PHARMA & MEDICAL DEVICE REGULATION

Sweden

LEXOLOGY
Getting The Deal Through

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Quick reference guide enabling side-by-side comparison of local insights, including into the regulatory framework; clinical practice; marketing authorisation; amending authorisations; recall; promotion; enforcement of advertising rules; pricing and reimbursement; off-label use and unlicensed products; sale and supply; and recent trends.

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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?

The Medical Products Agency (MPA) is the competent authority for approval of the marketing of new medicinal products and market entry for medical devices in Sweden.

The main regulatory frameworks for medicinal products are the Medicinal Products Act (2015:315) and the Medicinal Products Ordinance (2015:458) , which are both based on Directive 2001/83/EC (the Medicinal Products Directive). The definition of 'medicinal product' corresponds with the definition in the Medicinal Products Directive (see the chapter on the European Union).

The main regulatory framework for medical devices are:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, applicable since 26 May 2021 (MDR);
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, applicable from 26 May 2022 (IVDR);
- the Swedish Act (2021:600) with supplementary provisions to the MDR;
- the Swedish Ordinance (2021:631) with supplementary provisions to the EU regulations on medical devices;
- the General Act on Product Safety (2004:451); and
- the National Board of Health and Welfare's Regulation (HSLF-FS 2021:52) on the Use of Medical Devices in Healthcare.

Owing to the transitional periods of the mentioned EU regulations, the Swedish Medical Devices Act (1993:584), the Medical Devices Ordinance (1993:876), the MPA Regulations (LVFS 2003:11 on medical devices, LVFS 2001:7 on medical devices for in vitro diagnostics and LVFS 2001:5 on medical devices for implants), which are based on Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC (the Medical Devices Directives), still apply. For more details regarding the MDR and the IVDR, see the chapter on the European Union.

As for cosmetics, Regulation (EC) 1223/2009 on cosmetic products applies and is supplemented by the Cosmetic Products Ordinance (2013:413). The regulation (and the ordinance) defines cosmetic products as any substance or mixture intended to be placed in contact with the external parts of the human body exclusively or mainly to clean it, perfume it, change its appearance, protect it, keep it in good condition or to correct body odours. The main distinction between medicinal products and cosmetic products is thus that cosmetic products are applied externally without any intended internal effects; if a product is applied externally but has an intended internal effect, it is no longer a cosmetic product. All cosmetic products must comply with the Environmental Code (1998:808) and the Environmental Inspection Regulation (2011:13).

Dietary supplements are regulated by food laws and regulations in Sweden. However, if the purpose of a dietary supplement is to prevent or treat disease, or to adjust or modify physiological functions by pharmacological, immunological or metabolic mode of action (ie, in accordance with the definition of 'medicinal product' mentioned above), it shall be classified as a medicinal product.

Law stated - 04 August 2022

Approval framework

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

All medicinal products in Sweden must be approved by the MPA, sometimes in concert with other medicinal products agencies in other EU member states or the European Commission.

The requirements for the approval of new medicinal products included in the Medicinal Products Act are based on and correspond with the requirements of the Medicinal Products Directive. For more details regarding the requirements for approval of new medicinal products in the Medicinal Products Directive, see the chapter on the European Union.

All medicinal products must be of good quality and be appropriate as well as effective to obtain a marketing authorisation. The application procedure for clearance is included in the EU Clinical Trials Regulation (Regulation (EU) 536/2014). Labelling and package leaflets must comply with the EU Guideline on the readability of the labelling and package leaflet of medicinal products for human use and the packaging of medicinal products must comply with the Regulation (EU) 2016/161, laying down rules for the safety features appearing on the packaging of medicinal products for human use (see the chapter on the European Union). There are also special guidelines for Nordic packages for human and veterinary medicinal products that are published by the medicines' agencies of the five Nordic countries (latest edition No. 5 of 29 January 2022).

Medical devices do not need approval by the MPA. Instead, market access is conditional upon 'CE' marking. In relation to registration, every economic operator (EU and non-EU manufacturers, authorised representatives, system or procedure pack producers and importers) need to be registered in the European database on medical devices (EUDAMED) and provide the required information. Until EUDAMED is fully in place, the registration of economic operators that conduct operations in Sweden and their products shall be made with the MPA. For more details regarding the requirements for medical devices, see the chapter on the European Union. Manufacturers of custom-made devices, manufacturers of national medicinal information systems, distributors and importers with responsibility for translation or relabelling and repackaging according to articles 16.2 to 16.4 of the MDR shall be registered in the MPA's system.

All labelling and instructions for use of medical devices according to the MDR and IVDR must be written in Swedish according to the Swedish Ordinance (2020:315), which is a supplement to the Swedish Ordinance (1993:876) on medical devices. Furthermore, the MPA Regulations LVFS 2001:5, LVFS 2003:11 and LVFS 2001:7, which also prescribe that the labelling shall be in Swedish, apply to medical devices put on the market according to the Medical Devices Directives.

Law stated - 04 August 2022

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?

On 31 January 2022, Regulation (EU) 536/2014 applicable to medicinal products came into force (see the chapter on the European Union). From a Swedish perspective, this means that the ethical review procedure for medicinal products is regulated by a new Swedish Act (2018:1091) with additional provisions on ethical review to the EU Clinical Trials Regulation (Regulation (EU) 536/2014) instead of the Ethical Review Act (2003:460). Furthermore, the Medical Products Agency (MPA) Regulation LVFS 2021:109 on clinical trials applies to ethics committee approval and

performance of clinical trials. The Swedish Association of the Pharmaceutical Industry has also issued a framework for ethical rules for the pharmaceutical industry in Sweden, which contains specific rules on conducting clinical trials. The European Medicines Agency's Guideline on Strategies to Identify and Mitigate Risks for First-in-Human Clinical Trials with Investigational Medicinal Products also applies. Applications are filed with the Swedish Ethical Review Authority.

Furthermore, all clinical trials for medicinal products and medical devices must be conducted in accordance with the latest version of the World Medical Association's Helsinki Declaration. Clinical trials for medicinal products and medical devices require prior approval from both the MPA and an ethics committee (the Swedish Ethical Review Authority).

Law stated - 04 August 2022

Reporting requirements

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

For medicinal products, the reporting of the commencement of a trial shall be made through an application procedure in accordance with Regulation (EU) 536/2014.

For medical devices and in vitro diagnostic medical devices, EUDAMED shall be used. Until EUDAMED is fully in place, the application shall be submitted to the MPA. Since 15 July 2021, the MPA and the ethic committees have coordinated their application work through the MPA.

The results of clinical trials for medicinal products shall be reported to the European Clinical Trials Database (EudraCT). For more information, see the chapter on the European Union. The results of clinical trials for medical devices shall be submitted to the MPA.

Law stated - 04 August 2022

Consent and insurance

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

For clinical trials on medicinal products, see the chapter on the European Union.

For medical devices, clinical trials are to be conducted in accordance with the Helsinki Declaration, which requires consent from all trial subjects. For clinical trials performed in a healthcare principal's operation, the healthcare principal's insurance for patients applies.

Law stated - 04 August 2022

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 Sweden, being a part of the European Union, an application to obtain market authorisation for medicinal products can be made by four different procedures:

- a centralised procedure;

- a mutual recognition procedure;
- a decentralised procedure; and
- a national procedure.

In the centralised procedure, the assessment is made by two national competent authorities appointed by the Committee for Medicinal Products for Human Use. The assessment shall be completed within 210 days. The final opinion is forwarded to the European Commission for decision. Authorisation of medicinal products through the centralised procedure will entitle the companies in question to sell these products throughout the European Economic Area (EEA).

By the mutual recognition procedure, a company may request that an existing national authorisation shall be recognised in other EEA countries. The application is assessed by the competent authority where authorisation has already been granted (reference member state (RMS)) and the competent authority in the country where the authorisation shall be extended (concerned member state (CMS)). The total processing time may not exceed 90 days. The Swedish Regulation (2010:1167) concerning fees for the governmental control of medicinal products provides the general application fee for a complete application, which is 150,000 Swedish kronor when Sweden is the CMS and 200,000 Swedish kroner when Sweden is the RMS. There is also a yearly fee, in general amounting to 60,000 Swedish kronor for authorised medicinal products.

The decentralised procedure is applicable in cases where a company wishes to obtain marketing authorisations in a number of EEA countries for a medicinal product that has no previous authorisation. The application is assessed and approved by an RMS selected by the company and approved concurrently by the CMS. The assessment shall be completed within 210 days. The application fees are the same as for the mutual recognition procedure.

Through the national procedure, a right to marketing in one single country only can be obtained. The assessment by the Medical Products Agency (MPA) shall be completed within 210 days after the MPA has validated the application as complete (the validation period is 14 days). The general application fee is 600,000 Swedish kronor and the yearly fee amounts to 60,000 Swedish kronor.

There is no requirement for marketing authorisation for medical devices. For current registrations in relation to medical devices and in vitro diagnostic products, the following applies. Manufacturers and authorised representatives with business in Sweden shall pay a yearly fee of 30,000 Swedish kronor. Manufacturers and authorised representatives of legacy products shall pay a company registration fee of 2,150 Swedish kronor per year. Annual registration fees for products are as follows:

- for 10 products: 1,000 Swedish kronor;
- for 100 products: 2,000 Swedish kronor;
- for 500 products; 5,000 Swedish kronor; and
- for more than 500 products: 10,000 Swedish kronor.

Law stated - 04 August 2022

Marketing exclusivity

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

Data exclusivity is regulated by Regulation (EC) 726/2004. For more information, see the chapter on the European

Union.

Law stated - 04 August 2022

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?

Data exclusivity is regulated by Regulation (EC) 726/2004. For more information, see the chapter on the European Union.

Law stated - 04 August 2022

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?

This is regulated by Regulation (EC) 726/2004. For more information, see the chapter on the European Union.

Law stated - 04 August 2022

Regulation of specific medicinal products

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

The requirements and processes for marketing approval for medical devices follow from Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, applicable since 26 May 2021 (MDR) and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, applicable from 26 May 2022 (IVDR). For more information, see the chapter on the European Union. The Swedish Act (2021:600) with supplementary provisions to the MDR and the MPA Regulation (HSLF-FS 2021:32) complement these regulations.

The requirements and process for marketing approval for medicinal products follow from the Medicinal Products Act (2015:315).

Furthermore, MPA Regulation (HSLF-FS 2022:11) shall be complied with when registering homeopathic medicinal products. This regulation is based on relevant provisions of Directive 2001/83/EC (the Medicinal Products Directive). As for herbal medicinal products (ie, medicinal products in which the active ingredient consists exclusively of herbal materials or herbal preparations), these also fall within the scope of the Medicinal Products Directive. Furthermore, MPA Regulation LVFS 2006:3 applies.

When it comes to biologicals and biosimilars, the criteria for approval are specified in various guidance papers issued by the European Medicines Agency (EMA).

For dietary supplements to be released on the market, the National Food Agency's Regulation LIVSFS 2003:9 shall be complied with.

Regarding orphan drugs and products for paediatric use, see the chapter on the European Union.

Law stated - 04 August 2022

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?

MPA Regulation HSLF-FS 2017:75 shall be complied with when registering homeopathic medicinal products. This regulation is based on relevant provisions of the Medicinal Products Directive.

As for herbal medicinal products (ie, medicinal products in which the active ingredient consists exclusively of herbal materials or herbal preparations), these also fall within the scope of the Medicinal Products Directive. Furthermore, MPA Regulation LVFS 2006:3 applies.

When it comes to biologicals and biosimilars, the criteria for approval are specified in various guidance papers issued by the EMA.

Regarding orphan drugs and products for paediatric use, see the chapter on the European Union.

Law stated - 04 August 2022

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?

For medicinal products, there is a requirement to update product information in relation to new knowledge. In cases of non-compliance, the MPA may send a request regarding post-authorisation control of a medicinal product with demands for updates. Avoiding answering such a request might result in an injunction and other consequences, such as deregistration of the product.

Furthermore, there is a requirement for periodic safety update recording in accordance with Regulation (EU) 1235/2010, Directive 2010/84/EU and Commission Implementing Regulation (EU) 520/2012, implemented by MPA Regulation LVFS 2012:14. See the chapter on the European Union for more details regarding periodic safety update recording.

For medical devices, manufacturers are required to continuously monitor how their products work in practical use and are, for example, obliged to report any serious incident involving devices or any field safety corrective action in respect of devices according to the MDR and the IVDR. For more information, see the chapter on the European Union. During the transitional period, provisions of the Medical Devices Act and the relevant MPA regulations apply.

Law stated - 04 August 2022

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?

For medicinal products, a licence from the MPA is required for the manufacturing, import from and export to a country outside the EEA of medicinal products according to the Medicinal Products Act. The requirements for the authorisation

are included in MPA Regulation HSLF-FS 2021:102. For example, the application must include:

- general information regarding the applicant (such as name, registration certificate and billing address);
- whether the application concerns a certain medicinal product or medicinal products in general;
- the form of medicinal product or products;
- the location of the premises;
- details regarding the premises and equipment;
- a description of potential contract manufacturing or contractual analysis; and
- a proposal for an expert or adviser and his or her curriculum vitae.

A decision on an application shall in general be made by the MPA within 30 days of the submission of a complete application (this period can be prolonged to 90 days). The general application fees for manufacturing as well as the annual fees are provided by Regulation (2010:1167) concerning fees for the governmental control of medicinal products, and are between 60,000 and 215,000 Swedish kronor depending on the type of medicinal product. The licence is valid for as long as the yearly fees are paid, but not for a period longer than that indicated in the decision. An application for a wholesale licence costs 40,000 Swedish kronor and a yearly fee amounting to 13,500 Swedish kronor has to be paid.

For medical devices, no Swedish licence is required for manufacturing or importing medical devices. Naturally, and in accordance with the MDR, IVDR, Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC, medical devices with the appropriate 'CE' marking may be exported freely within the EEA. Countries outside the EEA may, however, request a free sales certificate, which ensures that the product may be exported without any legal restrictions. The MPA can issue such certificates. The application fee is 1,300 Swedish kronor for the first copy and 600 Swedish kronor for every following copy. The period of validity is commonly three years or the same as the time period of the 'CE' marking.

Law stated - 04 August 2022

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?

The MPA has the authority to issue the injunctions and prohibitions necessary to ensure compliance with the Medicinal Products Act and certain provisions of the MDR and IVDR (or the Medical Devices Act during the transitional period), and may combine such injunctions with a penalty fine.

As for criminal sanctions, violations of the Medicinal Products Act and certain provisions of the MDR and IVDR (or the Medical Devices Act during the transitional period) are penalised with a fine or imprisonment for a maximum of one year.

Law stated - 04 August 2022

Exemptions

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

There is an exemption from the marketing authorisation requirement for advanced therapy medicinal products defined

in article 2 of Regulation (EC) 1394/2007, which are produced in Sweden in accordance with a non-routine procedure for certain patients in accordance with a prescription and that are used in Swedish hospitals. A licence is required in accordance with the Medicinal Products Act and MPA Consolidated Regulation LVFS 2011:3.

Individual licences regulated by MPA Consolidated Regulation HSLF-FS 2018:25 and extemporaneous medicinal products as well as stock preparations produced by a pharmacy are also exempted from the marketing authorisation requirement. Extemporaneous medicinal products, stock preparations and national licences for stock preparations of more than 1,000 products per year are mainly regulated by the MPA Consolidated Regulations LVFS 2008:1, LVFS 2010:12, LVFS 2010:4, LVFS 2009:8, HSLF-FS 2018:26 and HSLF-FS 2021:102.

Law stated - 04 August 2022

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?

Parallel import of medicinal products from other EEA countries to Sweden (that have been approved in the other EEA country through the national procedure, the mutual recognition procedure or the decentralised procedure) is allowed but requires authorisation from the MPA in accordance with Regulation HSLF-FS 2022:8, and must comply with the labelling requirements in the regulation. Medicinal products that have been approved through the central procedure may instead be parallel distributed, which is authorised by the EMA (see the chapter on the European Union).

Parallel import of medical devices does not require authorisation from the MPA. However, the importer must comply with the requirements of the MDR and IVDR (or the Medical Devices Act and applicable MPA regulations during the transitional period). Furthermore, all labelling and instructions for use of medical devices must be written in Swedish.

Law stated - 04 August 2022

AMENDING AUTHORISATIONS

Variation

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

Regulation (EC) 1234/2008 regulates variations to a marketing authorisation for approved medicinal products (see the chapter on the European Union).

This is not applicable to medical devices.

Law stated - 04 August 2022

Renewal

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

A marketing authorisation for medicinal products is valid for five years and may be renewed after this period. One renewal after five years is usually sufficient for continued validity until further notice. However, the authority may, for safety reasons, decide that a further renewal is required. The application for renewal must be received by the Medical

Products Agency (MPA) no later than nine months before the renewal date for medicinal products for human use. The application must include documentation regarding the efficacy, safety and quality (including detailed pharmacovigilance data) as well as a list of all changes made since the first authorisation or last renewal.

This is not applicable to medical devices.

Law stated - 04 August 2022

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?

Application for transfer requires submission of an application form (available on the MPA's website), which must be accompanied by:

- a wholesale licence for the new marketing authorisation holder;
- proof of establishment of the new marketing authorisation holder;
- a summary of product characteristics and patient information leaflet and labelling text with tracked changes (if applicable); and
- the latest approved version of the mock-ups and the new final version (if applicable).

The application must be submitted at the latest two weeks after the transfer has been made. The time period of assessment by the MPA is three months.

This is not applicable to medical devices. The general registration requirements apply.

Law stated - 04 August 2022

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?

Manufacturers of medical devices have obligations in relation to incidents, recalls and reporting. These obligations are regulated by the EU regulations for medical devices (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, applicable since 26 May 2021) and in vitro diagnostic medical devices (Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, applicable from 26 May 2022), and the Medical Products Agency (MPA) Regulation HSLF-FS 2021:32 on information and reporting obligations in relation to medical devices (or the Medical Devices Act and the relevant MPA regulation for the product in question during the transitional period).

Manufacturers have an obligation to investigate and assess all cases of possibly serious incidents and report to the MPA through a manufacturer incident report. The manufacturer may take corrective actions to bring the device into conformity, withdraw it or recall it, as appropriate. The MPA may also obligate the manufacturer to take corrective measures. All field safety notices concerning Sweden shall be submitted to the MPA.

For medicinal products, the MPA is authorised to make decisions regarding their recall. The provisions regarding recall in the Medicinal Products Act are based on Directive 2001/83/EC. A medicinal product can be recalled from

wholesalers, pharmacies, points of sales outside pharmacies, healthcare facilities and storage as well as from consumers. A decision to recall a medicinal product shall always be taken in consultation with the MPA. All direct healthcare professional communication containing new and important information about medicinal products shall be published on the MPA's website and submitted to relevant recipients including specialists and pharmacies. This list of recipients is to be decided by the manufacturer together with the MPA.

Law stated - 04 August 2022

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?

The Medicinal Products Act contains specific provisions on marketing of medicinal products, while the Marketing Practices Act (2008:486) relates to marketing in general (thus, including marketing of medicinal products and medical devices). Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, applicable since 26 May 2021 and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, applicable from 26 May 2022 both include a prohibition on misleading marketing of medical devices (see the chapter on the European Union).

In short, the definition of 'advertising of medicinal products' described in Directive 2001/83/EC (the Medicinal Products Directive) corresponds to the interpretation of when the provision of information will be treated as promotional according to the Medicinal Products Act. In addition, Medical Products Agency (MPA) Regulation LVFS 2009:6 lists several measures that specifically should be included in the definition of 'marketing of medicinal products'. MPA Regulation LVFS 2009:6 also lists several measures that are not to be deemed marketing of medicinal products. These measures also correspond to the measures mentioned in the Medicinal Products Directive (see the chapter on the European Union).

The Marketing Practices Act applies to any kind of marketing, including online marketing. Under the Marketing Practices Act, the term 'advertising' is seen as part of the broader term 'marketing'. Even the sale itself, even though entirely passive, is considered to be a marketing measure. In addition, measures that aim to promote the supply of products are included in the definition.

The framework for ethical rules for the pharmaceutical industry in Sweden (the LER Rules) by the Swedish Association of the Pharmaceutical Industry (LIF) also includes rules regarding information on medicinal products. Further, if a company is subject to the LER Rules, it will be able to apply for prior permission from the Swedish Pharmaceutical Industry's Information Examiner Committee (IGN) to provide information regarding the medicinal product on a special website. The information provided on the website has to be reviewed by the IGN before it is published and before any changes can be made. Owing to the prohibition of advertising of medicinal products directly towards consumers, companies are not allowed to refer to, or in any way promote, their informational website. This means that consumers will have to find the website on their own.

Law stated - 04 August 2022

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?

In addition to general criminal rules on bribes that follow from the Penal Code (1962:700), the LER Rules by LIF provide for specific regulations relating to inducements to healthcare professionals in regard to medicinal products.

Any form of cooperation between healthcare professionals and pharmaceutical companies where there has been some kind of remuneration shall be documented. Donations made by the company are only permitted if they support research and development. The only gifts that are permitted are informational and educational material, under the condition that the material is of low value, directly relevant to the practice of the recipient and directly beneficial to the care of patients. Items of medical utility may be provided for purposes of educating employees and for the care of patients under the condition that the item is of low value and not such that it is routinely used in the recipient's business. Furthermore, it is not permitted to provide healthcare professionals with an inexpensive gift unrelated to the practice of medicine on an infrequent basis in acknowledgement of significant national, cultural or religious holidays.

For medical device companies, according to the cooperation agreement entered into with, among others, LIF, it is not permitted to offer benefits, gifts or other compensation to healthcare professionals. Gifts offered to medical entities (such as hospitals) that could be considered indirect gifts to the healthcare professionals working within the medical entity are, accordingly, also prohibited. Donations may never be offered or requested to fund healthcare's internal or regular activities. Donations to healthcare professionals are allowed only if they are made to support research and development and under the condition that the donation is transparent, well documented, and in accordance with the cooperation agreement and its intentions.

There is a specific rule in the Industry Code stating that donations and grants to healthcare professionals shall not be connected to past, present or potential future use, or recommendation, sale or prescription of the donor's products or services, and may not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Law stated - 04 August 2022

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?

LIF's ethical rules correspond to the European Federation of Pharmaceutical Industries and Associations' Discloser Code in this matter. Direct or indirect transfers of value, whether in cash, in kind or otherwise, made for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use, to a healthcare professional or organisation shall be recorded and published by the pharmaceutical company. In accordance with the cooperation agreement between, among others, LIF and the trade association, Swedish Medtech, the principle of documentation applies to (connected) medical device companies with regard to value transfers. These companies are, therefore, obliged to document information about value transfers, but they do not have to publish this information.

Law stated - 04 August 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.

Regarding law enforcement, the MPA is responsible for the supervision of compliance with the Medicinal Products Act and the Medical Devices Regulations (or, as applicable, the Medical Devices Act and any regulation issued based on

this act). The Marketing Practices Act is enforced by the Swedish Consumer Agency.

For self-regulation, LIF, the Information Examiner Committee and the Information Practices Committee have a duty to ensure LIF members' compliance with its framework for ethical rules for the pharmaceutical industry in Sweden.

Law stated - 04 August 2022

Sanctions

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

The MPA is entitled to demand information and issue orders and prohibitions necessary to ensure compliance with the Medicinal Products Act, the Medical Devices Regulations (or, as applicable, the Medical Devices Act and any regulations issued based on this act). Such demands, orders and prohibitions can be coupled with a fine.

Sanctions available under the Marketing Practices Act consist of prohibitions or orders coupled with a penalty fine, fines for disruptive marketing practices and damages.

Law stated - 04 August 2022

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?

The Medical Products Agency (MPA) recommends that products that have been authorised for a specific indication should be used if available. However, as a general rule, doctors have the right to freely prescribe or use products they deem fit for a particular purpose, including for off-label indications, if such use can be motivated based on scientific findings and proven experience. Certain limitations apply to, among others, narcotic pharmaceutical products authorised for the treatment of ADHD.

Pharmaceutical companies must be careful in drawing health professionals' attention to potential off-label uses, as the provision of such information would be likely to be considered marketing.

Law stated - 04 August 2022

Unlicensed products

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

Unlicensed medicinal products (ie, medicinal products that have not been granted marketing authorisation by the MPA), may, under certain circumstances, be dispensed after obtaining a special licence from the MPA if there is a need that cannot be satisfied with approved medicinal products on the market. The licence may apply to a certain patient (individual licence) or to one or more healthcare entities (general licence).

Furthermore, there is a separate licence to be obtained for the manufacturing of extempore medicinal products (ie, non-standardised medicinal products to be produced by a pharmacy for a certain patient or animal, which is regulated by MPA Regulation LVFS 2010:12 (for extempore pharmacies) or LVFS 2009:8 (for standard pharmacies)). Hospitals may manufacture extempore medicinal products without a licence from the MPA, but must notify the MPA of their supply of

medicinal products to the public. The manufacturing of extempore medicinal products that are produced for a certain patient but not for a certain occasion (ie, stock preparations of extempore medicinal products) also requires a licence from the MPA according to Regulation HSLF-FS 2021:102.

Law stated - 04 August 2022

Compassionate use

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

Compassionate use programmes for unlicensed products can be established in Sweden in accordance with Regulation (EC) 726/2004 for a group of patients with a life-threatening, chronically or seriously debilitating disease, which cannot be treated satisfactorily by currently authorised medicinal products. The medicinal product concerned must either be the subject of an application for a marketing authorisation or be undergoing clinical trials.

The manufacturer or the applicant for market authorisation must apply to the MPA before establishing a compassionate use programme. The application is free of charge and can be made through a standard form, which can be obtained from the MPA's website. Patients participating in the compassionate use programme must be provided with the product free of charge.

Law stated - 04 August 2022

SALE AND SUPPLY

Regulation

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

To dispense or sell prescription-free medicinal products, the Trade with Prescription Free Medicinal Products Act (2009:730) applies. For the dispensing or sale of prescription medicinal products, the Trade with Prescription Medicinal Products Act (2009:366) and the Ordinance (2009:659) on Trade with Medicinal Products apply as well as Medical Products Agency (MPA) consolidated Regulation LVFS 2009:8 apply. Each of those acts specifies which medicinal products can be sold under the applicable act. Both the dispensing or sale of prescription-free medicinal products and the dispensing or sale of prescription medicinal products requires authorisation from the MPA. There is no requirement for having a sales permit in relation to medical devices, although there are different registration requirements for different kinds of operators.

Law stated - 04 August 2022

Online supply

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

A pharmacy that wants to sell medicinal products online shall inform the MPA in connection with the application of operating a pharmacy or at least two months before the e-commerce starts. The EU common symbol shall be used by the pharmacies authorised to sell online. For such use, the pharmacy needs to enter into a licence agreement with the MPA. Online sales are regulated by the Trade with Prescription Medicinal Products Act (2009:366), the Ordinance (2009:659) on Trade with Medicinal Products and the MPA Regulation LVFS 2009:8.

Law stated - 04 August 2022

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?

The Dental and Pharmaceutical Benefits Agency (TLV) is responsible for deciding whether a pharmaceutical product or consumables should be eligible for reimbursement and included in the Swedish benefits scheme. The TLV is responsible for setting the purchase and selling price of those products. These decisions are made in accordance with the Act on Pharmaceutical Benefits (2002:160). Prices are based on an ethical platform with three basic principles:

- the human value principle;
- the need and solidarity principle; and
- the cost-effectiveness principle.

For products that are not included in the benefits scheme, free pricing applies.

The Swedish medical benefit scheme comprises two parts: the subsidising of medicinal products and consumables, and a high-cost threshold. Sweden applies a high-cost threshold for prescription medicinal products and consumables, which means that patients only have to pay for those products up to a certain threshold, beyond which all prescription medicinal products and consumables are free. The high-cost threshold starts to apply after purchases amounting to 2,400 Swedish kronor for prescription medicinal products and consumables during a 12-month period. However, not all products are included in the high-cost threshold scheme, although the scheme includes numerous types of medicinal products and consumables.

Medicinal products and consumables supplied to hospitals are purchased by regions and financed by local taxes as well as subventions.

Law stated - 04 August 2022

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 Swedish Act (2021:600) with supplementary provisions to the EU regulations on medical devices, was amended in July 2022 to include supplementary provisions in relation to in vitro diagnostic products.

On 25 January 2022, the E-recipe Committee released its inquiry concerning electronic prescriptions (e-prescriptions) within the European Economic Area and what is needed to maintain a patient-safe and effective process for e-prescriptions. The committee proposes that several amendments of the law shall enter into force on 1 May 2023.

Furthermore, the Medical Products Agency on 13 January 2022 released a draft regulation on the national medical information system that will replace the existing Regulation LVFS 2014:7. The purpose of the new regulation is to clarify the distinction between medical devices and medical information systems.

Law stated - 04 August 2022

Jurisdictions

Australia	Clayton Utz
Austria	Preslmayr Attorneys at Law
Brazil	Kasznar Leonardos
China	East & Concord Partners
Colombia	OlarteMoure
Denmark	Accura Advokatpartnerselskab
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