of products, withdrawing them from the market or from use or obliging those in charge of safety to take field safety correction action or to issue a safety note.

This can be done with the objective of protection of the life, health or safety of patients, users or other persons and also for the counteraction of a threat to health, safety or public policy. There are also penal measures such as fines for the restriction of liberty and imprisonment. These are classified as being part of criminal proceedings.

16 Can the authorities pursue actions against employees as well as the company itself?

Polish provisions regarding test proceedings and the surveillance of medicinal products, which are led by the PCI or the President of the Office, do not provide for closely controlled activities against employees of enterprises. Judgment of employee responsibility can result from special provisions involved in disciplinary proceedings. It can also result from observations regarding contractual character, in other words on the basis of the agreement between employee and employer. Moreover, the responsibility for non-performance or an unsatisfactory performance of employee duties is determined in the Labour Code of 26 June 1974. The employee bears responsibility for damage and loss incurred by the employer based only on actions from which the damage resulted. Obviously, any illegal behaviour of an employee may also be prosecuted under the Polish Criminal Code. Based on these provisions, the employee does not bear responsibility for any resulting damage in relation to acting within the limits of acceptable risk.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

Companies are able to appeal to discontinue enforcement actions following a pharmaceutical inspection in matters concerning their competence. In the event that a provincial pharmaceutical inspector is the body of the first instance, a PCI acts as the appeal organ. In view of the fact that the PCI is a central government administration authority, there is no entitlement to an appeal from a PCI decision if it is given in the first instance. However, the case can be reviewed as a result of an application to the PCI for re-examination. The rules of the Code of Administrative Procedure are then applied. Decisions given by the PCI as the organ of second instance and given by way of proceedings for the re-examination of the case could be challenged before the administrative court. The Provincial Administrative Court in Warsaw is the competent body for hearing an administrative complaint against a decision of the PCI.

There are similar procedures regarding submitting a complaint to the President of the Office. Moreover, during control proceedings the controlled entity can submit reservations about the protocol of the inspection.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

The possibility of enforcement actions is minimised when the company is functioning correctly, in other words based on procedures or internal regulations and in accordance with generally applicable provisions of the law. It is important that every entity maintain the quality level of medicinal products and the safe means of applying them. This will help to avoid adverse effects in the event of a control situation. Keeping reliable documentation and taking effective action in advance is essential. If the controlling action is already in motion, the company should provide controllers with access to documentation, rooms and the equipment and products that are the object of the control. If a controlled entity has submitted a control protocol ahead of the control action, it should then follow recommendations submitted after the control action has taken place.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Recently, when inspecting medicinal products, the authorities have emphasised meeting quality requirements and safety measures when applying the products. As a result of inspections and the detection of irregularities, the PCI has placed sanctions by stopping trade over the entire country.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

There are many self-governing bodies and organisations in charge of the sale of pharmaceutical products and medical devices in Poland. They include, inter alia, the Polish Association of Producers of Prescription Medicines and the Polish Chamber of Commerce of Medical Devices, which is the greatest and most representative organisation of producers and distributors of medicinal products in Poland. Moreover, in Poland a self-governing pharmaceutical company functions as part of the Principal Pharmaceutical Chamber and Provincial Pharmaceutical Chambers. Such a body is able to conduct disciplinary proceedings concerning its members. It also has an advisory voice in matters of revocation of a permit for a pharmacy or pharmaceutical wholesaler.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

No general rules apply to such relationships. Only a small number of entities that finance their activities with public funds are obliged by the legislature to carry out open competition for providing healthcare services. However, breach of this obligation does not result in sanctions. There is one binding prohibition, for advertising medicinal products and medical devices.

22 How are the rules enforced?

The obligation to conduct a competition for delivery of healthcare by entities specified in the Healthcare Delivery Act of 15 July 2011 is not enforced. Legislation does not provide appropriate procedures in this regard. Compliance with the prohibition of advertising is subject to inspection conducted by the Pharmaceutical Chief Inspector, and by the main veterinarian in relation to veterinary products.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The sole regulation for sustaining transparency in financial relationships between healthcare providers and suppliers of services, medicinal products or medical devices is contained in the Access to Information Act of 6 September 2001. However, entities that do not use public funds are not bound by this regulation.

Entities which use public funds for the delivery of healthcare on the basis of contracts with the NHF are obliged to place subcontractors' data in the portal that is dedicated to detailing contracts that are being performed.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The NHF is entitled to carry out inspections in order to verify healthcare entities' compliance with the provisions of the law and orders of the president of the NHF. For this purpose, the authority has been empowered to carry out inspections and, depending on the outcome, may:

- demand fund reimbursement if it finds that funds were unduly transferred to the entity; or
- impose a contractual penalty if it finds that the entity performed inappropriately or did not complete the contract.

The NHF may also terminate the agreement without notice.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

A healthcare provider inspection lasts from several days to a few years, and is initiated by delivery of a notice of initiation to the entity being subjected to such inspection.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

The entity subjected to an inspection is entitled to provide the authority with evidence supporting its assertions at any stage of inspection. The entity may also demand access to files at any stage of inspection proceedings, however this right is rarely used.

27 Through what proceedings do agencies enforce the rules?

The NHF enforces the law concerning provisions of healthcare services with its own procedures, set out in the Health Care Services Financed with Public Funds Act of 27 August 2004. This is not a civil or criminal procedure and does not specifically provide for the hearing of the case by a civil court. However, such conclusion should be drawn from the fact that the NHF is bound to the healthcare provider by a civil agreement.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Depending on the outcome of an inspection, healthcare providers may be subjected to following sanctions:

- reimbursement of funds, if the NHF finds that the funds were unduly transferred to the entity;
- imposing a contractual (financial) penalty, if the NHF finds that the entity performed inappropriately or has not performed the contract. However, the total amount of contractual penalty imposed during the term of the contract cannot exceed 4 per cent of the amount of the NHF's obligation towards the healthcare provider, resulting from the contract; or
- in the event of material infringements, the NHF may also terminate the contract without notice. Additionally, in consequence of such termination, the healthcare provider would be excluded from the competition for a new contract for the next five years.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare providers are entitled to submit objections to the inspection authorities (within seven days) and, in the subsequent phase of inspection proceedings, objections to the post-inspection statement issued by the inspecting authority after evaluating the objection to the protocol. The second objection must also be submitted within seven days. Notwithstanding the foregoing, the healthcare provider is entitled to file a complaint against any activities conducted with the director of regional branch of the NHF.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

As a rule, the risk of being subjected to an inspection cannot be minimised. Inspections are conducted in accordance with a plan accepted by the NHF. Aside from this, 'problem inspections' are conducted as a consequence of complaints against healthcare providers submitted by the patients to the NHF. In order to prevent inspections of this kind, the entity should comply with the rules, contractual provisions and procedures currently binding healthcare providers.

Minimising the risk of potential responsibility at the ongoing proceedings stage is limited to active participation in the inspection; in particular by means of initiating evidence and exercising appeal rights.

Healthcare providers should implement internal quality procedures and supervision of compliance with the provisions of law and contract provisions, as well as ensuring the constant education of their personnel in this respect.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

The NHF increasingly focuses on:

- evaluation;
- whether the procedures for which the NHF pays were correctly qualified and presented for payment;
- whether medical grounds for conducting these procedures were present; and
- whether another similar, less expensive procedure was available.

In such case, the NHF demands reimbursement for the healthcare provision that was contested.

Moreover, the inspection involves particular evaluation of whether medical documents are correctly maintained, whether the services are provided at the time and place specified in the contract and whether the personnel schedule reported to the NHF is observed. Infringements in this respect are the most common accusations against the healthcare providers. For such infringements, financial penalties are imposed on the healthcare provider for each infringement.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

There are no formal self-governing bodies for healthcare providers in Poland, except for the Chamber of Physicians and Dentists. However, voluntary bodies represent various entities; for example a national association for private hospitals, or bodies that unite entities providing primary health care services. These organisations do not have any far-reaching competences over their members.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Recently, in its contracts with healthcare providers, the government included some obligations regarding financing of individual treatments within an approved period of time. This resolution should lead to a faster route to oncology diagnosis and treatment.

Moreover the cost of some benefits (visits) is absorbed if, after commissioned diagnostic investigations, the patient comes back to the institution for another visit and stays for more diagnostic healing proceedings.

Negative quality assessment of granted benefits, which could be the result of an inspection by the NHF, negatively influences the immediate competition proceedings, resulting in a lower spot-price offer. It also reduces the chances of entering into another such agreement.

Most agreements with service providers contain regulations providing for sanctions, such as making the level of remuneration of service providers conditional on results achieved by them and the effectiveness of their action. Sanctions may only be imposed if provisions of law or provisions of contracts concluded with the NHF are infringed while performing medical benefits.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

In order to enforce healthcare system rules, citizens and other private entities can primarily apply to the court with a civil lawsuit proceeding to obtain proper compensation for the violation of the patient's rights.

This procedure is regulated in the Code of the Civil Procedure. There is also a non-judicial remedy based on a claim to the Provincial Commission for deciding on medical events. The injured party must submit a request to establish the medical event. The amount of compensation or proposed compensation depends on the discretion of the insurance company (the total amount of compensation is up to 300,000 zlotys).

Other non-judicial remedies are:

- a complaint against a violation of patient rights to the patient ombudsman; or
- a complaint against a doctor or nurse to the Supreme Medical Council or the Supreme Chamber of Nurses and Midwives.

35 What is the framework for claims of clinical negligence against healthcare providers?

The patient or his or her heirs (in case of the death of the patient) have the right to appear against the perpetrator of the mistake of clinical negligence with a civil action, or before the court, or before the Regional Commission for Evaluation of Medical Events.

Infecting a patient with a biological pathogen, inflicting bodily harm, causing disturbance to the health of a patient or causing the death of a patient can be an undesired medical event resulting in variance with current medical knowledge on:

- diagnoses, if it caused the improper treatment or delayed the due treatment, contributing to the progression of the disease;
- cure, including the performance of the operation treatment; and
- applying the medicinal product or the medical devices.

In the lawsuit the patient must show:

- the type of medical negligence and the circumstances deemed to be unacceptable, causing complications after the treatment;
- that medical negligence occurred as an effect of the actions of the medical staff or the service provider;
- the existence of the causative connection between the medical negligence and the just functioning of the medical staff or service provider; and
- the extent of injustice (the kind and the length of psychological suffering) experienced in relation to medical negligence, and the amount of extra costs incurred in relation to the medical event or in connection with the total or partial loss of paid work, or with the accretion of his or her needs or reducing views of success for the future.

It is possible to repair damage to the patient through the payment of compensation, damages or disability pension paid for the future.

During the statement, courts do not monitor whether the provider is a public or private entity. If, in the course of judicial proceedings, the expert opinion of a specialist judging the process of treating of the patient confirms the appearance of a medical event, these courts ruthlessly punish such infringements.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

There are no detailed provisions based on which purchasers or users of medicinal products can pursue their laws for infringements. They can initiate a civil action based on the general rules and demand compensation depending on the actual state of affairs, the character of the infringement and its effects. For example, in a case of misleading advertisement of a medicinal product the consumer can demand return of benefits or adjudge the appropriate amount of money to achieve the determined social objective associated with supporting the Polish culture, protecting the national legacy or providing consumer protection. This will be achieved during the civil proceedings.

37 Are there any compensation schemes in place?

The injured party may seek damages before a civil court on general principles. As a rule, the party must demonstrate the cause of damage and that the damage is caused by the culpable behaviour of the perpetrator (eg, the medical or therapeutic entity).

If damage was caused by a drug or a medical device used in accordance with the manufacturer's instructions, then it may incur the strict liability of the manufacturer. In such cases the patient does not have to prove that the manufacturer is to blame for the deliberate release of a dangerous product on the market.

For some of the damage caused during granting health benefits (medical events), legislation provides a simplified compensation procedure in extrajudicial proceedings before the special committees. However, there are certain limitations on the maximum amount of compensation that can be achieved this way.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

There is no regulation for the possibility of rolling out a party action or appearing as part of a collective pursuing a claim in a matter concerning medicines and medicinal products. The same goes for cases that are closely linked to the healthcare service. However, rolling out a party action in case of an entity violating patients' rights or disturbing the protection of personal data in relation to granted benefits of healthcare is possible. For a class action, Poland has some regulation regarding pursuing claims in group proceedings in provisions of the Code of Civil Procedure Act made on 17 December 2009.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

An act, omission or decision of a publicly acting entity in the healthcare sphere can become the object of administrative or judicial-administrative control as a result of filing a complaint. In the framework of administrative proceedings besides appropriate remedies against given decisions, the entity which is dissatisfied with the organs mentioned above is entitled to file a complaint to the competent authority to recognise this complaint. Positive recognition can result in resuming proceedings, repeal or a change in the decision. Settling the matter should take place with no unnecessary delay, and should take no longer than one month.

Court-administrative initiations of proceedings are aimed at judicial control of the decision given by the public agency, perhaps to take place only after using up the appeal route forseen in special provisions. For example, a complaint to the provincial administrative tribunals about the decision of the PCI can be folded only after prior recognition by the PCI of the application to look at the matter again. In such proceedings, the party can be only an entity connected to the decision.

The actions or failure to act of private entities in the healthcare sphere are subject to a control which can be started both ex officio and as the result of a complaint filed by third parties to competent bodies, for example to the NHF. The NHF investigates complaints concerning the improper completion of a contract by service providers who have agreements with the NHF. The NHF should recognise the complaint within a month. The person who submitted the complaint must be notified in writing about methods of settling the matter. If the NHF states that suspicions of irregularity are justified, inspection proceedings can be initiated.

40 Are there any legal protections for whistle-blowers?

There is no regulation about the protection of persons detecting malfunctions within the healthcare system. The sequence of notifications is anonymous so there is no need for whistle-blower protection. Irrespective of the above, if the disclosed information is detrimental to the whistle-blower, appropriate regulations provide further anonymity for the informer.

41 Does the country have a reward mechanism for whistle-blowers?

The only mechanism which awards informers is found in the area of protection of competition, and is titled 'leniency programme' and 'leniency programme plus'. A company conducting activities in healthcare, medicinal products or medical devices and participating in practices limiting competition may submit an application or information to the President of the Office of Competition and Consumer Protection. The president of that Office can impose or reduce a fine for the company. The leniency programme also encompasses company managers.

Moreover, within the framework of the leniency plus programme, the entrepreneur or managing persons who fulfil the conditions for applying the decrease of the fines can benefit from additional fine reduction if conditions are met ('plus').

Other provisions referring directly to medicinal products, medical devices or healthcare have no award systems for informers.

42 Are mechanisms allowing whistle-blowers to report infringements required?

There is no detailed regulation that provides possibilities for informers to report infringement. They can only file a motion or a complaint with the relevant organ. The procedure takes place according to the administrative rules. Settling the matter should take place without delay, and should take no longer than one month.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

The Department of Health performs assignments regarding Poland's membership of the European Union. Representatives of the Ministry of Health and experts in the work of EU institutions, among others councils of European Union, take an active part in working parties (parties of public health, pharmaceutical products, medical products and food centres) of the European Commission and the European Parliament.

Besides EU cooperation in healthcare, also important is bilateral and direct cooperation between Poland and its partners.

The Department of Health cooperates with Europe, Asia, Africa and the Middle East, and the Americas. Most active cooperation takes place between Poland and its neighbours: Germany, the Czech Republic, Slovakia and Lithuania. In addition, Poland has special cooperation agreements in healthcare and medical sciences with many countries. Thanks to those agreements, a regular exchange of knowledge and experiences in

medicine is possible. The bilateral cooperation is most often carried out in the form of meetings of health ministers, expert meetings, studio visits and information exchange.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

The institution of member states of the EU mutually ensures that the producers and distributors of medicinal products and the active substances act in accordance with principles of GMP and good production practice. Within that framework, there is the possibility of relevant institutions of member states conducting an audit or inspection of producers and distributors.

However, within the scope of healthcare there is no provision or pharmaceutical law which would directly enable initiation of proceedings by overseas institutions in Poland. To sum up, proceedings are only being conducted by Polish bodies. However, they could be initiated as a result of information about irregularities received from a foreign institution pointing out irregularities.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

As a rule, a foreign entity and foreign people can perform business activities in Poland following the same principles as Polish nationals. This means that whole provisions of Polish law apply to all entities on Polish territory. The responsibility of these entities is similar to that incurred by Polish nationals. Moreover, special provisions contain additional regimes for such persons. For example, the Polish Border Guard (BG) can conduct legal control foreign business activity in Poland. The controlled entrepreneur, at the request of BG officers, must present documents concerning the legality of the conducted business activity within seven days. These documents are, for example, the confirmation of entry in the central register and information on the business or the entry in the National Register of Court; entry in the Regulator Activity Register; a specified licence; or permission. Foreigners who conduct a business activity in Poland without an entry in the register of business activity, which is required by law, can be punished by fine or a penalty of restriction of liberty.

Update and trends

The Polish healthcare system is currently going through fundamental changes. The vast majority of medical services are delivered using the public system, and are financed from the budget. In big city areas, medical services are increasingly financed by the patients themselves.

Patients have a strong expectation that healthcare services will be delivered at a high professional level. The Polish government demonstrates understanding of that expectation, for example with the introduction of oncology treatment where medical services are provided by service providers faster and without a contractual limit. The increase in the professional standard of medical services will also be achieved by new investments in the healthcare system, which will be co-financed from the EU budget. The guidelines for EU spending require adequate planning and a result-oriented approach that will increase the level of services. To achieve a high professional level of services, higher budgetary spending seems to be inevitable.

Since the vast majority of medical services are publicly financed via the NHF system, service providers face important business risks connected with NHF tender proceedings which may leave some of them without a future contract. Nevertheless, the private medical providers' market is in the process of consolidation with many foreign financial groups and medical providers who are interested in playing an active role in the Polish market.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The funding of Swiss healthcare rests primarily on three pillars. The main contribution is made by social insurances. These consist of a mandatory health insurance, insurance on accidents, insurance on pension and disability and military insurance. Insurance premiums are paid by private households and businesses, in some particular cases subsidised by the state – for instance, students' healthcare premiums are subsidised by the cantons. The second pillar consists of contributions by private households that pay services not covered by the mandatory insurance. These contributions are covered by private insurances. Additionally, private households contribute to the financing by normal insurance cost sharing. The third pillar consists of direct payments from state entities, primarily the cantons, to the healthcare system in various ways (eg, tax breaks for insurers or funding of health care providers). The state not only emerges as a source of financing but also acts as a service provider, mainly by operating hospitals and medical schools. Taking into account all direct and indirect payments, the healthcare system is funded roughly by two-thirds from private households and by one-third from the state.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

In principle, healthcare falls under the jurisdiction of the cantons. However, the federal government has taken over responsibility in many areas, so that competences are scattered through the different levels and are often intertwined. Healthcare delivery is not only spread across different governmental levels (Confederation, cantons and municipalities) but also across private and public entities. Thus, Switzerland's healthcare delivery is a mix of a publicly and a competitively directed structure.

'Healthcare' is a wide term that can be broken down to treatment, prevention, education and supervision. The state is primarily responsible for prevention, education and supervision. Health services regarding treatment are delivered by public as well as by private entities. Outpatient services are mainly provided by the private sector. Inpatient services are organised both publicly and privately. Doctors' offices, pharmacies and alternative medicine offices, for instance, are normally organised privately.

One particularity of Switzerland's healthcare system is that every person in Switzerland must be mandatorily insured. This basic insurance covers a mandatory service catalogue, which is financed by a per capita premium. It is the Confederation that determines which services are covered by such basic insurance.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The key principles are anchored in the Swiss Constitution. Based on such principles, the following key acts can be identified, on which numerous ordinances and guidelines are based:

- the Code of Obligations (for the contractual relationship between doctor and patient);
- the Swiss Civil Code (for contractual relationships);
- the Swiss Criminal Code (for euthanasia, abortion and medical secrecy);
- the Therapeutic Products Act (TPA);
- the Federal Act on Health Insurance;
- the Federal Act on University Medical Professions;
- the Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act);
- the Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act);
- the Federal Act on Research involving Human Beings (Human Research Act);
- the Federal Act on Narcotics and Psychotropic Substances (Narcotics Act);
- the Federal Act on Protection against Dangerous Substances and Preparations (Chemical Act);
- the Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act);
- the Federal Act on Protection against Infectious Diseases in Humans (Epidemic Act);
- the Federal Act on Non-Human Gene Technology; and
- the Federal Act on Human Genetic Testing.

Legal stipulations regarding healthcare are scattered through various acts and are interlinked. International healthcare provisions can be added to this national set of regulations. For instance, Switzerland is member of different international conventions. In particular, it is a member of the World Health Organization. It also adheres – although with some reservations – to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, which sets a minimum standard for human rights in relation to biomedicine.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

In general, healthcare falls under the jurisdiction of the cantons. However, the federal government and its departments have taken over responsibility in many areas. In some areas, municipalities are also competent.

On the federal level, the Federal Office of Public Health (FOPH) is the competent authority with regard to health. As part of the Swiss administration, the FOPH is mainly sourced by public funds.

A further important authority is the Swiss Agency of Therapeutic Products (Swissmedic), a public institution of the Swiss government (for more details see question 6).

On the cantonal level, each of the 26 cantons has its own health department with the relevant agencies. Funding is regulated according to the diverse cantonal regulations. Activities related to healthcare can be funded by fees for such activities.

5 What is the scope of their enforcement and regulatory responsibilities?

The Swiss healthcare system is characterised by the federal system of Switzerland. Specific enforcement or regulatory responsibilities must therefore be examined on a case-by-case basis. Generally, the tasks are as follows.

As the federal health authority, the FOPH deals with social health and accident insurance, the regulations for chemicals and medicines as well as biosafety, the research on humans and transplantation medicine, health promotion, strategies with regard to combating addiction and sexually

transmitted diseases and radiation protection. It is further responsible for the regulation of university medical and health professionals. The FOPH is also the responsible authority with regard to international issues and representation. Besides informative and regulatory competences, it can issue administrative decisions on specific matters within its scope of responsibilities.

The cantonal health departments are responsible for the authorisation and education of non-doctor personnel, for funeral services and for the implementation of regulations with regard to medicinal products and devices as well as to foodstuffs. They control public hospitals, psychiatric clinics and care homes as well as physicians and pharmacies. To this end they can make inspections, ask for samples or information and issue administrative decisions. With regard to health insurance, they grant individual premium reductions.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

Swissmedic is the agency responsible for the regulation of pharmaceutical products and medical devices on a federal level. It is mainly funded by fees and payments from the Confederation. Fees are levied for licences, controls and services provided in relation to the TPA. They also cover costs for developing quality standards, monitoring the market, informing the public and taking measures against abusive or incorrect use. In general, the scale of fees is set in such a way that the costs for fulfilling Swissmedic's service mandate are covered.

7 What is the scope of their enforcement and regulatory responsibilities?

Together with the cantons, Swissmedic is entrusted with the implementation of the TPA. It is responsible for the authorisation of pharmaceutical products and the supervision of pharmaceutical products and medical devices. In particular, it grants licences and the authorisation for the manufacturing, import, export of and commerce with medicinal products. It further verifies and monitors the conformity of medicinal products and medical devices with the legal requirements and grants the required authorisations.

Swissmedic is authorised to issue guidelines and pamphlets, which have the characteristic of administrative ordinances. Based on legal delegation competence, it is further competent to enact specific regulations. It has the power to take all kind of administrative measures and to impose fines (see question 15).

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

In addition to Swissmedic, the FOPH and the cantons, the Federal Price Regulator has certain competences to monitor the pricing of therapeutic products and services provided by the healthcare providers. He or she can make recommendations and decisions with regard to price reductions.

Unlike the mandatory social insurance observed by the FOPH, complementary insurers and any complementary insurance activity are subject to the supervision of the Swiss Financial Market Supervisory Authority (FINMA).

In relation to any criminal proceedings with regard to healthcare, in physician-patient relationships, public prosecutors are typically responsible for procedural measures.

The Competition Commission (ComCom) supervises the Federal Act on Cartels. Thus, the ComCom has jurisdiction in case of competition restraints. In particular, it also combats harmful cartels or anti-competitive conduct in the pharmaceutical and healthcare industry.

In addition to these governmental agencies, there are private entities or self-regulation bodies, such as professional associations, imposing certain regulations on its members. The Swiss business association for chemical, pharmaceutical and biotech industries (scienceindustries Switzerland), the Federation of Swiss Medical Devices Trade and Industry Association (FASMED) and the Swiss Academy of Medical Sciences (SAMS) have developed different codes and guidelines, which provide different competences to such bodies.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

It is possible that the same set of facts affects different authorities. Therefore, it is possible for agencies to simultaneously conduct an investigation of the same subject within their competences. However, according to the principle of *ne bis in idem*, measures with a punitive character must not be cumulated.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Market surveillance occurs by periodic inspections that allow the verification of compliance with different regulations. In order to monitor the safety of therapeutic products, the authority shall further collect mandatory notifications and evaluate them. Based on this evaluation, they can take necessary administrative measures, such as the closing-down of establishments, or prohibiting the distribution of therapeutic products. To this end, they are also allowed to take samples and to request essential information and documents.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Investigations can be started in different ways, for example with an inspection, a notification or based on any other ground of suspicion. The length of any investigation depends on the individual circumstances.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Depending on the subject of the investigation, the responsible authority may vary between Swissmedic and the cantons.

According to the Federal Act on Freedom of Information in the Administration, which is applicable to Swissmedic, in principle any person has the right to inspect official documents. Exceptions to such inspection can be justified if, for example, the access to official documents significantly impairs the free opinion-forming and decision-making process of an authority or is likely to reveal professional, business or manufacturing secrets. Further, the Act is not applicable in relation to any civil, criminal or administrative judicial proceedings. In case of administrative judicial proceedings, such as investigations conducted by Swissmedic, the Federal Act on Administrative Procedure (APA) is applicable. Based on the constitutional right to be heard, a party has the right to inspect any submissions, documents serving as evidence or copies of rulings already issued to his or her case. This right can only be opposed by any essential public or private interest, as well as by required interests of an official ongoing investigation. According to jurisprudence, one further key limitation is the access to purely internal documents of an administrative body. Internal documents cannot serve as evidence. The limitation can often only be determined on a case-specific evaluation.

When a cantonal body is involved, the right to access any files is regulated in the different cantonal administrative procedural laws. The constitutional right to be heard serves again as the overarching principle. Therefore, even though the modalities may slightly differ in the different cantons, the right to access any files in a cantonal administrative proceeding follows the principles of the APA.

Outside any administrative proceedings, a person may ask for information based on the Federal Act on Data Protection, which grants certain information rights to persons whose data is gathered.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

With regard to medicinal products, Swissmedic has the competence to inspect the manufacturing at the expense of the importing company, who must be informed in advance. There are different international mutual agreements in relation to good manufacturing practices (GMP). The recognised good manufacturing practice within a country guarantees that a GMP-control system recognised in Switzerland is provided in the manufacturing place. Thus, such recognition facilitates import, because only an official confirmation instead of an actual inspection by Swiss authorities

is required in such cases. Nevertheless, inspection remains possible in substantiated cases and after consultation with the responsible foreign authority.

The Agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessment specifically regulates such mutual recognition of GMP-control systems for medicinal products and the certification of batches. In addition, it also contains such rules with regard to medical devices. Similar agreements exist between European Free Trade Association countries and Switzerland. Switzerland is also party of the Pharmaceutical Inspection Convention. Further, Swissmedic is part of different international commissions and working parties such as the Pharmaceutical Inspection Cooperation Scheme, which is an informal agreement between different responsible national agencies. Switzerland also observes the tripartite harmonised ICH Guidelines on Clinical Practice.

In practice, inspections are mainly carried out by foreign authorities in Switzerland. In 2014, 70 inspections were carried out in Switzerland involving authorities from Belarus, Brazil, China, Kazakhstan, Korea, Mexico, Saudi Arabia, Turkey, the USA and Yemen.

With regard to medical devices, the abovementioned agreement between the EU and Switzerland also contains regulations on mutual recognition with regard to the conformity assessment of medical devices. Swissmedic focuses on the monitoring of the conformity assessment bodies.

14 Through what proceedings do agencies enforce the rules?

The agencies can take all administrative measures necessary to enforce the rules as long as the proportionality principle is met. Any such administrative decision can be appealed before the competent court. Subsidiary to the Criminal Code and to the Narcotics Act, the TPA also contains specific criminal provisions. In particular, Swissmedic is authorised to conduct penal investigations that involve fines or financial penalties. In relation to custodial sentences or any appeal to any sanction imposed by the agencies, an application to a court is required.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The TPA provides a non-exhaustive list of administrative measures. For example, Swissmedic can raise objections and set an appropriate time period for restoring the state of law. It can suspend or revoke licence and marketing authorisations as well as close down establishments. Furthermore, it can prohibit the distribution, dispensing, import, export and foreign trade from Switzerland of therapeutic products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage. It can seize, hold in official storage, destroy or prohibit the use of illegal advertising media, and publish the prohibition at the expense of the responsible parties. It is also conceivable that Swissmedic will temporarily or permanently prohibit the advertising of a specific therapeutic product in the event of serious or repeated infringement of the rules, and publish the prohibition at the expense of the responsible parties.

Swissmedic is further authorised to provide the general public with any information of general interest about the therapeutic products sector within which the revocation decisions fall.

With regard to any penal investigations under the TPA, misdemeanours are sanctioned by imprisonment or by a fine not exceeding 200,000 Swiss francs. Contraventions are sanctioned by detention or a fine not exceeding 50,000 Swiss francs. In case the person acts in his or her professional capacity, the fines will be raised to 500,000 Swiss francs for misdemeanour and to 100,000 Swiss francs in case of contraventions. The criminal provisions of the Federal Act on Technical Barriers to Trade remain reserved.

16 Can the authorities pursue actions against employees as well as the company itself?

Administrative measures are generally directed towards the addressee of any previous application, in other words the authorisation holder, which in general is the company or a natural person.

In relation to any criminal proceedings, it is primarily the responsible natural person or the person in charge of any duties that have been violated who is addressed by an action. However, if the perpetrator cannot be identified, the company can be made responsible subsidiarily.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The general defences usually made in administrative proceedings are also available to drug and device companies. For example, it is the parties' right to be heard. The parties also have the right to access any files, which serve as basis for any decision, and offer additional proof. They can attend the examination of witnesses and ask supplementary questions. Defences can be based on or supplemented by information gathered through exercising such rights. Furthermore, the company can ask for a reconsideration of a decision in the presence of any legitimate reason. A decision must be appropriate, effective and proportional to accomplish the required results. Besides these material requirements, defences cannot be listed on an abstract level, but need to be evaluated on a case-by-case basis.

Any decision rendered by Swissmedic can be appealed before the Swiss Federal Administrative Court (FAC). Subsequently, a decision of the FAC can be brought before the Swiss Federal Supreme Court (FSC) with an appeal in matters of public law or with a subsidiary constitutional complaint.

A decision rendered by a cantonal authority can be appealed before the respective cantonal courts. A final cantonal decision can be brought before the FSC with an appeal in matters of public law or with a subsidiary constitutional complaint.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Generally, a company should comply with all legal requirements. It may be worthwhile to set up an internal unit monitoring the change of any legislation or issuance of new guidelines. Furthermore, all legal obligations and notification duties should be fulfilled in a timely manner. A clear and complete documentation ensuring the transparency of any steps may further minimise any risk before and during any enforcement action. Compliance with the applicable business code may also strengthen the company's position. In case of unclear situation it may be positive to approach the regulatory authority voluntarily and seek an early collaboration prior to any potential issues.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

With regard to medicinal products, the authorities have focused on illegal imports of narcotics. Since the international scandal on manufactured breast implants, the monitoring of medical devices and in particular of notified bodies has been intensified in accordance with the trend in the EU. In this context, inspections of conformity assessment bodies by foreign authorities almost doubled in 2014.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

In Switzerland, private associations have developed different standards and guidelines with a certain self-regulatory effect.

The Swiss business association for chemical, pharmaceutical and biotech industries (scienceindustries Switzerland) has adopted a Pharma Code and a Pharma Cooperation Code. The Pharma Code provides a code of conduct for the pharmaceutical industry. The Pharma Cooperation Code provides guidelines on cooperation with healthcare professional circles and patient organisations. The Code Secretariat is responsible for the implementation of both codes. There is an institutionalised procedure of investigation in case the guidelines are not complied with. The Code Secretariat acts on its own initiative or on notification. It can request documents from the concerned companies, set deadlines for compliance, initiate negotiations, set deadlines for remedial measures and ask for a guarantee to desist from such conduct in the future. In case of continuing contempt, the Code Secretariat has the right to transfer the matter to the official governmental body.

FASMED developed a Code of Business Conduct by providing guidelines for the interaction with healthcare professionals. It contains inter alia rules with regard to corruption, product training, conferences, marketing meetings, gifts and donations. In terms of enforcement, the code only provides for a reporting system to FASMED in case of misconduct.

SAMS has also issued guidelines for collaboration between the medical profession and industry. These measures are binding for all members of the Swiss Medical Association (FMH). Any disrespect of the guidelines will be investigated by a consultancy agency, which can bring the issue to the attention of the Consultancy Commission of Training and Continuing Education of the FMH.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

According to the TPA, promises and acceptance of material benefits in relation to medicinal products are prohibited. In particular, it is prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicinal products or to the organisations employing them. Furthermore, persons prescribing or dispensing medicinal products and organisations employing them are not allowed to solicit or accept material benefits.

There are two exceptions to these rules:

- material benefits of modest value and which are related to medical or pharmaceutical practice are permitted; and
- commercially and economically justified discounts, directly reflecting on the price, can be granted.

The term 'commercially and economically justified discounts' is, however, not clearly established. The current revision of the TPA is sought to clarify this issue.

Additionally, the Ordinance on Advertising for Medicinal Products (OAM) contains some limited regulations on small quantities of free samples, and on scientific congresses and promotional meetings, which must be addressed only to professionals and subordinated to the main purpose of the congress.

The Unfair Competition Act (UCA) further contains certain rules with regard to bribes in the private sector. Briberies of officials, such as may occur in public hospitals, are, however, regulated in the Swiss Criminal Code.

In addition to these legal requirements the guidelines of the SAMS, the Pharma Code and the Pharma Cooperation Code contain further rules with regard to the relationship between healthcare professionals and suppliers. The SAMS guidelines provide for the duty of public hospitals to internally regulate payments in cash or in kind. In particular, such internal regulations must contain rules on which gifts must be reported and specify limits for form requirements with regard to agreements on acceptance of payments in cash or in kind as well as permitted purposes of donation payments.

22 How are the rules enforced?

With regard to enforcement of the TPA, see questions 14 and 15.

Any person in breach of the UCA can be sued before the competent courts by clients, the competent government authority or any other person infringed in its rights. Bribery of an official will be pursued ex officio according to the criminal proceeding principles.

The Code Secretariat supervises compliance with the Pharma Code and the Pharma Cooperation Code. There is an institutionalised procedure of investigation in case the guidelines are not followed. In case of continuing contempt, the Code Secretary has the right to transfer the matter to the official governmental body.

Any disrespect of the SAMS guidelines will be investigated by a consultancy agency, which can bring the issue to the attention of the Consultancy Commission of Training and Continuing Education of the FMH.

The developed Code of Business Conduct of FASMED only provides for a system of reporting to FASMED in case of misconduct.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The TPA does not provide for a specific reporting system. However, the self-governing bodies contain some reporting requirements.

According to the Pharma Cooperation Code, the pharmaceutical industry adhering to the Pharma Cooperation Code will have to disclose any pecuniary benefits provided to professional or healthcare organisations on their website from 2016 onwards.

The SAMS guidelines require that public hospitals only provide for internal regulations with regard to such payments.

The Business Conduct Code of FASMED includes a documentation requirement in order to combat corruption.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

According to the Federal Act on University Medical Professions, physicians, dentists, chiropractors, pharmacists and veterinarians and, according to the Federal Act on Psychologic Professions, psychologists are supervised by cantonal supervisory authorities. The latter can take appropriate measures in order to assure compliance with the legal professional duties. Therefore, the detailed measures are regulated in each canton. Generally, the authorities can carry out (unannounced) inspections and take administrative measures, including confiscation of relevant items, closing down of services or requesting additional training certificates. Certain notification duties of professionals may further facilitate the monitoring. In addition, cantonal courts and administration as well as the federal agencies have the duty to notify any potential breaches of professional duties to the competent cantonal authority.

With regard to non-university professions such as occupational and speech therapists, nutritional advisers, midwives, naturopaths, nurses, physiotherapists or dental technicians, the cantons are competent. Therefore, the powers of the authorities to monitor compliance are regulated in the cantonal legislations. Generally, they also encompass the right of inspection and controls. Currently, a new act on healthcare professions is being elaborated which will regulate professionals graduating from higher educational institutions (as opposed to universities).

Healthcare institutions such as hospitals, care homes, and Spitex services (which are services in relation to patient care and assistance at home) are regulated on the level of the cantons. In general, the competent cantonal authorities can inspect and control these institutions. When municipalities are in charge, for example for Spitex-services, they dispose of similar competences.

In relation to healthcare delivery covered by the mandatory insurance, compliance is particularly important with regard to the quality and financial aspects of these services. Special independent medical officers monitor whether services fulfil the conditions in order to be covered by the insurance. In relation to the quality and financial aspect, scientific controls or the consultation of special units for quality assurance or of medical officers is required in order to benefit from insurance coverage.

Swissmedic and the cantons supervise the distribution of therapeutic products. With regard to their monitoring powers, see question 10.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Investigations can be started in different ways; for example, with an inspection, a notification or based on any other ground of suspicion. The length of any investigation depends on the individual circumstances.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

See question 12.

27 Through what proceedings do agencies enforce the rules?

See question 14.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

According to the Federal Act on University Medical Professions and the Federal Act on Psychologic Professions, warnings, reprimands, and fines up to 20,000 Swiss francs can be issued for physicians, dentists, chiropractors, pharmacists and veterinarians. Temporary prohibitions from practice for up to six years or definitive prohibitions for the complete or partial field of activities are further conceivable. For psychologists a definitive prohibition concerns only the private practices under their own authority.

In relation to sanctions with regard to institutions and the non-university professionals, cantonal regulations contain fines and administrative measures such as closing down institutions or confiscating items.

In addition, see question 15.

29 What defences and appeals are available to healthcare providers in an enforcement action?

See question 17.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 18.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Enforcement competences majorly lie with cantonal authorities with the consequence that authorities may emphasise various aspects of enforcement. However, recent developments show that the focus has been inter alia on the harmonisation of procedures in institutions whose services are covered by the mandatory health insurance. For example, harmonisation on quality control has been envisaged.

There have been no recent noteworthy sanctions. However, some individual cases of malpractice of doctors and dentists have obtained national attention. In severe cases the delinquent was sanctioned with an occupational ban.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

There are different codes or professional standards for different healthcare providers, mainly for professions requiring a university degree. For example, the FMH has developed a code of conduct (statute) for physicians. The competent cantonal professional committees deal with any breach upon notification by any member or third party. Similar regulations exist for dentists.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

See question 28.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

A citizen cannot enforce a healthcare regulation or law abstractly. He or she must be affected by its implementation in order to seek any action. Civil and criminal actions are conceivable. Although public law is applicable to various legal relationships within the healthcare sector, due to references in the public regulations or subsidiarity of civil law clauses, in most cases private law or criminal law is relevant. Nevertheless, certain cantonal regulations provide for state liability in case of any treatment in public hospitals. Proceedings are regulated according to such cantonal regulations. However, jurisprudence has established that any appeal before the FSC based on such public cantonal acts will be in civil matters. In the absence of such cantonal regulations on state responsibility, civil extra-contractual liability applies.

Possible claims under civil law can be based on breach of contract, agency without authority, tort, product liability or breach of the due care of a physician or his or her auxiliary personnel. Criminal proceedings are initiated upon request or ex officio by the public prosecutors. Under criminal law the following acts are relevant: intentional homicide, homicide through negligence, different forms of assault, breach of official secrecy or breach of professional confidentiality.

Besides citizens and private bodies, other parties may bring any issues in relation to healthcare to the attention of the competent authorities, which may investigate further on the subject. For example, the TPA stipulates that consumers, patient organisations or any interested third party have the right to notify of unintended side effects of drugs.

35 What is the framework for claims of clinical negligence against healthcare providers?

A successful civil claim of clinical negligence has to show:

- that the negligence is unlawful;
- that the negligence caused a loss;
- that the loss was causally caused by the negligence; and
- that the party alleged to be negligent was at fault.

For a contractually compliant course of action, an objective (as opposed to subjective) standard of care is applicable. Doctors have to act with due care, following the current best practice in the field. High demands are made on due care, including for example the use of a balanced risk and benefit relation of a treatment, the necessity to possess a level of knowledge which is up to date with recent medical developments and the obligation to inform patients, among others, about their state of health, drugs and procedures used.

Within criminal actions, homicide through negligence and different forms of assault are the most relevant cases when dealing with clinical negligence. A successful action has to show:

- a breach of duty of care;
- the predictability of the outcome;
- that prevention of the loss was possible; and
- a risk correlation between the breach of duty and the outcome.

Damages are only granted if an actual loss occurred; for example, to cover costs caused by additional required medical care or financial loss caused by inability to work. Compensation for personal suffering is granted restrictively.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Purchasers or users may seek recourse by a civil law action based on tort (see question 35). Furthermore, recourse can be sought on the grounds of product liability. Product liability is applicable to both pharmaceuticals and devices. The requirements for such claim are the proof of:

- a loss;
- the defendant being producer of the pharmaceutical or device;
- the product being defective; and
- the loss being casually caused by the defective nature of the product.

37 Are there any compensation schemes in place?

No, there are no compensation schemes in place since Swiss Law does not know such instrument. As mentioned in question 35, damages are granted in the amount of actual loss occurred and paid by the opposing party.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Under current Swiss legislation, no collective claims or class actions are possible, since this type of claim does not (yet) exist.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

A complaint can be reviewed by an action to a court. The injured party may submit a civil claim to court. In general, the person who suffered a loss due to an infringement is entitled to such action, which means that an interest itself is not enough. The conditions of a successful claim are laid out in questions 35 and 36. Stipulated claims for damages are subject to a limitation period depending on the type of claim involved. Claims based on contractual obligation become time-barred after 10 years. Extra-contractual claims become time-barred after one year and product liability claims after three years since the injured party became aware of the damage. The absolute limitation period is – in any case – 10 years. In case of any compensation based on state liability, cantonal regulations should be consulted. The time limitation period for filing an appeal of the first instance court decision is 10 or 30 days, depending on the type of procedure.

There are also some extrajudicial proceedings available. An interested party may contact the hospital's internal complaints office. Interested parties may also forward a procedure in front of an ombudsman. In the healthcare sphere they are structured as specialised centres, organised by the

Update and trends

Enforcement priorities are unlikely to change drastically in the coming years and there are no noteworthy cases pending at the moment. Nevertheless, there are ongoing projects in Switzerland concerning the revision of the present legal framework regarding the TPA. One of the topics regarding both medicinal products and medical devices is the granting of discounts and other advantages. The relevant rules and their enforcement are intended to become more strict.

In its healthcare strategy 2020, the federal government mentions several areas on which it wants to focus in the coming years. Among others, the rights of patients should be strengthened (extended rights of appeal and protection of personal data), the cost for the mandatory health insurance should remain affordable and the price-setting system of pharmaceuticals should be further developed. Another noteworthy development is the trend of continuous privatisations of public hospitals.

cantons. The centres primarily function as mediation bodies and cannot issue enforceable judgments.

40 Are there any legal protections for whistle-blowers?

The legal protection for whistle-blowers in Switzerland is weak. Swiss law addresses whistle-blowing only in specific areas, namely in competition law which provides for an immunity and leniency programme. Further applicable regulations are found in employment law. Employees have a secrecy obligation and, thus, are not allowed to release internal information to a third party that could harm the employer. An exception to this rule has been established by jurisprudence. If the higher-ranking interests of a third party or the public are touched, a complaint can be filed to the responsible authority. However, the specifics of mentioned interests are not defined and a judge has to weigh up interests of the employer with the public's interest in every case. Furthermore, a whistle-blower might face charges based on criminal law or the data protection act when revealing internal information.

41 Does the country have a reward mechanism for whistle-blowers?

There are no general reward mechanisms in place. In some specific areas, however, provisions for reward mechanisms exist. For example, in competition law, immunity or a reduction of competition law fines is granted to a company that notifies the competition authority of an illegal restraint of competition and cooperates in the subsequent investigation.

42 Are mechanisms allowing whistle-blowers to report infringements required?

As mentioned under question 40, a general reporting mechanism is currently only established by jurisprudence. The course of action has to follow the predefined order of the legal practice. First, notice has to be given internally (internal whistle-blowing). If there is no reaction within a reasonable timeframe, the employee may inform the responsible authority. The media shall only be contacted as a last resort. Since this mechanism is not stipulated by law, the Swiss parliament is currently debating a revision of the relevant regulations.

Under competition law aspects, it is advisable for undertakings active in Swiss markets to implement an internal antitrust compliance programme, and as part of such programme consider adequate procedures for internal whistle-blowing.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Generally, Switzerland provides international mutual assistance in civil, administrative and criminal matters.

In relation to medicinal products and medical devices, Switzerland cooperates with foreign counterparts. The cooperation focuses on information exchange along the complete process from authorisation to supervision of the therapeutic products. In particular it gives international administrative assistance by respecting the national data protection regulations. It has concluded numerous information agreements, both binding and non-binding, with other countries and authorities.

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44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

An investigation by foreign authorities will trigger an investigation in Switzerland if Switzerland is requested to provide administrative or legal assistance. Switzerland will further become active if such enforcement activities by foreign authorities are relevant in Switzerland, in particular, if public health is at risk.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

In case the infringement occurs on Swiss territory, foreign companies and foreign nationals will be pursued according to Swiss healthcare laws.

In particular, the scope of application of Swiss administrative law is generally limited to the Swiss territory (principle of territoriality). However, according to the practice of the FSC, Swiss administrative law may also be applied to cases taking place in a foreign territory but having considerable effects in Switzerland ('effects doctrine'), or if explicitly stated in the relevant law. However, Swiss authorities cannot directly become active against foreign entities outside Swiss territory. The authorities need to initiate a foreign administrative assistance procedure and request assistance of the competent foreign authorities. Similar concepts are applicable to criminal matters.

United Kingdom

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The majority of healthcare in the UK is provided by the publicly funded National Health Service (NHS). In 2013, public sector spending accounted for 83.3 per cent of the total healthcare expenditure in the UK of approximately £125.5 billion. The NHS budget for the 2015–2016 financial year is £115.4 billion.

With some exceptions (such as prescriptions in some parts of the UK), the NHS is free at the point of use. The vast majority of funding for the NHS (98.8 per cent in 2013) is generated through general taxation and national insurance contributions from employees and employers. The rest of the NHS is funded through patient charges.

Private medical care is also available, the majority of which is funded through private medical insurance policies. Some private medical treatment is purchased by the NHS, and a small minority of individuals self-pay for private medical treatment.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The Secretary of State for Health has overall financial control and oversight of all NHS delivery and performance in England. Responsibility for healthcare in Wales, Scotland and Northern Ireland is devolved to the relevant minister in each country.

In the public sector, healthcare is delivered either by general practitioners (GPs), NHS walk-in centres and pharmacists (known as primary care) or by hospitals (known as secondary care). As discussed below, the structure of primary and secondary care providers is very different, though they all provide care that is free at the point of use.

In contrast, private healthcare is delivered by either business enterprises or non-profit-making trusts. Many private healthcare groups, such as BUPA, provide private medical insurance and operate private hospitals for those insured by them, or those who self-pay for private treatment.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

In April 2013, the NHS underwent a significant reorganisation through the introduction of the Health and Social Care Act 2012 (the Act). The Act created a commissioning board known as NHS England, which is now responsible for commissioning healthcare services in England. While NHS England commissions some services directly, at a national level, most commissioning is now done by consortia of GPs, known as clinical commissioning groups (CCGs). CCGs hold approximately 60 per cent of the NHS budget.

The Act abolished the former commissioning bodies, primary care trusts. It also established Public Health England, a body charged with protecting and improving the nation's health and wellbeing, and Healthwatch UK, the 'consumer champion' for health and social care.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (HSCA (RA) 2014) introduced new 'fundamental standards', applicable to the care provided by registered providers, as well as a statutory 'duty of candour'; and a 'fit and proper persons' requirement for directors and equivalent employees.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Care Quality Commission (CQC) is the independent regulator of health and social care services in England. It regulates hospitals (including private hospitals), care homes, dental and GP surgeries, and all other care services in England. It is funded by a combination of a grant from the Department of Health and registration fees. While it has the power to levy fines against service providers, its funding is not dependent on the amount of fines imposed or paid.

Medicines and medical devices are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA operates as a government trading fund, which means that the majority of its income is generated by fees it charges. However, this income does not include fines.

The independent sector regulator for health services in England is an entity called Monitor. Like the CQC, it is also primarily funded by the Department of Health and is not funded by the fines that it has the power to impose.

5 What is the scope of their enforcement and regulatory responsibilities?

The CQC registers health and social care providers and managers, and sets essential standards for health and social care service providers in England, pursuant to the HSCA (RA) 2014 and the Care Quality Commission (Registration) Regulations 2009. It also monitors providers' performance against these standards.

Prior to 2013, Monitor's main role was to authorise, monitor and regulate NHS foundation trusts (which provided secondary care, and accounted for over 60 per cent of NHS trusts). Monitor's role was expanded under the Act such that its responsibilities now include ensuring that procurement, choice and competition operate in the best interests of patients.

Regarding enforcement and regulations, Monitor is now responsible for, inter alia, preventing anti-competitive behaviour, and regulating licensed providers to prevent them from failing financially.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The regulation of the safety, quality and efficacy of medicines, and medical devices, is undertaken by the MHRA. In particular, it is responsible for ensuring that medicines and medical devices supplied to the public (either through the NHS or privately) meet the necessary standards and regulations.

The MHRA charges fees to pharmaceutical companies for a variety of the tasks which it carries out, including applications for new marketing authorisations, or variations to existing authorisations (which accounted for 44 per cent of its fee income in 2014–2015); service fees for the monitoring activities undertaken by the MHRA; and inspections. It also receives grants from the Department of Health.

7 What is the scope of their enforcement and regulatory responsibilities?

On the medicines side, the MHRA primarily seeks to enforce the Human Medicines Regulations 2012. These regulations, the product of an MHRA review, consolidated and amended much of the Medicines Act 1968 and around 200 further statutory instruments.

The new regulations set out a comprehensive framework for the authorisation of medicinal products for human use; the manufacture, import, distribution, sale and supply of those products; labelling and advertising; and pharmacovigilance.

On the medical devices side, the MHRA derives its enforcement powers mainly through the Medical Devices Regulations 2002 (which implements the Medical Devices Directive (93/42/EEC) into UK law), the Consumer Protection Act 1987 (CPA 1987) and General Product Safety Regulations 2005 (GPSR 2005).

These encompass, inter alia, the investigation of allegations of non-compliance; monitoring the activities of those bodies designated by the MHRA to assess the compliance of manufacturers; and investigating medical devices based on vigilance reports or intelligence.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Healthcare professionals and organisations may be investigated by the police and prosecuted by the Crown Prosecution Service (CPS) for offences including gross negligence manslaughter, corporate manslaughter and, as of 13 April 2015, ill treatment or wilful neglect. The Serious Fraud Office (SFO) has jurisdiction to investigate the most serious fraud and corruption cases. For example, the SFO prosecuted the pharmaceutical company Goldshield and others (including individuals) for conspiracy to defraud the Department of Health arising out of a cartel that is alleged to have operated between 1998 and 2000. In 2008, the House of Lords concluded that price-fixing did not amount to a common law offence and the proceedings were dismissed shortly after (though civil proceedings by the Department of Health continued and were later settled).

In relation to competition matters, while one of Monitor's responsibilities includes ensuring that anti-competitive behaviour by commissioners or providers of healthcare services does not harm patients, the Competition and Markets Authority (CMA) as the national competition authority, or the European Commission (EC), has the power to investigate potential infringements of competition law. Both the CMA and the EC have the power to impose substantial fines for breaches of competition law.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

In theory, there is no restriction on the number of agencies that can investigate any particular subject, and each of them is free to pursue investigations as they see fit.

However, in practice, mindful of the need to avoid duplicating expenditure, many agencies have agreed procedures in place to ensure that the same conduct is not investigated by multiple agencies. For example, in February 2015, the CQC and Monitor signed a memorandum of understanding (MoU) setting out the framework for joint or parallel investigations between the two regulators.

This cooperation is formalised in the form of 'operational annexes' to the MoU, which set out the detailed working arrangements and processes. This requires both organisations to work together to identify what action is needed, and provides for the possibility of a lead regulator. Further, inspections and reviews may be carried out jointly or in parallel.

In section 3(d) of Annex B of the MoU, it is stated that any use of powers by Monitor does not preclude the CQC from taking enforcement action in relation to breaches of registration requirements or any other regulatory activity if it is appropriate to do so.

Equally, any CQC enforcement activity does not preclude Monitor from exercising its enforcement powers in relation to breaches of licence.

The SFO and the CMA have also entered into an MoU that will regulate which agency investigates allegations of criminal cartels, including in the healthcare sector. Broadly speaking, the CMA will lead an investigation into alleged cartels, but will refer any matters falling within the SFO's remit to the SFO, which can then decide whether to accept the case or not (in which case the CMA will continue with the investigation).

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The MHRA carries out a range of inspections. These include regular inspections of manufacturing sites, and samples of medicines, to ensure compliance with the relevant rules, but also inspections where there has been an allegation of non-compliance or where a potential problem has been identified.

MHRA enforcement officers and inspectors have the power to conduct site inspections and to require the production of records and take copies, seize or detain suspect records or goods, for example under the CPA 1987.

Beyond this, the MHRA facilitates a reporting scheme, and undertakes market surveillance, and a sampling scheme of high-risk products which are most likely to be counterfeited in the UK.

Further monitoring powers include internet vigilance: the configuration of web crawling software to monitor the internet for websites that engage in illegal advertising, supply and distribution of medicines and medical devices.

11 How long do investigations typically take from initiation to completion? How are investigations started?

According to the British Society of Interventional Radiology, on average, 50 per cent of 'specialist' investigations (ie, those undertaken directly by the MHRA) are concluded within 21 weeks. Meanwhile, 50 per cent of 'monitored' investigations (ie investigations conducted by the manufacturer, on the MHRA's behalf) are concluded within 10 weeks.

Investigations may be initiated by a complaint, which may be submitted by a number of sources including members of the public (through the 'yellow card' scheme where members of the public can report adverse side-effects directly), healthcare professionals and competitor companies, or through inspection or proactive monitoring conducted by the MHRA.

The MHRA case referral centre receives all complaints of alleged breaches of medicines legislation. It will assess the referral, in terms of risk, and consider whether it falls within the MHRA's responsibilities.

If it does, the referral centre will allocate the case to a member of the enforcement group for investigation. Cases falling outside the responsibilities of the MHRA will be referred to the relevant agency.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

This depends on the type of investigation. Different rules will apply to a criminal prosecution than to an investigation by the MHRA, for example.

Where an investigation by the MHRA is instigated by a third party, the MHRA will generally keep the identity of the third party confidential if asked to do so. If the investigation relates to the safety of a medicine or medical device, then certain information will naturally be shared with the subject of the investigation. Indeed, in many cases the subject of the investigation will carry out analysis of products, etc, themselves under the supervision of the MHRA.

When a criminal investigation is underway, there is usually very little disclosure to the subject of the investigation until formal charges are made, at which point the criminal rules of evidence apply and a significant amount of disclosure is required.

The MHRA and other regulators are public bodies and therefore fall within the scope of the Freedom of Information Act 2000 (FOIA). The FOIA entitles any person requesting information from a public authority to be informed whether that information is held (the duty to 'confirm or deny'), and to have the information communicated to them, subject to certain exceptions.

The European Medicines Agency and the Heads of Medicines Agency have prepared guidance to national authorities (such as the MHRA) in determining what information should be disclosed pursuant to such requests.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

It is likely that if there are concerns about products manufactured in a foreign jurisdiction, the authorities in the UK would refer the matter to the appropriate authority in that foreign country, rather than undertake investigations abroad themselves.

14 Through what proceedings do agencies enforce the rules?

The MHRA has enforcement powers conferred on it, in relation to both medicines and medical devices, through the Human Medicines Regulations 2012, the CPA 1987, the Medical Devices Regulations 2002 and the GPSR 2005.

These enable the MHRA to investigate possible breaches of the relevant regulations itself and without the need to take the matter to court. For the most serious breaches, the MHRA is able prosecute defendants before the criminal courts, but this is usually only done as a last resort, where a serious offence has been committed or all other measures to secure compliance have failed.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The principal sanction available to the MHRA is the power to issue notices, with which the recipient must comply. These notices can require the subject to provide further information, suspend or even prohibit the sale of particular products and require products to be recalled from the market. The MHRA can also obtain injunctions from the civil courts where necessary, for example in order to prevent the advertisement and supply of medicines that have not been properly authorised.

It is possible for fines to be imposed following a successful prosecution by the MHRA.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes. The MHRA and the CPS may pursue actions against employees (and ex-employees) of the company, including its directors. Successfully prosecuting corporates is difficult in the United Kingdom (unlike, for example, the United States) because of the requirement to show that there was a 'directing mind' of the corporate which authorised the relevant conduct. The focus of prosecutions has therefore tended to be against individuals.

For example, in 2013 the MHRA successfully prosecuted an ex-employee of a clinical research organisation, Aptuit, for illegally changing pre-clinical trial data to obtain a positive result, with a view to securing approval for clinical trials.

Notices served by the MHRA tend to be addressed to the company in question rather than individuals.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The defences available depend on the legislation the MHRA is seeking to enforce in any particular enforcement action.

For example, in proceedings under the CPA 1987, one defence is that a defect is attributable to EU law, or that the defect did not exist in the product at the relevant time.

The appeal route depends on the decision taken by the MHRA. In general, appeals against MHRA enforcement decisions are made directly to the courts. In certain circumstances (for example an appeal against a notice to warn under the CPA 1987) appeals are made by way of arbitration under the supervision of the Chartered Institute of Arbitrators.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

An obvious way of minimising the risk of enforcement action by the MHRA is to ensure that robust systems are in place to ensure compliance with the relevant regulations, as well as good manufacturing and distribution practice.

If a problem does arise and some form of enforcement action is contemplated, then the priority of the company must be to cooperate fully with the MHRA or other investigating authority and reduce the risk of a prosecution or other severe sanction.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

The MHRA's key objectives for this year include progressing work on EU negotiations in the field of clinical trials, falsified medicines and devices, and improving incident and safety reporting systems, chiefly the yellow card scheme.

In the last year, the MHRA has taken the following action:

- Conducted a joint investigation with the Metropolitan Police, which resulted in a sentence of 27 months' imprisonment against an individual, for her involvement in the supply of abortion pills, with the intent to unlawfully procure miscarriages.
- Taken action against two companies, for selling faulty pre-filled syringes, which resulted in the death of a diabetic patient and amounted to a violation of the Medicines Act 1968. Fines of £500,000 and £50,000 were imposed.
- Upheld a complaint made by Johnson & Johnson, in relation to a TV advertisement produced for a traditional herbal medicine, licensed on the incorrect assertion that the efficacy had been demonstrated.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The Association of the British Pharmaceutical Industry (ABPI) is the trade association of companies in the UK that produce prescription medicines and has produced a code of practice for its members (the ABPI Code). The ABPI Code covers issues such as advertising of medicines and the activities of sales representatives. The Code is administered by the Prescription Medicines Code of Practice Authority (PMCPA).

The PMCPA has entered into a memorandum of understanding with the MHRA concerning investigations of matters falling within the scope of the ABPI Code, which is in essence that the PMCPA is the first means of dealing with complaints, though the MHRA can intervene where there is a clear case for intervention. Similarly, the PMCPA has agreed a memorandum of understanding with the SFO that provides that any alleged breach of the ABPI Code which is also a potential breach of the Bribery Act 2010 will in the first instance be dealt with by the PMCPA.

When a complaint is made to the PMCPA, a code of practice panel determines whether a breach of the ABPI Code has taken place and, if so, the appropriate penalty. Decisions of the panel can be appealed to the Code of Practice Appeal Board. Where a breach is identified, the company is required to give an undertaking that the practice in question has ceased. Ultimately, the PMCPA can suspend or expel a company from the ABPI.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

Regulation 300 of the Human Medicines Regulations 2012 regulates inducements and hospitality between persons qualified to prescribe and supply medicines (PQPS), and persons promoting medicinal products.

It prohibits gifts to PQPS unless they are inexpensive, being less than £6 excluding VAT, and have a clear business use, relevant to the practice of medicine and pharmacy.

Section 6.14 of the MHRA Blue Guide, on the advertising and promotion of medicines in the UK, details the two stages involved in Regulation 300.

First, there are the broader limits that catch promotion of medicines, encompassing price promotions, loyalty schemes and bonus schemes. Secondly, within that broad remit, it prohibits the supply, offer or promise of pecuniary advantage to PQPS.

The Bribery Act 2010 in the UK and the Foreign Corrupt Practices Act 1977 in the USA (which has long-arm jurisdiction) are also relevant to the financial relationships between PQPS and suppliers.

22 How are the rules enforced?

Regulation 303 makes it a criminal offence to breach Regulation 300(4) by either soliciting or accepting inducements or hospitality falling outside the exceptions under Regulation 300(1) and 300(2). This essentially covers both sides of such a transaction.

Any such breach would be a summary-only offence, prosecuted in the magistrates' court, with a maximum fine of £5,000. A prosecution can be brought by the MHRA.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The European Federation of Pharmaceutical Industries and Associations agreed a Disclosure Code in June 2013. From 2016, it will become compulsory for every member company to disclose certain payments made by pharmaceutical companies to individual health care providers (HCPs) and healthcare organisations (HCOs), made in 2015, and thereafter into the future.

This mirrors the Physician Payments Sunshine Act in the United States, which requires disclosure of payments or other transfers of value made to doctors or teaching hospitals.

Under the code, pharmaceutical companies need to disclose details paid to HCPs or HCOs, or to employees on their behalf, for services such as chairing and speaking at meetings.

The information is published on a public platform (either the company's website, or a central website). Disclosures should be publicly available in the country where the HCP or HCO receiving a transfer of value or payment from industry has their practice.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Monitor use a risk assessment framework to monitor licence providers, and to ensure that, for example, NHS foundation trusts meet the conditions of their licence, are financially sustainable to ensure continuity of services, and that they meet governance requirements.

The CQC uses a process of continuous monitoring, examining over 150 indicators (intelligent monitoring). Factors include waiting times, mortality rates and feedback from service users. Action taken by the CQC depends on the variation identified, and includes carrying out an inspection or contacting the service to find out more information.

Both Monitor and the CQC have the power to require those they regulate to provide information or documents to them.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Neither Monitor nor CQC publish average investigation time frames, and the time taken can vary enormously depending on the scope of the investigation.

When Monitor becomes aware of a potential breach, it will first consider its 'prioritisation framework'. Regard is given to the importance of a breach and the benefits and costs of commencing an investigation.

Monitor will then decide whether to formally investigate a matter or to make a provisional finding that there has been a breach or infringement.

It will notify the relevant entities, setting out what it intends to investigate, the key contacts at Monitor and the expected timetable. Appropriate information is published on Monitor's website.

The CQC's intelligent monitoring helps it to decide when, where and what service user to inspect. This is the beginning of its formal inspection process. Inspectors examine health providers against a standard set of 'key lines of enquiry' to assess whether they are meeting the required standards.

The CQC also rates services into categories of 'outstanding', 'good', 'requires improvement' or 'inadequate'. The rating will determine the enforcement action taken by the CQC.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

There is no general right to disclosure of the regulator's files and materials during the course of an investigation. However, when enforcement action is taken by either Monitor or the CQC then certain information must be communicated to the subject of the enforcement action. For example, when Monitor issues a notice setting out the enforcement action it intends to take, the notice must include a statement of the evidence and the reasoning behind the proposed enforcement action.

Where there is a criminal prosecution then the ordinary rules of disclosure in criminal cases will apply.

27 Through what proceedings do agencies enforce the rules?

Monitor has the power to conduct its own proceedings, which are civil in nature. When matters are referred to Monitor, the first step is to ascertain whether to take any action and, if so, whether it should be formal or informal action. Cases are prioritised to ensure that Monitor uses formal enforcement action (and the resources which are required to pursue such an action) in appropriate cases.

If Monitor intends to use its formal enforcement powers to impose a discretionary requirement, it first issues the provider with a Notice of Intent, which sets out the proposed course of action and basis for it. The provider is entitled to make representations to Monitor, following which Monitor decides whether to impose the discretionary requirement in its original form, in a modified form or not at all. A Final Notice is then issued, which the provider can appeal to the First-Tier Tribunal, a specialist court.

It also has concurrent powers with the CMA to take action in respect of anti-competitive practices, and abuses of a dominant position in the market under section 72 of the Competition Act 1998 and articles 101 and 102 Treaty on the Functioning of the European Union.

The CQC has its own enforcement powers. These encompass those who carry out regulated activity without the appropriate registration with the CQC, and also those registered persons who breach conditions of their registration or breach the relevant legislation (eg, Care Quality Commission (Registration) Regulations 2009, HSCA 2008, HSCA (RA) 2014).

The CQC can pursue both civil and criminal actions. The former are carried out through its own proceedings, while the latter are prosecuted by the CQC in the criminal courts.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

When initiating a formal investigation, Monitor can use its powers under section 104 HSCA 2012 (the information provision), to require documents and information to be provided to it.

Monitor may also impose 'discretionary requirements' in relation to licensing breaches, which may result in a monetary penalty, a 'compliance requirement' to prevent further breaches, or a 'restoration requirement' to remedy the consequences of the breach (section 105 HSCA 2012).

Monitor may further impose enforcement undertaking requirements (eg, to secure that the breach does not occur again) (section 106 HSCA 2012), or impose licence conditions removing, suspending or disqualifying directors (section 111 HSCA 2012).

The CQC has the power to issue requirement notices, which identify steps to be taken to ensure compliance with the regulations. It can issue warning notices to registered persons, which outline failures and impose a deadline for compliance. The CQC can also impose conditions on, or suspend, a registration and in extreme circumstances can cancel a registration outright, urgently if required.

The CQC also has the power to prosecute criminal offences, which are heard by the criminal courts.

The CMA has extensive powers to investigate healthcare providers and to impose substantial fines in the event of a finding that they have engaged in anti-competitive conduct.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Subjects of enforcement action by both the CQC and Monitor have the right to make representations during the enforcement process.

Appeals against the imposition of a discretionary requirement, a penalty, an enforcement undertaking or a licence revocation by Monitor are made to the First-Tier Tribunal.

Similarly, appeals against civil enforcement action (save for warning notices and penalty notices) taken by the CQC are also to the First-Tier Tribunal. Appeals against a criminal conviction obtained after prosecution by the CQC are to the appropriate criminal court (the Crown Court or the Court of Appeal).

Appeals against findings of the CMA are to the Competition Appeal Tribunal (CAT).

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Again, healthcare providers can reduce their exposure to enforcement actions by ensuring that their systems are suitable to prevent any breach of the relevant regulations and that if a breach does occur it is swiftly identified and corrected.

For example, providers should consider the five key questions the CQC pose: are services safe, effective, caring, responsive to people's needs and well-led?

If enforcement action is contemplated, then full and transparent engagement with the regulator is likely to minimise the prospect of an adverse outcome for the healthcare provider. Regulators have limited resources and are likely to focus resource-intensive activity (such as formal enforcement action) on those providers who do not engage properly with them.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In its 2015–2016 business plan, the CQC has stated its intention to implement and improve a new approach to regulation, following guidance issued in Sir Robert Francis QC's Report into the Mid Staffordshire NHS Foundation Trust. This involves a renewed focus on taking action against people and services that do not meet fundamental standards.

This year, the authorities have taken the following action:

- In February 2015, the CQC issued a warning to Le Grand Nursing Home, to improve standards of care.
- In April 2015, the regulator fined St Helens Care Home £4,500 for failures to meet national standards.
- In June 2015, Monitor found Lancashire Teaching Hospital NHS Foundation Trust in breach of its licence, due to a lack of robust financial plans. It imposed a condition on the Trust's licence to ensure its concerns were addressed but did not impose a financial penalty.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The medical royal colleges maintain an important role in setting and monitoring professional standards for their members. These include the Royal Colleges of General Practitioners, Nursing, Surgeons and Physicians.

In the private sector there is the Association of Independent Healthcare Organisations, the trade association for independent healthcare organisations that operates the voluntary Independent Sector Complaints Adjudication Service.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

The NHS 'standard contract' is mandated by NHS for use by commissioners for all contracts for healthcare other than primary care.

This standard contract enables the relevant commissioning body to impose financial sanctions for breaches of national quality standards. Penalties in excess of £1,000 must be reported. Unless indicated otherwise, the proceeds are all reinvested in patient services.

Sanctions relate to issues such as waiting times, cancelled operations and mixed sex accommodation breaches. Penalties are based on whether an operational standard is met.

Commissioners of primary care services also generally include provisions to recover costs in the event of poor performance. For example, in 2014–2015 Bedfordshire Clinical Commissioning Group reported penalties applied of £41,894.68 in relation to failures to meet a 90 per cent target of patients starting treatment within 18 weeks from referral.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Other than claims for clinical negligence, the primary route for a private person or entity to enforce a healthcare regulation or law is a complaint to the relevant authority, which will then decide whether to take action. The decision of that authority is subject to judicial review by the courts.

Private enforcement of competition law is a growing area in the UK. It is possible for victims of anti-competitive conduct by healthcare providers to bring claims, either in the CAT or in the High Court, to recover any losses they have suffered.

35 What is the framework for claims of clinical negligence against healthcare providers?

All healthcare providers owe a duty of care to patients. The courts will adjudicate where claims of negligence are made.

To bring a successful claim, a claimant must prove a breach of duty by a healthcare professional (either through an act or omission) and that that breach caused, or materially contributed to, the injury in question. To prove a breach, it must be shown that the defendant acted in a way that was not deemed reasonable by a body of the same professionals: *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

The courts will hold both public and private healthcare providers to the same standard.

The remedy for clinical negligence is damages, which are designed to compensate the claimant for the losses they have suffered and are not punitive in nature. While a court cannot require healthcare providers to change its working practices, any criticism of healthcare providers by the courts is likely to be considered very carefully by the appropriate regulator.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The system of purchasing pharmaceuticals and devices in the UK is highly complex, but in essence pharmacists purchase pharmaceuticals from wholesalers and are reimbursed by the NHS. If there is a problem with those medicines, pharmacists would have a contractual claim against the wholesaler, and a claim in tort against the manufacturer. The NHS is also likely to have a claim against the manufactuer in some circumstances.

Users of medicines will have a claim against the manufacturer if it is defective and causes them an injury or loss. They may also make a report to the MHRA.

37 Are there any compensation schemes in place?

There is no general compensation scheme, but individual schemes have been set up for particular circumstances. In 2000 it was announced that the government would pay compensation to victims and families of Creutzfeldt-Jakob disease, which can be contracted through defective growth hormones. £67.5 million was committed for the first 250 cases.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Yes, in circumstances where a claim gives rise to common or related issues of law or fact the court may make a group litigation order (GLO). The group action rules apply to all areas of law, including healthcare.

The GLO procedure is 'opt-in': it permits persons, or legal entities who are bringing claims individually to have their claims managed together.

There is no certification procedure; rather, the courts impose a cut-off date by which claims must join the GLO. Consequently, there are very often different groups of claims managed under a single GLO.

A notable recent example was a GLO against Transform Medical Group in relation to defective implants used in breast augmentation surgery.

A major reform in this area is expected, through the Consumer Rights Act 2015 (CRA 2015), which enters force on 1 October 2015. This enables collective proceedings to be brought before the CAT, by a defined group, without the need to identify individual claimants.

The CRA 2015 will provide the CMA with the power to grant voluntary redress schemes, under which companies which have breached UK or EU competition law voluntarily agree to compensate those who are harmed by their actions.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes, judicial review is available within the healthcare sector, against NHS trusts and regulators such as Monitor and the CQC.

Cases are dealt with by the Administrative Court, a specialist court within the Queen's Bench Division of the High Court of Justice.

A judicial review must be filed promptly, and in any event within three months of the decision or action that is subject to a challenge.

The current test for standing requires the applicant to have a 'sufficient interest' in the matter to which the application relates.

Decisions by public bodies can be challenged on a number of grounds, including where the body does not have the power to make the decision, the decision was irrational, or where the procedure was unfair or biased or in breach of the Human Rights Act 1998.

The court has the power to quash decisions which it finds to have been unlawful, and require them to be reconsidered.

40 Are there any legal protections for whistle-blowers?

Yes. The Public Interest Disclosure Act 1998 incorporated a number of provisions into the Employment Rights Act 1996 which were designed to protect whistle-blowers.

This leglisation protects whistle-blowers from detrimental treatment by their employer when they make a 'protected disclosure'. Any claims

Update and trends

The MHRA's stated priorities for 2014–2015 include making regulation more supportive of safe innovation, and introducing a combined reporting system for adverse incidents, medicines, medical devices, blood and counterfeit products. Further cooperation with UK, EU and global partners to prevent counterfeit and substandard products is also expected

Monitor's regulatory strategy for 2014–2017 includes focusing on improving monitoring powers, in particular through the risk assessment framework, promoting innovation through increased flexibility towards new business models adopted by existing foundation trusts, and increased cooperation with the NHS Providers, the trade body for foundation trusts.

The CQC's 2013–2016 strategy includes a focus on improving inspections, notably through the appointment of a chief director of Hospitals and Social Care and Support.

by whistle-blowers in respect of detrimental treatment must be brought within three months.

41 Does the country have a reward mechanism for whistle-blowers?

Currently the UK does not have a public incentivised whistle-blowing process.

In July 2014, the UK's financial regulators, the Financial Conduct Authority, and the Bank of England's Prudential Regulation Authority, recommended that parliament should not create a programme to reward whistle-blowers, saying that it would cost too much and would undermine companies' in-house whistle-blower programmes.

42 Are mechanisms allowing whistle-blowers to report infringements required?

In recent years, there has been a raft of measures introduced with a view to encouraging, or imposing a responsibility, on NHS staff to voice concerns.

Perhaps most importantly, there is a now statutory duty of candour, imposed under Regulation 20 of the HSCA (RA) 2014. This applies to registered persons when they are carrying out a regulated activity. The CQC can prosecute for a breach of parts 20(2)(a) and 20(2), and proceed with a prosecution without first seeking a warning notice.

In February 2015, the NHS published a report following the Review chaired by Sir Robert Francis QC, into whistleblowing in the NHS, entitled 'Freedom to Speak Up?'. This provided further recommendations for healthcare providers to adopt, in order to create a more open and honest culture in the NHS.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes – in recent years the level of cooperation with prosecutors and law enforcement authorities throughout the world has been on the increase.

A notable example was a 2014 criminal investigation by the SFO and Chinese authorities into GlaxoSmithKline for alleged bribery offences.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

There is no specific mechanism that triggers an investigation in the UK following an investigation in another jurisdiction, but clearly where the UK authorities become aware of possible breaches or offences in the UK (either through information received from a foreign agency, or by a request for assistance) they will be investigated in the normal way.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

There is no restriction on investigations being limited to UK companies or nationals, and the authorities in the UK are capable of, and regularly do, investigate the activities of foreign companies or nationals provided that the relevant conduct has taken place in the UK.

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The US federal government funds healthcare for the elderly (defined as individuals over the age of 65), the disabled and persons suffering from end-stage renal disease (regardless of age) through Medicare. The Medicare programme has four parts:

- Part A that governs hospital insurance benefits for the aged and disabled, including payments for hospital care, skilled nursing facility care and home health care;
- Part B that provides for supplemental medical insurance for medical and other health services, including physician services, outpatient hospital services, diagnostic services, laboratory services, durable medical equipment, ambulance services and outpatient physical therapy;
- Part C that provides for Part A and B coverage through a managed care programme (ie, managed care organisations (MCOs) or health maintenance organisations (HMOs)); and
- Part D that provides for payment for certain non-injectable drugs and biologics which patients take in an outpatient setting through prescription plans.

The federal government funds Medicare through the Medicare Trust fund, which consists of:

- the hospital insurance trust fund, which is funded by payroll taxes and premiums paid by some beneficiaries for Part A coverage; and
- the supplemental Medical insurance trust fund, which is funded by authorisations from US Congress and premiums and copayments paid by Medicare beneficiaries. In 2011, Medicare covered 48.7 million beneficiaries at the cost of $549.1 billion.

The US federal government also funds healthcare for members of the US military and dependents through the Tricare programme, and for veterans of the US military through a government agency called the Veteran's Administration.

The Center for Medicare and Medicaid Services (CMS) is responsible for the payment mechanisms established for paying for care under the four parts of the Medicare programme. Part A payments are made through a prospective payment system. For acute care inpatient settings (eg, hospitals), the CMS utilises diagnostic related groupings (DRGs) categories to set a payment amount for each episode of care provided to a Medicare beneficiary in that type of setting. For residents in skilled nursing facilities (SNFs), the CMS employs resource utilisation groups (RUGs) to set a payment amount based on the medically necessary therapy and other care a patient requires in that type of setting. The CMS calculates DRG and RUG payment levels based on an assessment of costs typically incurred in a specific episode of care to a patient, including any drugs or devices typically used in treating a patient in that particular DRG or RUG. A hospital or SNF will only receive the DRG or RUG amount, regardless of the actual cost incurred in delivering care to that specific patient. For example, the established price for the DRG for coronary artery bypass graft surgery includes the cost of all drugs and devices normally used in that surgery, which are not separately billable to Medicare.

The CMS generally pays for Part B care on a fee-for-service basis. To receive payment for care provided through Part B, the provider must submit a bill to Medicare describing the service provided based on established codes identifying a particular procedure performed on a beneficiary. For example, the CMS established the Health Care Common Procedure Coding System, which represents items, supplies and non-physician services that may be provided to a programme beneficiary. The American Medical Association established the Current Procedural Terminology Code, which sets forth codes for medical procedures and physician services. The Part B fee-for-service system also covers payments for drugs delivered to patients by physicians through injections (commonly referred to as 'J code' drugs) and devices delivered to patients in an outpatient setting.

Medicare Part C is an alternative to Parts A and B, and its overall insurance coverage is comparable. The CMS pays for Part C care through a managed care programme using a complex algorithm that provides a payment to the MCO or HMO based upon an assessment of the disease burden of each Medicare beneficiary. During each calendar year, each MCO must provide the CMS with information known as adjustment data, which the CMS uses to calculate the disease burden of the risk beneficiary, classify the patient by that disease burden and determine the payment owed to the MCO for covering the patient's health risk for that calendar year. The payments are made without regard to the actual cost of care incurred by the MCO in paying for the patient's care. The MCO will enter into contracts with physicians, hospitals, SNFs and other providers to pay those providers for the care provided to the MCO's Medicare beneficiaries in a calendar year from the payments it receives from the CMS. An MCO and its providers craft the agreements in order to share some of the risk of the patient's cost of healthcare.

In Part D, enrolled programme beneficiaries have a deductible payment and a copayment. The coverage is also subject to a coverage gap, commonly referred to as 'the doughnut hole,' in which the programme beneficiary is responsible for all costs. Each Part D plan must meet coverage criteria (eg, offer at least two drugs in each therapeutic category and class).

While there are exceptions, the CMS generally does not pay for unapproved use of medical devices and drugs.

Each state individually funds a Medicaid programme to cover healthcare for the indigent, and is jointly funded by the state's own source of revenue and the federal government. The criteria coverage and care provided varies by state. In 2011, Medicaid provided healthcare to approximately 31 million children living in low-income households, 11 million pregnant women with low income, 8.8 million low-income disabled individuals and 4.6 million low-income individuals over the age of 65.

If a US citizen does not receive healthcare through Medicare or Medicaid, he or she purchases healthcare through a health insurance programme obtained through an employer (which most employers subsidise at least in part), a healthcare insurance exchange or directly from a private insurer.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare for US citizens is delivered by privately run (ie, not run by the government) entities and practitioners, with the exception of healthcare for current and veteran members of the US military.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Medicare was established by the Social Security Amendments of 1965. Parts of the structure of and some of the payment mechanisms for Medicare, as well as some rules governing private insurance coverage, were changed by the Patient Protection and Affordable Care Act of 2010, and the Health Care and Education Reconciliation Act of 2010. The majority of laws regulating the delivery of and payment for healthcare are set forth in Title 42 of the United States Code, with corresponding regulations set forth in Title 42 of the US Code of Federal Regulations.

The US Congress established Medicaid in 1965 for states that elect to provide medical services to impoverished individuals. A state that wishes to establish such a programme must design a plan for coverage and, if approved by the CMS, the federal government will pay a percentage of the costs of the programme (typically around 50 per cent).

The CMS is the federal agency charged with managing Medicare and Medicaid. In managing Medicaid, the CMS requires drug companies to enter into an agreement with the Secretary of the Department of Health and Human Services governing the sale of their products to Medicaid beneficiaries, which requires the drug manufacturer to sell its products to Medicaid at a price equal to or lower than the best price for any other customer. Determining the best price is a complex matter, and the US Congress and the CMS have established extensive reporting requirements for manufacturers, including reporting average manufacturer prices and best prices. There is no similar best price requirement for medical devices.

The Federal Food, Drug and Cosmetic Act (FDCA), Title 21, United States Code section 301 et seq and the corresponding regulations at Title 21 of the Code of Federal Regulations govern the distribution of drugs, biologics and medical devices. (Although drugs and biologics are legally distinct from one another, the FDCA generally regulates them in the same manner. Accordingly, references in this chapter to drugs can also be read to include biologics.) Drugs may not be distributed for human use unless they have been approved by the Food and Drug Administration (FDA) through a new drug application (NDA) submitted by the company seeking approval to distribute the drug. In that application, the company must provide evidence that the drug is safe and efficacious for an intended use, as well as a proposed label and instructions for use.

The distribution of medical devices is controlled by amendments to the FDCA enacted in 1976, which classified devices into three classes: I, II and III. The FDA then identified certain types of devices as falling within each group. Class I devices are those devices that are not life sustaining and do not present a potential unreasonable risk of illness or injury. Class I devices are subject only to minimal or general controls by the FDA and may be distributed without prior FDA approval, such as a tongue depressor. Class II devices present greater but not life-threatening risk. Class II devices are subject to special controls and may not be distributed absent submission of a premarket notification document (a 510(k)), in which the manufacturer must demonstrate that the device is substantially equivalent to a device already on the market. If the FDA agrees, the manufacturer receives clearance to distribute the device. An example of a Class II device is a hypodermic needle. Class III devices present the greatest risk to the patient. Companies intending to distribute Class III devices must submit to the FDA a premarket approval application (PMA), demonstrating with evidence the safety and efficacy of the device for the intended use. An example of a class III device is a pacemaker or kidney dialysis machine.

Once a drug or device is approved for distribution, the company may only promote it for those uses approved by the FDA. While manufacturers of approved drugs and devices are subject to this distribution limitation, physicians can choose to use a drug or device off-label – a non-approved use – on any patient if the physician determines that such use is medically indicated and necessary for the treatment or diagnosis of a patient's disease or condition.

The Federal False Claims Act, Title 31, US Code sections 3729–3733, prohibits the submission or causing the submission of false claims to any federal government programme, including Medicare and Medicaid. Nearly all 50 US states have state False Claims Acts patterned after the Federal False Claims Act.

The federal anti-kickback statute (AKS), set forth at Title 42, US Code section 1320a-7b prohibits payment of remuneration to induce the referral of an item or service paid for by a federal health care programme. Federal healthcare programmes include Medicare, the Medicaid programmes run by each state, Tricare and the Federal Employees Health Benefit Program, which provides health insurance for employees of the federal government.

The Stark Law, set forth at Title 42, US Code section 1395nn prohibits compensation arrangements between physicians and referral sources. Most states have anti-kickback statutes patterned after the federal statute and some states have a state Stark Law counterpart.

The Health Insurance Portability and Accountability Act (HIPAA), passed in 1997, created criminal penalties, set forth at Title 42 US Code section 1320d-6 for the misuse of patient-identifying information. Regulations adopted in 2003 and set forth at 45 CFR Part 160 et seq set forth a series of complex rules governing the use of patient-identifying information, including the sharing of such information between healthcare providers and their business associates.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

There are two independent law enforcement systems that enforce laws and rules applicable to the delivery of healthcare in any location in the US: the federal law enforcement system run by the federal government and a state law enforcement system run individually by each state government.

The federal enforcement system includes prosecution agencies and agencies devoted to investigations and audits. The Department of Justice (DOJ) is the main prosecution agency and led by the United States Attorney General, who is appointed by the President and is the chief law enforcement officer for the US. In addition to the DOJ, there are 93 United States Attorneys, also appointed by the President, who are the chief federal law enforcement officers for geographic regions of the United States. There is only one US Attorney for each geographic region, and while that US Attorney reports to the US Attorney General, he or she has an independent law enforcement authority to enforce federal laws in that geographic region. Federal investigative agencies that are involved in the enforcement of healthcare laws and rules include the Federal Bureau of Investigation, the Office of Investigations for the Office of Inspector General for the Department of Health and Human Services, the Drug Enforcement Administration and the FDA's Office of Criminal Investigations.

The DOJ and federal enforcement agencies investigate allegations that providers and others submitted false claims for payment to the Medicare and Medicaid programmes. Prosecutors employed by the Department of Justice and each of the 93 United States Attorneys may investigate and prosecute violations of:

- the anti-kickback statute;
- the Stark Laws;
- the FDCA; and
- any federal crime set forth in United States Code Title 18 that may apply to the specific conduct at issue, which ranges from making a false statement to the CMS on a claim form seeking payment in violation of 18 United States Code section 1,001 (making a false statement to a federal agency on a matter within its jurisdiction) to knowingly executing a scheme to defraud a healthcare programme by distributing unapproved drugs or devices, in violation of 18 United States Code section 1,347 (healthcare fraud).

Federal prosecutors may pursue civil False Claims Act violations simultaneously with federal criminal prosecutions and investigations. A claim may be false for many reasons, and there have been federal civil and criminal investigations and prosecutions in the US concerning drugs and devices for the following conduct over the past decade:

- claims submitted for a drug or device that was not medically necessary for the treatment of the patient's disease or condition;
- claims submitted for a drug or device when a different drug or device was actually used;
- claims submitted for a drug or device following a payment to the healthcare professional, who made the medical judgment to use the drug or device, by the manufacturer of the drug or device to induce the use;
- claims submitted for a drug or device that were placed by a hospital, MCO or pharmaceutical benefits manager on a formulary because the manufacturer of the drug or device made a payment to that entity to secure formulary placement;
- claims submitted for a drug or device that was promoted for an off-label use;
- for the distribution of a drug or device that was not approved for human distribution;

- for the distribution of a drug or device for use outside the directions of use as set forth in the label;
- for the distribution of a drug or device following submission of an NDA, PMA or 510(k) that contained false statements regarding either the efficacy or safety of the device;
- for false best price and other price reporting for drugs sold to Medicaid beneficiaries;
- for claims submitted for drugs or devices where the cost of those drugs or devices had already been paid for through a DRG or a RUG;
- for claims submitted because a drug or device was advertised to the public for a use or indication not approved on its label; and
- for sharing patient identifying information, such as patient lists obtained from a physician reflecting the identify of patients prescribed a particular drug, for business marketing purposes without the permission of the patient.

For the state enforcement system, each state has an Attorney General, who is the chief law enforcement officer for that state. Most states have a consumer protection branch or division and a Medicaid Fraud Control Unit within the Attorney General's office that enforce violations of state statutes regarding the delivery of healthcare and the states' payment for healthcare. Each state has enforcement agencies that can assist in these investigations, although the 50 states are not equally active in enforcement of healthcare laws and rules, with many state enforcement officers and Attorneys General deferring to federal law enforcement. For example, when a federal investigation of a company involved in the distribution of a drug or device is nearing resolution through a civil settlement, a criminal plea or a global settlement involving both, one or more state enforcement agencies may seek to collect a judgment and payment based upon the same conduct, either as a part of the federal resolution, or as a separate standalone resolution.

5 What is the scope of their enforcement and regulatory responsibilities?

The federal authorities investigate and enforce violations of federal statutes, but do not have jurisdiction to investigate and enforce violations of state laws. Similarly, each state investigates and enforces violations of its own statutes and does not have the authority to enforce federal laws or the laws of any other state. Accordingly, a healthcare company engaged in business in all 50 states is subject to federal laws and enforcement authorities and the laws of each of the 50 states and each state's enforcement authorities.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The FDA is principally responsible for the approval and regulation of the distribution of drugs and medical devices, which is funded by the US Congress.

7 What is the scope of their enforcement and regulatory responsibilities?

The FDA has the authority to:

- classify drugs and medical devices;
- regulate the distribution of those drugs and devices for use by humans;
- regulate and inspect the plants, both domestic and foreign, in which those devices and drugs are manufactured;
- order the recall of drugs and devices that are no longer considered safe and efficacious for the intended use; and
- otherwise enforce the provisions of the FDCA.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Securities and Exchange Commission (SEC) has authority to oversee and regulate businesses whose stock is publicly traded (15 US Code section 78a et seq). The SEC may investigate allegations that management made false statements about a company's product, which caused the price of the stock to go up or down or withheld material information about a company's product to keep the company's stock price from tumbling.

Both federal prosecutors and the SEC may investigate drug and device companies for making payments to government officials in other countries, in violation of the US Foreign Corrupt Practices Act.

State prosecutors may pursue drug and device companies for violation of state laws by distribution of an unapproved drug or device, or by promotion of a drug or device for a use not approved by the FDA.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Yes. A company can be investigated by different agencies at the same time for federal and state criminal and civil violations. There are principles that can operate to bar successive prosecutions by different sovereigns for the same conduct, including the Department of Justice's Pettit policy; but practically, if different sovereigns (ie, the federal government and state governments involved) can show distinct and separate injuries, those principles will not act to bar successive and multiple investigations, criminal prosecutions or civil suits.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

In addition to securing approval to distribute a drug or device, a manufacturer must establish a quality manufacturing system and meet established 'current good manufacturing practices'. The regulations for drugs are set forth at 21 CFR sections 210 and 211 and the regulations for devices are set forth at 21 CFR section 820. The regulations for biologics are set forth at 21 CFR sections 600-680. Anyone who owns or operates an establishment engaged in the manufacture of any drug or device must register that establishment, which is subject to inspection, including surprise inspections (21 USC section 360(b) and (j); 21 USC section 374). Finally, manufacturers of drugs and devices are required by law to maintain records regarding the manufacture and distribution of the drug and device and required to file annual reports with the FDA, which reflect, among other things, any changes in the design or formula, or the manufacturing process, of the device or drug (21 CFR section 314.81(b)(2) (for drugs)). Medical device manufacturers must also file medical device reports whenever the manufacturer becomes aware of information that suggests that its device may have caused or contributed to a death or serious injury, or is aware of a malfunction that, if it were to recur, could cause death or a serious injury (21 CFR section 803.1). Pharmaceutical manufacturers are similarly required to file adverse event reports when they become aware of an adverse event involving their product (21 CFR section 310.305).

11 How long do investigations typically take from initiation to completion? How are investigations started?

There is no typical length of time for an investigation, although investigations can last as long as five or six years. The statute of limitations for most criminal matters is five years and for most civil matters is six years.

Many investigations are started by whistle-blowers filing a Federal False Claims Act suit or simply making an anonymous call to federal law enforcement authorities. Other investigations are commenced because of government audit results.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Until the government files criminal charges or commences a civil suit, the subject of an investigation does not have any right to government investigation files and materials, and cannot use either the federal or state court systems to help it collect evidence in its defence in advance of such filings.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes. If a company is distributing a product in the US, the FDA may conduct an investigation of any manufacturing process located in other countries, as long as that process is used for the manufacture of critical components of the drug or device.

14 Through what proceedings do agencies enforce the rules?

The type of proceeding depends on what matter the agency is seeking to enforce.

A federal agency cannot enforce federal criminal laws or statutes that provide a basis for civil liability. The court system governs those processes and only the DOJ can make the decision to seek criminal charges or to bring a civil suit against a drug or device company for submission of false claims to the federal government. The same is true for state crimes and civil suits – only the Attorney General (or lower-level prosecutors called District Attorneys) in each state may make that judgment.

The CMS has the authority to grant or revoke a licence to a provider or supplier to federal healthcare programmes. If the CMS revokes a licence, the provider or supplier may appeal that revocation to an administrative law judge. The ruling by the administrative law judge may thereafter be appealed by the provider, supplier or the CMS to federal court.

The Office of Inspector General (OIG) has the statutory authority to debar, or exclude, a provider or supplier from participation in federal healthcare programmes (42 USC section 1320a-7). There are numerous bases upon which the OIG may exclude a provider or supplier, some mandatory (ie, required by the statute) and others permissive (ie, the OIG may choose whether to exclude). The OIG also has the authority to impose civil monetary penalties for certain conduct. An exclusion decision and a decision to impose CMPs may be appealed to federal court.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

In a criminal case, the government may seek a criminal fine, as well as restitution for any losses and seizure of the instrumentalities used in the criminal offence. If a provider is convicted of a federal healthcare programme offence, the provider will be automatically excluded for a minimum of five years.

In a civil Federal False Claims Act case, the government may seek a fine of three times the loss, plus restitution, and a penalty of between $5,000 and $10,000 for each false claim, in addition to restitution. Similar penalties may be sought by states for violation of a state False Claims Act.

The OIG may seek exclusion of a provider on numerous grounds. The exclusion is mandatory if the provider or supplier was convicted of a federal healthcare programme related offence, for a crime of patient abuse, for a felony related to healthcare fraud or for a crime related to controlled substances (42 USC section 1320a-7(a)). The exclusion is permissive for 16 different categories of conduct, including:

- a misdemeanour conviction related to healthcare fraud;
- a non-healthcare fraud felony;
- conviction relating to the obstruction of an audit or investigation;
- conviction for misdemeanour offences related to controlled substances;
- the provider having its licence to provide healthcare revoked or suspended; or
- the provider being excluded from other federal programmes on grounds of professional competence, performance or financial integrity or for submission of charges to Medicare or Medicaid substantially in excess of the charges made to others or of the providers costs (42 USC section 1320a-7(b)).

Additionally, the FDA has the authority to debar or disqualify individuals or companies convicted of certain violations of the FDCA. Once debarred, the person may no longer work for an FDA-regulated company, and a company may no longer submit drug applications to the FDA.

16 Can the authorities pursue actions against employees as well as the company itself?

Employees may be prosecuted for federal and state criminal violations that they personally committed or as responsible corporate officers in the case of the FDCA. In criminal actions against employees, the government has the burden of proving beyond a reasonable doubt that the employee had the criminal intent specified in the charged criminal statute.

In addition, employees may be sued for violation of the federal and state False Claims Acts. When such civil suits are brought, the government has the burden of proving by a preponderance that the employee caused the company to file a false claim, and that the employee knew that the claim was false when filed, or was reckless as to the falsity of the claim.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The available defences will vary depending on the conduct under investigation and the applicable criminal and civil statutes. Such defences can include:

- that the service or item was provided or billed precisely as ordered by the physician and was medically necessary and reasonable for the treatment and diagnosis of the patient;
- that the drug or device was approved for the use for which it was promoted;
- that the company made payments to a healthcare professional to compensate him or her for services rendered to the company (eg, the physician provided consulting services and the payment represented a fair market value payment for those services);
- that the government, in its interactions with the company or with other companies similarly situated, had approved or condoned the conduct in question;
- that the rules at issue were confusing, vague or ambiguous and did not fairly put the defendant on notice that its conduct was criminal; and
- that the defendant acted in good faith upon reliance of statements made by the government that the defendant believed approved the conduct, or in reasonable reliance upon advice of counsel.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should establish a strong culture of legal compliance, which is best achieved by active messaging and participation by company leadership. Depending on the size of the company and the scope of its operations, the company may establish a corporate compliance department. When a company becomes aware of potentially non-compliant conduct, it should take immediate steps to determine whether any employees may have violated federal or state laws or regulations and impose appropriate sanctions on any offending employees.

Once a company is aware of a government investigation, it should immediately take steps to understand the scope of the investigation and conduct an internal investigation to determine potential exposure. If the company discovers improper or illegal conduct by an employee during the internal investigation, the company should take steps to correct the conduct and appropriately sanction the employee without waiting for government action.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Recent enforcement actions concerning drug and device companies in 2015 include the following:

Company	Allegation	Settlement payment
AstraZeneca LP	Knowingly underpaying rebates owed pursuant to the Medicaid Drug Rebate Program	$46.5 million
AstraZeneca LP	Payment of remuneration to Medco Health Solutions in exchange for identifying AstraZeneca's drug as the 'sole and exclusive' proton pump inhibitor on certain formularies	$7.9 million
Cephalon Inc	Knowingly underpaying rebates owed pursuant to the Medicaid Drug Rebate Program	$7.5 million
Daiichi Sankyo Inc	Payment of remuneration to physicians in the form of speaker fees as part of company's Physician Organization and Discussion programmes, in violation of the anti-kickback statute	$39 million
ev3 Inc (formerly known as Fox Hollow Technologies Inc)	Causing hospitals to submit claims for unnecessary patient admissions related to atherectomy procedures	$1.25 million

Company	Allegation	Settlement payment
Medco Health Solutions Inc	Soliciting remuneration from AstraZeneca in exchange for identifying its drug as the 'sole and exclusive' proton pump inhibitor on certain formularies	$7.9 million
Medtronic Inc	Knowingly causing physicians to bill for non-reimbursable investigational procedures	$2.8 million
Medtronic Inc	Making false statements regarding the country of origin of medical devices sold in the United States	$4.41 million
PharMerica Corporation	Violating the Controlled Substances Act by dispensing drugs without a valid prescription and the False Claims Act by submitting false claims to Medicare for these improperly dispensed drugs	$31.5 million

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

For pharmaceutical products, Pharmaceutical Researchers and Manufacturers of America (PhRMA) represents biopharmaceutical and biotechnology companies. PhRMA has a Code on Interactions with Health Care Professionals, which provides guidance on appropriate and ethical relationships with healthcare professionals. While the Code is voluntary and PhRMA does not actively police compliance with the Code, PhRMA asks that all member companies adopt procedures designed to assure adherence to the Code and publicly identifies those members who have agreed to adhere to the Code.

For Medical Devices, Advamed is a trade association with more than 300 members worldwide. Its members produce approximately 90 per cent of the healthcare technology sold in the United States. Advamed has a Code of Ethics governing interaction with healthcare professionals and a code certification programme in which members can certify adoption of the Advamed Code. While Advamed conducts seminars featuring good corporate governance and compliance, Advamed does not actively police its members' conduct or adherence to its Code of Ethics.

For biologics, the Biotechnology Industry Organization (Bio) is a trade association that provides advocacy, business development and communications services for more than 1,000 members around the world.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

The AKS, 42 US Code section 1320a-7b, prohibits, among other things, knowingly and wilfully offering or paying any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, to any person, including healthcare professionals, to induce that person to purchase or order, or to recommend the purchasing or ordering of any good, service or item that may be paid for in whole or in part by a federal healthcare programme. The AKS is a criminal prohibition and carries a punishment of up to five years in prison and fines of $250,000 per violation.

The AKS has eight statutory exceptions and 24 regulatory safe harbours, each with specific requirements, which can insulate or protect conduct from potential criminal prosecution (or from providing the basis for a Federal False Claims Act suit) if all requirements are satisfied. Those exceptions and safe harbours include certain price reductions and discounts; personal services and management contracts; investment interests; payments to a group purchasing agent; payment of bonuses to employees; space and equipment rentals; warranties, ambulance restocking plans; and electronic health records.

The Stark Self-Referral Law, 42 US Code section 1395nn, prohibits physicians from making referrals to any entity with whom that physician has a financial relationship, including ownership or investment interests or any kind of compensation arrangement, where the referred item may be paid for by Medicare or Medicaid. The Stark Law also prohibits that entity from billing for the service referred by physicians with whom it has a financial relationship. The Stark Law is a civil statute and has no criminal penalties. Like the AKS, the Stark Law, has 16 statutory and 30 regulatory safe harbours, covering matters similar to those listed above for the AKS.

22 How are the rules enforced?

The DOJ and the 93 US Attorneys enforce the AKS and the Stark Law, along with assistance from the FBI and the OIG. Most investigations are commenced by the filing of a *qui tam* or whistle-blower suit under the Federal False Claims Act, which typically allege that an individual or an entity, including a drug or device manufacturer, submitted or caused the submission of a false claim to a federal healthcare programme because that manufacturer paid a kickback to a physician, in violation of the AKS, or had a prohibited compensation arrangement with that physician, in violation of the Stark Law, or promoted the product for a use not approved by the FDA, in violation of the FDCA.

In criminal investigations, attorneys employed by the DOJ and the US Attorneys may use the following tools, among others:

- when probable cause presents, they may seek permission from a federal court to conduct a search of a premise for evidence of a crime;
- they may issue grand jury subpoenas to entities for the production of documents and other items, and they may use those subpoenas to require individuals to appear and testify under oath before a grand jury;
- they may issue DOJ subpoenas (commonly called HIPAA subpoenas) to require entities and individuals to produce documents and other items;
- they may seek permission from a court to conduct a wire interception and record electronic communications;
- they may ask an individual to record a conversation with another person;
- they may seek a court to issue an order of immunity to compel an individual to testify after that individual has declined to testify on the basis of the fifth amendment privilege against self-incrimination; and
- they may ask a grand jury to return an indictment charging individuals and entities with one or more federal crimes.

If an indictment is returned by the grand jury, the individuals or entities charged will be arraigned in federal court and individuals will be evaluated for release on bail, depending on their risk of flight and danger to the community. If the individuals or entities charged plead not guilty, they will be entitled to discovery of the evidence the government has collected and intends to use against them, and they will be entitled to any exculpatory or significant impeachment evidence in the government's possession. They will also be entitled to have the charges tried by a jury, and in that trial the government bears the burden of proving the charges by proof that is beyond a reasonable doubt. If the individuals or entities are convicted after a trial, or if they choose to plead guilty, they will be entitled to a sentencing hearing before a federal judge, who will impose a sentence within statutory limits.

In civil investigations, attorneys employed by the DOJ and the US Attorneys may use the following tools, among other things: they may issue Civil Investigative Demands requiring individuals and entities to produce documents and other items, to answer specific questions (called interrogatories) and to appear and answer questions under oath. If the government chooses to sue, it may file suit in federal court. Any action filed in federal court is subject to the Federal Rules of Civil Procedure, which allow for reciprocal and broad discovery. Any individuals or entities that are sued may seek discovery of the government's evidence, take depositions of government employees and third parties, and provide questions to the government seeking its responses. If the matter is not settled, the suit will be tried by a jury if either the government or the defendant requests a trial by jury. In such a trial, the government will have the burden of proving its allegations by a preponderance.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

Drug manufacturers that sell drugs that require a prescription to be dispensed and medical device manufacturers that sell devices that require premarket approval by or notification to the FDA must report payments in excess of $10 to any physician and teaching hospital annually to the CMS. The reporting includes the amount, date and form of the payment, the recipient, a description of the nature of the payment, and whether the payment was related to marketing, education or research specific to a drug

or medical device. The data is reported publicly at www.cms.gov/openpayments/index.html.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

In addition to the FDCA, there are licensing authorities and regulatory bodies in each of the 50 states that govern the delivery of healthcare by physicians, hospitals, nursing homes, nurses, physician therapists and others. These rules are principally regulatory and provide for:

- entry requirements that the individual or entity must satisfy in order to be a provider of healthcare (eg, education requirements to get and retain a medical licence); and
- provision requirements specifying the manner of delivery of care (eg, minimum number of hours of certain types of physician therapy that an SNF must provide for certain types of patients).

Typically, there are few federal investigations that focus on the manner of delivery of healthcare. Most federal investigations focus on whether payments were made by a drug company or device manufacturer to induce a physician or other healthcare provider to use that company's product, whether a provider billed for a service that was not provided or not medically necessary, and whether a drug or device company failed to follow one of the many rules governing the approval of the drug or device or its marketing and sales to healthcare professionals.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Investigations can last as long as six years and typically take at least three years from initiation to completion. Most investigations are initiated by whistle-blowers.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

The subject of an investigation has no rights of access prior to the filing of criminal charges or the initiation of civil suit against that subject.

27 Through what proceedings do agencies enforce the rules?

Agencies do not have the authority to enforce criminal laws; their role is exclusively investigative. Various of the agencies have the authority to pursue certain civil remedies. Thus, the FDA can seek to enforce the FDCA through consent decrees and other civil actions. The OIG can seek to debar or exclude an individual or entity from being a provider or supplier to federal healthcare programmes, and the OIG may seek to impose civil monetary penalties on individuals or entities. None of these agencies can file suit to seek monetary damages for false claims submitted to the government; only the DOJ or a US Attorney may authorise such an action.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

See question 15.

29 What defences and appeals are available to healthcare providers in an enforcement action?

See question 17.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 18.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

We are not aware of any federal enforcement actions focused on the delivery of healthcare.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Self -governing bodies for healthcare professionals include the American Medical Association (for physicians), the American Nurses Association, the American Hospital Association and the American Health Care Association (for long-term and post-acute care providers). In addition, there are similar organisations in almost all 50 states (eg, there is a Massachusetts Medical Society for physicians, the Massachusetts Senior Care Association for nursing facilities, the Massachusetts Nursing Association for nurses and the American Physical Therapy Association of Massachusetts for licensed physical therapists).

For the most part, these organisations do not police members' conduct beyond providing or establishing broad voluntary codes of conduct.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Until the Affordable Care Act in 2010, the government typically did not include remedies for poor performance in contracts. The standard government claim form used by providers, the HCFA 1500 form, requires a provider to certify that the services provided to the patient and included on the claim form were 'medically indicated and necessary to the health' of the patient. In addition to this express certification, most federal courts have recognised an implied certification requirement – any provider who submits a claim for reimbursement for care provided to a Medicare or Medicaid beneficiary impliedly certifies that the claim for reimbursement implies compliance with all governing federal laws as a precondition to payment. See, for example, *United States ex rel Mikes v Straus* (2d Cir 2001). If a physician submits a claim to Medicare Part B for a J Code drug injected into a programme beneficiary, that claim impliedly certifies that the physician complied with all applicable federal laws, including the AKS. If the physician has, however, taken remuneration from the drug company to induce his or her prescription of that drug, he or she has violated the AKS and the implied certification on the claim form is false. As a result, the physician may be sued under the Federal False Claims Act for submission of a false claim, and be subject to treble damages and payment of a penalty. The drug company that paid the remuneration in violation of the AKS may also be liable for having caused the physician to file the false claim.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

The Federal False Claims Act allows any citizen to file suit on behalf of the United States alleging that another person or entity has submitted a false claim to the federal government. These suits are commonly referred to as *qui tams*, false claims suits or whistle-blower suits. In such suits, the private citizen may allege that a claim was false because of the payment of a kickback in violation of the AKS, the existence of a prohibited compensation arrangement in violation of the Stark Law, or that the claim was false for another reason (eg, the claim sought payment for 'drug X' when in fact a cheaper drug was delivered to the patient). Once the suit is filed, under the statute, the government has an opportunity to determine whether to intervene in, or take over, the private suit. If the government intervenes and there is a recovery, the private citizen is entitled to between 15 and 25 per cent of the recovery. If the government does not intervene, the private citizen may still pursue it, and if there is a recovery, the private citizen's share can be as high as 30 per cent.

In addition to Federal False Claims Act suits, private insurance companies can also bring suit for violation of agreements with drug and device companies where the basis for the Federal False Claims Act litigation provides a basis for suing for breach of agreement.

Private citizens may also file suit against a provider for injuries they allegedly suffered because of the provider's negligence or against a drug or device manufacturer because of injuries they allegedly suffered because of use of the drug or device.

35 What is the framework for claims of clinical negligence against healthcare providers?

The standard for negligence against a healthcare provider is governed by state law in each of the 50 states and may vary from state to state. In general, the standard of care that a healthcare provider must meet is the level of care, skill and treatment that under the circumstances would be recognised as acceptable and appropriate by a reasonably prudent

Update and trends

While there has been a downward trend in financial recoveries in healthcare cases over the past four years, we expect that enforcement will remain rigorous. The level of enforcement over the past decade has triggered a substantial increase in industry efforts to assure compliance with the various federal and state laws, especially by larger organisations. As enforcement efforts are largely driven by leads obtained from whistle-blowers, we expect that enforcement efforts over the next several years will focus on smaller companies and on new entrants into the marketplace, especially foreign companies that have determined to enter the US marketplace, either through acquisition or by establishing a presence in the US and seeking regulatory approval to distribute a drug or device already approved in one or more foreign markets.

similar healthcare provider. Some states apply a locality rule, looking at the standard of care in the locality where the care at issue was provided. The same rules of negligence generally apply to physicians in private practice and to physicians who are employed by a public entity (eg, a Veteran's Administration hospital).

Negligence standards and violations of the standard of care are rarely, if ever, relevant in federal or state law enforcement proceedings.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Whistle-blowers can allege and have alleged that a drug or device company caused the submission of false claims to federal healthcare programmes in the following circumstances that involve regulatory issues:

- The drug or device company made a false statement in the documents submitted to the FDA to secure permission to distribute the drug or device for human use. The purchaser or user of the drug or device may file a Federal False Claims Act case and can allege that every claim submitted for the drug or device was false because the company lied to the FDA when securing approval for the drug or device.
- The drug or device company failed to get permission to distribute the drug or device for the use for which it marketed that drug or device. In this circumstance, which is commonly referred to as 'off-label promotion', the purchaser or user may file a Federal False Claims Act case and can allege that the claims submitted for payment for the drug or device were false because the company did not comply with the rules governing distribution of the drug or device.
- The drug company failed to report its best price to Medicaid and overcharged Medicaid for the drug. The purchaser or user, who could be a Medicaid beneficiary, would allege that the drug company made a false statement in its best price reporting and caused the submission of false claims for that drug.

37 Are there any compensation schemes in place?

Not applicable.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Class actions are not relevant in federal or state law enforcement proceedings and are typically pursued by lawyers for plaintiffs for injuries allegedly caused by a drug or device. If a company has concealed a safety problem with a drug or a device from the FDA, that concealment or related false statements can form the basis for a federal criminal prosecution for making a false statement to the FDA and for a Federal False Claims Act for drugs and devices sold to federal healthcare programmes. Such prosecutions can trigger follow-on class action litigation.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Not applicable.

40 Are there any legal protections for whistle-blowers?

Yes, state and federal law prohibits retaliation against a whistle-blower.

41 Does the country have a reward mechanism for whistle-blowers?

Yes. See question 34.

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42 Are mechanisms allowing whistle-blowers to report infringements required?

Companies are not required by law to have mechanisms in place to allow for reporting by whistle-blowers. Nevertheless, many companies establish hotlines or other mechanisms to allow for anonymous reporting by whistle-blowers. Because of the financial incentive created by the Federal False Claims Act to file suit, many whistle-blowers who file suit never complain about the activity to company management prior to filing suit.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. DOJ attorneys routinely cooperate with their counterparts in foreign countries, especially regarding enforcement of the Foreign Corrupt Practices Act.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

On occasion, foreign investigations may identify a pattern of payment of bribes or kickbacks to foreign physicians that can trigger an investigation by the DOJ to determine whether similar patterns of payments were made to physicians in the US. Such cross-border case-pollination is very rare.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Insofar as the healthcare laws described above are concerned, foreign companies and nationals will be treated just like US citizens, subject to the same rules, reporting requirements and civil and criminal remedies.

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