Healthcare Enforcement & Litigation

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

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GETTING THE DEAL THROUGH

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Global Overview

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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.

Germany

Anke C Sessler and Max D Stein
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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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