The Life Sciences Law Review

second Edition

Editor
Richard Kingham

Law Business Research

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Second Edition

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Richard Kingham

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EDITOR'S PREFACE

The second edition of the *Life Sciences Law Review* provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in 30 jurisdictions. As before, each chapter contains information on legal requirements relating to the key stages in the life cycle of a regulated product, from discovery, through the clinical development process, registration, manufacturing and promotion, plus other issues of special interest, such as pricing and reimbursement, special liability regimes, competition and commercial transactions in the context of the medical products business. Each of the chapters has been prepared by a recognised expert in the relevant jurisdiction, and the resulting work product will assist industry lawyers, regulatory affairs staff and others who need to have an understanding of the issues in each major market.

This edition also includes a new chapter on international harmonisation, which plays an increasingly important role in the regulation of pharmaceuticals and medical devices. In particular, the guidelines adopted by the International Conference on Harmonisation (ICH) have been incorporated into the national requirements for pharmaceuticals in the European Union, United States, Japan and most other developed countries, and are increasingly influential in developing countries. Readers may find it useful to review this chapter before consulting the national chapters, because it is often key to understanding many of local requirements.

Once again, I wish to thank all of the lawyers who contributed to this reference work. It is a pleasure to be associated with them.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2014

Chapter 3

AUSTRIA

Karina Hellbert[1]

I INTRODUCTION

Austria spends approximately 11 per cent of its GDP on health-care expenditure, amounting to €32.4 billion, of which 12.8 per cent is spent on medicinal products.[2] In comparison with other European countries, Austria has a low production value per capita for medicinal products because in Austria it is mainly generic products that are produced. From a regulatory point of view, at the beginning of 2013 approximately 13,080 medicinal products for human use were either authorised or registered.[3] No concrete figures exist for the medical device sector, but it is assumed that around 13 per cent of health-care expenditure relates to medical devices.

Medicinal products are regulated by the Medicines Act,[4] providing the framework for the authorisation, manufacturing, distribution and advertising of medicinal products. The import of medicinal products is regulated separately, namely by the Act Governing the Importation of Medicinal Products.[5] The Importation Act also regulates private importation of medicinal products via the internet. The Medicines Act contains various provisions authorising the Minister for Health to implement regulations governing the conduct of pharmaceutical companies, for instance, the Regulation governing the activities of companies producing, controlling or placing medicinal products on the market,[6] or regulations concerning the labelling of package leaflets as adopted in 2008, and the Pharmacovigilance Regulation of 2006.

1 Karina Hellbert is a partner at Fiebinger Polak Leon & Partner Rechtsanwälte GmbH.

2 Pharmig, Facts and Figures 2013 (www.pharmig.at).

3 www.basg.gv.at/news-center/statistiken/arzneimittel-in-oesterreich/.

4 Federal Law Gazette No. 185/1983, as amended.

5 Federal Law Gazette I No. 79/2010, as amended.

6 Federal Law Gazette II No. 234/2008.

The production and distribution of medical devices is regulated by the Medical Devices Act[7] and by various regulations such as the Regulation for the Establishment, Manufacturing, Use and Maintaining of Medical Devices in Institutions Active in the Health Field.[8] In addition, the Federal Office for Safety in the Health Field (the Federal Office) issued an ordinance obliging retailers and physicians providing end-users with a medical device to pay a certain lump sum to the Federal Office as a contribution towards the vigilance tasks it carries out.

For medicinal products, normally the Federal Office is in charge, except for gene-therapy products, where the Ministry for Health has competence. The Federal Office is supported by the Austrian Medical Surveillance Agency scientifically as well as with respect to manpower.

II THE REGULATORY REGIME

i Classification

If a company is not sure whether a product qualifies as a medicinal product or not, the company can ask the Borderline Counsel established at the Ministry for Health to issue an expert opinion on whether such product would classify as a medicinal product or not. In practice, these questions are normally clarified via civil proceedings based on the Unfair Trade Practices Act.[9] The leading cases relate mostly to food supplement products, and whether or not such products, due to their presentation, can be considered as medicinal products. The Supreme Court held that the definition of 'presentation medicinal products' has not changed, even if the German wording of Directive 2004/27/EC would indicate so. Thus, products having disease-related claims still need a marketing authorisation. Even if there is a reference to a complimentary medicine method and the product is labelled as a food supplement, it would not suffice to exclude the products from the scope of the Medicines Act[10] when claims relating to the lowering of 'dangerous blood fats' are made.

In another case, the Supreme Court had to decide whether a cigarette dummy for supporting nicotine withdrawal would classify as a medicinal product, a medical device or food. The plaintiff argued that the substances contained in the nicotine dummy – menthol and valerian – must be considered as a food, because they are digested and the dummy is not intended for treatment of nicotine abuse but for modifying smoking habits because the device simply engages the hands and the mouth. The Supreme Court refused the argument by stating that the substances are only inhaled and not digested through the gastro-intestinal tract, because the molecules of food products must be digested, and digestion means passing through the gastro-intestinal system. The Supreme Court classified the product as a medicinal product also due to its claims. Since the claims mentioned that the product was developed by a 'pharmaceutical faculty', can

7 Federal Law Gazette No. 657/1996, as amended.

8 Federal Law Gazette II No. 70/2007, as amended.

9 Federal Law Gazette 448/1984, as amended.

10 Supreme Court of 16 February 2011; 17 Ob 14/10y.

only be purchased via a pharmacy, and reduces stress and nervousness – disease-related side effects in the case of nicotine withdrawal – the defendant has clearly presented the product as a medicinal product.[11]

ii Non-clinical studies

In 2006, the Ministry for Health has issued an Ordinance with respect to Good Laboratory Practices (GLP).[12] The Ordinance requires that pharmaceutical companies conducting non-clinical studies notify the Federal Office before starting the respective tests, and conformity must be proven in the context of an audit by the Federal Office. When such tasks are outsourced, the pharmaceutical company has to ensure via a written contract that the institution conducting the test complies with good clinical practices and was audited by the Federal Office prior to conducting such study. Of course, inspections can occur without notice. The Federal Office has issued guidance with respect to the conduct of GLP inspections, stating, *inter alia*, that the OECD principles of GLP and Directive 2004/10/EC are the basis for evaluation of compliance. The audited company has the right to comment and to provide action plans with respect to corrective measures.

The use of animals in the development of a medicinal product is regulated by the Act on the Conduct of Research on Living Animals, which entered into force on 1 January 2013.[13] Article 6 lays down the leading principles for conducting animal experiments:

a animal experiments must comply with state-of-the-art scientific methods;

b the assumption to be proven as well as the procedure must be sound and in accordance with state-of-the-art scientific methods;

c animal experiments are only allowed in the context of projects;

d experiments are only allowed to be conducted in institutions of registered users, except if there is a scientific reason for deviating, and must be approved by the relevant authority;

e the animals must be in a suitable condition of health;

f the experiment must be conducted so as to cause the minimum pain, suffering, distress or lasting harm; and

g experiments shall only be conducted with such animals that have the lowest capacity of suffering harm, distress or pain.

In addition, the law foresees that there should be a commission at a national level supporting the relevant ministry with respect to issues relating to such experiments. A person conducting an animal experiment without having the necessary approval can face an administrative fine up to €10,000, or up to €20,000 in the event of recidivism. Also in cases of negligence, fines can be imposed.

11 Supreme Court of 18 April 2008; 4 Ob 27/08m.

12 Federal Law Gazette II No. 450/2006.

13 Federal Law Gazette I No. 114/2012.

iii Clinical trials

Neither the Medicines Act nor the Medical Devices Act requires the sponsor to be established in Austria, but if the sponsor is established outside the EEA, a legal representative has to be appointed. Whether such a representative must actually be nominated depends on the institution in which the clinical trial is conducted. Ethics committees specifically focus on whether the insurance is indeed sufficient to adequately cover the risks of the trial. The Medicines Act requires that Austrian law must apply to the insurance contract, the subject must be able to file a claim in Austria and the Austrian judgment must be enforceable in the country in which the sponsor is established. In addition, the ethics committees are rather reluctant to accept any compensation of clinical trial subjects going beyond the actual travel cost for participating in the clinical trial.

As required by EU legislation, the clinical trial must be approved by the Federal Office as well as by an ethics committee. In the case of a multi-centre study, the leading ethics committee must be specifically authorised to handle such multi-centre clinical trials. Although not specifically imposed by the Medicines Act, normally the authority requires a leading investigator to be appointed.

With respect to consent, the majority of ethics committees have agreed on a common consent form with respect to medical and medical devices trials, and a deviation from such consent form must be specifically discussed in the application. There is also a specific template when genetic testing is involved. It is generally prohibited to conduct clinical trials on prisoners, conscripts and persons held in a special institution under the Hospitalisation Act.[14]

Concerning safety reports, the rules as implemented in Austria are in line with EU legislation. The Federal Office has published several forms on its webpage.[15] The rules discussed above also apply in the case of investigator-initiated studies, which are not treated differently. With respect to clinical trials relating to medicinal products containing GMOs, the Ministry for Health is in charge.

iv Named-patient and compassionate use procedures

The Federal Office distinguishes between 'compassionate use', 'named-patient use' and 'off-label use'. According to the understanding of the Federal Office, named-patient use is regulated by Article 5 of Directive 2001/83/EC and is implemented via Article 8(1) No. 2 of the Medicines Act. Article 8(1) No. 2 stipulates that no marketing authorisation is needed if a physician or dentist has confirmed that the medicinal product is used for treating a life-threatening disease or for a disease resulting in severe health damages and, according to the most up-to-date methods, no accurate treatment can be achieved with a product authorised in Austria. Named-patient use always relates to one specific person.

This is also the difference with the compassionate use programme that relates to a group of patients where the individual names are unknown. In addition, the compassionate use programme can only relate to products covered by Regulation 726/2004/EC. With respect to the compassionate use programme, the approval will be granted for one year

14 Federal Law Gazette No. 155/1990, as amended.

15 www.basg.gv.at.

and the application can only be filed in conjunction with a protocol discussing the therapeutic treatment. The Federal Office has specifically emphasised that if aligned the format and contents of the applications to those of the German applications. The Federal Office will charge a fee of €500 if the report of the CHMP is already enclosed, without such a report the fee amounts to €1,500.

Concerning 'off-label use' the Federal Office states that no definition is contained in the Medicines Act and it should be understood as the use of a medicinal product in the context of a medical treatment outside the approved summary of product characteristics. Off-label use is not prohibited *per se* but the sole responsibility rests with the physician, who has more stringent information obligations as well as an enhanced duty of care. Physicians must also specifically justify via the Federal Office why off-label use should take place.

v Pre-market clearance

A marketing authorisation is issued by the Federal Office but the actual scientific review is carried out by the Medical Surveillance Agency, which is a limited liability company owned wholly by the Austrian state. Applicants for marketing authorisations must be established within the EEA, but there is no requirement that an EEA applicant be specifically located in Austria or that such applicant appoint a local agent. All relevant forms for obtaining a marketing authorisation can be downloaded from the Federal Office website. General conditions for obtaining a marketing authorisation are as follows:

a according to the most up-to-date information and practical experience, the medicinal product must not be harmful when used;

b the ingredients (active substances as well as excipients) must be harmless; this must be proven scientifically;

c the product must be state of the art;

d any description of the medicinal product and the product *per se* must not be misleading; and

e its efficiency must be sufficiently proven and the labelling must comply with the relevant regulations.

The Federal Office must decide within 210 days whether to grant a marketing authorisation; however, the actual handling time for such applications is currently not published. If Austria is acting as Reference Member State in the mutual recognition procedure for new active substances, the Federal Office charges €39,300; when acting as a Reference Member State in the decentralised procedure it charges €50,000. If Austria is acting as a Concerned Member State, then in both cases the Federal Office charges €6,800.

With respect to homeopathic products as well as traditional herbal medicinal products, a simplified registration procedure applies if the products are only used orally or externally and comply with all the other obligations imposed by the relevant EU provisions. Pharmacy-own medicinal products are also covered by a simplified registration procedure.

Parallel-imported products are only allowed to be distributed if a parallel import licence was granted by the Federal Office. The application must include information

on name and marketing authorisation number of the product authorised in Austria, the state in which the parallel-imported product is authorised and marketed, the name and marketing authorisation number of the product to be parallel-imported, name and address of the marketing authorisation holder established in the exporting country, description of the packaging, name and address of the person responsible for re-labelling and repackaging and a declaration that, for instance, the summary of product characteristics, packaging and labelling do not deviate from the product authorised in Austria. The Federal Office has to decide within 45 days with respect to a parallel import application. For obtaining a parallel trade licence as well as registration of a homeopathic product, a fee of €1,000 is charged.

With respect to generic products and biosimilar products, the provisions comply with the respective EU legislation; however, the fees are substantially reduced, for instance, if the Federal Office acts as a Reference Member State in the decentralised procedure to €37,000; with respect to biosimilars in a national procedure to €5,600.

Products meeting an unmet need are regulated no differently to 'ordinary' medicinal products.

The Austrian Medical Devices Act does not require authorisation by an authority, but such products must be examined by notified bodies. What is required is that certain devices are registered prior to use, for instance, pacemakers, implantable cardiac defibrillators and loop recorders. Because notified bodies are private bodies, the fee depends on the negotiating power of the entity submitting a dossier to a notified body.

vi Regulatory incentives

The Austrian legislation does not provide any other incentives as adopted at EU level.

Patents and supplemenary protection certificates

With respect to medicinal products, the Medicines Act specifically states that a patent or supplemenary protection certificate (SPC) does not hinder the review of a marketing authorisation of a generic product. Also, the non-marketing of a product due to an existing patent or SPC would not automatically result in the withdrawal of the marketing authorisation of the generic product after three years of non-marketing according to the sunset clause.

Data protection

The Highest Administrative Court stated that under the old data protection rules there would be no violation of innovator rights if the Federal Office evaluated such an application before the data exclusivity expired but granted a marketing authorisation only one day after such period elapsed. Under the new provisions, no case law exists discussing the rights of an innovator company. Austria is not really considered an innovator-friendly country because there is no specific legal instrument allowing the innovator company to challenge a decision for generic products being based on the originator product as, for instance, there is in Germany. It is also the firm understanding of the Federal Office that innovator companies shall have no legal standing with respect to such decisions.

Medical devices companies can only rely on the general instruments such as patent protection or utility model protection, but not on data protection.

vii Post-approval controls

With respect to pharmaceutical companies, the relevant rules, for example, for staffing, risk management and post-approval testing, can be found in the Regulation governing the activities of companies producing, controlling or placing medicinal products on the market, the Pharmacovigilance Ordinance and the Medicines Act, and with respect to medical devices in the Regulation for the establishment, manufacturing, use and maintaining of medical devices as well as the Vigilance Ordinance. In essence, the pieces of legislation concerning the manufacturing and distribution of such products provide only general guidelines except with respect to the qualification of persons being entrusted with certain tasks, for instance, the qualified person. Also, the Federal Office makes it clear that the appropriate measures with respect to risk management, post-approval testing, etc., depend on the harmfulness of the product and must either be dealt with appropriately by the dossier or by the quality assessment of medical devices.

Transfer of ownership must be notified to the Federal Office accompanied by two statements, namely that the original marketing authorisation holder will waive any rights with respect to the marketing authorisation and that the new owner will take over any and all obligations with respect to such a marketing authorisation. Of course, the statements must be accompanied by the relevant documents with respect to a variation. Only after receipt of such statements, the company taking over will be considered as the marketing authorisation holder. For medical devices, no specific rules apply. Of course the notified body must be informed that the CE marking can be accordingly amended, and if the new owner is situated in Austria, the register of medical device manufacturers must be informed.

In case of renewal of a marketing authorisation, the Medicines Act foresees a strict deadline by which an application can be filed – at the earliest, four years from the moment the marketing authorisation became legally binding, but at the latest nine months before the five-year period elapses.

viii Manufacturing controls

According to Section 63 of the Medicines Act, manufacturing, distributing or controlling of medicinal products needs an authorisation from the Federal Office. With this application the following documents must be enclosed:

a the kinds of tasks envisaged, the production volume, the place where such activities will be conducted;

b the building's condition, size of the facility, zoning classification, equipment and the exact location; and

c a description of the technical equipment and, if needed, the name of the qualified person.

The Federal Office must grant an authorisation if the facility does not endanger human or animal health. The Federal Office is, however, entitled to require trial operations to evaluate if humans or animals are endangered. The facility is normally inspected before an approval is granted. The Federal Office charges €700 per half inspection day, if such inspection occurs in Austria. For the approval itself, a fee of €3,000 is charged. A further prerequisite for obtaining a licence in accordance with Section 63 is that the company

must engage a person that has passed the exam for the manufacturing of medicinal products according to the Trade Act.

After having obtained a Section 63 licence, the facility is normally inspected at least every three years. The Federal Office has published guidance with respect to the conduct of an inspection and what is expected from the facility. In addition, the Federal Office publishes a list of companies to be inspected and provides the date the inspection occurred, when a clock stop is imposed and when the final report was issued. In 2013, approximately 190 institutions obtained a letter from the Office that they would be inspected. With respect to the transfer of such manufacturing licence, there are no specific rules contained in the Medicines Act; however, this must be notified to the Federal Office. This would also require that the trade licence be adapted accordingly.

With respect to medical devices, there is no specific authorisation needed under the Medical Devices Act for operating such a facility; however, a licence is needed under the Trade Act.

ix Advertising and promotion

The relevant rules can be found in the Medicines Act, and Pharmig – the industry association – has also issued a code of conduct for compliance with advertisement rules. In general, any and all advertising must comply with certain core principles, namely that the properties of a medicinal product are not exaggerated, the information or pictorial presentations do not indicate that the product has an effect exceeding its actual effect and that a success can be expected in any event. No advertising should be misleading, either for consumers or for health-care professionals.

Violations of advertising rules can be enforced by the public authorities or by competitors via the Unfair Trade Practices Act or arbitrated under the Pharmig Code of Conduct. Advertising to laypersons of prescription-only products is prohibited, advertisement of over-the-counter products is generally permissible, except if the product is reimbursed by the social security fund. This prohibition does not apply if the product was included against the will of the marketing authorisation holder. Advertisement for non-approved medicinal products or non-approved indications is permissible at scientific events, mainly targeting non-Austrian professionals.

The Pharmig Code of Conduct has specific rules for advertising via the internet, for instance, requiring them to reveal even the indirect support of a website by a pharmaceutical company. Websites may generally contain non-promotional information on medicinal products, for instance, with respect to side effects or interaction with other substances, but must state that a physician or a pharmacist must be consulted. Links to a complete evaluation report published by the CHMP or to websites of national authorities, medical research institutions, etc. are also acceptable. With respect to advertisement to health-care professionals, the Code requires that an access system be implemented to ensure that only health-care professionals have access to such information.

The industry association for medical devices (Austromed) has also published a code of conduct, which provides further guidance concerning the restrictions imposed by the Medical Devices Act. The Austromed Code of Conduct specifically stipulates that financial means designated for research purposes must be transferred to accounts supervised by independent bodies. The costs for accommodation and participation in a

congress not organised by the medical device company can be taken over if the congress aims to provide scientific knowledge with respect to the product of the supporting company. The participating physician must provide a report about the knowledge gained, and this is considered as a possible reason for taking over the accommodation and participation costs. If the medical device company organises the congress or an educational event, physicians can only be invited if the invitation is issued to the department and not to the individual physician.

x Distributors and wholesalers

Wholesalers and distributors also need a licence according to Section 63 of the Medicines Act. Furthermore, the wholesale and distribution of medicinal products is a regulated trade, meaning that a company must employ a special managing director in the terms of the trade law, who must have passed an exam, covering, *inter alia*, legal and scientific aspects of trading with medicinal products. This person must (1) be in charge of compliance with the provisions of the Trade Act, (2) be hired for at least 20 hours per week, (3) be in possession of EEA citizenship or Swiss citizenship; and (4) be replaced within six months of his or her leaving, but the period granted by the authorities is normally less than six months. If the trade is conducted without appointing such person, a company can face a fine of up to €3,600. A fine is also imposed if such person is appointed, but the person actually works less than 20 hours per week for the company.

xi Classification of products

The Prescription Act[16] provides the rules when a product has to be classified as a prescription-only product or an over-the-counter product. The Act stipulates that the Ministry for Health must adopt a regulation concerning substances that can only be given out on prescription. When classifying such a substance, the Ministry has to take into account whether the labelling, the package leaflet, as well as the information provided by a pharmacist, indicates that the use of such product is associated with a low risk, by taking into account the duration of the intake as well as the affected target group. The Act also states that if a product is switched from being classified as a prescription-only product to an over-the-counter product, the data used for such a switch cannot be relied upon for amending the respective regulation for one year. When evaluating such substances, the Ministry for Health is supported by the Prescription-Only Council, consisting of members of the Physicians' Chamber, the Pharmacy Chamber, social security funds, an expert for producing medicinal products and a pharmacologist employed by one of the Austrian universities.

With respect to the distinction between products only for hospitals or for outpatients, no specific provisions apply in Austria. This distinction is only relevant if such products may be reimbursed by the sickness funds, because they only have to pay for such products that are prescribed in the outpatient scenario. The costs for hospital-only products are paid by the hospitals themselves.

16 Federal Law Gazette No. 413/1972.

The Medical Devices Act states that the Ministry for Health can issue a regulation with respect to products that, according to their low endangerment, could be directly distributed to lay persons, but due to the specific circumstances also need a prescription. The Ministry for Health issued one ordinance, namely with respect to magnetic resonance equipment.[17] In addition, the Ministry has also issued a regulation specifying which medical devices can be sold directly by every retailer, for example, condoms or blood-pressure products; by chemists, for example, light therapy products; or only in a pharmacy or by specialised retailers with a licence to sell medical devices according to the Trade Act.[18]

For certain products, a prescription is needed because otherwise the medical device would not be reimbursed by the various sickness funds.

xii Imports and exports

An importation approval is necessary for such medicinal products not covered by an EEC marketing authorisation. Imported products with a marketing authorisation from somewhere in the EEA but without a national one, and which are either re-exported, used for scientific purposes or for medical purposes, must be notified to the Federal Office.[19] Products either centrally approved or with an Austrian marketing authorisation, or products being used in clinical trials being manufactured in the EEA or in Switzerland, can be freely imported without any approval by or notification to the Federal Office. This Act also regulates the purchase of non-prescription medicinal products over the internet within the EEA. It is permissible for a private person to purchase non-prescription medicinal products from a pharmacy established within the EEA if this is done for private purposes – this is normally assumed if no more than three packages per medicinal product are purchased. Prescription-only products can only be purchased in a national public pharmacy where the pharmacy has to comply with strict documentation requirements controlled by the Federal Office.

Different rules exist for blood products because the import of such products must always be notified even if the products are approved within the EEA. Products imported in violation of this Act have to be either sent back or destroyed at the purchaser's expense. In addition, a fine of up to €3,600 can be imposed and, in the event of repetition, up to €7,260. The Federal Office has far-reaching competence when dealing with such imported products. Employees at the Office are specifically entitled to enter any premises where such products could be stored, and are also entitled to open any containers for taking samples. The Preparatory Parliamentary Materials to the Importation Act[20] specifically stipulate that such inspection could also occur in customs warehouses when there is a risk that such products could infiltrate the Austrian market.

For medical devices, no specific rules exist.

17 Federal Law Gazette II No. 343/2003.

18 Federal Law Gazette II No. 355/2004.

19 Federal Law Gazette I No. 79/2010.

20 ErläutR 773 BlgNR XXIV.GP 6.

xiii Controlled substances

The import, trade and export of substances covered by Schedule I or II of the Single Convention on Narcotic Drugs, respectively Schedules III and IV of the Convention of Psychotropic Substances, is strictly controlled.[21] Substances can only be purchased:

a for medical, veterinary or scientific purposes by entities with a trade licence with respect to the manufacturing of medicinal products or for wholesale, as well as a licence issued by the Ministry for Health;

b by a scientific institution after the supervising authority has confirmed that the possession of such substances is needed for scientific purposes;

c by the police and customs authority for training purposes; or by

d prisons that have the facilities for the rehabilitation of prisoners for substance abuse.

Wholesalers have to apply for such a licence every year, and it is only granted up to a certain maximum amount. Each year by 31 January, the companies must file a report with the Federal Office and must justify when certain amounts are missing.

Pharmacies are only allowed to provide such products to end-consumers based on a prescription issued by a trained physician. Such products must always be stored separately from normal medicinal products and must be locked up. The authorities can also order special security measures for these products. Furthermore, only the Austrian Agency for Health and Food Safety is allowed to grow cannabis for producing medicinal products.

For the export of products covered by the Addictive Substances Act, specific export documentation must be provided; in particular, there must also be a request from the importing country stating that such products are needed.

xiv Enforcement

Enforcement and the respective penalties are discussed in the various sections.

III PRICING AND REIMBURSEMENT

Currently, 22 social sickness funds exist in Austria, supervised by an umbrella organisation, the Main Social Security Association (the Association). The system is financed by mandatory contributions from employers, employees and self-employed people, with some exemptions; for instance, lawyers have their own health-care systems. The Austrian system is a benefits-in-kind system, meaning that health services and medicinal products are provided instead of a financial contribution to health expenditure.

The Association decides whether a product will be reimbursed. Reimbursed products are included in a box system that distinguishes between red, dark yellow, light yellow and green boxes. Products listed in the red or dark yellow boxes must be approved by a physician employed by the Association; for light yellow products a

21 Federal Law Gazette I No. 112/1997, as amended.

specific documentation system applies, and green products can be freely prescribed. Each category is described below:

a Green box: the free prescription by a physician must be medically and economically justifiable, meaning that the price must be less than the EU average price, and the volume of potential prescriptions must not be so high that it would trigger closer monitoring. If a comparable therapeutic alternative is already included in the Reimbursement Codex, the new product will only be accepted by the Association if there is a substantial price difference from the included product.

b Light yellow box: innovative products are included in this box, whose financial impact is considered by the Association as not requiring special approval by an Association physician. Producers included in the light yellow box are regulated via an ordinance of their own.

c Dark yellow box: products with an additional therapeutic benefit and that are rather expensive are contained in the dark yellow box. Such products can be approved up to the average European price. The physician wanting to prescribe such products must justify it.

d Red box: products for which an application for being reimbursed is filed with the Association will be automatically included in the red box.

The Association must decide within 90 days whether the product is *per se* refundable – thus suitable for an outpatient scenario – and in the next 90 days, whether the product will be listed either in the green or in the yellow box, and how much it will cost.

A generic product will only be included in the Reimbursement Codex if it is at least 48 per cent cheaper than the originator product; the second generic product must, again, be 15 per cent cheaper than the first generic product, and the third generic product 10 per cent cheaper than the second. In addition, if the first generic product is included in the Reimbursement Codex, the originator must lower its price by 30 per cent.

Negative decisions by the Association about whether a product will be included in the Reimbursement Codex can be appealed to the newly established administrative national court. The senate consists of one presiding judge, two pharmacologist or toxicologists and two economists with expertise in social security matters.

With respect to medical devices, the sickness funds only reimburse certain products. Co-payment of patients is always required; for instance, for glasses it costs €21.60 for children under 15, and for adults, €88.80. The various social security funds can also introduce caps, for instance, for prostheses.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

If a marketing authorisation is refused, the decision can now be appealed to the newly established administrative national court. Therefore, the administrative procedure provides, for the first time, for at least three instances of review of such decision, namely after the decision has been appealed to the administrative national court a further appeal to the highest administrative court is now possible.

Violations of the Medicines Act are investigated by the Federal Office, but the fines are actually imposed by the regional administrative authorities. Fines can be appealed to the newly established regional administrative courts.

The Federal Office can annul a manufacturing licence if the company violates a requirement imposed by the Federal Office three times, or if the company refuses to let the officials of the Federal Office enter the premises for taking samples. Such a decision can now be appealed to the national administrative court.

Fines regulated by the Medical Devices Act are also imposed by the regional authorities and can be appealed to the also newly established regional administrative courts.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Austria has recently tightened its anti-bribery provisions. It has extended the applicability of the anti-bribery provisions to persons employed by companies or entities owned by majority by the state, a region or a community, or where the state, community, or region has a decisive influence. Thus, university employees, as well as most of the employees of hospitals, are now covered by the relevant anti-bribery provisions. Also, the Criminal Code now contains new criminal offences, such as trading in influence, and a more restrictive sweetening provision.

For the first time, the Criminal Code provides some reliable guidance on what would not be considered undue advantages – those:

a whose acceptance is permissible by law, for example, according to the Medicines Act pharmaceutical companies can take over accommodation costs for physicians;

b that are given during the course of an event and an official's participation was justified by reasons of exercising his or her function, for example, a flower bouquet for giving a presentation;

c that are in the form of donations given for charitable purposes where the official receiving the donation is not allowed to have any major impact on choosing who should receive such a donation; and

d that are in the form of customary tokens and gifts of small value.

During the parliament discussion, a fixed limit for gifts of small value of €100 was nullified by arguing that it must be decided case by case whether a gift of €100 would still be considered a token or a gift of small value.

Both industry codes of conduct provide that cooperation with physicians must be based on a written contract, and the remuneration must be according to the arm's length principle. The cooperation must not be intended to influence the physician with respect to his or her prescription manner, or with respect to his or her treatment of the patient. Payments for a physician simply attending a congress are impermissible. Rebates in kind are normally permissible under the Medicines Act, except to physicians operating a physician's pharmacy.

Within the first year in which the product is on the market, physician samples not exceeding an amount of 30 per medicinal product can be provided; in the following year

only two per request, but not exceeding five in total per year. Of course, such physician samples must be given for free and must be specifically labelled. Certain institutions require that such physician samples are not given directly to the physician, but are submitted to the in-house pharmacy for further distribution.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

There are two specific provisions with respect to compensation schemes in the case of damages caused by a medicinal product, namely in the case of clinical trials (Medicines Act) and, in cases of vaccination, for smallpox vaccination, vaccination required by the 'mother-child pass' or for any vaccination that was specifically recommended by the Ministry for Health.[22]

The compensation will only be paid after the person has reached 15 years of age, and the ability to work is reduced by 20 per cent for more than three months. If the damage was substantial, a one-time payment as compensation for pain and suffering will be also granted. For children under 15, parents can apply for a special care allowance.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

The competition authority has not issued any specific guidance concerning what they would consider as problematic with respect to settlement disputes, in particular, patent disputes. There is also no announcement that there will be a specific focus concerning enforcement activities with respect to the life sciences sector. The main focus of the authorities is currently on the food retail market, which is extremely oligopolistic, and the freight sector. There is a tendency that the authorities, when making a dawn raid, focus more specifically on private housing of leading employees, assuming that business documents are ever more often stored in private surroundings. In addition, due to the amendment of the law, the possibility to object to the seizure of documents was extremely limited. Thus, it is expected that, in daily practice, courts are now more willing to exclude improperly obtained evidence.

ii Transactional issues

Due to the fact that around Vienna a biotech cluster has established itself during the past few years, many transactions relate either to cooperation between start-ups and bigger pharmaceutical companies, or mergers between companies both currently in the process of obtaining marketing authorisations. In the case of cooperation between companies, it has to be carefully checked whether the merger will have an impact on the reimbursement status of the product, for instance, in the case of co-marketing agreements.

22 Federal Act of 3 July 1973 concerning compensation for vaccine damage, as amended.

VIII CURRENT DEVELOPMENTS

The anti-bribery and lobbying provisions were tightened due to various bribery scandals, which had their origin in other industry sectors, but this has nevertheless had a major impact on the pharmaceutical sector. Certain activities by employees of pharmaceutical companies are now considered lobbying, necessitating the company as well as the employees being registered with the newly established lobbying register. The industry association has also adopted a new code of conduct with respect to the lobbying activities of pharmaceutical companies. The companies are still in the process of adjusting to this new situation.

In addition, the trade in fake medicinal products now constitutes a criminal offence for the first time. It will be seen what actions are taken by the enforcing authorities with respect to these new criminal offences and how companies will be encouraged by the authorities to actively combat such trade.

Appendix 1

ABOUT THE AUTHORS

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Karina Hellbert joined Fiebinger Polak Leon Attorneys-at-Law in 2004; she is head of the life sciences department. She holds a degree in law and a degree in natural sciences and specialises in pharmaceutical law, medical devices, intellectual property law, patent litigation, unfair competition law, licensing, customs matters, IT, product liability and food law.

Ms Hellbert is associate professor at the IMC University of Applied Sciences Krems and has written numerous articles in the fields of, *inter alia*, regulatory issues, product liability and pharmaceutical advertising.

In recent years, Ms Hellbert has been involved in running various major patent and supplementary protection certificate cases for multinational companies, not only before the civil courts but also the criminal courts. In addition, she regularly represents clients in product liability cases before the civil courts. Her work in the life sciences field also includes advice on regulatory issues such as data protection, labelling, borderline issues, clinical trial agreements, reimbursement and compliance with anti-bribery provisions in the health field.

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