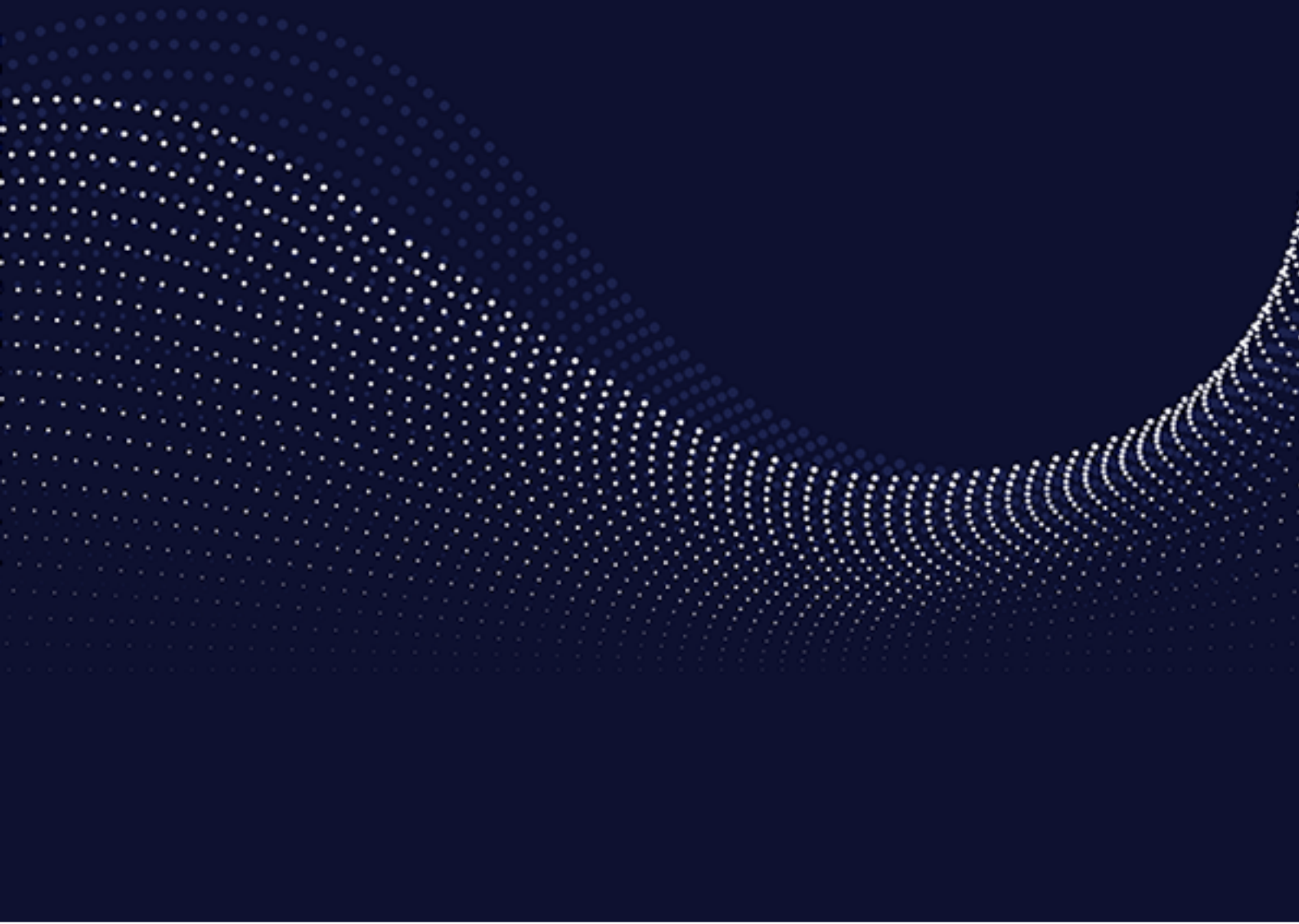
LEXOLOGY
Getting The Deal Through

PHARMA & MEDICAL DEVICE REGULATION

Austria



Pharma & Medical Device Regulation

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REGULATORY FRAMEWORK

Competent authorities for authorisation

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

Marketing authorisation for medicinal products 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 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, read in conjunction with Regulation (EC) No. 1901/2006 on medicinal products for paediatric use; and
- Regulation (EC) No. 1394/2007 on advanced therapy medicinal products.

There is no approval necessary for the marketing of medical devices in Austria. Medical devices can be marketed under the responsibility of the manufacturer that places the CE label on the device and declares that the medical device complies with the requirements of Regulation (EU) No. 2017/745 on medical devices (MDR) and Regulation (EU) No. 2017/746 on in vitro diagnostics (IVDR) as well as applicable national legislation. The competent national authority in the sense of the MDR is the BASG. For medical devices of higher risk classes (Classes IIa, IIb and III, as well as active implants and certain in vitro diagnostics), a notified body must be involved that verifies manufacturing and establishes the necessary certificates. Currently, QMD Services GmbH is the only notified body for in vitro diagnostics in Austria, but they expect to get approval also for medical devices in late 2023.

In accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use, the Austrian Act on Medicinal Products, section 1, defines medicinal products as any substance or combination of substances presented for treating or preventing disease in humans and animals, and as any substance or combination of substances that may be administered to humans or animals with a view to restoring, correcting or modifying physiological functions, or to making a medical diagnosis. Food (including food supplements and dietary supplements), cosmetics and medical devices are expressly excluded from the definition of medicinal products.

Article 2 of the MDR defines medical devices as instruments, apparatuses, appliances, software, implants, reagents, materials or other articles intended by the manufacturer to be used, alone or in combination, for human beings for several purposes such as:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy, or of a physiological or pathological process; or
- providing information by means of in vitro examination.

To fit the definition of a medical device, the device must not achieve its principal intended action by pharmacological, immunological or metabolic means.

Approval framework

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

Medicinal products

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

BASG may dismiss the application if the application contains wrong or incomplete data, the medicinal product contains substances considered unsafe, the product's quality does not meet the state of scientific knowledge, the effectiveness of the product is not sufficiently substantiated, or the clinical data is inappropriate for the evaluation of the product or does not correspond to the state of scientific knowledge or the labelling, the information leaflet or the summary of product characteristics do not comply with the legal requirements.

Medical devices

There exists no approval framework for medical devices. Nevertheless, medical devices may be placed on the market or put into service only if they bear the CE marking, which may be affixed if the device meets the essential requirements and the process of conformity assessment has been carried out. Medical devices must be registered in the unique device identification system by one of the designated entities (eg, Global Standards One, the Health Industry Business Communications Council, International Council for Commonality in Blood Banking Automation, and IFA GmbH).

CLINICAL PRACTICE

Applicable rules

What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Medicinal products

The conduct of clinical trials for medicinal products is governed by Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use (the Clinical Trials Regulation) and the Act on Medicinal Products, sections 28 to 48b, of which sections 32 to 36 apply to ethics committees.

Medical devices

Clinical trials for medical devices are governed by Regulation (EU) No. 2017/745 on medical devices (MDR), articles 61 to 82, and the Act on Medical Devices 2021, sections 13 to 36, of which sections 20 to 24 deal with ethics committees. Performance studies are governed by Regulation (EU) No. 2017/746 on in vitro diagnostics (IVDR), articles 56 to 77.

Ethics committees

Ethics committees for clinical trials of medicinal products and those for medical devices consist of physicians, nurses, lawyers, pharmacists, representatives of patients, representatives of disabled and elderly people, a person with biometric expertise and a minister. The committees have to evaluate the relevance of the trial and the study protocol, the qualification of the investigator and his or her collaborators, the information brochure, the appropriateness of the institution, the appropriateness of the insurance, and the amounts and modalities of the compensation paid to investigators and participants.

Reporting requirements

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

Medicinal products

Prior to the commencement of a clinical trial, the sponsor has to apply for approval of the trial with the Austrian Federal Agency for Safety in Health Care (BASG). The application has to contain all necessary data for the evaluation, including the opinion of the appropriate ethics committee. BASG has to validate the application within 10 days and notify the sponsor within 10 days of the submission of the application regarding whether the application dossier is complete. Otherwise, the dossier shall be deemed complete.

Within 45 days of the validation date, the BASG shall submit an assessment report through the EU portal. If the trial concerns more than one member state, each member state concerned shall notify the sponsor as to whether the clinical trial is authorised within five days of the report date.

Modifications to the study protocol have to be notified to the competent ethics committee and BASG. The sponsor and the investigator shall keep a clinical trial master file, which shall contain the essential documents relating to the clinical trial. The sponsor and the investigator shall archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial so that they are readily available and accessible to BASG upon request.

Medical devices

Prior to the commencement of a clinical trial, the sponsor has to apply for approval from BASG, according to MDR, article 70. The application has to contain all necessary data for the evaluation, including the opinion of the appropriate ethics committee. The sponsor may

commence the trial for devices of Class I and non-invasive devices of Classes IIa and IIb immediately after validation of the application. For all other devices, the sponsor has to wait for the BASG's approval which shall be provided within 45 days. Modifications to the study protocol have to be notified through the electronic system in accordance with MDR, article 73. At the end of the clinical trial, the sponsor has to provide a comprehensive final report. The same applies to performance studies for in vitro diagnostics.

Consent and insurance

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

Medicinal products

Unless otherwise provided for, clinical trials require the subject's consent after proper education according to the Clinical Trials Regulation, article 28 et seq. The consent may be revoked at any time. If the subject is a minor, the minor's legal guardian must also consent to participation. The same is true for the participation of incapacitated subjects. However, if a trial is designed for emergency situations and the subject's consent cannot be obtained within a reasonable time, no consent is required if:

- due to the urgency of the situation, the subject is unable to provide informed consent;
- there are scientific grounds to expect that the participation of the subject will have the potential to produce a direct and clinically relevant benefit for the subject;
- it is not possible within the therapeutic window to supply all prior information to, and obtain prior informed consent from, the subject;
- the investigator certifies that he or she is not aware of any objections against participation; or
- the clinical trial relates directly to the subject's medical condition and the clinical trial poses minimal risk to the subject.

The sponsor must arrange personal injury insurance covering all damages that a subject may suffer to life or health for which the investigator was responsible in case of fault, excluding damages caused by modifications of genetic material in cells of the germline. The law does not provide for a particular limit.

Medical devices

Unless otherwise provided for, clinical trials require the subject's consent after proper education according to the MDR, article 63 (IVDR, article 59). According to MDR, article 69, and the Act on Medical Devices 2021, section 26, (which also applies to in vitro diagnostics), the sponsor has to provide sufficient personal injury insurance.

MARKETING AUTHORISATION

Time frame

How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

In general, it takes seven months to obtain an authorisation from application to grant.

The fees for the marketing authorisation depend on the type of the application (national marketing authorisation, marketing authorisation with Austria as reference member state or Austria as concerned member state), the type of active ingredient (new or known) and whether the product is an 'ordinary' medicinal product, a homoeopathic medicinal product or a medicinal product described in a pharmacopoeia. The fees range from €1,235 to €61,734. Following marketing authorisation, an annual fee must be paid, which ranges from €372 to €3,581.

The initial period of validity of a marketing authorisation is five years. The holder of the authorisation may apply for prolongation, which is granted for an unlimited period of time.

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

The authorisation or registration of a medicinal product does not provide any exclusivities or protections other than those available under patent law. According to article 8 of the Regulation (EC) No. 141/2000 on orphan medicinal products, no applications for marketing authorisation nor applications for the extension of existing marketing authorisation for the same therapeutic indication in respect of a similar medicinal product shall be accepted, nor shall marketing authorisation be granted.

According to Regulation (EC) No 1901/2006, article 36, read in conjunction with Regulation (EC) No 469/2009, article 13, the protection period under patent law (including supplementary protection certificates) is extended for medicinal products for paediatric use.

Protecting research data

What protections or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

The data submitted by originators is confidential. However, the applicant for a generic may refer to the non-clinical trials and clinical trials if the first authorisation in a member state of the European Economic Area (EEA) is older than eight years or the holder of the marketing authorisation has consented to the reference in writing and irrevocably. A generic so authorised may be put on the market after 10 years from the first authorisation of the reference medicinal product.

If the holder of marketing authorisation of a reference medicinal product obtains marketing authorisation for one or more new indications within the first eight years after the initial

marketing authorisation is granted, which are deemed to have a significant clinical benefit over existing therapies in the scientific evaluation of the Austrian Federal Agency for Safety in Health Care (BASG), the period of 10 years is extended to 11 years.

Freedom of information

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

Although Austria has an Act on the Obligation to Give Information, this act does not give the right to review such files, because Austrian authorities and their officers are subject to the obligation of official secrecy according to the Federal Constitution, article 20. There is no Freedom of Information Act (FOI) in Austria, so third parties cannot make FOI applications. The draft Freedom of Information Act of February 2021 was withdrawn due to strong objections from local authorities. A new draft is expected by the end of 2023.

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

Regarding the application of homoeopathic medicinal products, it is not necessary to provide information on the effectiveness of the product, clinical data and non-clinical data. There is also no need to submit pharmaceutical data, results of non-clinical pharmacological and toxicological tests, or the results of clinical trials. The applicant must only provide:

- the name of the homoeopathic substances, indicating the various modes of application and dilutions;
- documentation:
    - describing the extraction and control of the substances; and
    - proving their homoeopathic use by means of appropriate bibliographic records.

If the medicinal product contains biological substances measures must be taken to ensure it is free of pathogens, and documentation on the preparation and control of the dosage, and descriptions of the method of dilution and dynamisation must be provided.

Less data is required for applications of medicinal products described in a pharmacopoeia.

Regarding orphan drugs, Regulation (EC) No. 141/2000 on orphan drugs applies.

Regarding medicinal products for paediatric use, Regulation (EC) No. 1901/2006 applies.

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

Article 8 of Regulation (EC) No. 141/2000 on orphan drugs grants market exclusivity for a period of 10 years, which may be reduced to six years if, at the end of the fifth year, it is established that the criteria for designation as an orphan drug are no longer met.

Article 36 of Regulation (EC) No. 1901/2006 on medicinal products for paediatric use provides for an additional extension of six months of the patent or the supplementary protection certificate. Article 37 extends the 10-year period for orphan drugs for paediatric use to 12 years.

Generic drugs and biosimilars may enjoy the benefits of a referenced application if the authorisation of the original product is older than eight years.

Post-marketing surveillance of safety

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

Medicinal products

The holder of a marketing authorisation is obliged to appoint a qualified person to record pharmacovigilance data and to make this data accessible to BASG within seven days at any time. The responsible person must be domiciled within the EEA. The holder must also establish a risk management system for each medicinal product to supervise the benefit–risk ratio and to supervise pharmacovigilance data to identify new risks or the modification of existing risks. If the notification of adverse effects results in an amendment to the labelling, the leaflet or the summary of product characteristics (SmPC), the holder of the marketing authorisation must notify healthcare professionals immediately. The holder of the marketing authorisation must collect information on all presumed serious adverse events within the EEA and submit the data within 15 days electronically to the European Medicines Agency's EudraVigilance database. Information on non-serious adverse events must be transmitted within 90 days. The holder must also provide regular periodic safety update reports.

Medical devices

The manufacturers and distributors of medical devices have to collect all data on incidents and adverse events in connection with the medical device and notify BASG of such incidents through the electronic system, according to MDR, article 92, respectively IVDR, article 87. They must undertake all measures to identify possible risks and dangers for the health and safety of patients, users or third parties and to support investigations by the competent authorities. They also have to appoint a qualified person to comply with the provisions of the MDR and IVDR.

Other authorisations

What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

The manufacture, import, export and conduct of wholesale distribution of medicinal products require a (qualified) trade licence. The manufacturer or wholesaler has to appoint a responsible person domiciled within the EEA who has to fulfil certain qualification criteria (eg, the study of pharmacy, chemistry, biology or medicine and practical experience, or practical experience and a proficiency exam).

The manufacture, import, export and conduct of wholesale distribution of medical devices and in vitro diagnostics also requires a (qualified) trade licence. The manufacturer or wholesaler has to appoint a responsible person domiciled within the EEA who has to fulfil certain qualification criteria (eg, studied chemistry, medicine or pharmacology plus practical experience or proficiency exam, or elongated practical experience).

The licences are granted for an unlimited period of time.

Manufacturing and storage of medicinal products or medical devices and in vitro diagnostics also require a permit for the operational plant. The applicant has to provide data that the plant will not endanger the life or health of the applicant, the employees or the neighbours. The applicant has to provide the authority with a description of the plant, a list of equipment, detailed plans, a technical description and a waste management concept. The permit is granted for an unlimited period of time, although any changes to the plant have to be notified (and permitted).

There are no official fees to be paid for the licence. However, the holder of a licence must be a member of the Chamber of Commerce and has to pay an annual contribution, which is based on the number of employees and the annual turnover.

There are also no official fees for the permit for the plant, but the cost of preparing the application and the commissioning will arise.

Sanctions

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

Operating a business without the proper trade licence is subject to an administrative fine of up to €3,600 that is imposed on the managing director. The same is true if the business does not appoint a responsible person for the conduct of the business or operates the business without a permit for the operational plant. If the appointment of a responsible person has been notified, the fines are to be imposed on the responsible person. Repeated infringements also may lead to a withdrawal of the trade licence.

Tampering or falsifying medicinal products is a criminal offence subject to imprisonment of up to three years (Act on Medicinal Products, section 82b). According to the Act on Medicinal Products, section 83, marketing medicinal products without marketing authorisation and other infringements of the Act on Medicinal Products are administrative offences, subject to a fine of up to €7,500 (in the case of repetition, €14,000). Marketing of medicinal products that do not meet the required quality criteria or are unsafe or marketed without marketing authorisation is an administrative offence and subject to a fine of up to €25,000 (in the case of repetition, up to €50,000).

Marketing unsafe medical devices, marketing medical devices without proper instruction, marketing medical devices without the CE label or marketing medical devices without evaluation of conformity (among other similar offences) are administrative offences subject to a fine of up to €25,000 (in the case of repetition, up to €50,000). The same is true for marketing unsafe in vitro diagnostics, in vitro diagnostics without proper instructions, without a CE label, or without an evaluation of conformity.

Exemptions

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

Medicines described in an Austrian pharmacopoeia monograph and medicines 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 marketing authorisation.

Marketing authorisation is also not required for conducting a (pre)clinical trial or upon prescription by a physician admitted in Austria in cases of an urgent need to fend off 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 marketing authorisation. Finally, pharmaceuticals for medical treatment in cases of emergency (eg, natural disaster, terrorism, war) may be marketed without a marketing authorisation.

Furthermore, no marketing authorisation is required for medicinal products if BASG has permitted the distribution of a medicinal product according to Regulation (EC) No. 726/2004, article 83, under a compassionate use programme.

Parallel trade

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

Medicinal products do not require an Austrian authorisation if a qualified physician, dentist or veterinarian confirms that:

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the medicinal product is urgently needed to fend off a threat to life or severe health injury and this result cannot be achieved with an authorised and available medicinal product;

- the medicinal product is necessary for medical treatment in the case of army deployment; or
- the medicinal product is necessary in connection with a catastrophe, terroristic threat or war.

Medicinal products corresponding to a medicinal product that has obtained a marketing authorisation under the Act on Medicinal Products may be imported, provided that they are imported from an EEA member state, and the evaluation of the safety and effectiveness of the medicinal product that has obtained a marketing authorisation can be applied to the imported product.

Prior to marketing in Austria, BASG has to be notified and the marketing in parallel trade must be approved. The application for approval must contain:

- the name and the registration number of the medicinal product admitted in Austria;
- the composition of the medicinal product;
- the member state of origin;
- the name and registration number of the product in the state of origin;
- the name and address of the holder of the authorisation in the state of origin;
- if applicable, the name and address of the manufacturer in the state of origin;
- the package of the imported product;
- the package sizes to be used in Austria;
- the description of the relabelling or repacking;
- the name and address of the entity providing the relabelling or repacking; and
- the declaration that the text of the package, the primary package, the instructions for use, and the SmPC will not be amended, unless for necessary references to the distributor.

AMENDING AUTHORISATIONS

Variation
What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Medicinal products

Any variation of the (national) authorisation of a medicinal product relevant to the marketing authorisation must be notified to the Austrian Federal Agency for Safety in Health Care (BASG). Variations regarding the name, the composition in respect of quality and quantity,

the retail distribution, fields of application (except their reduction), the dosage, and the mode of application require the approval of BASG. Variations to the package and the labelling, instructions for use or summary of product characteristics regarding contraindications, warning notices, interdependencies, fertility, pregnancy and nursing period, adverse events and overdosing require the approval of BASG. Approval is deemed to be granted unless BASG objects within six months. Variations of European marketing authorisations have to be notified in accordance with Regulation (EC) No. 1234/2008 concerning the examination of variations to the terms of marketing authorisation for medicinal products for human use and veterinary medicinal products.

Medical devices

As there is no marketing authorisation for medical devices, there are no requirements for the variation of the marketing authorisation. However, a new CE certification may become necessary.

Renewal

What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

Marketing authorisations for medicinal products are granted principally for a period of five years. No earlier than one year and no later than nine months prior to expiry, the licence holder of a medicinal product for human use may apply for a prolongation, provided that the criteria for obtaining the marketing authorisation are still fulfilled. The applicant has to provide an overview of pharmacovigilance data and, if necessary, a report discussing any data that could possibly influence the assessment criteria as well as a consolidated version of the particulars to be filed for obtaining the marketing authorisation with all amendments since registration. If BASG extends the marketing authorisation, it is unlimited in duration, unless an explicit limit of another five years is set owing 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. BASG may provide exemptions for reasons of health protection. If the marketing of a medicinal product is impossible solely because of patent protection, the grace period only starts after the expiry of patent protection.

As there are no marketing authorisations for medical devices, there are no requirements for renewal.

Transfer

How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

Medicinal products

The transfer of the existing approvals and rights to market medicines has to be notified to BASG by the holder of the marketing authorisation and the acquirer of these rights. The

transferor has to renounce the marketing authorisation and the transferee has to declare the takeover. Upon receipt of these declarations, the transferee is deemed the holder of the marketing authorisation and assumes all rights and obligations in connection with the marketing authorisation.

Medical devices

A change of the manufacturer of a medical device will transfer all the obligations and requirements relating to the medical device to the new manufacturer. A transfer of approvals is not necessary provided that the subsequent manufacturer continues to comply with the provisions set forth in Regulation (EU) No. 2017/745 on medical devices.

RECALL

Defective and unsafe products

What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

According to the Act on Medicinal Products, section 75q, the holder of a marketing authorisation has to notify the Austrian Federal Agency for Safety in Health Care (BASG) of any observed quality defects. BASG has to evaluate the notification and qualify the risk in classes (Class III: no serious danger to health; Class II: danger to health may cause disease or maltreatment; and Class I: danger to life or serious danger to health). According to its assessment, BASG may impose a recall of the product.

According to the Act on Medical Devices 2021, section 44, BASG may impose a recall of a medical device if the device could endanger the health or safety of patients, operators or third parties, or of products not in compliance with the safety requirements according to Annex I of Regulation (EU) 2017/745 on medical devices or Annex I of Regulation (EU) 2017/746 on in vitro diagnostics.

ADVERTISING AND PROMOTION

Regulation

Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

Advertising aimed at the general public is prohibited for medicinal products subject to prescription and over-the-counter (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, covid-19).

Advertising of OTC medicinal products 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
- 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 the case of audiovisual media, this information has to be provided both audibly and visibly.

Advertising aimed at professional circles has to provide a legible summary of the essential information of the summary of product characteristics. It must contain the time when the information was published. The information must be exact, current, verifiable and complete enough to allow the recipient to evaluate the therapeutic value of the medicine. Citations from literature must be verbatim and the source has to be identified.

Provided that there is a direct or indirect reference to a specific medicinal product, the provision of information will be treated as promotional. The decisive issue is whether the general impression of the advertisement focuses on the presentation of the pharmaceutical enterprise or the promotion of a specific – or, at least, identifiable – medicinal product.

Similar restrictions apply to the advertising of medical devices (and in vitro diagnostics).

Inducement

What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

The collaboration of the pharmaceutical industry with healthcare professionals is governed by the Act on Medicinal Products and, in the case of medical devices and in vitro diagnostics, by the Act on Medical Devices 2021. Neither the Act on Medicinal Products nor the Act on Medical Devices 2021 distinguishes between physicians in the outpatient and inpatient sector. Specific anti-corruption rules, however, apply to public officials and physicians in the outpatient sector. Physicians working in public hospitals are public officials.

The main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals are contained in the Act on Medicinal Products, sections 55a and 55b. 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 healthcare 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 must not be extended to persons other than healthcare professionals. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any such inducement.

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.

Product samples may be granted only for medicinal products that have already obtained marketing authorisation. The packages have to be the smallest package on the market and labelled with 'Doctor's sample – not for sale'. The number of samples is limited to the use of 10 patients and 30 samples of a medicinal product per physician in the first year after the marketing authorisation and, thereafter, to two samples per request up to a maximum of five samples per year.

The Act on Medical Devices 2021, sections 70 to 77, offers similar provisions on the advertising of medical devices and in vitro diagnostics to healthcare professionals and the general public, but fewer detailed regulations with regard to the collaboration of manufacturers with healthcare professionals. This is because of the proprietary differences between medicinal products and medical devices, and the fact that no detailed provisions under EU Directives had to be implemented verbatim. The anti-corruption provisions of the Austrian Criminal Code also apply to manufacturers of medical devices.

The Austrian Criminal Code penalises passive bribery (the request or acceptance of a benefit by a public official or arbitrator in exchange for the execution of a service in breach of their duties) and active bribery (the grant, promise or offer of a benefit to a public official or arbitrator in exchange for a service in breach of their duties) by imprisonment for up to 10 years. Also, the illegal acceptance of an advantage (the request or acceptance of a benefit by a public official or arbitrator in exchange for a dutiful execution of their services) is punishable by up to five years' imprisonment. The granting of undue advantages (the grant, promise or offer of a benefit to a public official or arbitrator in exchange for the dutiful execution of a service) may be punished with imprisonment of up to five years.

A public official is any person working for, or authorised by, a national public service organisation, an international organisation, a foreign state, or an enterprise of which at least 50 per cent is directly or indirectly owned by a national or foreign political body.

Reporting transfers of value

What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

There are no particular provisions provided by law in terms of transparency requirements. However, self-regulation under the Association of the Austrian Pharmaceutical Industry (Pharmig) Code of Conduct provides for a disclosure of the cooperation of pharmaceutical companies with healthcare professionals. Pharmig's Code of Conduct only applies to its members. According to the Code of Conduct, article 9, pharmaceutical companies have to document and disclose any and all transfers of value granted to healthcare professionals or institutions. Regarding medical devices, there are no transparency requirements similar to the rules established by Pharmig in respect of medicinal products. Guidelines are provided

by the Austromed Code of Conduct andMedTech Europe's Code of Ethical Business Practice (March 2022).

Enforcers

Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The Austrian Federal Agency for Safety in Health Care (BASG) is responsible for the enforcement of legislation relating to medicinal products and medical devices, including advertising control.

Pharmig is a lobby group based on voluntary membership. It has published a Code of Conduct containing provisions on general principles, information or advertisement. Pharmig is a member of the International Federation of Pharmaceutical Manufacturers and Associations.

Austromed is an Austrian association established to promote the interest of companies manufacturing medical devices. Its Code of Conduct deals with healthcare-related topics such as collaboration and interaction between stakeholders in the medical devices industry, delivery and ethical standards, and cartel law. Austromed is a member of MedTech Europe.

Physicians, dentists, veterinarians and pharmacists are members of the respective professional chambers. In the case of physicians and dentists, there are nine provincial chambers and one federal chamber and, in the case of veterinarians and pharmacists, there is one federal chamber with nine provincial offices. Their main functions are to facilitate and represent the interests of their members. They also have disciplinary powers ranging from reprovals and fines to prohibiting the exercise of the profession. Such sanctions can only be imposed after a formal disciplinary procedure.

Sanctions

What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

Advertising that does not comply with the provisions of the Act on Medicinal Products constitutes an administrative offence and is subject to a fine of up to €25,000 (in the case of repetition, up to €50,000) according to the Act on Medicinal Products, section 84. Advertising not corresponding to the provisions of the Act on Medical Devices 2021 is also an administrative offence, subject to a fine of up to €25,000 (in the case of repetition, up to €50,000) according to the Act on Medical Devices 2021, section 81.

Furthermore, competitors and consumer protection organisations and organisations of competitors may sue for infringements of the advertising rules under the Unfair Competition Act for cease and desist actions.

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Health professionals may provide and use products for off-label indications under their responsibility.

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 summary of product characteristics, it is almost impossible to lawfully provide information regarding off-label use. Information to healthcare professionals limited to the international non-proprietary name of the active ingredient and its administration without any reference to the product's name or trademark, thus not directly advertising the off-label use of a specific medicinal product, seems to be possible.

Unlicensed products

What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

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 that the medicinal product is urgently needed to fend off 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 marketing authorisation. The physician must confirm these requirements. Based on this confirmation, a pharmacy or a pharmaceutical wholesaler may apply for an import certificate to be issued by the Austrian Federal Office for Safety in Health Care (BASG).

Medicine described in an Austrian pharmacopoeia monograph that is prepared in a pharmacy for direct distribution by that pharmacy may be marketed without authorisation. In addition, 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 marketing authorisation.

Marketing authorisation is also not required for conducting a (pre-)clinical trial or upon prescription by a physician admitted in Austria in cases of an urgent need to fend off 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 marketing authorisation. Finally, pharmaceuticals for medical treatment in cases of emergency (eg, natural disaster, terrorism, war) may be marketed without a marketing authorisation.

Furthermore, no marketing authorisation is required for medicinal products if BASG has permitted the distribution of a medicinal product according to article 83 of Regulation (EC) No. 726/2004 under a compassionate use programme.

Compassionate use

What rules apply to the establishment of compassionate use programmes for unlicensed products?

Upon application by the manufacturer of a medicinal product (if he or she is the sponsor of an approved clinical trial) or by the applicant for a marketing authorisation according to Regulation (EC) No. 726/2004, article 6, BASG may approve the 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 Regulation (EC) No. 726/2004, article 83. BASG issues guidelines for applications for compassionate use programmes, which are available in English and German on its website.

SALE AND SUPPLY

Regulation

Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

Dispensing or sale of medicinal products (whether over-the-counter (OTC) or prescription only) to individuals is reserved for pharmacies in Austria.

No such restriction applies to medical devices unless their retail to individuals is limited to pharmacies or qualified businesses by an ordinance of the Ministry of Social Affairs, Health, Care and Consumer Protection.

Online supply

What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

According to the Act on Medicinal Products, section 59, the online dispensing, sale and supply of OTC medicinal products with a marketing authorisation in Austria by an Austrian pharmacy or a pharmacy of a European Economic Area member state is permitted. Online dispensing, sale and supply by Austrian pharmacies are only permitted for pharmacies that have:

- notified their intention to provide online sales to the Austrian Federal Office for Safety in Health Care (BASG);
- have a website that, according to Directive 2001/83/EC, article 85c:
    - displays the address and contact information for BASG;
    - displays the safety logo; and
    - provides a link to BASG's website.

Pricing and reimbursement

What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

Theoretically, manufacturers or distributors of medicinal products are free to establish the prices of their medicinal products. Practically, however, the Social Security Fund only reimburses patients for the cost of medicinal products that are listed in the Reimbursement Code, which is established by the Umbrella Association of Austrian Social Security Institutions. In order for a product to be included, the manufacturer must negotiate a price with the Umbrella Association.

Upon being prescribed by a physician (or a dentist), the Austrian health insurance system reimburses the cost of the medical product. Physician or dentist prescriptions for products contained in the yellow or red boxes of the Reimbursement Code may be subject to approval or review by the head physician of the local health insurance fund.

Reimbursement for off-label or compassionate prescriptions requires the approval of the head physician, if no other reasonable treatment currently available in Austria is likely to be successful, or such a treatment was unsuccessful and the off-label treatment has a reasonable probability of success.

Inclusion in the Reimbursement Code

After obtaining marketing authorisation for a medicinal product, a manufacturer or distributor may apply for the product to be included in the yellow or green box of the Reimbursement Code by suggesting a retail price, and providing information on the product's therapeutic properties and the duration of the patent protection. Upon such an application, the product will be included in the Code's red box for a period of 90 days (or 180 days if the Umbrella Association also decides on the product's price). After this period elapses, a product will be removed if the Umbrella Association decides that the product will not be included in the yellow or green boxes.

After the product is included in the Code, the Price Commission will calculate the product's average price within the European Union and the Umbrella Association will negotiate a reimbursement price with the manufacturer or distributor.

The prices of products included in the Reimbursement Code are re-evaluated every six months. If the Price Commission finds a product's EU average price has fallen in that time, the Umbrella Association may demand a price reduction from the manufacturer and repayment of the difference.

The price of a product in the red box must not exceed its EU average price. If no average price is established, the price suggested by the manufacturer applies. If the Price Commission determines the EU average price is lower, the manufacturer has to repay the difference within six months.

A product may be included in the yellow box if an evaluation by the Evaluation Commission ascertains it presents a significant therapeutic innovation.

A product may be included in the green box if the Evaluation Commission ascertains a similar or equal therapeutic effect in comparison to a product that is already in the green box and there is a substantial price difference between these products. If the manufacturer wishes the product to carry a higher price, the Evaluation Commission must first establish the product offers added therapeutic value.

Generics and biosimilars

When a generic or a biosimilar enters the market, the Umbrella Association will ask the manufacturer of the original product to reduce its price by 30 per cent; if the manufacturer refuses, the product will be removed from the Code.

For a generic or biosimilar to be listed in the Reimbursement Code, the manufacturer must agree to a price that is lower than the discounted price of the original product, or lower than the previously released generic product. (See tables 1 and 2, below.)

If a third generic product is registered, the original product's manufacturer or importer must offer a further price reduction, or it will be removed from the Reimbursement Code. In such cases, the price difference between the cheapest and the most expensive products cannot exceed 20 per cent.

Table 1: Pricing of generic products in Reimbursement Code

Product	Price reduction	Reference price
First generic	28.6 per cent	Original product
Second generic	18 per cent	First generic product
Third generic	15 per cent	Second generic product

Table 2: Pricing of biosimilar products in Reimbursement Code

Product	Price reduction	Reference price
First biosimilar	11.4 per cent	Original product
Second generic	15 per cent	First released biosimilar
Third generic	10 per cent	Second released biosimilar

Unlisted products

The cost of medicinal products that are not listed in the Reimbursement Code (no-box products) will only be reimbursed if the prescription is approved by the Social Security Fund's head physician in well-founded individual cases.

Over the past few years, the pharmaceutical industry has increasingly made use of this exception by not applying for innovative – and expensive – medicinal products to be included in the Reimbursement Code. However, if sales of a medicinal product exceed €750,000, its price in Austria must not exceed the EU average price. If no EU average price has been determined, the manufacturer's price applies provisionally. If the EU average price is later established to be lower than the manufacturer's price, the manufacturer has to repay the difference plus 6.5 per cent to the Umbrella Association.

Hospitals

The administration of medicinal products is an integral part of hospital in-patient treatment, so such patients do not have to pay additional charges for products.

Hospitals may directly negotiate the prices of medicinal products with suppliers. However, the Social Security Fund does not directly compensate hospitals for purchasing medicinal products, as this is included in the global reimbursement for hospitalisation which the Fund pays.

Medical devices

The Social Security Fund only reimburses part of the cost of a limited number of medical devices (primarily spectacles, contact lenses, wheelchairs and incontinence pads). The maximum contribution is €1,560.

UPDATE AND TRENDS

Forthcoming legislation and regulation

Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

The price adjustment process in the Reimbursement Code was amended. As of 1 January 2024, upon a generic product becoming available on the market, the manufacturer of the original product must reduce its price by 30 per cent; if they refuse, the product will be removed from the Reimbursement Code.

For a generic or biosimilar product to be included in the Reimbursement Code, its price must be 25.7 per cent lower than the original product's reduced price. Further generics/biosimilars are included if they offer a sufficiently large price difference to the first generic/biosimilar. As soon as a third price reduction has been made, the original product's manufacturer must agree to a further price reduction with the Umbrella Association; otherwise, the product will be removed from the Reimbursement Code. If it is foreseeable that, notwithstanding a legal possibility, no generic/biosimilar will be available to allow the Umbrella Association to

request a price reduction, the Umbrella Association may tender the active ingredient or the active ingredient's class one year in advance.

A recent amendment to the Act on Pharmacies prevents agreements that require prescriptions be collected at, or transferred to, specific pharmacies as such agreements are contrary to a patient's free choice of pharmacies. The amendment opposes business models that involve collecting various patients' prescriptions and transferring them to a certain pharmacy to prevent a pharmacy from serving those patients. The amendment also permits the creation of stations to collect pre-ordered, over-the-counter medicinal products by entering a code (eg, a QR code).

In view of Regulation (EU) 2019/6 on veterinary medicinal products, the Austrian Act on Medicinal Products, which currently applies to medicinal products for human and veterinary use, shall be amended, and a new Act on Medicinal Products for Veterinary Use will be enacted to supplement the Regulation. Stakeholders were able to submit comments on the draft bill until 4 August 2023, and it shall be adopted by parliament by the end of 2024.