GETTING THE DEAL THROUGH

Life Sciences

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2014

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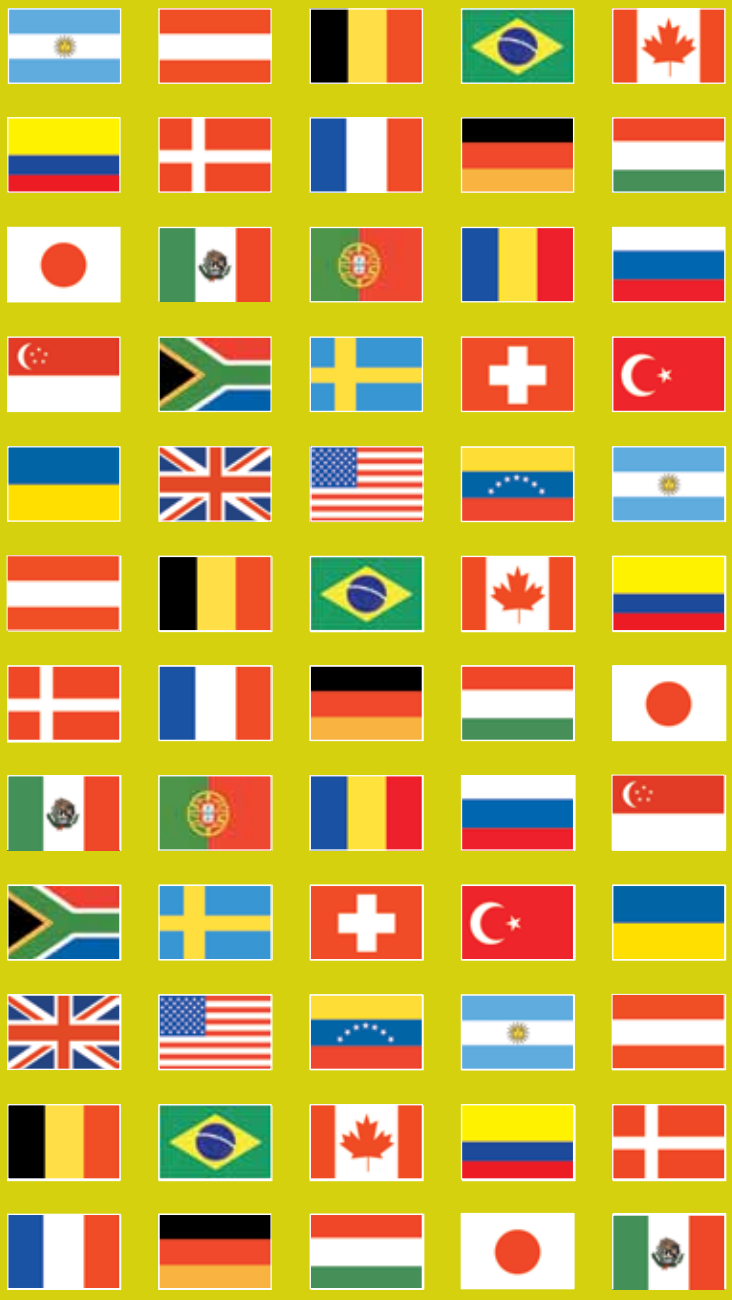

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Austria

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Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The Austrian health-care system is characterised by the federalist structure of the country, the delegation of competences to self-governing bodies in the social security system, and the cross-stakeholder structures at federal and province level, which possess competences in cooperative planning, coordination and financing. With the exception of the hospitals sector, almost all areas of the health-care system are primarily the regulatory responsibility of the federal authorities. In the hospitals sector the federal legislator is only responsible for enacting basic law; legislation on implementation and enforcement is the responsibility of the nine federal provinces. In the outpatients sector, as well as in the rehabilitation sector and in the field of medicines, health care is organised by negotiation between the 21 social security funds and the Federation of Austrian Social Security Institutions on the one hand, and the chambers of physicians and pharmacists (which are organised as self-governing public law bodies) and the statutory professional associations of midwives or other health professions on the other.

The various sectors of the health-care system have traditionally been characterised by different stakeholders and regulation and financing mechanisms. However, in recent years there have been increased efforts to introduce decision-making and financing flows that are effective across all sectors. Since 2000, all federal provinces (except Vienna), as well as some of the private non-profit owners, have privatised their hospitals in the form of organisational privatisations. The various private operating companies have one thing in common: they are responsible for the management of hospitals, whereas the provinces or local authorities, as (majority) owners, usually act as guarantor. The Austrian health-care system has developed almost completely into a model based mainly on decentralised contracts with all service providers.

2 How is the health-care system financed in the outpatient and in-patient sectors?

Austria spends approximately €32 billion on health care; this corresponds to approximately 11 per cent of the gross domestic product. Austrian health-care expenditure appears above average in comparison with other EU member states.

The financing of the health-care system is pluralistic in accordance with the Austrian constitution and social insurance laws. The social health insurance system, which is the most important source of financing, provides almost 50 per cent of total health-care expenditure. There is no competition between health insurance funds since mandatory insurance is based on membership of an occupational group or place of residence.

In case of need, all those insured with the social health insurance system have a legal entitlement to benefits in kind and cash benefits within the legal framework of the specified (wide) range of benefits. Alongside statutory obligatory benefits, the health insurance funds also provide various levels of voluntary benefits according to their statutes, such as in the field of prevention.

Of total health-care expenditure, 25 per cent is tax-financed by the federal government, the provinces and local authorities. Of this share, 10 per cent was accounted for by tax-financed long-term care cash benefits, which are paid out to people in need of long-term care. Long-term care provision in Austria is financed almost exclusively by the federal government's budget and is paid to individuals as a money transfer in seven stages, depending on their needs. Long-term care is also a sector where federal cooperation instruments are used, specifically to ensure the uniformity of entitlement criteria and quality standards of long-term care institutions.

Around 25 per cent of health-care expenditure is financed privately. Private households bear around 17 per cent of health-care expenditure by means of indirect cost-sharing (services whose costs were fully borne by the insured) and direct cost-sharing (co-payments). In addition, 5.5 per cent was financed by private insurance premiums, 1.4 per cent by private non-profit organisations and 0.2 per cent by employers (for the services of company physicians). Indirect cost-sharing is accounted for mainly by hospitals (primarily as private health insurance) and by dental treatment. Direct cost-sharing has increased in recent years and affects almost every service provided by social health insurance. A large part of direct cost-sharing (47 per cent) is accounted for by the services of non-contracted physicians, prescription fees (19 per cent) and therapeutic products (17 per cent). Certain people in need of social protection and the chronically ill are exempt from the prescription fee. Furthermore, health insurance funds issue their own guidelines on exemptions in other service areas. A total of around 490,000 persons, or about 6 per cent of the Austrian population, are exempt from direct cost-sharing.

Outpatient sector

Those covered by health insurance can choose freely between physicians in the outpatient sector, the majority of whom work in individual practices. In addition, 800 outpatient clinics and hospital outpatient departments offer outpatient care. Around 45 per cent of the approximately 18,500 self-employed physicians in private practice have a contractual relationship with one or more health insurance funds. Around 55 per cent work as non-contracted physicians. Insured persons who consult non-contracted physicians are reimbursed with 80 per cent of the fee that the health insurance funds would pay to the contracted physicians. The population density of practising physicians is around 3.5 per 1,000 inhabitants, but there is a considerable variation in this figure between the nine provinces. Outpatient physician treatment is financed by (mandatory) insurance contributions, the premiums from private supplementary insurance and copayments of private households. The payment of physicians in private practice is, in principle, set so that operating costs and investments for the practice can be amortised. The physicians'

chambers at province level negotiate annual general agreements with the Federation of Austrian Social Security Institutions on the provision of contracted physician services. This has to be approved by the individual health insurance funds. The general agreements include, in particular, payment regulations, agreements on service volumes and a capacity plan ('location plan'). On this basis, individual contracts are awarded to those physicians in private practice in accordance with the location plan. Contracted physicians receive a mixture of their capital payments for basic services and a fee-for-service payment for services that go beyond the scope of basic services. The distribution of these payment elements varies according to speciality, province and public due to the type of health insurance fund. In part, agreements on volume limitations for physicians' services are combined with decreasing payment scales. In principle, the utilisation of resources in the outpatient sector is subject to monitoring by the supervisory physicians or head physicians employed by the health insurance funds.

In-patient sector

Hospitals that are listed in the hospitals plan of a federal province ('fund hospitals') are subject to public law and have a statutory requirement to provide care and admit patients. They are entitled to legally prescribed subsidies from public sources for investment, maintenance and operating costs. The ratio of 7.5 beds per 1,000 persons is clearly above the EU average. The admission rate of 27.9 per 100 inhabitants is one of the highest in the EU.

Public and non-profit hospitals, which are licensed to provide acute in-patient care in the hospitals plan of the respective province, have a mandate to provide care to all inhabitants. In return, they have a right to subsidies and to the reimbursement of operating costs. The expenditure on these hospitals reaches around €10 billion. Approximately 45 per cent are financed by social health insurance funds, 7.5 per cent by private insurance (for better accommodation), and 3 per cent by private households by means of copayments and out-of-pocket payments. A further 10 per cent are financed by budgeted funding from the federal government, the provinces and local authorities. The remaining approximately 35 per cent is borne by the owners of public hospitals, that is, from the provinces or private non-profit organisations.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

Advertisement of medicinal products to the general public and health-care professionals is governed by the Act on Medicinal Products, implementing Directive 2001/83/EC (Community code relating to medicinal products for human use).

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

With regard to health-care professionals, advertising is only permitted for medicinal products with a marketing authorisation, registered traditional medicinal products, registered homeopathic medicinal products, medicinal products accepted for parallel import and officinal medicinal products. Any advertisement must describe the properties of the medicinal product objectively and without exaggeration. The information provided by the advertisement must not contradict the summary of the product characteristics (SmPCs). Advertising aimed at health-care professionals may contain information that supplements the SmPC, provided that this information does not contradict the SmPC but confirms or articulates its content without distorting it.

Advertising of medicinal products subject to the mandatory publication of product characteristics and made through printed matter, electronic media or by means of telecommunication has to contain clearly legible SmPCs. All information has to be exact, up to date, verifiable and complete to allow the addressee a personal evaluation of the therapeutic value of the medicinal products. Citations, tables and other information have to be reproduced verbatim and must contain a reference to their source. Citations from literature have to provide the essential content objectively. Furthermore, it is prohibited to offer premiums or other financial or tangible benefits to health-care professionals unless such benefits are of minor value and provide a medical or pharmaceutical benefit.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertising aimed at the general public is prohibited for medicinal products subject to prescription, (OTC) medicinal products marketed under the same or a similar name as a medicinal product subject to prescription, and registered homeopathic pharmaceuticals. However, this prohibition does not apply to publicly funded vaccination campaigns (eg, flu, ticks). Advertising has to be clearly recognisable as such and must contain the name of the medicinal product, the international non-proprietary name (INN) of the active ingredient (if the medicinal product contains only one active ingredient), the necessary information for sensible medical usage and the clearly discernible advice that the medicinal product might have adverse effects and therefore the directions for use have to be consulted or the advice of a physician or pharmacist should be obtained. In case of audio-visual media this information has to be provided both audibly and visually. Furthermore, advertising aimed at the general public must not:

- contradict or go beyond the SmPC;
- contain pictures of health-care professionals;
- allege that:
  - there are no side effects;
  - good health might be improved by using the medicinal product; or
  - non-use of the medicinal product might be detrimental to good health; or
- mislead the addressee or induce mail orders.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

Although there are no statistics available, based on the quota of cases published in legal journals, probably the most common infringements committed with regard to the advertisement rules are misleading (comparative) advertising.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Since Austrian law prohibits the advertising of medicinal products that do not have a marketing authorisation (and off-label use is the use of a medicinal product for an indication beyond the product's marketing authorisation) and restricts advertising to the contents of the SmPCs, it is almost impossible to lawfully provide information regarding off-label use. Information to health-care professionals limited to the INN of the active ingredient and its administration without any reference to the product's name or trademark, thus not advertising directly the off-label use of a specific medicinal product, seems to be possible. Furthermore, to limit the risk of product liability, it is appropriate to indicate that – notwithstanding the results of clinical studies – a marketing authorisation for this off-label use has not yet been obtained.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the in-patient and outpatient sector?

The collaboration of the pharmaceutical industry with health-care professionals both in the in-patient and outpatient sector is governed by the Act on Medicinal Products. Austrian law does not apply different rules to physicians in the in-patient and outpatient sector.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals are sections 55a and 55b of the Act on Medicinal Products. They prohibit the supply, offer or promise of gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply medicinal products unless they are inexpensive and relevant to the practice of a health-care profession. The provision shall not prevent hospitality including travel expenses and accommodation offered directly or indirectly at events for purely professional and scientific purposes; such hospitality shall always be strictly limited to the main scientific objective of the event, and it must not be extended to persons other than health-care professionals (such as the doctor's wife). Persons qualified to prescribe or supply medicinal products shall not solicit or accept any such inducement. The federal minister of health may establish guidelines on the acceptable value of benefits, type and scope of hospitality and may establish criteria for the qualification of exclusively business-related scientific events, but has not yet done so.

The offer or promise of discounts in kind to persons qualified to prescribe or supply medicinal products is allowed, unless such medicinal products are included in the Code of Reimbursement established by social security. In any case, persons qualified to prescribe or supply medicinal products must not solicit or accept discounts for medicinal products included in the Code of Reimbursement.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

Although there are no statistics available (and no cases published in legal journals), probably the most common infringement is excessive hospitality.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The association of the pharmaceutical industry in Austria PHARMIG (www.pharmig.at) has issued a code of conduct that also deals with the industry's cooperation with patient organisations. The Pharmig's Code of Conduct provides that cooperation between patient organisations and the pharmaceutical industry is based on common interests and has to take place in an ethical and transparent way. Support of patient organisations shall serve solely the interests of the patients and their families. Any support may only be provided on the basis of a written agreement which shall in any event contain information about the nature and scope as well as a description of the support involved and the consent of the patient organisation to disclosure by the pharmaceutical company. Pharmaceutical companies must not influence the editorial work of the publications of patients organisations supported by them without a justifiable factual reason (such as correction of inaccuracies of content of correction from scientific aspects). Pharmaceutical companies shall detail on their website all the patient organisations they support by giving information about the nature and scope as well as description of the support involved. The assumption of costs for members of patient organisations, patients or their families as well as other invited participants in the course of educational events shall be limited to travel costs, accommodation abroad as well as the admission fee and shall be appropriate.

12 Are manufacturers' infringements of competition law pursued by national authorities?

There is no record of manufacturers' infringements of competition law, but the Federal Cartel Authority (FCA) has pursued competition infringements with increasing vigour in recent years.

In spring 2009 the FCA brought an action in the cartel court for fines relating to printing chemical wholesalers; the action was based on leniency applications. The cartel court imposed a fine of €1.5 million on the concerned undertakings in April 2010, which was upheld by the Supreme Court in October 2010. It is noteworthy that in this case a fine has been imposed also on the crown witness for lack of cooperation. In autumn 2010 the Federal Cartel Authority filed an action against sugar producers for alleged allocation of customers and price-fixing agreements. In 2011 the FCA brought actions for vertical price fixing agreements against producers of insolating materials and retailers. In spring 2013 the cartel court imposed a fine of €20.8 million against REWE (a large grocery chain) for vertical price-fixing agreements with suppliers.

13 Is follow-on private antitrust litigation against manufacturers possible?

Follow-on private antitrust litigation to recover damages is possible. However, there has been only one such case in Austria, awarding damages of €218 to a claimant for an illegal price cartel established by driving schools. In February 2010 several real estate companies filed follow-on damage claims of some €100 million for antitrust infringements committed by lift manufacturers. These cases are still pending.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Sections 102 to 108 of the Act on Medical Devices offer similar provisions on the advertising of medical devices to health-care professionals and the general public but less detailed regulations with regard to the collaboration of manufacturers with health-care professionals. The differences result from the proprietary differences between medicinal products and medical devices and the fact that no detailed provisions under EU directives had to be implemented verbatim.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The regulatory framework for granting marketing authorisations and placing medicines on the market is provided by the Act on Medical Products. The provisions closely follow Directive 2001/83/EC on the Community code relating to medicinal products for human use.

16 Which authorities may grant marketing authorisation in your jurisdiction?

Marketing authorisation is granted by the Austrian Federal Agency for Safety in Health Care (BASG), unless an authorisation has been granted in accordance with Regulation (EC) No. 726/2004, read in conjunction with Regulation (EC) No. 1901/2006 of the European

Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No. 1394/2007.

17 What are the relevant procedures?

A marketing authorisation may only be granted to an applicant established in the European Economic Area. The application shall be accompanied by the particulars listed in article 8, paragraph 3 of Directive 2001/83/EC. Forms for obtaining marketing authorisation are available on the Federal Agency's website (www.basg.gv.at). Easements apply to the marketing authorisation of generic medicinal products.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Marketing authorisations are granted principally for a period of five years. No later than six months prior to expiry the licence holder may apply for a prolongation provided the criteria for obtaining the marketing authorisation are still fulfilled. The applicant has to provide an overview of pharmacovigilance data, if necessary a report discussing any data that could possibly influence the assessment criteria and a consolidated version of the particulars to be filed for obtaining the marketing authorisation with all amendments since registration. If the BASG extends the marketing authorisation it is unlimited in time, unless an explicit limit of another five years is set due to reasons of pharmacovigilance.

If the marketing authorisation is not used within three years by putting the medicinal product on the market, the licence becomes invalid. The BASG may provide for exemptions for reasons of health protection. If marketing of a medicinal product is only impossible due to patent protection the grace period only starts after expiry of patent protection.

19 Which medicines may be marketed without authorisation?

Medicines described in an Austrian Pharmacopoeia monograph that are prepared in a pharmacy for direct distribution by that pharmacy may be marketed without authorisation. Also, medicinal products prepared by a pharmacy according to the instruction of a qualified physician, dentist or veterinarian may be marketed without authorisation. Furthermore, certain veterinary medicinal products do not need a marketing authorisation.

A marketing authorisation is also not required for conducting a (pre-)clinical trial or upon prescription by a physician admitted in Austria in cases of urgent need to fend off a danger to life or a substantial detriment to health, and this purpose cannot be achieved through the use of a medicinal product that has already obtained a marketing authorisation. Finally, pharmaceuticals for medical treatment in case of emergency (natural disaster, terrorism, war) may be marketed without a marketing authorisation.

Furthermore, no marketing authorisation is required for medicinal products if the BASG has permitted distribution of a medicinal product according to article 83 of Regulation (EC) No. 726/2004 under a compassionate use programme. The programme has to define a group of patients suffering from chronic or severe diseases causing invalidity or a danger to life that cannot be treated by available medicinal products that have obtained marketing authorisation.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Upon prescription by a physician admitted in Austria, medicinal products that have not yet obtained a marketing authorisation may be administered under the physician's responsibility provided the medicinal product is urgently needed to fend off a danger to life or a substantial detriment to health, and this purpose cannot be achieved through the use of a medicinal product that has already obtained a marketing authorisation. The physician has to confirm these requirements. Based on this confirmation a pharmacy or a pharmaceutical wholesaler may apply for an import certificate to be issued by the BASG.

Upon application by the manufacturer of a medicinal product (if he is sponsor of an approved clinical trial) or by the applicant for a marketing authorisation according to article 6 of Regulation (EC) No 726/2004, the BASG may approve marketing of a medicinal product without marketing authorisation under a compassionate use programme for a defined group of patients suffering chronic or severe diseases. The modalities for such application are governed by the guideline on compassionate use of medicinal products pursuant to article 83 of Regulation (EC) No 726/2004. In November 2012, the BASG issued guidelines for applications for compassionate use programmes. The guidelines are available in English and German on the BASG website (www.basg.gv.at/uploads/tx_basginfobox/l_z24_compessionate_use_at_en_01.pdf).

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

Theoretically, the manufacturer or distributor of a medicinal product is free to establish the price for his medicinal products. Practically, however, social security only reimburses patients the costs of medicinal products listed in the Code of Reimbursement. The Code of Reimbursement is established by the Federation of Austrian Social Security Institutions according to the General Social Security Act (ASVG). The details of the pricing and reimbursement process are described under question 24.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

Since social security only reimburses patients the costs of medicinal products listed in the Code of Reimbursement, pharmaceutical manufacturers must negotiate the prices of their products with the public health-care providers to achieve inclusion in the Code of Reimbursement. The details of the process are described under question 24.

23 In which circumstances will the national health insurance system reimburse the cost of medicines?

Upon prescription by a physician (or dentist), the Austrian health insurance systems reimburse the cost of medicines. For medicines in the yellow or red box of the Reimbursement Code, the physician's or dentist's prescription may be subject to approval or review by the local health insurance fund's 'head physician'. In case of off-label use or compassionate use, upon approval by the head physician, the cost of the medicine is reimbursed provided there is no other reasonable current treatment available in Austria that is likely to be successful, or such treatment has been unsuccessful and the off-label treatment has a reasonable probability of success.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

After obtaining the marketing authorisation, the manufacturer or distributor may apply for the inclusion of the medicinal product into the Code of Reimbursement by suggesting a retail price. Upon the manufacturer's application the product is included in the 'red box' of the Code of Reimbursement for a period of 90 days (or 180 days in cases where the Social Security Fund also decides on the price) and has to be deleted if the Social Security Fund decides that the

Update and trends

In April 2013 the Austrian parliament adopted the Healthcare Reform Act of 2013, which intends to achieve a significant cost containment by six measures:

- curative care at 'best point of service', and in particular relief of the in-patient sector;
- enforcement of innovative outpatient care and development of existing possibilities for interdisciplinary cooperation in the outpatient sector;
- targeted health promotion and prevention, development of evidence-based early diagnosis and early intervention;
- nationwide workmanship on the levels of structure, process and resulting quality;
- establishment of a monitoring system; and
- effective and efficient application of medicines.

To achieve these aims, a federal health commission (comprising representatives of the federal government, the provincial governments, the fund of social security institutions and various stakeholders, but no industry delegates) will develop efficiency orientated financing models for hospitals, establish financing guidelines, define health aims and indicators for monitoring and develop a documentation and information system.

As a first step, the annual growth of public healthcare expenditure shall be reduced to 3.6 per cent until 2016. Thereafter, the annual growth shall be kept at the average annual growth of GDP.

product is non-reimbursable after this period has elapsed. The price commission investigates the EU average price and informs the Social Security Fund, which negotiates the reimbursement price with the manufacturer or distributor. With the establishment of the EU average price, the medicinal product remains in the red box for a maximum of two years. The manufacturer, however, may apply within that period for inclusion in the 'yellow box' or the 'green box'. This application has to be made at least 90 days prior to the end of the two-year period. Where a decision on the price is also made, the application has to be made at least 180 days prior to the expiry of this period. Prices are evaluated every six months; if the price commission finds the EU average price cheaper, the Social Security Fund may demand a price reduction from the manufacturer and repayment of the difference.

Generics may be included in the Reimbursement Code, provided they are substantially cheaper than the original product. Upon inclusion of a generic product, the manufacturer or importer of the original product must reduce the reimbursement price by at least 30 per cent to avoid delisting. A second generic product is eligible for inclusion in the Code of Reimbursement if it offers a substantial price difference when compared with the first generic product. If a third generic product is registered, the manufacturer or importer of the original product has to offer a further price reduction to avoid delisting.

In the outpatient sector, the patient is entitled to receive any medicinal product upon prescription by his or her physician free of charge in any pharmacy except for the payment of a minor prescription fee.

In the in-patient sector, the administration of medicinal products is an integrated part of the hospital treatment so the patient does not have to pay additional charges for them. Hospitals may negotiate the prices of their supply of medicinal products directly. The Social Security Fund, however, does not compensate the purchase price of the medicinal products separately because these costs are included in the global reimbursement for hospitalisation paid by the Social Security Fund to the hospitals.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

From 2004 until 2006 manufacturers and distributors had to pay a discount of 2 per cent of their annual turnovers with the social security funds, however, currently there is no statutory discount applicable in Austria.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Under the rules that generally prevent counterfeiting and illegal distribution of products, counterfeiting of medicines may infringe the originator's trademark or patent rights, or both. Moreover, the originator may induce customs action against goods suspected of infringing certain intellectual property rights under Council Regulation (EC) No. 1383/2003. The competent customs authority for actions taken under this Regulation is the Villach Customs Authority. Furthermore, AGES PharmMed is given authority to start investigations and search premises and transport devices to control compliance with the Act on Medicinal Products and the Act on the Importation of Medicines.

The adoption of Directive 2011/62/EU amending Directive 2001/83/EC, as regards the prevention of the entry into the legal supply chain of medicinal products that are falsified, has been implemented in Austria by amendments to the provisions of the Medicinal Products Act.

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

No measures have been taken in Austria to facilitate the general public's access to information about prescription-only medicines. Since advertising prescription-only medicines to the general public is prohibited, only information brochures aimed at improving patient compliance through general information are permitted. Such brochures, however, must not contain direct or indirect appraisals of the medicinal product and must not create direct or indirect incentives to use a particular medicinal product.

Upon adoption of the Commission's proposal for a regulation amending Regulation (EC) No. 726/2004 as regards information to the general public (COM/2012/049 final), prescription-only medicinal products would have to be excluded from the general prohibition of advertising to the general public. Furthermore, the Austrian Act on Medicinal Products would have to be amended in accordance with the proposal for a directive amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription.

28 Outline major developments to the regime relating to safety monitoring of medicines.

There have been no major developments to the regime relating to safety monitoring of medicines, since the implementation of Directives 2001/83/EC and 2003/94/EC; however, by Ordinance of 17 September 2008 BGBl II 324/2008 the Ministry of Health enacted a new Ordinance on the Production and Marketing of

Medicinal Products 2009 that codified the various amendments to the Ordinance on the Production and Marketing of Medicinal Products 2005.

Following the adoption of Directive 2010/84/EU amending, as regards pharmacovigilance, Directive 2001/83/EC, the Austrian Act on Medicinal Products as well as the Ordinance on the Production and Marketing of Medicinal Products 2009 have been amended accordingly.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

The first vaccination recommendations for children were issued by the Austrian government in 1959. In 1973 a 'mother-child-passport' was introduced to record and monitor the administration of vaccines. Since 1984 the Ministry of Health has issued an annual vaccination plan providing for free vaccination of infants and children as well as vaccination recommendations for adults. Notwithstanding free vaccination against diphtheria, tetanus, pertussis, polio, hepatitis B, mumps, measels, rubella and rotavirus for infants, and subsidised vaccination against influenza, pneumococcus and HPV, most vaccination rates are below the WHO targets. This is probably because vaccination is not mandatory but only recommended, and no central register of vaccination is maintained.

Only doctors may administer vaccines in Austria.

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