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Austria

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REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

Medicinal products are heavily regulated in Austria. In particular, the Medicines Act (*Bundesgesetz über die Herstellung und das Inverkehrbringen von Arzneimitteln, BGBl No 185/1983, as amended*) contains rules concerning:

- Manufacture and distribution.
- Marketing authorisations.
- Clinical trials.
- Labelling.
- Pharmacovigilance issues.
- Advertising.
- Gifts to healthcare professionals.
- Monitoring by state authorities.
- Penal provisions.

Medicinal products imports are also regulated. A licence issued under the Act Governing the Importation of Medicinal Products (*Bundesgesetz über die Einfuhr von Arzneiwaren, BGBl I No 28/2002, as amended in 2009*) is generally required to import medicinal products. However, products imported from a European Economic Area (EEA) member state are exempt from the licence requirement if they are covered in Austria by a national marketing authorisation or are authorised according to Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation). The importation by a patient is now regulated.

Various regulations require compliance with principles of good manufacturing practice (GMP) and good distribution practice, such as the Regulation Governing the Activities of Companies producing, controlling or placing medicinal products on the market. Further regulations were adopted in May 2008 relating to the labelling of outer packages, summary of product characteristics (SmPCs) and package leaflets. The Pharmacovigilance Regulation 2006 also applies.

The General Social Insurance Act (*Allgemeines Sozial-Versicherungsgesetz, BGBl No 189/1955, as amended*) and its implementing regulations set out basic rules for including a medicinal product in the Reimbursement Codex. Reimbursement is handled by the Main Association of Austrian Social Insurance Institutions (*Hauptverband der österreichischen Sozialversicherungsträger*) (Association).

Regulatory authorities

The main regulatory authorities are the:

- Federal Ministry for Health (*Bundesministerium für Gesundheit*).
- Federal Institute for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG).
- Medicines Supervision Agency (*Medizinmarktaufsicht*), formerly AGES PharmMed.

See box, *The regulatory authorities*.

Biotechnology and combination products

Combination products are covered by the same rules as other medicinal products. Biotechnology products fall outside the scope of the national marketing authorisation procedure and must be centrally approved by the European Medicines Agency (EMA) (*EMA Regulation*).

PRICING AND STATE FUNDING

2. What is the structure of the national healthcare system, and how is it funded?

The healthcare system is not financed through tax revenue but through a mandatory public insurance system funded by contributions from all employers, employees and self-employed people. Certain individuals are exempt from contributing, including:

- Persons earning EUR374.02 or less per month (as at 1 November 2011, US$1 was about EURO.7).
- Persons carrying out a business (including farmers) that generate income below a certain level.
- Certain self-employed persons whose professional organisations opt out of the mandatory insurance system (such as lawyers).

Individuals covered by the mandatory system are allocated to various funds according to their profession. The largest funds regulating private sector employees are the nine independent regional health insurance funds (*Gebietskrankenkassen*). Separate health insurance funds exist for, among others, self-employed people and public servants. All public funds are members of the Association.

Public health insurance funds provide a wide range of benefits. Financial cover is provided, for example, for illness or for self-employed women when giving birth. The insured person does not generally pay directly for medical services. However, certain co-payments are imposed, such as for obtaining a medicinal product (prescription fee of about EUR5.1) but no individual pays more than 2% of his net income for the prescription fee. It is unnecessary to specifically apply for this exemption.

Since 2005 only persons with an e-card can receive medical services paid for by social institutions. Each insured person must pay EUR10 per year for the e-card.

Individuals who are not regulated by the mandatory health insurance system can choose between:

- Insurance provided by the national health system.
- Private coverage.

The private system is based on a cost-reimbursement principle (that is, insured persons pay in advance for certain medical treatment and are reimbursed afterwards).

3. How are the prices of medicinal products regulated?

The marketing authorisation holder for over-the-counter (OTC) products can freely determine the price.

Prescription products are reimbursed under the national health insurance system. If the product has been included in the Reimbursement Codex, the reimbursement price is fixed. The General Social Insurance Act sets out basic rules for including a medicinal product in the Reimbursement Codex and calculating the price to be reimbursed (*see Question 4*). However, implementing regulations, and guidelines issued by various committees (for example, the Medicinal Evaluation Board), must also be considered. The guidelines are not binding, but can heavily influence the price of a medicinal product. The committee responsible for establishing the price is the Price Setting Committee (*Preiskommission*) (Committee) within the Ministry for Health (Ministry).

The price for a reimbursed product must not generally exceed the Average European Price (AEP). The AEP is defined as the arithmetic mean of the factory price or deposit price of most EU member states (not considering member states which joined after 2 May 2004, therefore 24 member states) where the medicinal product is marketed. To establish the AEP, all identical medicinal products must be considered. Products with the same active principle, strength, pharmaceutical form and package size are considered identical. The applicant must provide:

- Information enabling the Committee to calculate the AEP.
- A list of all rebates granted in the various EU member states.

Margins for wholesalers are also regulated (*Regulation Concerning the Maximum Margins at Wholesale Level (Verordnung der Bundesministerin für Gesundheit und Frauen über Höchstaufschläge im Arzneimittelgroßhandel)*).

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

Only products listed in the Reimbursement Codex are reimbursed by the national health insurance system. If an individual is a member of one of the mandatory regional health insurance funds, the pharmacist is reimbursed through a special arrangement with the social fund.

The Reimbursement Codex has four different boxes: red, dark yellow, light yellow and green. Reimbursement of a product listed in the red or dark yellow box is generally subject to approval by a physician employed by the Association (*see Question 2*). For certain products, a documentation system applies (*see below, Light yellow box*).

Red box

Each product for which an application to be listed in the Reimbursement Codex is filed is automatically included in the red box. The Association must decide whether the medicinal product can remain in the Reimbursement Codex within 180 days of the application being filed.

If the Committee has not established an AEP, the price proposed by the applicant is the relevant reimbursement price. However, if the AEP is lower than the proposed price, the difference between the AEP and the proposed price must be refunded by the applicant.

Yellow box in general

All products with a significant additional therapeutic value are included in the yellow box. All products in the yellow box are reimbursed up to the AEP. The Association must decide whether the product is to be included and at what price, within 180 days from receipt of the complete application, by taking into account the recommendation by the Medicines Evaluation Commission (*Heilmittel-Evaluierungskommission*) as to whether the product should be reimbursed. The Commission must specifically discuss for which indication(s) and for which group of patients a significant additional therapeutic value is given, and how this can be assessed economically.

Light yellow box

Products in the light yellow box are products the Association has decided need not be approved by an Association physician, but can be dealt with by a documentation system. Under the documentation system, the medicinal product must satisfy various economic criteria to be reimbursed. Allocation of the products to different systems (approval or documentation) is regulated by Association ordinances (21 have been issued so far).

Green box

For a product to be included in a green box, its prescription by a physician (not directly controlled by the Association) must be medically and economically justified. If products with a similar therapeutic use are already listed, the new medicinal product is only reimbursed if there is sufficient price difference when compared to products that are already included. Products with additional therapeutic value can be reimbursed at a higher price.

Generic products

A generic product is included in the Reimbursement Codex if it is substantially cheaper than the original product. If included, the holder of the marketing authorisation of the original product must offer a price reduction of at least 30%. A second generic product is eligible for inclusion in the Reimbursement Codex if it offers a substantial price difference when compared with the first generic product. If a third generic product is registered, the applicant of the original product and the Association can negotiate a further price reduction because, according to the Association, the price of the original product should not be higher than that of the third generic product. If a generic product is theoretically available, but not sold in Austria, the Association can undertake a tender procedure for the manufacture of a generic version.

Appeals

Decisions refusing the inclusion in the yellow box or green box, decisions deleting a product from the Reimbursement Codex or decisions re-transferring a product into another box, can be appealed to the Independent Medicines Commission (*Unabhängige Heilmittelkommission*) (UHK). Companies are now using this appeal more frequently than compared to the last couple of years.

MANUFACTURING

5. What is the authorisation process for manufacturing medicinal products?

Application

An application for a manufacturing authorisation must be submitted to the Federal Institute for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (Federal Institute). The application form and guidelines can be downloaded from the Federal Institute's website (*see box, The regulatory authorities*).

Conditions

A manufacturing authorisation is granted if the applicant complies with all requirements established in the Regulation Governing the Activities of Companies producing, controlling or placing medicinal products on the market, and if the quality of the medicinal product is guaranteed by the use of appropriate equipment. The Federal Institute can impose other, more specific, obligations.

Restrictions on foreign applicants

No restrictions apply to foreign EU/EEA applicants. However, certain restrictions apply to foreign non-EU/EEA applicants (for example, when purchasing land for production facilities). It is also often burdensome in practice to get diplomas, which were issued in non-EU/EEA countries, recognised in Austria.

Key stages and timing

An authorisation must be granted within 90 days of making the application. The time period can be extended, if the Federal Institute requires additional information.

Fee

The application fee is EUR3,000, plus EUR650 per half-day inspection in Austria. Foreign country inspections cost EUR750 per half-day.

Period of authorisation and renewals

A manufacturing authorisation is valid indefinitely, but can be revoked.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

The Federal Institute has authority to monitor compliance with manufacturing authorisations. The Minister for Health (Minister) can regulate, through an ordinance, which kind of premises should be inspected by the head of the regions (*Landeshauptmänner*). In addition, the Minister must establish general guidelines concerning inspections and taking samples. These guidelines must be respected by the Federal Institute. During an inspection, the Federal Institute has authority to:

- Enter the premises.
- Copy documents.
- Take samples, photographs and film footage.

These inspections should generally occur during normal business hours, except in an emergency. Facilities must be inspected at least every three years (*Medicines Act*) and inspections are performed on a regular basis.

Imposing penalties

Non-compliance with a manufacturing authorisation can result in either (or both):

- Its revocation or suspension.
- The imposition of various obligations.

If the offence is not punishable under criminal law, the relevant authority can also impose an administrative fine. Fines can be up to EUR25,000, or EUR50,000 for repeat offences. Companies can also face criminal charges.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Directive 2001/20/EC on the conduct of clinical trials was implemented by an amendment to the Medicines Act. The Federal Institute approves and supervises clinical trials.

Authorisations

The applicant must submit an application to undertake a clinical trial to the Federal Institute. The relevant form is available on the Federal Institute's website (*see box, The regulatory authorities*).

One of the documents needed for approval is a positive opinion from an ethics committee at the hospital or university where the clinical trial will be performed. The opinion can either be obtained before, or at the same time as, the filing of the relevant application. Special rules apply for multi-centre clinical trials.

If the applicant is not informed that the application has been refused within 35 days of its submission, the applicant can begin the clinical trial. This time limit does not apply to clinical trials performed with medicinal products that are used in:

- Gene therapy.
- Somatic cell therapy.
- Xenogenic cell therapy.

For these categories of products, the Federal Institute must issue a decision without undue delay (at the latest, within 90 days of the application's submission). If an advisory board is consulted, the deadline is extended to 180 days.

Even if an ethics committee issues a negative opinion, the Federal Institute can still approve the clinical trial if the Medicine Advisory Board (*Arzneimittelbeirat*) issues a positive recommendation. The fees for notifying a clinical trial concerning phase I to phase III studies to the Federal Institute are EUR2,500. Medicinal products consisting of or containing genetically modified organisms are approved by the Minister for Health.

Consent

Clinical trial subjects must give their informed consent. Consent must be in writing, signed and dated. For consent to be valid, the clinical trial subject must be informed of certain matters, including:

- That not taking part in the trial or the withdrawal of consent does not adversely affect his medical treatment.
- That personal data is subject to inspection.
- That personal data is kept absolutely confidential.
- That an insurance contract has been taken out.
- The scope, extent and risks associated with the clinical trial.

If a clinical trial subject cannot write, consent must be obtained in the presence of a witness, who must sign the form instead of the clinical trial subject. In the case of a minor, consent must be given by his legal representative. However, if the minor is capable of understanding the scope, extent and risks associated with the clinical trial, his consent must also be obtained. A forum consisting of all Austrian ethics committees has developed specific guidelines for drafting informed consent forms to be used for minors. Similar rules apply to persons incapable of giving informed consent.

Clinical trials on emergency patients not capable of providing informed consent are generally permitted if both:

- The hospital performing the trials informs the public about the conduct of the trials.
- Emergency patients, after being able to consent, consent to further participation in the trial, as well as to the use of their personal data.

It is prohibited to conduct clinical trials on the following:

- Prisoners.
- Persons held in a special institution under the Hospitalisation Act (*Bundesgesetz über die Unterbringung psychisch Kranker in Krankenanstalten*) (*BGBl No 155/1990, as amended*).
- Conscripts.

Trial pre-conditions

Other conditions include that:

- An insurance contract, which must be regulated by Austrian law, must be taken out by the applicant.
- The sponsor must provide detailed standard operating procedures (SOP).
- The clinical trial study medicinal product must be provided for free. Only under very limited circumstances is the clinical trial study medicinal product reimbursed by health insurance funds.

Procedural requirements

Clinical trials must be conducted in accordance with GCP and the approved protocol. Suspected serious and unexpected adverse reactions must be reported. After termination of the clinical trial, the Medicines Supervision Agency and the Ethics Committee must be informed.

MARKETING

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

A marketing authorisation is required for medicinal products (*Arzneimittelspezialitäten*), which are all of the following:

- Produced to guarantee the same composition for each batch.
- Have packages sold under an identical name.
- Available in a pre-packaged form to the end user.

These medicinal products also include medicinal products to be distributed to patients or end users when being produced through an industrial process or on a commercial basis (*gewerbsmäßig*).

The Federal Institute, which is scientifically supported by the Medicines Supervision Agency issues marketing authorisations. The Medicines Supervision Agency is part of the Austrian Agency for Health and Food Safety (*Österreichische Agentur für Gesundheit und Ernährungssicherheit*) and provides the Federal Institute with personnel and scientific support (*see box, The regulatory authorities*).

In addition to the Federal Institute, for certain products, applications for marketing authorisation can or must be made to the EMA, under the centralised EU system.

Authorisation conditions

The following requirements, among others, must all be satisfied to obtain a marketing authorisation under the national system:

- The applicant must be established in the EEA.
- The product, according to available knowledge and practical experience, must not be harmful in its normal conditions of use.
- The product must only contain substances or preparations whose harmlessness is proven by scientific knowledge or practical experience.

- The quality of the product must comply with the state of scientific knowledge.
- The description of the medicinal product and the product claims must not be misleading.
- The product's efficacy must be sufficiently proven.
- The labelling must comply with the relevant regulations.

Other conditions

Aside from the stricter reporting obligations imposed on newly marketed medicinal products (such as certain labelling and shorter PSUR reporting requirements) a company must only comply with further obligations if they are specifically imposed in the order granting the marketing authorisation.

Key stages and timing

Forms for obtaining marketing authorisation are available on the Federal Institute's website.

The Medicines Act requires marketing authorisations to be granted within seven months of receiving the application. If an application for marketing authorisation is refused by the Federal Institute, the applicant can only file a complaint with the Highest Administrative or Constitutional Court (under the Austrian system, an appeal to the Minister is not available).

The data exclusivity formula provides that all products are granted eight years' data exclusivity and an additional two year marketing restriction, irrespective of the route of approval.

Fee

Details of fees are set out on the Federal Institute's website. For example, if Austria is acting as a reference member state in the decentralised procedure (*see Question 10*) for a new active substance, a fee of EUR50,000 applies. For a purely national application of a new active substance, the fee is EUR10,700.

Period of authorisation and renewals

A marketing authorisation when issued for the first time is generally valid for five years. A renewal application must be submitted to the Federal Institute between:

- Four years after the marketing authorisation became binding.
- Six months before the marketing authorisation expires.

The application must include an overview of pharmacovigilance data, and if necessary, a report discussing any data that could influence the assessment criteria. After the first renewal has been obtained, the marketing authorisation is normally granted for an indefinite time period. However, under certain circumstances, the validity of a marketing authorisation can be limited to a further five-year period.

Post-marketing commitments and pharmacovigilance obligations

Post-market commitments are normally agreed between the Federal Institute and the applicant. They can cover a wide range of activities, from conducting post-marketing studies to implementing a traceability scheme allowing identification of the actual end user. The marketing authorisation holder must submit its PSUR (*Pharmacovigilance Regulation 2006*):

- Every six months (for the first two years from obtaining a marketing authorisation).
- Annually for the following two years.
- Once every three years after that.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

A simplified procedure exists for products that can be classified as generic products under Article 10 of Directive 2004/27/EC on the Community code relating to medicinal products for human use) (Code for Human Medicines Second Amendment Directive).

The applicant does not have to provide documents on pre-clinical and clinical trials, if the applicant can provide documents on well-established medical use of the active substance for at least ten years in the EU. In addition, the applicant does not have to provide pre-clinical and clinical data if either:

- The marketing authorisation holder has consented to the use of the data.
- The product has already been on the market in the EU for eight years.

Forms for obtaining a marketing authorisation are available on the Federal Institute's website, which is the competent authority.

10. Are foreign marketing authorisations recognised in your jurisdiction?

Articles 27 *et seq.* of Directive 2001/83/EC (as amended) on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) provide for a European mutual recognition procedure (MRP) and a decentralised procedure (DCP). As the Medicines Act does not contain any specific rules concerning MRP and the DCP, the guidelines provided by Articles 27 *et seq.* of the Code for Human Medicines Directive should be followed.

However, if an applicant intends to designate Austria as its reference member state, a special form (AT-RMS, available on the Federal Institute's website) must be completed.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

The Federal Institute monitors compliance with the Medicines Act. For example in 2009, 20 inspections relating to clinical trials for medicinal products and clinical investigations for medical devices (also in Russia and Ukraine) occurred. 398 samples of legally available medicinal products were tested, and 593 samples of illegally available medicinal products. 16 inspections relating to clinical trials occurred in 2010, as well as system inspections by three ethics committees.

Imposing penalties

A marketing authorisation can be suspended, revoked or withdrawn if, for example, the marketing authorisation holder:

- Does not comply with obligations imposed by the marketing authorisation.
- Places unsafe products on the market.
- Does not apply in time for renewal of a marketing authorisation.

In addition, an administrative fine (where these actions are not punishable under criminal law) can be imposed of up to EUR25,000, or for repeated offences, EUR50,000. Companies can also face criminal charges.

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

The Medicines Act specifically regulates the procedure for obtaining a parallel import licence. Only applicants established in the EEA can file an application, which must include:

- The name and marketing authorisation number of the product authorised in Austria.
- The qualitative and quantitative composition of the active substance.
- The state where the parallel imported product is authorised and marketed.
- The name and marketing authorisation number of the product to be parallel imported.
- The name and address of the marketing authorisation holder established in the exporting country.
- The name and address of the manufacturer established in the exporting country, where appropriate.
- A description of the packaging.
- The size of the packages to be distributed in Austria.
- A description of the relabelling and repackaging process.
- The name and address of the person responsible for the relabelling and repackaging.
- A declaration that the labels, the packaging, the summary of the product characteristics and so on, do not deviate from the product authorised in Austria.

The Federal Institute must decide, within 45 days of receiving the application, whether to grant the parallel import licence.

An IP holder can oppose parallel imports, for example, if repackaging and re-labelling:

- Is not necessary for market access.
- Affects the quality of the product.
- Does not mention the repackager and the manufacturer.
- Harms the trade mark owner's reputation.
- Occurs without the provision of notice to the IP holder.

The owner's consent for placing the product on the market is not assumed if the product to be exported was placed on the market under a compulsory licence system.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

It is illegal to offer, grant, or promise gifts or any other incentives, whether in kind or monetary, to health professionals for prescribing a medicinal product. Accepting incentives is also prohibited. Exceptions exist for:

- Gifts of low value, relevant to the medical or pharmaceutical practice.
- Hospitality offered during a scientific event, though this is strictly limited to its main purpose and must not be extended to persons other than healthcare professionals.

Offering incentives is an administrative offence and can result in a fine of up to EUR25,000, or EUR50,000 for repeat offences.

The bribery of public servants and officials (*Amtsträger*) is prohibited (*Criminal Code*). This also covers bribes to foreign officials.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Only pharmacists can supply medicinal products to end-consumers (the pharmacy monopoly). As a result, medicinal products cannot be sold to end-consumers by mail order or e-mail. A similar restriction is contained in the Austria Trade Code (*Gewerbeordnung, BGBl I No 194/1994, as amended*).

Although the Medicines Act has been constantly amended since the EU Court of Justice's *DocMorris* decision (*Case C-322/01*), it is still prohibited to sell OTC products on the internet, or to advertise on internet distribution channels. However, this prohibition only applies to national pharmacists and not to other pharmacists established in the EU. This is now reflected in new legislation, which allows three packages of the same medicinal product to be imported from EU pharmacists.

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The Medicines Act defines advertising for medicinal products according to Article 86 of the amended Code for Human Medicines Directive.

The Federal Institute is in charge of enforcing compliance with advertising restrictions. The industry association has also established a specific procedure concerning advertising violations.

Restrictions

Advertising of medicinal products is only allowed for the following medicinal products:

- Those for which marketing authorisation or an approval for distribution in parallel imports has been granted.
- Those produced according to the Medicines Act in pharmacies.

Advertising for pharmaceutical products must:

- Objectively describe the properties of the medicinal product without exaggeration.
- Not contain information or illustrations, which attach to the medicinal product an effect exceeding its actual effect.
- Not give the impression that success can be expected in general.
- Be in line with the SmPC and must not go beyond what is mentioned in the SmPC, for example by naming non-approved indications.

The Medicines Act distinguishes between advertising directed to healthcare professionals (persons qualified to prescribe or supply medicinal products) and those directed at the general public, as follows:

- Advertising to healthcare professionals is allowed, if the information is provided according to the SmPC.
- It is illegal to advertise to the general public:
  - prescription-only products;
  - OTC products with the same invented name or the same scientific name as a prescription-only product;
  - registered homeopathic medicinal products.

Advertising medicinal products for which marketing authorisation has not yet been obtained and non-approved indications is generally prohibited, other than at scientific events where participants are mainly from outside Austria.

The Code of the Austrian Pharmaceutical Manufacturer Association 2009 (*Pharmig*) provides some guidance (see *www.pharmig.at*, heading: "*Publikationen*").

Certain advertising restrictions also apply to OTC products. These are substantially in line with rules set out in the amended Code for Human Medicines Directive.

Internet advertising

Advertising over the internet is not treated differently to paper advertising from a legal perspective.

PACKAGING AND LABELLING

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

Packaging and labelling requirements are in line with the amended Code for Human Medicines Directive (*Section 17, Medicines Act*).

In addition, the Minister has published various regulations concerning SmPCs, package leaflets and labelling of the primary package as well as of blisters. The requirements are monitored by the Federal Institute.

Information requirements

As well as name, dosage and so on, the following characteristics must be displayed:

- Whether the product is available:
  - on prescription only, and only in pharmacies (*rezept- und apothekenpflichtig; verschreibungs- und apothekenpflichtig*);
  - only in pharmacies (*apothekenpflichtig*); or
  - other than in pharmacies, in which case this must be appropriately declared by symbols or pictograms.
- The following wording: "Attention! This medicinal product can influence your reactions and your ability to drive" (*Achtung! Dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen*).
- Reference to doping (*Anti-Doping-Grenzmengenverordnung* (ADGMV) 2010).

The following markings are also accepted, but not mandatory:

- The telephone, fax number or e-mail address of the marketing authorisation holder.
- Green dot (*Der Grüne Punkt*). This indicates the manufacturer is licensed by PRO-Europe (an umbrella organisation of national compliance schemes responsible for the recovery and recycling of packaging waste).
- European Article Numbering (EAN) code. This is a commercial distribution code system (barcode) that is widely used (a standardised way of representing barcodes).

Other conditions

All particulars on the outer and inner packaging must generally be in German. Certain information must also now be given in Braille. Austria does not require price or reimbursement conditions to be displayed on the label.

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Directive 2004/24/EC on traditional herbal medicinal products (Traditional Herbal Medicines Directive), which entered into force in April 2011, has been implemented in Austria. Due to its stricter rules, a large amount of herbal products disappeared from the market. However, a simplified registration procedure applies to homeopathic products not containing any indication.

PATENTS

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Inventions can obtain patent protection if they are all of the following (*Austrian Patent Law (Patentgesetz, or PatG, BGBl 259/1970, as amended)*):

- Novel.
- Not obvious from the state of the art to a person skilled in the art.
- Of industrial application.
- Not excluded from patent protection (for example, discoveries).

Inventions that fulfil these requirements are patentable even if they concern a product that consists of or contains biological material, or a process that produces, processes or uses biological material. Biological material is any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. Any such patentable inventions consist of:

- Biological material that is isolated from its natural environment and produced by a technical process, even if it previously occurred in nature.
- An element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of the natural element.

Scope of protection

The following (related to the life science sector) are not considered inventions:

- The human body, at the various stages of its formation and development.
- The simple discovery of one of its elements, including the sequence or partial sequence of a gene.

Patents are not granted for the following (relating to the life science sector):

- Methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body.
- Processes for cloning human beings.
- Processes for modifying the germ line genetic identity of human beings.
- Uses of human embryos for industrial and commercial purposes.
- Processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Patent protection is available for chemical compounds used as pharmaceuticals (substance protection). In addition, the Patent Office (*see Question 19*) accepts claims to protect new indications of known substances (Swiss claims). Any substance or composition, which is state of the art, is patentable for use in a method to treat the human or animal body for surgery or therapy (or any such diagnostic methods), provided that its use for such methods is not state of the art.

19. How is a patent obtained?

Application and guidance

An application is made to the Patent Office (*Österreichisches Patentamt*) (*www.patentamt.at*).

The following fees apply:

- The application fee is EUR230 and the fee for publishing specifications in the Patent Bulletin is EUR200 for the first 15 pages (each additional 15 pages costs EUR130).
- The first annual renewal fee is EUR100, starting with the sixth year after application and increasing annually up to a maximum of EUR1,700.
- The initial annual fee for the supplementary protection certificate is EUR2,200, increasing annually up to the fifth year to EUR3,400.

Process and timing

A separate application must be filed for each invention, and must include:

- Contact details of the applicant, including bank account.
- Contact details of the legal representative (if applicable).
- The title of the invention.
- Enclosures, such as:
  - descriptions;
  - patent claims;
  - drawings;
  - a summary;
  - the names of all inventors; and
  - information concerning claimed priority.

The application is examined by a member of the technical department of the Patent Office (*Technische Abteilung*). The patent application is published, at the latest, 18 months after the application is filed. On the day of publication, rights conferred by the patent provisionally enter into force. Any third party can file an objection against the (impending) grant of the patent, although any such person does not become party to the proceedings and is not entitled to reimbursement of costs.

If there is no reason to refuse the patent, the patent is granted. Any third party can file an opposition to the grant within four months of publication of the patent specification. If there are oppositions, an oral hearing is scheduled, if appropriate.

Deposit system

Except for under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Protection 1977 (as amended in 1980) (Budapest Treaty), inventions do not have to be deposited. However, they must be sufficiently described in the patent application to enable a person skilled in the art to perform the invention. Applications are examined by the Patent Office to see whether substantive legal conditions for patentability are met before a patent is registered.

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

The maximum term of protection of a patent is 20 years from the application date. No renewal process is available for patents.

Extending protection

For pharmaceutical products, the period of patent exclusivity can be extended by a supplementary protection certificate.

21. How can a patent be revoked?

The nullity department of the Patent Office (*Nichtigkeitsabteilung*) has exclusive power to revoke a patent for any of the following reasons:

- The subject matter of the patent was not patentable.
- The patent does not disclose the invention sufficiently clearly and completely as to enable a person skilled in the art to carry out the invention.
- The micro-organism deposited is not constantly available.

22. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

A patent confers on its owner the exclusive right to manufacture, distribute, offer for sale, use or import or possess for these purposes the patented subject matter. These rights do not cover studies or trials and any practical matters deriving from them, as far as these are required for marketing authorisation of a medicinal product.

If a patent granted is directed to a process, the effect of this patent also covers any product directly obtained by this process.

Contribution. The concept of contributory infringement was introduced in the Patent Act as amended in 2005 (*PatG*). A patent owner is entitled to prevent any third party from offering or supplying to a direct infringer with means relating to an essential element of the invention, if the third party knows, or it is obvious in the circumstances, that this information is suitable and intended for putting the invention into effect (*section 22(3), PatG*). In addition, any person assisting or supporting a direct infringer with intent is also liable.

Equivalence. According to court practice, confirmed by the Supreme Court and the Supreme Patent and Trademark Senate, equivalent use of a patented invention occurs if a person skilled in the art at the priority date and equipped with a general technical knowledge, considering the state of the art, takes (an) exchanged feature(s) without inventive effort, as a method of functioning in the same way as the patent.

Infringement through equivalence does not occur if the new invention uses features having equal effect while altering the protected idea in essence or contradicting the fundamental idea of the invention.

Claim and remedies

Civil proceedings. Patent infringement can be pursued by civil proceedings, where the Commercial Court of Vienna (*Handelsgericht Wien*) is exclusively competent. Its decisions can be appealed to the Higher Court of Vienna, whose decisions can be appealed further, under limited circumstances, to the Supreme Court.

A person whose patent right has been infringed (or is at risk of being infringed) can apply for a preliminary injunction before, simultaneously with or after bringing the main civil action.

The following remedies are available in civil proceedings:

- Injunctive relief (including preliminary injunctions).
- Removal of the interference.
- Monetary remedies, including:
  - adequate remuneration;
  - in the case of fault on behalf of the defendant, either damages (including lost profits) or payments of the profits achieved by the infringing party.
- In the case of gross negligence or intent, twice the amount of the appropriate remuneration is payable instead.
- Adequate compensation for any damage other than financial losses, provided this is justified by the particular circumstances of the case.
- Rendering of accounts.
- If appropriate, a request for information concerning distribution channels.
- Publication of a judgment in favour of the patent owner.

Criminal action. The patent owner can bring a criminal action against the infringer, and as part of this the applicant can apply for a house search and seizure. The Criminal Court of Vienna (*Landesgericht für Strafsachen Wien*) has exclusive competence.

23. Are there non-patent barriers to competition to protect medicinal products?

Medicinal products are granted eight years' data exclusivity, and an additional two year marketing restriction. This applies irrespective of the authorisation route and if they are, among others, considered to contain a new active substance or covered by a paediatric use marketing authorisation.

TRADE MARKS

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

Under the Austrian Trade Mark Protection Act (*Markenschutzgesetz, BGBl 1970/260, as amended*) (MSchG), product brands can be protected by a registered trade mark if they both:

- Can be graphically displayed.
- Possess a distinctive character in relation to the goods or services of an undertaking for which they are to be registered.

Scope of protection

Trade marks that cannot be registered include marks that:

- Are devoid of any distinctive character.
- Consist exclusively of signs or indications, which are used for designating the kind, quality, quantity, intended purpose, value, origin or time of production of the goods or of the provision of the services, or other characteristics of the goods or services.
- Consist exclusively of signs and indications that have become customary in current language, or in the bona fide and established practices of the trade.
- Consist exclusively of the shape that results from the nature of the goods themselves.
- Are contrary to public policy or principles of morality.
- Deceive customers in relation to the nature, quality or geographical origin of the goods or services.

A medical brand can be registered as a trade mark if it is not confusingly similar to an international nonproprietary name.

25. How is a trade mark registered?

Application and guidance

An application is made to the Patent Office. Standard forms and guidance on the application procedure are available only in German on its website (*www.patentamt.at*).

The following fees apply:

- **Registration fee.** The registration fee is EUR359, including three classes of goods and services. The fee for each additional class is EUR72.
- **Renewal fee.** A new fee schedule, including a gradual increase in renewal fees was introduced on 1 January 2012 as follows:
  - first renewal fee (due after ten years) is EUR650;
  - second renewal fee (due after 20 years) is EUR750; and
  - all subsequent ten-year renewal fees are EUR850.

Process and timing

The following information must be provided when filing an application for trade mark registration with the Patent Office:

- Contact details of the applicant. (Bank account details are not obligatory.)
- Contact details of the legal representative, if any. A legal representative must be appointed if the holder of the trade mark has no domicile or establishment in Austria.
- The nature of the trade mark (including word mark, figurative marks and 3-D marks).
- Enclosures, such as:
  - a description of the trade mark (if applicable);
  - in the case of a collective trade mark, the statutes of the association;
  - for sound trade marks, the melody saved on a disk;
  - information relating to priority claimed (if applicable);
  - five drawings of the trade mark (maximum size eight by eight centimetres, if applicable) if it does not only consist of words;
  - a description of goods and/or services for which the trade mark is designated.

The application is examined by a member of the legal department of the Patent Office (*Rechtsabteilung*). Trade mark applications cannot be rejected on the grounds that prior trade mark applications or registrations exist. However, any right holder of a prior trade mark can file an opposition against registration of a younger, identical or similar trade mark, within three months of a trade mark publication.

It normally takes the Patent Office six months from the date of application to issue the certificate of registration.

26. How long does trade mark protection typically last?

Duration and renewal

A trade mark right is created by registration in the Patent Office's register. Protection initially lasts for ten years from the date of registration. While production can start earlier, distribution of products bearing a trade mark is only allowed after the trade mark is registered. The trade mark can be renewed for an indefinite number of ten-year periods, on timely payment of the renewal fee. Renewal fees are due on the last day of the month in which the trade mark was registered. If not paid within six months, the trade mark will be revoked.

Extending protection

There are no other ways to extend the term of protection of a trade mark.

27. How can a trade mark be revoked?

A trade mark can be revoked by the Nullity Department of the Patent Office on various grounds, including:

- On the application of the trade mark owner.

- If the trade mark was not renewed in time.
- If the nullity department issued a decision ordering the revocation of the trade mark.
- Following successful objection to the trade mark.
- On the application of a prior right holder if the trade mark:
  - is identical to an earlier registered trade mark and its goods and services;
  - is similar or identical to an earlier registered trade mark and its goods and services and there is a risk of confusion;
  - is identical or similar to an earlier prior right (such as a firm name), which is not necessarily a registered right;
  - has been registered by an agent without the consent of the prior right holder abroad;
  - exploits the reputation of the older trade mark;
  - acquired secondary meaning as a designation of the goods and services of the company of the prior right holder (irrelevant if the trade mark is registered or not).
- On the application of any third party if:
  - the trade mark is not registrable;
  - the trade mark was not genuinely used within the first five years after issuance for all the goods and services registered;
  - the trade mark, following registration, has become customary in current language as a way of designating a good or service for which the trade mark is registered, as a result of the holder's conduct or failure to act in the course of business;
  - the trade mark has become deceptive (concerning the nature, characteristics and geographical background of the goods and services) because of the holder's use or because of use with the holder's consent;
  - the applicant acted in bad faith when obtaining trade mark protection.

28. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

The holder of a trade mark has the exclusive right to prevent any third party from using (without his consent) in the course of trade:

- Any sign identical to the trade mark in relation to goods or services that are identical to the goods or services for which the trade mark is registered.
- Any sign identical or similar to the trade mark used for identical or similar goods or services, if there is likelihood of confusion on the part of the public. This includes likelihood of association between the sign and the trade mark.
- Any sign identical or similar to the trade mark in relation to any goods or services, where the trade mark has a reputation in Austria and where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the reputation of the trade mark.

The following uses of a sign are considered infringement of a trade mark:

- Fixing the sign to goods, their packaging or to objects relating to a service rendered.
- Offering goods or putting goods on the market (or stocking them for these purposes) under the sign, or offering or supplying services under the sign.
- Importing or exporting the goods under the sign.
- Using the sign on business papers, in announcements or in advertising.

Claim and remedies

Infringement proceedings are handled by the ordinary civil courts acting as commercial courts. However, for an infringement of a Community trade mark, the Commercial Court of Vienna has exclusive jurisdiction.

Under civil law, the injured party can claim:

- Injunctive relief (including preliminary injunctions).
- Payment.
- Provision of accounts relating to the infringing product.
- Destruction of infringing objects.
- Publication of an advantageous judgment.
- Information on the source of supplier and channels of commerce.
- Adequate compensation, or damages, including lost profits or profits gained by the infringer (if there is culpable infringement).
- Appropriate compensation for any damage other than financial losses (immaterial damages).
- Punitive damages in cases involving gross negligence or fault, without having to prove actual damage. This is usually twice the amount of the actual damages awarded.

Under criminal law, wilful infringement constitutes a criminal offence, which is only prosecuted if requested by the injured party. The court can impose a fine of up to 360 daily rates. (The court looks at the offender's actual income minus children allowances and other basic living expenses to calculate the daily rate. The amount reflects the guilt of the offender, taking his financial situation into account.) Imprisonment up to two years can be imposed in cases involving wilful infringement on a commercial scale.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

There is no requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body. If the research is funded by the state or an organisation linked to the state, then sometimes the fund terms require that the organisation must consent to grant such a licence.

There is no requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body.

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Austria is party to a number of conventions, including the:

- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) (as amended in 1979).
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement) (as amended in 1979).
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957 (as amended in 1979).
- WIPO Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions 1963.
- Patent Cooperation Treaty 1970 (as amended in 2001).
- Strasbourg Agreement Concerning the International Patent Classification 1971 (as amended in 1979).
- WIPO Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973 (as amended in 1985).
- Budapest Treaty.
- WIPO Protocol Relation to the Madrid Agreement 1989 (as amended in 2006 and 2007).
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) (amendments of 2005 ratified, but no legal effect yet).
- WIPO Patent Law Treaty 2000 (ratified in 2010).
- European Patent Convention 2000.
- Agreement on the application of Article 65 of the European Patent Convention 2000 (London Agreement) (not ratified yet).

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

Liability can arise under:

- The Product Liability Act (Bundesgesetz über die Haftung für ein fehlerhaftes Produkt, BGBl 99/1988) (PHG).
- The Civil Code.
- Criminal law.

However, none of these rules contain specific provisions regulating liability for medicinal products.

Substantive test

In compliance with Directive 85/374/EEC on liability for defective products (old Product Liability Directive), the Product Liability Act establishes strict (non-fault) liability for defective tangible products.

The producer must indemnify all damages (other than consequential damage) caused by the defective product itself, including the death of a human being, bodily injury, damage to health and damage caused to other objects by the defective product.

A product is considered to be "defective" if it does not provide the safety that can be expected, taking into account all the circumstances, including the:

- Presentation.
- Use that is reasonably expected.
- Time when the product was placed on the market.

If an entrepreneur suffered damage because he used the defective object in his business and the amount of compensation does not exceed EUR500, the damage does not have to be indemnified.

The claimant must provide the court with proof of damage, a defect, and the causal relationship between them. However, the PHG provides for a shift in the burden of proof to the defendant for certain defences, including where an importer argues he did not place the product on the market or the product was not defective when it was placed on the market.

However, the PHG does not impose a product-monitoring obligation. This is specifically imposed by the Law on Food and Consumer Safety (*Lebensmittelsicherheit und Verbraucherschutzgesetz, BGBl I 13/2006*).

Liability

Any of the following can be held liable:

- The manufacturer.
- The person displaying his name or trade mark on the product.
- An importer of a product from a non-EEA country.
- The distributor, if the manufacturer or the importer cannot be identified, and if the distributor does not provide the consumer or client with the contact details in due time.

32. How can a product liability claim be brought?

Limitation periods

The following limitation periods apply to product liability claims:

- Three years from the date on which the damage and the identity of the infringer are discovered. (This is extended to 30 years if the damage was intentionally (*Section 1489, Civil Code*).)
- Ten years, from the date the product is placed on the market, for rights conferred by the Product Liability Act.

Class actions

Class actions (*Sammelklagen*) are not allowed in Austria. In certain circumstances the Civil Procedure Code allows claimants to join their cases (for example, where the claims are based on similar facts and the same court has jurisdiction to deal with all the claims). However, the individual claimants remain independent parties to the trial and a separate judgment is delivered for each claimant. In addition, the court has authority to refer the case to another court if referral will result in the trial taking less time or has a cost-saving effect.

A new kind of class action was recently approved by the Austrian Highest Court (*Oberster Gerichtshof*) in a claim concerning financial services. It will be permitted if:

- The court has jurisdiction to hear all the relevant claims.
- The same court procedures must apply to all the claims.
- The subject matter of all the claims must have the same nature, in relation to the facts and legal issues.

Since each patient has its own medical history, it is unlikely that this procedure will apply in product liability cases concerning medicinal products.

Foreign claimants

A claimant does not have to be a resident of, or have used the product in Austria, to be able to bring a claim in Austria. If a claimant is not resident in an EU/EEA member state, the defendant can ask for a security payment covering potential court costs and legal fees.

Jurisdiction for cross-border cases in the EU is regulated by Regulation (EC) 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels Regulation). Persons domiciled in an EU member state must be sued in the courts of EU member states. In particular, in matters relating to a contract, the person must be sued in the courts of the place of performance of the obligation. The place of performance in a sale of goods contract is the member state where, under the contract, the goods were delivered or should have been delivered.

In relation to consumer contracts:

- If a consumer enters into a contract with a party who is not domiciled in a member state but has a branch, agency or other establishment in a member state, the party is, in disputes relating to operations of the branch, agency or establishment, deemed to be domiciled in that member state.
- A consumer can sue the other party to a contract in the courts of the member state in which that party is domiciled, or in the courts where the consumer is domiciled.
- A consumer can only be sued by the other party to the contract in the courts of the member state where the consumer is domiciled.

These provisions can only be departed from by agreement in certain circumstances. Prorogation of jurisdiction is allowed under specific circumstances.

THE REGULATORY AUTHORITIES

Federal Ministry for Health (*Bundesministerium für Gesundheit*)

W *www.bmg.gv.at*

Main areas of responsibility. General supervision of the Federal Institute for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG).

Federal Institute for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG)

W *www.basg.at*

Main areas of responsibility. Granting various authorisations, such as for importation, manufacturing, clinical trials and marketing of medicinal products.

Medicines Supervision Agency (*Medizinmarktaufsicht*)

W *www.ages.at*

Main areas of responsibility. The Medicines Supervision Agency performs scientific evaluations in the context of granting marketing authorisation, manufacturing licences, clinical trials and so on. Marketing authorisation itself is granted by the Federal Institute for Safety in the Health Field.

The Medicines Supervision Agency is also involved in:

- Monitoring compliance with advertising, pharmacovigiliance, clinical trials and various authorisations.
- Conducting inspections.

33. What defences are available to product liability claims?

Liability can be avoided if:

- The defect arose because mandatory provisions issued by a competent authority were adhered to.
- The state of scientific and technical knowledge when the product was placed on the market was not such as to enable the discovery of the defect.
- In the case of a manufacturer of a component, the defect is attributable to the design of the product in which the component has been fitted or to instructions given by the manufacturer of a product.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

A consumer can only be compensated for damages if they exceed EUR500 (*Product Liability Act*). The complaint must generally be filed with the commercial court (at first instance) where the defendant has his seat of business or where the harmful event

occurred. Decisions of the Commercial Court can be appealed to the Higher Regional Court. The last instance of appeal is to the Supreme Court.

Punitive damages are not allowed for product liability claims.

REFORM

35. Are there proposals for reform and when are they likely to come into force?

The Austrian government implemented the new Blister Packaging Regulation (*BGBL Nr. II 474/2010*) on 1 January 2011. It applies to all establishments (including pharmacies) that repackage medicinal products in blister packaging. This ensures common quality standards. The Federal Office for Health monitors compliance with these regulations.

Also, the Regulation for the electronic transmission of applications 2010 (*Elektronische Einreichverordnung*) was enacted on 4 July 2011. It regulates the electronic transit of applications in proceedings concerning medicinal product imports. The Federal Office for Health provides a web portal where the documents must be submitted (*www.basg.at/eServices*).

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Areas of practice. Life sciences; intellectual property litigation; data protection.

Recent transactions

- Advising international companies in patent/SPC-infringement proceedings (including Merck & Co).
- Life sciences: specific focus on regulatory issues, reimbursement issues, unfair trade practices, data protection issues and product liability litigation.
- Advising companies on their social media policy and anti-bribery codes of conduct.

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Areas of practice. Intellectual property; life sciences; media.

Recent transactions

- Acting for Merck & Co Inc in patent infringement proceedings against several generics, based on a patent concerning a new pharmaceutical use of a substance.
- Acting for a global player in the healthcare sector.
- Structuring, negotiating and drafting a multimillion Euro sponsoring agreement with an independent provider of a continued medical education (CME).

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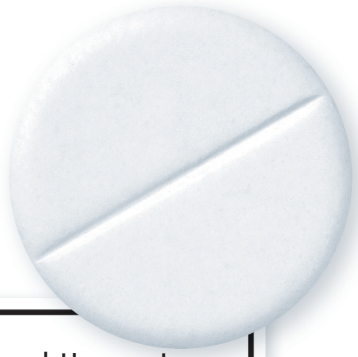

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