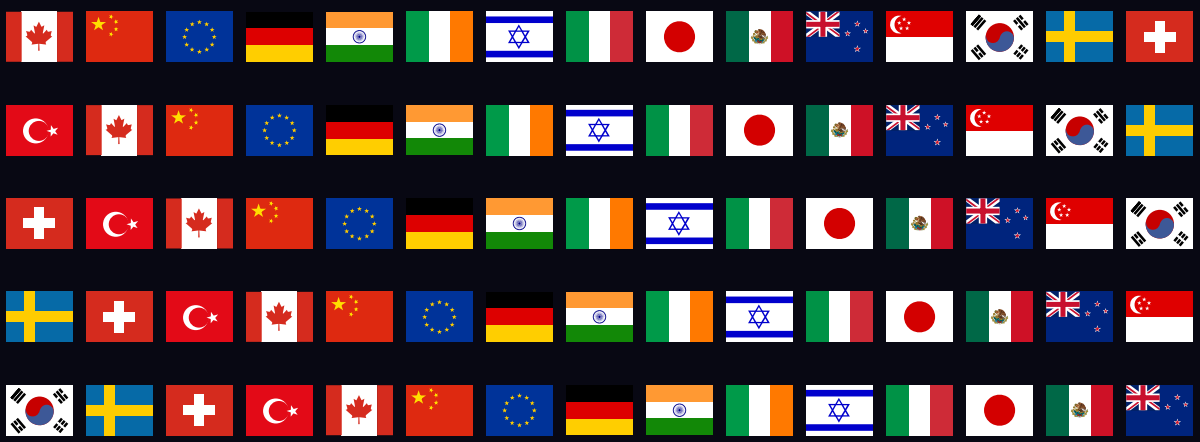
LIFE SCIENCES

Sweden



LEXOLOGY
Getting The Deal Through

Consulting editor
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Life Sciences

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Quick reference guide enabling side-by-side comparison of local insights, including into organisation and financing; authorisation of providers; advertising; data protection, privacy and digitisation; collaboration with healthcare professionals and patient organisations; competition law; pricing and reimbursement; and recent trends.

Generated 13 December 2021

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Sweden

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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

How is healthcare in your jurisdiction organised?

In Sweden, healthcare is a shared responsibility of the state, regions (formerly known as county councils) and municipalities. The state is responsible for the overall health and medical care policy.

The Ministry of Health and Social Affairs acts to meet the objectives set by the Swedish parliament and the government. Several independent agencies answer to the Ministry of Health and Social Affairs. The following agencies support the Ministry's activities in the area of health and medical care: the National Board of Health and Welfare, the Medical Responsibility Board, the Swedish Agency for Health Technology

Assessment and Assessment of Social Services, the Medical Products Agency (MPA), the Swedish Agency for Health and Care Services Analysis, the Dental and Pharmaceutical Benefits Agency and the Health and Social Care Inspectorate (IVO). In addition, the Swedish eHealth Agency and the Public Health Agency of Sweden were implemented on 1 January 2014.

Sweden, with its approximately 10.4 million citizens, is divided into 21 regions and 290 municipalities. The Swedish healthcare system is regulated by the Health and Medical Service Act (2017:30), which, inter alia, sets out the respective responsibilities of regions and municipalities for health and medical care. The Health and Medical Service Act states that the aim in Sweden is good health and medical care on equal terms for the entire population. Medical care shall be provided with due respect for the equal worth of all people and the dignity of the individual. Priority shall be given to those who are in the greatest need of health and medical care.

The Swedish laws are in many respects adapted to the applicable EU legislation. The applicable EU directives are transposed into acts and ordinances by the government and into provisions by the relevant authorities, inter alia, the MPA.

In 2009, the pharmacy market was re-regulated, which lead to a de-monopolisation of the former state-owned pharmacy monopoly. Since then, a number of private actors have entered the Swedish pharmacy market.

Law stated - 25 October 2021

Financing

How is the healthcare system financed in the outpatient and inpatient sectors?

The healthcare system in Sweden is mainly financed through tax revenues. Fees play a relatively limited role as a source of finance. A significant part of publicly funded healthcare is provided by private healthcare providers that have been procured by a region or municipality. Private care, where patients themselves pay the entire cost, represents only a very limited part of the healthcare system. There is also a relatively small amount of private health insurance, but the number of people covered by such insurance has increased in recent years. On 8 October 2021, the final report on 'Regulation of private health insurances – increased knowledge and control' (SOU 2021:80) was handed over to the Swedish government. Among other things, the public inquiry proposes that:

- the regions' demands on private care providers are tightened. If a healthcare provider has other clients than the region, the agreement must state how it is ensured that the healthcare provider's publicly funded assignment is not adversely affected; and
- that the state should take increased responsibility, partly because IVO is given better conditions to exercise supervision over issues relating to insurance-financed care, and partly because the state should enable access to

data and increased knowledge about the effects of health insurance. These are requirements for increased reporting and reporting of data that can be used by authorities, researchers, the general public and other actors. The report will now be circulated to concerned parties for consideration and is likely to become relevant in the upcoming general election in 2022.

The responsibilities of the regions require considerable resources, as the most important task is health and medical care, and the major portion of their budgets is spent on health and medical care and dental care. The regions are responsible for organising their services so that all citizens have access to adequate care.

Approximately 70 per cent of the regions' services are financed by regional taxes. Regions also receive revenue from patient charges and the sale of services. State support is in the form of general central government grants. The state also gives targeted grants to increase access to care and to pharmaceutical benefits.

Medicinal products have three financial sources in Sweden: the state, the regions and patients. The regions pay all costs for medicinal products for inpatient care. They are responsible for providing healthcare to the population, and they have the right to levy taxes to finance their duties. The regions receive a specific government grant for financing of prescription medicinal products for outpatient care.

Law stated - 25 October 2021

Basic structures

What are the basic structures of the provision of care to patients in statutory and private care?

In general, public and private health and medical care providers are subject to the same rules and requirements on the health and medical care provided. Like public health and medical care, most private health and medical care services are publicly funded through tax revenues, for example, if the private health and medical care provider has entered into an agreement with regions or municipalities or if the private health and medical care provider has applied to provide services in a region that has adhered to a voluntary system on free choice of healthcare for patients. Publicly funded health and medical care are partly financed through patient fees. However, there is also private health and medical care where the patients themselves pay the entire cost (eg, it is common that eye correction and plastic surgery care services are fully privately financed).

Law stated - 25 October 2021

HEALTHCARE SERVICES

Authorisation

What steps are necessary to authorise the provision of health services, and what law governs this?

According to the Patient Safety Act (2010:659), new healthcare providers should submit a notification to the Health and Social Care Inspectorate (IVO), which is the competent authority responsible for supervision of healthcare and is responsible to keep a record of healthcare providers, no later than one month before the healthcare operations commence. The healthcare provider must also appoint a person responsible for the operations and submit a notification for registration in the register.

In general, there is no need for a permit to authorise the provision of health services, but there are a few exceptions. For instance, healthcare providers carrying out operations relating to blood, tissue, abortion, circumcision or syringe exchange for drug addicts require a permit from IVO.

Law stated - 25 October 2021

Structure

Which types of legal entities can offer healthcare services?

Healthcare services can be provided by legal entities (such as public institutions, companies, associations and foundations) or a sole trader.

Law stated - 25 October 2021

Services of foreign companies

What further steps are necessary for foreign companies to offer health services?

One of the most important further steps necessary for foreign companies to offer health and medical care in Sweden is to ensure that the healthcare professionals engaged in providing the services have obtained a permanent or temporary licence or a special authorisation to practise medicine in Sweden. Such licences and special authorisations are provided by the National Board of Health and Welfare. The requirements are different for EU and non-EU residents applying for a permanent or temporary licence or a special authorisation. In addition to fulfilling requirements on sufficient medical skill and knowledge, as of April 2016, the National Board of Health and Welfare also examines the language skills of those applying for a Swedish licence to make sure that the applicant's language proficiency is sufficient to obtain a licence. To obtain a licence (permanent or temporary), the applicant must provide a certificate stating that she or he has the necessary language skills in Swedish, Danish or Norwegian for the profession. A special authorisation does not require language skills in Swedish, Danish or Norwegian.

Law stated - 25 October 2021

ADVERTISING

Legislation

Which legislation governs advertising of medicinal products to healthcare professionals?

The Marketing Act (2008:486) governs advertisements in general and is also applicable to advertisement of medicinal products. The Marketing Act protects consumers as well as businesses (including healthcare professionals) from unfair and misleading advertising and other unethical marketing practice, and it states, inter alia, that marketing practices shall be consistent with generally accepted marketing practices, generally accepted business practices or other accepted norms, and be fair towards consumers and traders The Radio and Television Act (2010:696) is also applicable.

In addition, the Medicinal Products Act (2015:315) and the provision (2009:6) from the Medical Products Agency (MPA) published in the Agency's Code of Statutes (LVFS), govern the advertising of medicinal products.

The legislation includes a number of important requirements on advertising, such as being up to date, being matter-of-fact and being balanced. The advertising must not be misleading and must be in accordance with best practice for the advertisement of medicinal products. This includes advertising both to the public and to healthcare professionals. Fundamental rules also stipulate that only medicinal products with a granted marketing authorisation may be advertised in Sweden, and that advertising aimed towards children and advertising of prescription-only medicinal products is not allowed (except for campaigns for vaccination against human infection diseases). The Medicinal Products Act stipulates that pharmaceutical companies are responsible for the surveillance of their advertising through

an in-house function with scientific competence.

The research-based pharmaceutical industry in Sweden has, through its trade organisation, the Swedish Association of the Pharmaceutical Industry (LIF), developed a system of self-regulation in the pharmaceutical sector. LIF has thus adopted ethical rules and a self-regulation system concerning, inter alia, advertisement to the public sector and healthcare professionals in The Ethical Rules for the Pharmaceutical Industry (LIF Ethical Rules), which came into force on 1 October 2007 and were last revised on 1 November 2021. In recent revisions of the LIF Ethical Rules, the rules regarding marketing of medicinal products have been adapted to new international demands through, inter alia, the new version of the EFPIA Code of Practice. Furthermore, the LIF Ethical Rules also apply to interactions between pharmaceutical companies and individual patients and their relatives. The LIF Ethical Rules play a very important role in the pharmaceutical industry, even though they are not legally binding. However, these Rules are often considered by the courts as an expression of fair and ethical marketing. In the most recent revision of the LIF Ethical Rules, the 'Congress exemption' was removed due to a recent court ruling stating that marketing (pre-launch) of non-approved medicinal products is prohibited according to the Medicinal Products Act even at international scientific congresses for healthcare professionals and similar events.

Law stated - 25 October 2021

Main principles

What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

In addition to the more general regulations in the Marketing Act and the Medicinal Products Act, the LIF Ethical Rules specify in greater detail the requirements on information that is addressed to doctors and other healthcare professionals. The basic principle is laid down in Chapter 1, section 1, article 1 of the LIF Ethical Rules, and states that the information on medicinal products must include accurate, objective, meaningful and balanced particulars dealing adequately with the favourable and unfavourable properties of the medicinal products. The LIF Ethical Rules are extensive and specify, for example, that:

- the information should be within the formulation of the summary of the product characteristics (SmPC);
- the product information may not be offensive and shall be compatible with good taste and practice;
- the information must be truthful and not misleading and must also be easy to recognise as such;
- the information as to the quality and efficacy shall be capable of substantiation by means of documentation;
- the information, including comparisons between effects, must be presented in a fair way; and
- product samples must be distributed in a very restricted manner: at most, one per product per year to one and the same person.

It is the responsibility of the pharmaceutical company, or its representatives in Sweden, to observe the LIF Ethical Rules, and the pharmaceutical company should be able to substantiate any facts, statements, claims and other representations in words or pictures contained in its product information. However, it is only pharmaceutical companies that are members of LIF that may be subject to a penalty fee.

Law stated - 25 October 2021

Advertising of medical devices

Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The main difference is that medical devices are generally not subject to the advertisement rules in the LIF Ethical Rules (except to the extent the medical device is classified as a medicinal product). However, medical devices are subject to rules on advertisement set out in, for example, the Marketing Act and the Medical Devices Regulation. The Collaboration Agreement establishes on a self-regulation basis certain guiding principles relating to interactions between the public-funded healthcare and the life science industries including manufacturers of medical devices.

Law stated - 25 October 2021

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

The fact that the Swedish healthcare system is rather complex and divided among several responsible bodies and stakeholders (at least in relation to the size of the country), could be a reason for many recent and ongoing Swedish government initiatives in the area of e-health and healthcare information standardisation.

For example, in March 2016, the Swedish government and the Swedish Association of Local Authorities and Regions published a report titled 'Vision for eHealth 2025', endorsing a common vision that, in 2025, Sweden should be a world leader at using e-health and digitalisation in health and welfare. Since the date of the report, extensive work has commenced with the goal of establishing, inter alia, standards for health data with the purpose of achieving technical and semantic interoperability between different healthcare IT systems to facilitate use of available information and to simplify access to health data for different actors within healthcare.

In June 2018, the Swedish parliament passed the new National Medication List Act (2018:1212) to implement a new national medication register. The National Medication List Act will enter into effect between 1 June 2020 and 1 June 2022. According to the bill for the new act, the national medication list is intended to improve patient safety by improving the transfer of information on prescribed medicines that needs to be shared between healthcare providers, pharmacies and patients.

Law stated - 25 October 2021

Provision of digital health services

Which law regulates the provision of digital health services, and to what extent can such services be provided?

In recent years, especially during the covid-19 pandemic, the use of digital health services has increased significantly. There are several, mainly private actors on the Swedish market that offer digital health services as well as digital platforms that are offered to healthcare providers creating their own digital health services.

There is no specific law that regulates the provision of digital health services. Healthcare organisations, including, inter alia, conventional clinics and hospitals as well as digi-physical services and online medical consultation services, are considered healthcare providers, and in general the same rules apply to conventional healthcare and digital healthcare.

In March 2018, the Swedish government commissioned the National Board of Health and Welfare to provide

recommendations on which type of care and treatment are appropriate to manage via digital healthcare services addressed to patients. In summary, the National Board of Health and Welfare concluded four principles that should be fulfilled for digital healthcare to be appropriate:

- applicable rules or relevant medical experience does not require a physical meeting;
- the digital service is adapted to the individual patient's needs and ability to use the service;
- the healthcare provider has access to sufficient information about the patient's health and medical history to be able to provide good and safe healthcare; and
- necessary follow-up and coordination with other instances is possible.

Law stated - 25 October 2021

Authorities

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The Swedish Authority for Privacy Protection is responsible for compliance with data protection and privacy. The Authority for Privacy Protection has not issued specific formal guidance or regulations for data protection and privacy in the healthcare sector, but regularly publishes notes, news and the authority's opinion on best practices on its website.

The healthcare sector is subject to the rules and requirements set out in the General Data Protection Regulation (EU) 2016/679 (GDPR) and the Data Protection Act (2018:218) supplementing the GDPR. In addition, healthcare providers and employees working in healthcare are subject to rules on secrecy and confidentiality (including professional secrecy) set out in the Public Access to Information and Secrecy Act (2009:400), the Patient Safety Act (2010:659), the Patient Data Act (2008:355), the Health and Medical Services Act (2017:30) and the Pharmacy Data Act (2009:367). In the Penal Code (1962:700), there are provisions imposing penalties for breach of professional secrecy (including by healthcare professionals).

Law stated - 25 October 2021

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

As a starting point, healthcare providers process to some extent health data that is considered a special category of personal data under the GDPR, and some healthcare providers process health data on a large scale. This entails general obligations under the GDPR, for example, requirements to carry out data privacy impact assessments and, in some cases, to appoint a data protection officer. The Patient Data Act (2008:355) states that the healthcare provider is the data controller for the processing of personal data that the healthcare provider performs. In a region and in a municipality, any authority conducting health and medical care is the data controller for the processing of personal data that the healthcare provider performs.

In addition, healthcare providers and healthcare professionals are subject to specific rules, including, for example, professional secrecy and requirements on keeping medical records and restricting access to such records.

Law stated - 25 October 2021

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

In 2019, the Swedish Authority for Privacy Protection initiated supervision cases concerning eight healthcare providers' internal routines and restrictions on access to patients' medical records, including routines and logs to prevent and discover unauthorised access. In December 2020, the Swedish Authority for Privacy Protection announced its decisions. In summary, the authority had identified deficiencies that in seven out of eight cases lead to administrative penalty fees amounting up to 30 million kronor. Five healthcare providers appealed the decisions. In one of the cases, the administrative court lowered the sanction fee, while the court rejected the appeals in the other four cases.

Following the decisions, the Authority for Privacy Protection issued a written guidance on 'Necessity- and risk analysis in healthcare' to emphasise the importance of healthcare providers' insurance that necessity and risk analysis are conducted and to support healthcare providers in conducting the analysis that is needed before access to medical records is permitted and allocated.

The Authority for Privacy Protection has also stated that it is not uncommon for healthcare providers to have insufficient routines and practices relating to carrying out privacy impact assessments under the GDPR in general.

Law stated - 25 October 2021

COLLABORATION

Legislation

Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

There is no specific legislation governing the collaboration of the pharmaceutical industry with healthcare professionals. However, the Swedish Association of Local Authorities and Regions, the Swedish Association of the Pharmaceutical Industry (LIF), Swedish Medtech (trade organisation for MedTech companies) and Swedish Labtech (trade organisation for Labtech companies) have agreed on common rules for how employees in the publicly funded healthcare and the life science industries (pharmaceutical industry, medical technology industry and laboratory technology industry) shall cooperate and interact with each other (the Collaboration Agreement). It is the view of the parties that collaboration between healthcare employees and the industries is an important part of the development of both the healthcare system as well as the industries. With these rules, the parties wish to safeguard the continued development of collaboration in a trusted manner. The rules have been jointly developed in response to external demands for increased transparency, moderation in all collaboration, and the need for a clearer allocation of responsibilities between healthcare professionals and the industries, such as the responsibility of healthcare providers to provide training to their employees.

The Collaboration Agreement stipulates that the parties shall work to ensure that the members of each industry party, respectively, have a properly functioning self-regulatory system for the purpose of maintaining a good level of compliance with the rules under the agreement. The Collaboration Agreement has been effective since 1 January 2014, was updated with effect as of 1 January 2020 and has been implemented in Chapter 2 of the LIF Ethical Rules. Accordingly, Chapter 2 of the LIF Ethical Rules contains rules governing agreements on forms of collaboration with the healthcare sector. The same rules apply regarding physicians in the outpatient and inpatient sectors.

Law stated - 25 October 2021

Collaboration with healthcare professionals

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

Articles 2 and 2a in section 1 of Chapter 2 of the LIF Ethical rules lay down the main principles for collaboration between industry participants and employees in the publicly financed healthcare, ie:

- the principle of trust, meaning that a collaboration may not jeopardise the independence of publicly financed healthcare and shall uphold the trust of the public by not entailing an undue influence and by complying with applicable legislation;
- the principle of mutual benefit, which means that a collaboration shall benefit both or all parties participating;
- the transparency principle, meaning that the collaboration between healthcare employees and the pharmaceutical industry shall be open and transparent and in accordance with the LIF Ethical Rules, applicable law, business codes of conduct and other policies;
- the principle of proportionality, meaning that a party's obligations shall be in proportion to the other party's obligations and that all forms of compensation shall be in proportion to the market value of the services provided;
- the principle of moderation, meaning, for instance, that meetings supported or arranged by pharmaceutical companies cannot be extravagant but must be kept at a moderate level; and
- the documentation principle, which stipulates that all collaboration between healthcare employees and the pharmaceutical industry, involving a transfer of value, shall be documented in writing in a decision or an agreement, that must be kept for at least two years (together with ancillary documentation).

Law stated - 25 October 2021

Collaboration with patient organisations

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

Chapter 3 of the LIF Ethical Rules includes rules regarding the interaction of the pharmaceutical industry with organisations and politicians, and section 1 includes ethical rules as to the collaboration between pharmaceutical companies and user organisations or interest groups.

The purpose of the LIF Ethical Rules is to ensure that any collaboration between organisations and pharmaceutical companies takes place in a responsible and meaningful manner, and that any cooperation, information and training are also conducted in such a manner that the parties' independence from one another is not jeopardised or questionable from either a legal or ethical standpoint; this means that the chosen collaborative projects may not comprise an overwhelming share of the organisation's activity or economic resources, or both.

The following principles serve as guidance for all collaboration between pharmaceutical companies and various organisations under the LIF Ethical Rules:

- respect for each other and each other's roles;
- reciprocity in relationships;
- openness and transparency to the outside world;
- restrictiveness in the choice of collaborative fields; and
- the independence of the collaboration partners shall be safeguarded.

The LIF Ethical Rules are applicable to pharmaceutical companies. Certain organisations and companies have set their own rules as to collaboration, and such rules are to be seen as complementary to the LIF Ethical Rules.

Law stated - 25 October 2021

Common infringements

What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

Common infringements include, inter alia, luxurious locations for conferences, leisure activities in connection with conferences and insufficient information regarding marketing in invitations to events that include marketing. In October 2021, the LIF Ethical Rules has been amended to extend the prohibition of marketing of non-approved medicinal products to marketing information at international scientific congresses for healthcare professionals as a result of a decision by a Swedish court applying the Swedish Medicinal Products Act.

Law stated - 25 October 2021

Collaboration on medical devices

Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

The Collaboration Agreement applies also to medical devices and the summary of the terms of the Collaboration Agreement is, thus, applicable also on collaborations concerning medical devices.

The only material difference between the rules governing medicinal products and medical devices sectors with respect to collaborations with healthcare employees are that the LIF Ethical Rules include an express prohibition of gifts to healthcare providers and its employees, except for information of education material of low value, with direct professional relevance and directly relevant for the care of patients. Swedish Medtech has issued a guidance on gifts to healthcare providers or its employees that is restrictive although it does not establish a blanket ban as under the LIF Ethical Rules.

Law stated - 25 October 2021

COMPETITION LAW

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

Yes. Infringements are pursued by the Swedish Competition Authority, by the Patent and Market Courts and/or by the European Commission.

Law stated - 25 October 2021

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

Yes, follow-on private antitrust litigation against healthcare providers is possible in Sweden. Private enforcement actions follow the general procedural rules for damage claims. According to the Competition Damages Act (2016:964), a lawsuit is filed with the Patent and Market Court.

Law stated - 25 October 2021

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

Sweden is a signatory to multiple international anti-corruption conventions, including, but not limited to, the UN Convention against Corruption and the Council of Europe's Civil Law Convention on Corruption. Anti-corruption rules exist in the form of anti-bribery rules in Chapter 10 of the Swedish Penal Code, as well as self-regulation in the form of the LIF Ethical Rules and the Collaboration Agreement (although these ethical rules are strictly speaking not mandatory law). The Swedish non-profit organisation the Anti-Corruption Institute has issued guidance in the form of a 'Code on gifts, rewards and other benefits in trade and industry'.

The 2013 EFPIA Code on disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (the EFPIA Disclosure Code) has been implemented into the LIF Ethical Rules Chapter 2, section 3. Pharmaceutical companies that are active in the Swedish market shall pursuant to said Chapter 2, section 3, publish the individuals or organisations in Sweden that have received transfers of value during a given year, and the aggregate value of the transfers. On 31 May 2016, LIF opened its database for reports concerning transfers and reports are now available on the LIF website.

Law stated - 25 October 2021

PRICING AND REIMBURSEMENT

Price regulation

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

The pricing of non-prescription (over-the-counter) medicinal products can be freely set. The patient pays the entire cost for these medicinal products. Prices are regulated for prescription medicinal products that benefit from reimbursement, which are co-paid by the patient (up to a fixed amount). The prices for inpatient care medicinal products are established in public procurement processes, and the patient pays the patient fee that applies for the inpatient treatment concerned. The Dental and Pharmaceutical Benefits Agency (TLV) decides to what extent an outpatient medicinal product shall be reimbursed, according to the Pharmaceutical Benefits Act (2002:160).

The TLV's decision can be appealed to the Administrative Court. For a medicinal product to be covered by the reimbursement scheme, the company applies to the TLV. In the application the company states the price of the medicinal product and health economic documentation is enclosed. The application is granted if the TLV finds that the health economic analysis shows that the requested price is justified on the basis of the value the medicinal product delivers in terms of improved health. The decision whether to grant reimbursement is based on general principles such as cost-effectiveness and the principle of prioritising patients with the greatest needs. The reimbursement decision is thus based on value, which is often described in Swedish terms as applying 'the value-based pricing of medicinal products. In actual fact, prices can be freely set under a value-based ceiling price. There are only a few countries that

apply the value-based pricing of medicinal products. Instead, most EU countries apply international reference pricing in some form.

The TLV also decides and sets the retail margin, which is the fee paid by the state when pharmacies sell a prescription medicinal product. In addition, Sweden has a system for substitution of generically equivalent medicinal products. The system demands that pharmacies dispense the least expensive generic product available to the patient, regardless of the prescription, if the prescribing doctor has not opposed a substitution for medical reasons in writing. The patient may also refuse a substitution if he or she is willing to pay the difference between the prescribed medicinal product and the generic alternative. Before June 2020, only reimbursed medicinal products could be substituted. As of June 2020, the Pharmaceutical Benefits Act (2002:160) was amended to also enable substitution of prescribed medicinal products that are not included in the reimbursement scheme if there is an equivalent medicinal product in the reimbursement scheme.

As of November 2014, certain rules apply for the pricing of some older medicinal products (see TLV's Code of Statute TLVFS 2014:9, last amended by HSLF-FS 2018:30). The change is based on changes in the Pharmaceutical Benefits Act (2002:160) and means that the TLV will lower the price of medicinal products by 7.5 per cent when they are older than 15 years. The first price reductions under these rules came into effect on 1 January 2015. The intention is to contribute to a more cost-effective use of medicinal products in Sweden. The changes were initiated by an agreement on lowering the prices of some older medicinal products, between the government and the Swedish Association of the Pharmaceutical Industry in 2013.

The prices for medical devices are generally established in public procurement. From 2020, there is also a national board, the Medical Device Board, that issues recommendations concerning the procurement of new medical devices based on health economics assessments. Manufacturers of consumable goods that are classified as medical devices can submit an application to the TLV to have the product included in the reimbursement system, in which case the TLV determines a price. Consumable goods medical devices are not subject to generic substitution.

Law stated - 25 October 2021

Negotiations between manufacturers and providers

Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

The pricing of medicinal products differs in outpatient and inpatient treatment. For outpatient care (pharmacies), the TLV sets the pharmacy purchasing price for medicinal products that is reimbursed and included in the high-cost threshold as regulated by the Pharmaceutical Benefits Act.

There is free pricing for medicinal products that are not reimbursed, and pharmaceutical manufacturers can negotiate the prices with pharmacies.

The prices for medicinal products and medical devices used in inpatient care (hospitals) are established in public procurement processes initiated by the regions, which are regulated by the Swedish Public Procurement Act (2016:1145).

Law stated - 25 October 2021

Reimbursement

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

The TLV has been appointed by the government as the competent authority to decide whether the costs of a medicinal product should be reimbursed. Such a decision can be appealed to the Administrative Court. There are generally three principles that are taken into account when assessing a medicinal product to be reimbursed: the human value principle; the need and solidarity principle; and the cost-effectiveness principle. Normally, only prescription medicinal products are subsidised by the system.

Law stated - 25 October 2021

Price adjudication

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

The TLV is the competent body for decisions regarding the pricing and reimbursability of medicinal products.

Law stated - 25 October 2021

Discount

Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

No.

Law stated - 25 October 2021

UPDATE AND TRENDS

Key developments of the past year

Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

In 2016, the Swedish government instigated a public inquiry to carry out the first review of the financing of subsidised medicines since 1998. The investigation also reviews the national systems for pricing and reimbursement of pharmaceuticals. The main goal of the investigation is to find a long-term sustainable system for financing, pricing and reimbursement of medicinal products. The final report was submitted to the Swedish government in January 2019 (SOU 2018:89).

The inquiry report proposes several changes to the current system, including increased responsibility for regions to fund medicinal products (with a decreased responsibility for the state). A new special subsidy to support use of drugs within certain areas (eg, cell and gene therapies) has been proposed. The inquiry also proposes several new responsibilities for existing competent authorities, with the purpose of increasing the state's ability to facilitate a more equal and cost-effective use of pharmaceuticals, while making new innovative drugs and therapies available to patients quicker. The inquiry report has been heavily criticised by several important and influential parties on the market, including LIF, which is of the opinion that the inquiry must be fundamentally reworked, and large patient organisations that believe the inquiry focuses too heavily on costs and moving funds between different parties, but without paying sufficient attention to patient need or enabling timely access to new treatments (which was an express objective of the inquiry). Time will have to tell whether the inquiry report will result in any governmental bill for new and amended legislation. As of the date of this chapter, no governmental bill has been presented.

In June 2020, the Pharmaceutical Benefits Act (2002:160) was amended to also enable substitution of prescribed medicinal products not included in the reimbursement scheme, to equivalent medicinal products that are included in the reimbursement scheme. By reason of these amendments, the Dental and Pharmaceutical Benefits Agency (TLV) initiated a reassessment of several reimbursed pharmaceuticals, to either adjust medicines subject to restricted reimbursement and make them generally reimbursed, or in some cases harmonise reimbursement restrictions within specific substitution groups. As a result, in April 2020, several decisions by the TLV entered into force, adjusting the reimbursement status for approximately 680 medicinal products. The intention with the legislative amendment and the TLV's reassessments was, inter alia, to enable more patients to receive their prescription drugs within the benefits scheme and subject to high-cost protection.

A public inquiry was initiated during 2020 into the healthcare sector (SOU 2021:19) that presented a first report on 31 March 2021 that, among other things, included proposals to strengthen the supply chain for medicinal products and healthcare products through warehousing at several levels. For pharmaceutical companies, it is proposed a statutory obligation to provide safety or emergency stocks for six months' normal consumption.

The Swedish government has assigned TLV to develop a model for an environmental premium for pricing of medicinal products to be presented in 2022. It is intended that the model developed by TLV will initially be tested on a pilot basis for four years starting in 2024, allowing pharmaceutical companies to be part of the pilot on a voluntary basis.

Law stated - 25 October 2021

Jurisdictions

Canada	Stikeman Elliott LLP
China	East & Concord Partners
European Union	Simmons & Simmons LLP
Germany	Ehlers Ehlers & Partner
India	LexOrbis
Ireland	Matheson
Israel	S Horowitz & Co
Italy	CMS Legal
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
New Zealand	Tompkins Wake
Singapore	Drew & Napier LLC
South Korea	Lee & Ko
Sweden	Cirio Advokatbyrå AB
Switzerland	Wenger Vieli Ltd
Turkey	Gün + Partners