Healthcare Enforcement & Litigation

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

2018

GETTING THE DEAL THROUGH

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CONTENTS

Austria

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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.

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, which is why more than two-thirds of Austria's healthcare system is funded through social insurance contributions and general tax revenue.

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

According to data from 2016:

- those who are insured contribute approximately 81.9 per cent (€14.624 billion) to the national health insurance;
- earnings from prescription fees for medicines (which currently amounts to €5.85 per pack of pharmaceutical products) contribute 2.2 per cent (€403 million);
- compensation payments by the government contribute 10.2 per cent (€1.825 billion);
- capital of the equalisation fund of the health insurance agencies contributes 1.7 per cent (€299 million);
- yield on assets contributes 0.2 per cent (€33 million); and
- another 3.8 per cent of miscellaneous income (€679 million) contributes to the national health insurance agencies' total annual income of €17.863 billion.

The insured are entitled to receive healthcare covering medical care, medicines and medical devices. Healthcare needs to be 'sufficient, appropriate and non-excessive'. Simply, 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 and Public Servants must pay a treatment contribution of 10 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 that 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.

Significant changes are emerging, especially concerning self-employed physicians. Together with the Healthcare Reform Implementation Act 2017, the Primary Healthcare Act 2017 is expected to become effective soon. The delivery of healthcare is anticipated to change from individual self-employed physicians to larger primary healthcare units comprising a multitude of physicians or other healthcare providers (see 'Update and trends').

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, in effect, hospital institutions, but their services are important for primary healthcare 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 healthcare is delivered in public hospitals, which are mainly operated by the local state. However, private hospitals are also available. Persons insured with a social healthcare 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 medical devices and in vitro diagnostics deals with instruments, equipment and other devices that are designed for certain medical purposes. The Medical Practitioners Act contains provisions on the medical profession, whereas the Pharmacy Act covers pharmaceutical-related issues. The Hospitals Act provides the framework for the operation of hospitals and sanatoriums at a national level, whereas the regional laws of the nine states provide for the details of these institutions operated within their territory.

The General Social Security Act governs the requirements of the following:

- healthcare entitlement;
- the contributions of the insured;
- social insurance benefits; and
- partial organisation of the healthcare infrastructure.

The Public Officers Health and Accident Insurance Act contains special provisions for public-sector workers; 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 Healthcare (BASG) and the Austrian Medicines and Medical Devices Agency (AGES MEA)

supervise the medicinal market and enforce the applicable laws to medicines and medical devices.

In respect of health insurance benefits, the primarily competent agencies are the following health insurance institutions:

- nine regional health insurance institutions (one in each state);
- 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 and overall-organisational function. It negotiates agreements with the associations of healthcare providers and is considerably involved in the setting of reimbursement prices of pharmaceutical products.

The Austrian Chamber of Physicians (see questions 20 and 32) is responsible for the education of physicians and quality management in respect of medical professionalism. Austrian dentists are organised in the separate Austrian 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 state are in charge of sanitary surveillance (eg, hygiene, quality assurance in hospitals, documentation, organisation and technical security). The state governments are responsible for the economic governance of hospitals within their territory. The economic financial management of these public institutions is reviewed by the Court of Auditors.

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 Austrian 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. For certain outpatient clinics, the notification of the surveillance report by the ÖQMed or comparable quality assurance associations suffices. 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 in charge of the regulation of pharmaceutical products. It is an agency subordinate to the Ministry of Health. AGES MEA is a sub-department of the Austrian Agency for Health and Food Safety, a national government agency, 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 the following:

- 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 enforcing the following:

- the Act on Medicinal Products;
- the Medicinal Products Import Act;
- the Blood Safety Act;
- the Medical Devices Act;
- the Compulsory Prescription Act; and
- the Human Tissue Safety Act.

The activities of the BASG comprise the following:

- admission of clinical studies;
- 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 high-street pharmacies. Staff and equipment for these tasks is provided to the BASG by AGES MEA, which acts on behalf 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; each one of whom has a 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 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?

Only one particular agency is responsible for an investigation of the same legal subject. Indeed, facts may relate to a variety of legal issues, so that parallel competences in respect of the same facts are possible. For example, if two pharmaceutical companies agree on an allocation of customers, the BWB 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 following:

- the AMG;
- the Ordinance on Medicinal Production Sites;
- the Medicinal Products Import Act;
- the Addictive Drug Act;
- 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 of the 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 of the 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. The BASG distinguishes between different fields of investigation as follows:

- good laboratory practice (GLP);
- good manufacturing and distribution practice (GMP);
- clinical evaluations;
- medicinal market surveillance;
- pharmacovigilance inspection; and
- mail-order pharmacy, etc.

For instance, in the field of GLP, 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?

In general, subjects of an investigation 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 functioning 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?

In general, 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 of up 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 may 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 giving 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 Administrative Court can be challenged by means of two appeals, which lead to two different supreme courts; the Court of Administration or the Constitutional Court.

Concerning administrative criminal procedure, first instance is the particular district administration authority. Its decisions may be challenged by an appeal that 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 national Federal Administrative 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 recently established BASG Enforcement Department has dealt with individual small-scale contract production of medicinal products by foreign physicians. Contrary to various foreign jurisdictions (eg, section 13 of the German Pharmaceuticals Act), in Austria the manufacture is limited to pharmacies only, meaning that physicians are not allowed to produce medicines, but can provide pharmacists with recommendations or instructions.

There have also been enforcement actions against experimental cell-based therapies. In conjunction with a foreign colleague, an Austrian physician offered medical treatment, including unauthorised cell preparations, and has been finally convicted to an administrative fine of more than €10,000. According to current figures, the BASG had 86 enforcement cases in 2015. In total, 19 enforcement inspections were carried out and only three inspections resulted in a report to the criminal enforcement authorities.

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 (http://www.pharmig.at/uploads/VHC_2015_englisch_web_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. Its code of conduct 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 is one national branch and nine state branches to the respective chambers. Their main function is to facilitate and to represent the interests of their members. Nevertheless, they also have disciplinary powers ranging from reprimands 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 the following:

- section 55a of the AMG;
- section 108 of the MPG;
- section 53 of the 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 the 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. Regarding article 9 of the Pharmig Code of Conduct and Pharmig's corresponding Ordinance (Transparency), see question 23.

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 that do not comply with the Austromed Code of Conduct could 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 Pharmig members are obliged to disclose any and all transfers of value (eg, 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. The Pharmig Ordinance on Transparency includes a standardised template for the documentation of data to be disclosed, which shall enable uniform data documentation. The use of this standardised template is not mandatory, but may facilitate proper disclosure and documentation.

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

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 undertake a self-evaluation that 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 specifically 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 owing to a specific occasion, complete the authorities' competences to monitor and enforce the applicable legal provisions. The duration of investigations depends on the individual case. Routine controls are finalised comparatively quickly, 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 12.

27 Through what proceedings do agencies enforce the rules?

Proceedings by public authorities are ruled by the AVG and the VStG (see question 14). 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 the following:

- monetary fines to reprimands;
- 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 17. However, the Federal Administrative Court is not competent for legal issues not subject to national enforcement or directly executed by national agencies; instead, the regional administrative courts (one in each state) are responsible for these issues. The Federal Court of Finance is in charge of financial and tax-related matters.

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.

Update and trends

The Healthcare Reform Implementation Act 2017 including the necessary legal framework (eg, the Primary Healthcare Act 2017) has been passed by the Austrian Parliament (decisions of 28 June and 6 July 2017) and is expected to enter into force soon. The reason is that official healthcare development plans aim at the overall improvement of outpatient healthcare and reduction of inpatient care in hospitals. According to this Act, primary healthcare units shall be established. They are intended to be the first contact point for patients and should cover all or at least a broad variety of medical disciplines.

Because primary healthcare units shall allow public access to the vast majority of medical services, they may result in significant changes in the sector of self-employed (general) physicians. By 2021, 75 primary healthcare units are scheduled to be opened. The Chambers of Physicians basically oppose the wide-ranging establishment of primary healthcare units. They demand upper limits for these new units in order to protect existing structures of healthcare service, more influence on selection procedures and price fixing as well as elevated requirements for contract termination.

Once enforcement action has 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. Owing to potential misuse of billing opportunities, health insurance institutions may have a closer look on drug costs charged by pharmacists. The procedure of a recent product recall revealed that a considerable number of pharmacists claimed reimbursement for drugs that had never been delivered to patients. Furthermore, health insurance institutions continue practising 'mystery shopping' by sending healthy persons to healthcare providers (primarily physicians) in order to investigate whether the healthcare provider is willing to issue incorrect medical certificates or actually provided the treatment charged to the social insurance fund. In such instances of issuing incorrect medical certificates or incorrect billing, the health insurance institution terminates its contract with this healthcare provider. In addition to its other tasks, the BASG controls the online marketing as well as advertising of pharmaceuticals.

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 the chamber is mandatory.

Moreover, the Austrian Chamber of Dentists (one national and nine state branches) represents the interests of dentists and also has partial sovereign power. For instance, it decides on the admission and revocation of authorisation, manages education or conducts negotiations with health insurance agencies.

Apart from the 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 providers shall undertake, and the remuneration they shall receive, but primarily, they do not include contractual penalties for improper performance. Nevertheless, marked 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 the individual contract. 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. In extraordinary cases, the authorisation to deliver healthcare services may be withdrawn or the initiation of corresponding proceedings may be suggested.

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 owing to the infringement of healthcare regulations is 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. Moreover, 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.

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 defective product that 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 €300 to €330 per day of heavy pain, €200 to €220 per day of medium pain and €100 to €110 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 (eg, a lotion against neurodermatitis contained an aggressive form of cortisone), hepatitis C infection owing to contaminated blood plasma donations and magnetic therapy devices.

Since 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 upon to substantiate its case. Consequently, the entity on whom the individual persons have assigned their claims 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 Administrative Court adjudicates 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 Reimbursement Code have to be filed online with the Association of Austrian Social Security Institutions within four weeks after receipt. The 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 whistleblowers?

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

The Ministry of Justice operates a whistleblowing website, which allows reporting of suspicious observations to the Public Prosecutor's Office against Corruption and White-Collar Crime anonymously. As of January 2016, an amendment to the Public Prosecutor's Office Act approves the admissibility of this whistleblowing system, which has actually been used since March 2013.

41 Does the country have a reward mechanism for whistleblowers?

Whistleblowers 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 of the StPO or section 29 of the Financial Criminal Act).

42 Are mechanisms allowing whistleblowers to report infringements required?

Companies are not obliged by law to install whistleblowing 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, the health data of individuals) or the authority is not attributed to a European Economic Area 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 German-language DACH countries (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 the Austrian authorities become aware of foreign investigations that may have an effect on the Austrian market or involve Austrian interests. The agencies responsible for the enforcement of the relevant laws and regulations 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.

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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 within domestic property are generally subject to domestic jurisdiction.

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