SECOND EDITION 2015

COMMERCIALISATION OF HEALTHCARE

A GLOBAL GUIDE FROM PRACTICAL LAW

This second edition of *Commercialisation of Healthcare* provides a high level practical overview of the regulatory framework for the commercialisation of medical products in 24 jurisdictions around the world, including key requirements for manufacturing, advertising and selling drugs, medical devices, biological products and natural health products.

Written by leading lawyers in their countries, contributors are ideally placed to provide clear, concise and practical commentary on the inner workings of their respective legal systems.

General Editors:
Jeffrey S Graham, *BORDEN LADNER GERVAIS LLP*
Jeffrey N Gibbs, *HYMAN, PHELPS & MCNAMARA, PC*

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Published in October 2015 by Thomson Reuters (Professional) UK Limited
Friars House, 160 Blackfriars Road, London, SE1 8EZ
(Registered in England & Wales, Company No 1679046.
Registered Office and address for service:
2nd floor, 1 Mark Square, Leonard Street, London EC2A 4EG)

A CIP catalogue record for this book is available from the British Library.

ISBN: 9780414051232

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PREFACE

Jeffrey S Graham, BORDEN LADNER GERVAIS LLP

It is very rewarding to think that the first edition of our book has been so well received by those responsible for providing advice on the regulatory requirements for the commercialisation of health products. The success of the first edition reinforces the view of the co-editors, Jeffrey Gibbs of Hyman, Phelps & McNamara, PC (Washington) and Jeffrey Graham of Borden Ladner Gervais LLP (Toronto) that our effort helps to fill a need for advisers, being asked to provide strategic advice on international commercialisation strategies, to have access to a concise multi-jurisdictional reference tool.

This second edition continues to draw upon many of the leading legal advisory firms with expertise in health products that participated in the first edition. In addition, the second edition has contributions from leading firms and practitioners in a number of new jurisdictions, notably Indonesia, Ireland, Spain and Switzerland, reflecting our view that we are all better off as advisers in our particular jurisdictions having a sense of the very dynamic international regulatory environment in which our clients find themselves. In addition, the network of legal advisory firms that we have created, with the assistance of Thomson Reuters, gives each of the participating firms comfort when making international referrals that they have access to firms of high standing in other jurisdictions with expertise in health products.

We would also want to recognise the support we have received from Thomson Reuters in all phases of this project. We feel very privileged to have partnered with this outstanding global organisation. Not only does Thomson Reuters have the highest editorial standards, as reflected in the content of each chapter, but their extraordinary distribution capabilities ensure that our publication will receive the broadest possible readership.

Free trade negotiations between North America and the European Community and in the Pacific Rim are but two examples of efforts to promote further globalisation in trade, including health products. As a result, there is no doubt that future editions of this book will have new issues and opportunities to address.

Toronto, September 2015

Jeffrey S Graham

FOREWORD

Jeffrey N Gibbs, HYMAN, PHELPS & MCNAMARA, PC

The first edition of this guide was published two years ago. Since then, the importance of drugs, devices and biologics has grown even further. The sales of these products have continued to expand, and are now expected to reach an estimated US$514 billion by 2020.

Many different factors drive this trend. One factor is technology itself. There have been extraordinary advances in basic and applied sciences, leading to the development of new products. The deciphering of the human genome, followed by tremendous strides in understanding the basic underlying disease processes, has helped pharmaceutical companies develop drugs that are targeted at specific disease-causing mechanisms. Researchers have learned to differentiate between different types of cancer based not on the site of the tumour, but on its underlying biology. The focus has increasingly shifted from where the cancer is found to its genetic make-up. That, in turn, has led to targeted therapies and the growth in diagnostic tools required to differentiate between these types of cancer. A whole range of disciplines that did not exist a few years ago (such as bioinformatics, metabolomics and proteomics) are spurring the development of new therapies and diagnostics. Similarly, new technologies, new materials, greater computer power and a better understanding of human physiology have accelerated growth in the medical industry. For example, the US recently approved the first drug manufactured with a 3D printer. New or improved non-invasive diagnostic devices have enhanced clinical diagnoses and improved patient management, which can in turn spur the use of pharmaceuticals. Further technical breakthroughs are highly likely with the heightened research focus by governments, academia and industry on the functioning of the brain. The results of those studies will almost surely lead to new therapies and diagnostics.

Other factors have also contributed to the growth in new products. Life expectancies are increasing and global populations are aging, stimulating demand for drugs and devices. The middle class has grown dramatically in many developing nations, such as China, India and Brazil. There is an increasing emphasis on access to healthcare in more countries. For example, in China, healthcare expenditures have risen from US$156 billion in 2006 to US$357 billion in 2011, and they are projected to reach US$1 trillion by 2020 (McKinsey & Company: Healthcare in China: 'Entering uncharted waters', July 2012).

Global growth is promoted both by:

- An increased supply of more attractive goods (that is, better, more advanced and effective products and technologies).
- Increased demand, due to demographics, economics, consumer expectations and social factors.

Therefore, there are powerful forces that should lead to continued substantial growth in the research, development and introduction of healthcare products. There is a profound trend in favour of growth despite the existence of significant impediments, such as issues relating to cost, third party coverage and payment, the limited investment in certain key areas such as therapies for infection, product liability litigation, and patent thickets.

Another powerful force is globalisation. The healthcare market is an increasingly global market. More companies are looking to markets not just in their home country or region, but around the world. Sophisticated manufacturers are crafting strategies for multiple types of markets. Some companies try to incorporate plans for global marketing from the outset, while others take a more stepwise approach. The very concept of "home country" has changed, with companies redomiciling or opening key facilities in multiple countries. Companies are also looking at cross-border transactions, with a record volume of mergers and acquisitions in the healthcare sector in the last year.

While it is easy to advocate a global strategy, executing such a strategy is anything but easy. A company selling in the US cannot just replicate its experience in Europe and expect to succeed, let alone in even more diverse markets, such as India and China, or in smaller, less developed countries. The term "global market" is itself a misnomer; companies can sell throughout the world, but markets all have very different characteristics.

One of the most important differences between markets is the applicable regulatory regime. Drugs, devices and biologics are regulated products. In many countries, a company cannot simply start selling a new cardiovascular drug or knee implant without first complying with some government regulatory requirements. These requirements can be extensive and complex. In addition, the continued marketing of products must also comply with the relevant regulatory framework.

These regulatory regimes vary significantly from country to country. A manufacturer that assumes its regulatory experiences in one country will help guide its experiences elsewhere is very likely to stumble. Drawing false analogies between countries can be costly and dangerous. For example, one of the best developed regulatory laws, the US Federal Food, Drug, and Cosmetic Act, which was enacted in 1938 and amended many times since then, applies both to drug and device manufacturers. Some of the provisions, such as the prohibitions on the introduction of "adulterated" or "misbranded" products, are identical for both drugs and devices. Based on their familiarity with US law, drug manufacturers will sometimes assume that they understand key facets of the device regulatory system (and vice versa). Usually, they are wrong. Even terms that are the same for drugs and devices (such as "good manufacturing practice" (GMP)) have different meanings in the two systems. While it may be reasonable to assume that a key regulatory concept (such as GMP) expressed in the same words in the same statute would have the same meaning, such an assumption can be wrong. Although there are similarities between drug and device GMPs, these also differ in material ways.

The example above can be used throughout the world. Given that a US drug company cannot rely on its drug GMP experience when evaluating a US device company's compliance with GMP, it is considerably harder (and more dangerous) to apply local experience to an entirely different country, with different laws, rules, policies, cultures and norms. Therefore, it is critical for companies, or individuals advising companies, to have information about the regulatory systems in various countries. However, this information is difficult to obtain. There is a need for a single source that allows companies, lawyers, analysts or others interested parties to rapidly and conveniently obtain insights into the healthcare regulatory regimes in key markets around the world. This guide helps to fill that gap.

By compiling descriptions of the drug and device regulatory regimes for 24 different countries, this guide provides in a single source key insights into how these products are regulated around the world. The countries represented in the guide account for the majority of the global population (about 60%), the global economy, and global expenditures on drugs, devices and healthcare products. While not all countries are covered, the countries that are included provide insights into diverse types of markets. Chapters cover developed countries

that are both leading consumers of healthcare products and developers of such products, including the US, UK, Germany and Canada. Critical emerging markets are also covered, including China, India and Brazil. In addition, other smaller but important markets are included, such as Mexico and South Korea.

The structure of the guide enables readers to obtain a rapid overview of the regulatory system for each country. The same format is followed in each chapter, addressing key elements of the regulatory regime for each country, such as the drug and device approval systems, and controls on marketing and post-marketing enforcement. The use of the same structure facilitates cross-country comparisons. This approach makes it easier to quickly discern key similarities and differences between countries with respect to a particular regulatory area, and to appreciate the types of questions to ask when contemplating a new market.

Each of these chapters was written by individuals who work with that country's regulatory system, which is an important strength. In theory, one could carefully "parse" the laws of various countries and conclude that they now understand how a particular country regulates a specific area; but such an approach does not work. Under a regulatory scheme, words can have very different meanings from their ordinary meaning. Persons who simply rely on their understanding of the ordinary and customary meaning of words used in the laws and regulations will have unpleasant surprises when trying to obtain approval for a product or dealing with government regulatory authorities. Understanding how healthcare products are regulated requires knowledge of "lore", not just law. Gaining insights into this "lore" can only come from experienced individuals who routinely advise companies on the applicable regulatory requirements.

Another principal feature of healthcare regulation is the pace at which the regulatory landscape changes. For example, the US Food and Drug Administration (FDA) is regularly issuing new regulations and adopting new policies that can profoundly affect healthcare manufacturers. For example, since the first edition of this guide was published:

- FDA approved its first biosimilar drug.
- Australia took a step forward to promote biosimilars through "a" flagging of biosimilars, unless clinical evidence provides a basis for not doing so. Such "a" flagging enables brand substitution by pharmacists.
- apan created a new regulatory category for regenerative medicine, including provisions for expedited approvals.
- Turkey has introduced changes that require the tracking of value transfers to healthcare providers. Device companies must also address the May 2014 reforms on advertising and promotion, and there are new provisions governing comparative advertisements aimed at consumers.
- China has introduced many new device regulations, including one relating to inspections and manufacturing.

These are just a small handful of the numerous regulatory changes in the past two years.

This guide is intended to provide a summary, not a comprehensive review of each regulatory framework. Many of the individual topics covered could be the subjects of books in their own right. There will be times when a comprehensive review of a particular topic is needed, and other resources or direct contact with experts will be required. However, this guide is a valuable resource as it provides current information on a wide variety of key markets in a standardised, easy-to-compare and digest format.

The healthcare industry is poised for continued growth around the world. However, this growth will neither be linear nor simple. Companies that wish to participate in this global growth need to understand the regulatory framework of the countries in which they wish

to sell. Such knowledge will help when developing products, conducting clinical studies, crafting intended use statements, positioning a product, complying with ongoing regulatory requirements, negotiating agreements, making strategic decisions, evaluating investment options and in a multitude of other ways. This updated, refreshed, and expanded guide should help companies, investors, analysts, researchers and others better understand this critical and evolving global regulatory landscape.

AUSTRIA

Karina Hellbert, FIEBINGER POLAK LEON & PARTNER RECHTSANWÄLTE

REGULATORY OVERVIEW

1. WHAT IS THE REGULATORY FRAMEWORK FOR MEDICAL PRODUCTS?

Legislation

Medical products are regulated by the Medicines Act, which contains rules on:

- Manufacturing and distribution.
- Marketing authorisation.
- Clinical trials.
- Advertising.
- Gifts to healthcare professionals.

The manufacturing of products is further detailed by an Ordinance governing the Activities of Companies Producing, Controlling, or Placing Medicinal Products on the Market. The import of medicinal products is also separately regulated by the Act on Importation of Medicinal Products 2010.

For medical devices, the main body of rules can be found in the Medical Devices Act and in the Act on the Manufacturing of Medical Devices. All types of medical devices are governed by the Medical Devices Act. Under the Trade Act, medicinal products and medical devices can normally only be manufactured and distributed by individuals who have passed a certain examination and can prove practical experience concerning these product categories. However, for certain medical devices, the Ministry of Health issued a specific ordinance also allowing general retailers and specialised shops providing primarily health-related products to sell certain low-risk medical devices.

Regulatory authorities

Generally, the Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) is the regulatory authority responsible for medicinal products, in particular for granting marketing authorisations and supervising compliance with medicine rules. The BASG itself is supervised by the Federal Ministry for Health. In particular, it is assisted with marketing authorisations, scientific evaluations and inspections by the Medicines Agency (*Medizinmarktaufsicht*), which is organised as a limited liability company. Therefore, the Medicines Agency has the expertise and the resources for handling marketing authorisations, inspections and surveillance measures and prepares the decisions for the BASG. The decisions adopted are publically available. The Medicines Agency also handles the granting of marketing authorisations for Liechtenstein.

The BASG and the Medicines Agency also handles medical devices.

For more information on the BASG and Medicines Agency see box: *The regulatory authorities*.

Private parties

Private parties do not play any role in the evaluation of marketing applications for medicinal products. They simply file an application and therefore become a party to the administrative proceedings. Competitors play an indirect role since, if there are violations of advertising rules applicable to medicinal products or medical devices, then competitors can initiate civil proceedings based on the Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb*). With a medical device, private bodies accredited by the Ministry for Economics are involved in establishing conformity with the essential requirements imposed by the EU legislation applicable to medical devices. If conformity is established, a CE marking can be affixed to the product.

2. WHAT TYPES OF MEDICAL PRODUCTS ARE REGULATED?

The Medicines Act covers various types of medicinal products, including:

- Medicinal products per se.
- Generics.
- Biosimilars.
- Homeopathic products.
- Traditional herbal products.
- Products used for somatic gene therapy.
- "Traditional" drug substances.

For medicinal products containing genetically modified organisms, the Gene Technology Act also applies. Food products serving special dietary needs must be notified to the Ministry of Health before being placed on the market for the first time. For this notification, the label must be enclosed. For other food products, such as food supplements, no licence is needed for placing those products on the market. These products are generally governed by the Act concerning the Safety of Food Products and Protection of Consumers. In essence, these products are not allowed to be of such quality that would endanger human health and must not contain any disease-related claims. The Medical Devices Act covers:

- Medical devices.
- In vitro diagnostics.
- Active medical devices.

DRUGS

3. WHAT ARE THE GENERAL REQUIREMENTS FOR A DRUG TO BE MANUFACTURED, ADVERTISED AND SOLD?

Manufacturing

The manufacturing of medicinal products is governed by the Trade Act and the Medicines Act. It is a "restricted trade" that requires a specific licence under the Trade Act.

The manufacturing, distributing or controlling of medicinal products requires an authorisation from the Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) (*section 63, Medicines Act*). An application for such a manufacturing licence must include:

- A description of the tasks envisaged.
- The production volume.
- The place of manufacturing.
- The condition of the manufacturing facility.
- The size of the facility.
- The zoning classification.
- The equipment used.
- A description of the technical equipment.
- The name of the qualified person, if applicable.

Before such a licence is granted, the BASG performs at least one inspection of the manufacturing premises.

If the facility does not compromise human or animal health, the authorisation is granted after an initial inspection. Further inspections will occur regularly (at least every three years).

To obtain the necessary approval under the Trade Act, at least one person must have passed an examination, proving that he has the necessary legal and scientific knowledge and skills for manufacturing or distributing medicinal products. In addition to the licence under the Medicines Act, an operation licence under the Trade Act is also required.

Advertising

Advertising medicinal products is regulated in the Medicines Act and via codes of conduct, for example, the industry association Pharmig's Code of Conduct. Generally, advertising must not be misleading, either to consumers or to healthcare professionals. This means that, for example:

- Properties of the medicinal product must not be exaggerated.
- Information or pictorial presentation must not indicate that the product's effect exceeds the actual effect.
- Success cannot be claimed as achievable in any event.

Violations of those rules can be enforced by public authorities or competitors under the Unfair Trade Practices Act, or arbitrated under the Pharmig Code of Conduct. Off-label advertisement is prohibited, except during international congresses.

Sale

For medicinal products to be sold, the BASG must issue a marketing authorisation, which is granted to applicants established within the European Economic Area (EEA) and fulfilling the requirements imposed by the Medicines Act. Once granted, the authorisation is initially valid for five years and then subsequently indefinitely unless revoked or suspended. For certain products, a second five-year period can be imposed. An authorisation can be revoked if the BASG finds evidence of non-compliance with certain requirements during one of their regular inspections of manufacturing facilities, or if the risks associated with the product outweigh the benefits.

Medicinal products can only be sold by pharmacists (a pharmacy monopoly). Recently, sale via the internet through approved internet pharmacies has also been allowed. This is regulated by the Medicines Act and the Pharmacy Act, which clearly establish the distribution chain for sales of medicinal products. The fees that can be charged by wholesalers are also regulated.

Regarding the price of medicinal products, marketing authorisation holders can freely determine the price of over-the-counter (OTC) products. However, the price of prescription products is fixed and reimbursed under the national health insurance system. This price cannot exceed the EU average price. People who work in Austria (and certain non-working family members such as spouses and children) are members of mandatory regional health insurance funds, which reimburse pharmacists for prescribed medication. To be reimbursed, products must be included in the Reimbursement Codex, which consists of four types of box:

- The red box is where every reimbursement application begins.
- Within 180 days, those products are then placed in the:
  - dark yellow box (this is for products with a significant therapeutic value and the use of which must be approved by a physician employed by one of the sick funds;
  - light yellow box (this is for products that do not need to be approved by a physician employed by one of the sick funds but must be documented according to binding guidelines); or
  - green box (this is for all other products whose prescription by physicians must be medically and economically justified).

4. ARE THERE DIFFERENT REQUIREMENTS FOR PATENTED AND GENERIC DRUGS?

The Medicines Act provides that a patent is not an obstacle for the review of a generic product's marketing authorisation. In addition, if a product is not marketed due to an existing patent, the marketing authorisation of the generic product will not automatically be withdrawn after three years of non-marketing (as stipulated in the sunset clause).

Marketing authorisations for generic products are granted through a simplified procedure. There is no need for applicants to provide documents concerning pre-clinical and clinical trials if:

- The active substance has been in well-established use for ten years within the EU.
- The marketing authorisation holder has consented to using the data.
- The product has been on the EU market for eight years.

Biosimilar medicinal products are regulated slightly differently because, due to their characteristics, they are not classified as generics. Applications for biosimilar medicinal products must show that, due to the degree of natural variability, the biosimilar does not affect safety or effectiveness in comparison to the innovator.

The provisions of Austrian law comply with EU legislation, but fees in the approval process are substantially reduced for generic products.

5. WHAT AUTHORITY IS RESPONSIBLE FOR REGULATING THE MANUFACTURE, ADVERTISING AND SALE OF DRUGS?

The Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) is the regulatory authority responsible for regulating drugs, in particular for granting marketing authorisations. The technical aspects of the dossier are examined by the Medicines Agency, which also prepares the decision on whether a medicinal product should be approved or not.

For more information on the BASG see box: *The regulatory authorities*.

6. ARE THERE FEWER OR DIFFERENT REQUIREMENTS FOR DRUGS THAT HAVE ALREADY BEEN LICENSED/APPROVED IN ANOTHER JURISDICTION?

Under Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive), there is a mutual recognition procedure (MRP) and a decentralised procedure (DCP). For an applicant that chooses one of these routes, the Medicines Agency has posted on its webpage the relevant forms to be completed, depending on whether Austria acts as a reference member state or as a concerned member state. In relation to quality or efficacy, the requirements cannot be lowered. However, in countries where the Medicines Agency only acts as a concerned member state, the fees for obtaining a marketing authorisation are substantially lower. Concerned member states have limited possibilities to object to a marketing authorisation if the reference member state is of the opinion that the marketing authorisation must be granted or has already been granted. In cases of objections, an arbitration procedure applies at EU level.

In addition to the Medicines Act, the Act Governing the Importation of Medicinal Products regulates the commercial and private importation of medicinal products, in particular over the internet.

The importation of medicinal products not covered by a European Economic Area (EEA) marketing authorisation must be approved in Austria. Imported products with an EEA marketing authorisation which do not have a national authorisation and are either re-exported or used for scientific or medical purposes must be notified to the Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG). If the products are used as investigational products, no notification is required. Recently, this has also applied to products manufactured in Switzerland.

The following can be imported freely without the necessity of approval by or notification to the BASG:

- Centrally-approved products.
- Products with an Austrian marketing authorisation.
- Products that do not require a marketing authorisation at all.

However, blood products must always be notified to the BASG, even if they have been approved within the EEA.

If products are imported in violation of these rules, they will be sent back or destroyed at the cost of the purchaser, and fines of up to EUR3,600 can be imposed (this amount is doubled in the case of repetition). The BASG can carry out inspections, open containers and take samples

at premises (including customs warehouses) suspected of storing these products. Parallel-imported products can only be distributed if the BASG has granted a parallel import licence. To apply for this licence, information is required on, among other things:

- The name and marketing authorisation number of the product authorised in Austria.
- The state where the parallel-imported product is authorised.
- The name and marketing authorisation number of the product to be parallel-imported.
- The name and address of the marketing authorisation holder.
- The name and address of the person responsible for re-labelling and re-packaging.
- A declaration that, for example, the summary of product characteristics (SPC) and packaging and labelling do not deviate from the product authorised in Austria.

7. IS IT POSSIBLE TO SELL DRUGS TO OR BUY DRUGS FROM OTHER JURISDICTIONS?

For private purposes (that is, up to three packages), a private person can buy non-prescription medicinal products from a pharmacy established within the European Economic Area (EEA) over the internet.

However, prescription-only products can only be purchased in a national public pharmacy. Such pharmacies must comply with strict documentation requirements controlled by the Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG).

8. IS IT PERMITTED TO ADVERTISE DRUGS TO CONSUMERS? ARE THERE RESTRICTIONS ON ADVERTISING?

Over-the-counter (OTC) products that are not reimbursed by the social security funds can be advertised to consumers. Even reimbursed OTC products can be advertised if they were included against the will of the marketing authorisation holder in the Reimbursement Codex. Such advertising must objectively describe the properties of the medicinal product without any exaggeration:

- It cannot include information or illustration indicating an effect exceeding its actual effect.
- It cannot indicate that success can be expected in any way by taking such medicinal product.
- Any and all information must be in line with the summary of product characteristics (SPC).

Non-approved medicinal products can be advertised at scientific events that primarily target non-Austrian professionals.

The Pharmig Code of Conduct also specifically regulates advertising via the internet. For example, websites can include non-promotional information on medicinal products, such as information on side effects or interaction with other substances. However, such information must be accompanied by an instruction to contact a physician or pharmacist. A company can also link complete evaluation reports, for example, those published by the Committee for Medicinal Products for Human Use (CHMP) established by the European Medicines Agency (EMA), or on websites of national authorities or medical research institutions. The Code also requires that, in the case of advertising to healthcare professionals, an access system is implemented so that only healthcare professionals can actually gain access to such information.

MEDICAL DEVICES

9. WHAT ARE THE GENERAL REQUIREMENTS FOR A MEDICAL DEVICE TO BE MANUFACTURED, ADVERTISED AND SOLD?

Manufacturing

The manufacturing and distribution of medical devices is regulated by the Medical Devices Act and by implementing regulations such as the Regulation for the Establishment, Manufacturing, Use and Maintaining of Medical Devices in Institutions Active in the Health Field. There is also an ordinance issued by the Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) which imposes on retailers and physicians the requirement to pay a contribution in the form of lump sums to the BASG in exchange for performing its vigilance tasks. The provisions of the Trade Act must also be complied with.

To manufacture medical devices, the Medical Devices Act does not require a specific authorisation for operating a production facility. However, a licence is required under Trade Act. The manufacturer must also comply with the Medical Devices Manufacturing Regulation 2007. Medical device manufacturers, when placing a medical device on the market for the first time, must notify *Gesundheit Österreich Gmbh.*

Advertising

The advertising of medical devices is regulated by the Medical Devices Act. Any advertising for medical devices must not:

- Attribute characteristics that the product does not have.
- Convey the message that success can be expected in any case.
- Convey the message that (if used in compliance with the manual for use) the products cannot be harmful.
- Contain misleading representations on complying with the essential requirements as imposed by the relevant legislation.

It is also forbidden to advertise products that by their presentation could be considered as medical devices, but which do not have the characteristics of a medical device.

Sale

The retail sale of medical devices requires a trade licence (with a few exceptions).

Medical devices bearing a CE mark, even if affixed in another EU member state, can be freely sold in Austria. They do not need any further approval by any Austrian authority.

10. WHAT AUTHORITY IS RESPONSIBLE FOR REGULATING THE MANUFACTURE, ADVERTISING AND SALE OF MEDICAL DEVICES?

The Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) and Medicines Agency (*Medizinmarktaufsicht*) are responsible for regulating the manufacture, advertising and sale of medical devices.

For more information on the BASG see box: *The regulatory authorities*.

11. ARE THERE FEWER OR DIFFERENT REQUIREMENTS FOR MEDICAL DEVICES THAT HAVE ALREADY BEEN LICENSED/APPROVED IN ANOTHER JURISDICTION?

Medical devices can be freely imported from any other EU/European Economic Area (EEA) member states provided that they bear a CE mark.

12. IS IT POSSIBLE TO SELL DEVICES TO OR BUY DEVICES FROM OTHER JURISDICTIONS?

Medical devices bearing the CE mark can be freely imported by individuals from other EU/European Economic Area (EEA) member states.

13. IS IT PERMITTED TO ADVERTISE MEDICAL DEVICES TO CONSUMERS? ARE THERE RESTRICTIONS ON ADVERTISING?

Advertisement to consumers is prohibited for medical devices that:

- Bear no CE mark.
- Are only available on prescription.
- Are intended to be solely used by professionals.

BIOLOGICAL PRODUCTS

14. WHAT ARE THE GENERAL REQUIREMENTS FOR A BIOLOGICAL PRODUCT TO BE MANUFACTURED, ADVERTISED AND SOLD?

Biological products are medicinal products and must also be licensed.

Manufacturing

See *Question 3, Manufacturing*.

Advertising

See *Question 3, Advertising*.

Sale

See *Question 3, Sale*.

15. WHAT AUTHORITY IS RESPONSIBLE FOR REGULATING THE MANUFACTURE, ADVERTISING AND SALE OF BIOLOGICAL PRODUCTS?

The Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) and Medicines Agency (*Medizinmarktaufsicht*) are responsible for regulating the manufacture, advertising and sale of medical devices.

For more information on BASG see box: *The regulatory authorities*.

16. ARE THERE FEWER OR DIFFERENT REQUIREMENTS FOR BIOLOGICAL PRODUCTS THAT HAVE ALREADY BEEN LICENSED/APPROVED IN ANOTHER JURISDICTION?

Biological products are considered medicinal products. Therefore, to be sold in Austria, biological products that have already been licensed/approved in another jurisdiction must therefore be authorised under the mutual recognition procedure (MRP) or the decentralised procedure (DCP).

17. IS IT POSSIBLE TO SELL BIOLOGICAL PRODUCTS TO OR BUY BIOLOGICAL DEVICES FROM OTHER JURISDICTIONS?

All biological products sold in Austria are prescription-only products, so they can only be obtained via a pharmacy. In general, buying prescription-only products over the internet is prohibited. The Medicines Importation Act allows the importation of three packages for personal use; in the case of prescription-only-products this must be through a public pharmacy.

18. IS IT PERMITTED TO ADVERTISE BIOLOGICAL PRODUCTS TO CONSUMERS? ARE THERE RESTRICTIONS ON ADVERTISING?

All biological products sold in Austria are prescription-only products and cannot be advertised to consumers.

NATURAL HEALTH PRODUCTS

19. IS THERE A CATEGORY FOR NATURAL HEALTH PRODUCTS (INCLUDING, FOR EXAMPLE, TRADITIONAL MEDICINES, HOMEOPATHIC MEDICINES, SUPPLEMENTS, VITAMINS AND MINERALS)?

Natural health products include different types of product:

- Traditional medicinal products and homeopathic medicinal products are covered by the rules of the Medicines Act.
- Food supplements, vitamins, dietary products, minerals or similar products are normally considered as food governed by the food provisions, in particular by the Federal Safety Act concerning Food, Commodities and Cosmetic Products for the Protection of Consumers.

20. WHAT ARE THE GENERAL REQUIREMENTS FOR NATURAL HEALTH PRODUCTS TO BE MANUFACTURED, ADVERTISED AND SOLD?

Manufacturing

Traditional medicinal products and homeopathic products. The manufacturing, advertising and sale of traditional medicinal products and homeopathic products are regulated by the Medicines Act and the Trade Act.

Traditional medicinal products or homeopathic medicinal products must simply be registered. The following restrictions apply to homeopathic products:

- They can only be administered orally or externally.
- They cannot bear any specific therapeutic indication.
- They must have a sufficient degree of dilution to guarantee the safety of the homeopathic product.

The following restrictions apply to traditional herbal medicinal products:

- They can only display an indication exclusively appropriate to the traditional use of such products.
- They must be exclusively used for administration in accordance with a specific strength and posology.
- They can only be used orally, externally or via inhalation.

The registration procedure for traditional herbal medicinal products does not act as a substitute for a normal marketing authorisation procedure. Therefore, the period of traditional use (that is, the product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the EU) must have elapsed. The requirements regarding quality of these products are the same as for conventional medicinal products.

Food products. The production facilities for food supplements must be approved in accordance with the Trade Act. To obtain such approval, the application must contain among other things:

- Details of the applicant.
- Location of the facility.
- A brief description of the activities that are planned to be undertaken at the facility.
- An extensive project description of the business undertaking.
- An assessment of the influence on the neighbourhood of the emission of noise, smell and water pollution.
- Technical details concerning the equipment used in the facility and waste disposal.

Approval is granted by the competent regional trade authority.

Advertising

Whether advertising restrictions apply depends, for example for homeopathic products, on whether the homeopathic product requires a full licence or a simplified registration. If it is fully licensed, the same rules apply as for medicinal products (*see Question 3, Advertising*). If it only requires registration, claims for the homeopathic product must not contain any reference to a disease. Therefore, no therapeutic claims can be made. The claim used for homeopathic products cannot suggest nor imply efficacy, which is normally permissible for medicinal products. Food supplements can be advertised provided that the advertisement is not misleading and does not make any disease-related claims. Health-related claims are permissible if such claims have been approved by the European Food Safety Authority.

Sale

Traditional medicinal products and homeopathic products. These products can only be sold if they are registered in Austria. Such products can only be sold in pharmacies (pharmacy monopoly).

Food products. To place food products and supplements on the market, the following requirements must be met:

- They must be safe.
- They cannot endanger human health or be of minor quality.
- They must be labelled in accordance with the relevant provisions.

For food supplements, the Ministry for Health has issued its own ordinance concerning labelling requirements. There is no need to obtain prior approval for placing these products on the market. These products do not need to be either notified to or registered with any Austrian authority. Food supplements can be freely sold in Austria if they comply with the requirements imposed at EU level.

21. WHAT AUTHORITY IS RESPONSIBLE FOR REGULATING THE MANUFACTURE, ADVERTISING AND SALE OF NATURAL HEALTH PRODUCTS?

Natural health products do not qualify as medicinal products provided that, taking into account the scientific state of the art, they do not trigger any adverse events. Therefore, they are considered as normal food products for which the Austrian Agency Food Safety (*Österreichische Agentur für Ernährungssicherheit*) (AGES) and the Ministry of Health are responsible.

Homeopathic and traditional medicinal products

The Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) and Medicines Agency (*Medizinmarktaufsicht*) are responsible for regulating the manufacture, advertising and sale of Homeopathic and traditional medicinal products.

For more information on the BASG see box: *The regulatory authorities*.

Food products

Food regulations are normally enforced by the nine Austrian regions. Several institution are involved in risk management and general policies. For example, the Austrian Agency Food Safety (*Österreichische Agentur für Ernährungssicherheit*) (AGES) is responsible for:

- Evaluating the risk of food.
- Providing risk communication.
- Carrying out risk management for the public sector.

The Austrian regions are responsible for enforcing food regulations. The Ministry of Health oversees all activities in this field.

For more information on the Ministry of Health see box: *The regulatory authorities*.

22. ARE THERE FEWER OR DIFFERENT REQUIREMENTS FOR NATURAL HEALTH PRODUCTS THAT HAVE ALREADY BEEN LICENSED/APPROVED IN ANOTHER JURISDICTION?

Homeopathic and traditional medicinal products

A product must always be registered in Austria. For homeopathic products, the mutual recognition procedure (MRP) and decentralised procedure (DCP) are also available. This means that the fees for obtaining a registration under Austrian law are lower and the Federal Office for Safety in the Health Field (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) can only object to the registration for limited reasons.

For traditional herbal medicinal products, certain restrictions apply to the use of the MRP or DCP procedures.

Food products

Food products that are sold in other EU member states can also be sold in Austria, provided that the labelling is in German. However, certain food products may be considered by Austrian authorities to be, for example, medicinal products as Austria is still applies medicine rules to many food supplement products (for example, those containing a high level vitamins).

23. IS IT POSSIBLE TO SELL NATURAL HEALTH PRODUCTS TO OR BUY NATURAL HEALTH PRODUCTS FROM OTHER JURISDICTIONS AND/OR ELECTRONICALLY?

Homeopathic and traditional medicinal products

The same restrictions apply as for medicinal products. Therefore, these products can be sold over the internet if they are considered as over-the-counter (OTC) products, and by a registered "internet" pharmacy. No such restrictions apply to food products (*see below, Food Products*).

Food products

Any and all advertising of food supplements must not be misleading nor drafted in such a way that indicates that they will cure a disease or that the use of such products constitutes a surrogate for a healthy life. The electronic sale of food supplement products is possible, but has no good standing because of counterfeits, products of poor quality being sold and so on.

24. IS IT PERMITTED TO ADVERTISE NATURAL HEALTH PRODUCTS TO CONSUMERS? ARE THERE RESTRICTIONS ON ADVERTISING?

Homeopathic and traditional medicinal products

For traditional medicinal products and homeopathic products, certain restrictions apply under the Medicines Act. In particular, homeopathic products cannot have any specific therapeutic indication.

Food products

Any and all advertising of food supplements must not be misleading nor drafted in such a way that indicates that they will cure a disease or that the use of such products constitutes a surrogate for a healthy life.

REFORM

25. ARE THERE ANY PLANS TO REFORM THE RULES ON THE DEVELOPMENT, MANUFACTURE, ADVERTISING AND SALE OF MEDICAL PRODUCTS?

The rules applying to medical products are constantly changing. The framework for these rules is adopted at EU level and the authors are not aware of major changes to the Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive), which is the core legislation for the marketing of medicinal products.

THE REGULATORY AUTHORITIES

MINISTRY OF HEALTH (*BUNDESMINISTERIUM FÜR GESUNDHEIT*)

W www.bmg.gv.at

Principal responsibilities. The Ministry of Health oversees all activities relating to food safety, medicinal products and medical devices.

FEDERAL OFFICE FOR SAFETY IN THE HEALTH FIELD (*BUNDESAMT FÜR SICHERHEIT IM GESUNDHEITSWESEN*) (BASG)

W www.basg.gv.at

Principal responsibilities. The BASG is responsible for regulating the licensing, manufacturing of medicinal products and for enforcing rules relating to medicinal products. It is also in charge of enforcing rules and carrying out inspections relating medical devices.

AUSTRIAN AGENCY FOR FOOD SAFETY (*ÖSTERREICHISCHE AGENTUR FÜR ERNÄHRUNGSSICHERHEIT*) (AGES)

W www.ages.at

Principal responsibilities. The AGES's main task is to provide risk management relating to food products and investigate food. In particular, AGES operates various laboratories to examine food.

ONLINE RESOURCES

AUSTRIAN LAWS

W www.ris.bka.gv.at

Description. This is a cost-free website allowing all Austrian laws to be downloaded as well as the laws of the nine regions. Certain laws are also provided in English.

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