Healthcare Enforcement & Litigation

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

2017

GETTING THE DEAL THROUGH

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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, required to have health insurance. Approximately 90 per cent of the population is insured by one of the country's several public health insurance companies. In these cases, the insurer pays the healthcare provider directly for costs that include medical treatment, drugs and medical devices. Public health insurance companies are financed by contributions from employers and employees; the contribution amount depends on the employee's income. Persons who are self-employed or who earn in excess of around €56,000 per year can opt for private health insurance. They pay their medical bills themselves and submit them to the insurance company, which then reimburses them. The premium that a private insurance holder pays depends on the contractual agreement and is generally based on the individual's age and overall health. Private health insurance may also be used to complement public health insurance coverage.

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 both in private practice and employed in hospitals. In 2013, of the country's 1,996 hospitals, 596 were state-owned, 706 were private non-profits 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 federal and state laws and regulations that govern the healthcare sector. 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, and 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 must 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-governing group 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.

The prosecutor's office is responsible for criminal offences committed in the context of the delivery of healthcare, such as malpractice amounting to physical assault or fraud. The territorial jurisdictions of prosecutor's offices, which are organised at the state and regional levels, correspond with those 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 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-Institut (PEI) (the Federal Agency for Sera and Vaccines) is competent. The PEI is responsible for regulating sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, tissues, allergens, advanced therapy medicinal products, xenogeneic medicinal products and blood components manufactured using genetic engineering. Its main source of revenue is fees charged for acts, such as authorising the marketing of pharmaceutical products and batch testing. Additional revenue is generated by mandates from the European Medicines Agency (EMA) and other healthcare institutions. If pharmaceutical products are sold not only in Germany but also in other EU member states, the EMA is generally responsible for their scientific evaluation.

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

The regulatory responsibilities of the PEI comprise authorising the marketing of medicinal products, providing scientific advice on the development of medicinal products, approving clinical trials, experimental product testing and the official testing and release of batches of products as well as the assessment of adverse reactions to such products. The BfArM's focus is on the authorisation of proprietary medicinal products according to the provisions of the AMG, during which time the products' effectiveness and pharmaceutical quality are assessed. It also 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 that may have jurisdiction over healthcare-related cases include 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?

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

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 broad monitoring powers. Pursuant to subsection 4, the persons in charge of ensuring compliance with the rules on drugs and medical devices 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 activities related to processing medicinal products;
- prepare or request transcripts or photocopies of documents or printouts, or copies of data storage media on which documents are stored, insofar as personal data from patients are not concerned;
- demand from natural and legal persons and associations without legal capacity all necessary information, in particular on company operations; and
- issue provisional orders on the closing of a company or facility, as long as the closure is deemed necessary to avoid 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 those in power 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. Necessary measures include 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 competent authority. The inspections can also be carried out at the request of another EU member state, the European Commission or the EMA. Enterprises and facilities requiring manufacture or import authorisation are to be inspected every two years, according to section 64(3a) AMG.

The duration of investigations depends on the measures taken and whether provisional orders are issued.

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

For pharmaceuticals, pursuant to section 64(3d) AMG, the competent authority is obliged to draft a report on the inspection and inform the enterprises, facilities or persons under scrutiny of the draft report's contents. The entity under investigation must be granted an opportunity to comment on the draft before it is completed. In criminal proceedings, in principle only, the incriminated individual's lawyer is entitled to inspect the files and materials held by the prosecutor's office (section 147 of the German Code of Criminal Procedure (StPO)). In practice, a defence lawyer's request to inspect all or some of the files during an ongoing investigation may be denied if his or her knowledge of the contents may endanger the investigation. The accused does not have a similar right to inspect the files. In some cases, even though there is no concept of corporate criminal liability in Germany, 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?

Such extraterritorial investigations may be 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), authorisation of the import requires only that the manufacturer prove it is entitled to manufacture medicinal products in accordance with the legal regulations of the country of manufacture (cf section 22(5) AMG).

For products from other countries, import is only possible without inspection where certificates of the proper manufacturing process are mutually recognised by Germany and the manufacturing company. Such mutual recognition is in place for all member states of the Pharmaceutical Inspection Convention and countries that the EU has signed mutual recognition agreements with, notably Japan and the United States. For all other states, the necessary certificate may only be obtained after a competent authority from Germany or the EU or EEA has conducted inspections in the country of manufacture and deemed that the manufacturing process meets the requirements of section 72a(1) sentence 2 AMG.

14 Through what proceedings do agencies enforce the rules?

Pursuant to section 69 AMG (and, respectively, section 28 MPG), the competent authorities may issue the necessary directives to rectify any violations that have been identified and 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. In the event that a company intends to quash such directive, this company will 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 may issue the necessary directives to rectify any identified offences and prevent offences in the future. Under certain conditions, they may prohibit the marketing of medicinal products or active substances, order their recall from the market and seize them (sections 22 b, 27 and 28 MPG, respectively).

In criminal proceedings of individuals, in particular in corruption cases (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 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, an employee's behaviour may become criminally relevant under section 95 et seq AMG (and, respectively, section 40 et seq MPG). Where individual guilt is suspected, the prosecutor's office will initiate an investigation 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, that is, a formal order or decision of an authority, directly with the acting authority, pursuant 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 per 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 crucial that the healthcare provider immediately initiates its own investigation into the matter. This will allow it to better assess the risk it faces and also 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 and advocate for the least burdensome measure possible. In most cases, there is room for negotiation, provided that the alleged violations are not too grave.

For incriminated individuals and companies that are involved in criminal proceedings because a fine may be levied against them (see question 12), correspondence with the law firm in charge of the internal investigation is privileged and thus not subject to seizure (section 97 StPO). By contrast, any correspondence within the organisation with in-house lawyers is generally not privileged. In criminal proceedings, it is also advisable for a company to ensure that all charged employees are represented by individual 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 perpetually 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 typically 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 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 55 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 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?

Doctors must maintain their independence, according to section 30 et seq of the Model Professional Code of Conduct (MBO-Ä). In particular, they must not accept gifts or other benefits if this could create the impression that the doctor's independence is compromised. If found to be acting against this principle, the authorities may revoke the doctor's medical licence (cf sections 5(2), 3(1) sentence 1 No. 2 of the Federal Medical Practitioner's Act).

According to section 331(1) of the German Criminal Code (StGB), a public official or person entrusted with special public service functions who demands, allows himself or herself to be promised a benefit or accepts one for himself or herself or for a third person in return for acting in a certain way in his or her official capacity may face up to three years' imprisonment or a financial penalty. The same applies for a person who offers, promises or grants such benefit. Doctors who work at state-owned hospitals 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. Until recently, owing to a legislative gap, doctors who work at privately owned hospitals or in private practice (even if working under contract with public health insurance companies) could not be criminally charged for the same actions. However, in May 2016, a law against corruption in the public health sector was passed, which, inter alia, introduced two new provisions to the German Criminal Code, sections 229a and 229b StGB. These provisions specifically deal with corruption in the public health sector and apply to all members of medical professions, including doctors, pharmacists, psychotherapists, physiotherapists and midwives. As per section 229a StGB, a member of any medical profession may face up to three years' imprisonment or a financial penalty if he or she demands, accepts a promise for or accepts a benefit for himself or herself or for a third person in return for, for example, prescribing specific pharmaceutical products or medical devices or for ordering such products. Correspondingly, section 229b StGB sets out the same penalty for persons offering benefits in return for such actions.

22 How are the rules enforced?

If found to be in breach of MBO-Ä provisions, the authorities can impose mandatory administrative deeds against a doctor. In cases 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 that imposes strict duties on its members to report different kinds of financial relationships between pharmaceutical companies and healthcare providers. From 2015, pharmaceutical companies have been under an obligation to document relevant information, and in July 2016 they, for the first time, published such information on their websites.

Regulation of healthcare delivery

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

The authorities that monitor hospitals typically have the power to ask for certain pieces of information and 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, which 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 has wide-ranging powers – for instance, 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 typically individual doctors, not the hospital itself, 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. For an administrative body, the first step in a new investigation will usually be a request for information from the doctor or hospital, while the prosecutor's office is more likely to covertly investigate before attempting 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 for a legitimate interest.

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 for the hospitals or doctors against which they are directed. These proceedings are neither criminal nor civil. In Germany, the relationship between an individual, whether a 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 file indictments in court.

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

A wide range of sanctions and enforcement measures is available. 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 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 deeds. If the authority fails to amend or revoke the administrative deeds, the affected healthcare provider can turn to the competent administrative court to have the deed quashed. Informally, communication by various means with the respective authorities is possible, for instance to avoid the issuance of an administrative deed by voluntarily complying with requests by the authorities.

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 recent years, many directors of large hospital groups and doctors have been investigated for fraud, namely for submitting false claims to insurers or patients. Sanctions have included financial penalties and prison sentences (mostly suspended, at least for first-time offenders) as well as the loss of medical licences.

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 they are practising in. Each chamber has a set of rules concerning doctors' conduct. 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 in the criminal, civil (if the bereaved or his or her insurance company claims damages) and medical courts. However, civil and medical court proceedings are often suspended until the criminal proceedings have been completed.

Update and trends

Of particular interest will be the enforcement of the newly established provisions of the German Criminal Code dealing with corruption in the public health sector.

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 with public health insurance. Such contracts can be terminated by the public health insurance companies if they find that the hospital can no longer ensure its contractual obligations of 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 legislation if they themselves have been negatively affected by it – in other words, if they have a personal interest in the enforcement. In general, these are cases involving 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 an individual doctor, or, where the doctor has practised in a hospital, also against the hospital. Liability can be based on both a breach of the relevant 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 must 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 to that rule in order to level the playing field, taking into consideration that the patient generally is in a weaker position in terms of ability to provide evidence. There is no expectation that the courts will rule in favour of hospitals, even if they are state-owned. The damages to be awarded primarily serve to cover all costs incurred because of the purported malpractice, namely all costs for treatments, care and rehabilitation. In addition, a patient may demand a reasonable monetary compensation – 'money for pain' – for any damage that is not a pecuniary loss. The amount 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 warning labels or manuals are 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 the 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 bring claims jointly only under strict prerequisites that are usually not given in cases related to drugs, medical devices and the provision of care. In addition, health insurance companies typically assume any costs for treatment, care and rehabilitation. 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 (ie, the insurance company can then enforce these claims against the doctor or the hospital). 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.

40 Are there any legal protections for whistleblowers?

There is no specific legislation for the protection of whistleblowers in place, although this has been the subject of ongoing debate for the past few years. However, whistleblowers are generally understood to be protected from any discriminatory or retaliatory action by the employer through existing labour law.

41 Does the country have a reward mechanism for whistleblowers?

No reward mechanism exists. In the case of a criminal proceeding where the whistleblower 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 for that individual.

42 Are mechanisms allowing whistleblowers to report infringements required?

There are no legal requirements for the implementation of such mechanisms under the applicable laws. However, there is a legal obligation to implement a critical incident reporting system whereby employees can log 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, the cooperation 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 an investigation 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) is applied to all acts committed in Germany, whether by German or foreign nationals. Such criminal investigations can only be directed at foreign individuals, not against companies, as there is no concept of corporate criminal liability.

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