

Sweden

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REGULATORY OVERVIEW

- Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities. If biotechnology products are treated differently, please specify the differences.**

The Swedish pharmaceutical market is extensively regulated in the interest of protecting public health. The national regulatory framework for medicinal products is largely based on EU legislation, and namely:

- Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) (as amended by Directive 2004/24/EC on traditional medicinal herbal products).
- Directive 2004/27/EC on the Community code relating to medicinal products for human use.
- Directive 2004/28/EC amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (New Medicines Legislation).

The main legislation regulating medicinal products is:

- The Medicinal Products Act (*SFS 1992:859*).
- The Decree on Medicinal Products (*SFS 2006:272*).
- The Regulations and General Recommendations issued by the Medical Products Agency (MPA).

In addition, Sweden has a number of country-specific regulations relating to, for example, generic substitution and pricing of medicinal products.

PRICING AND STATE FUNDING

- Please give a brief overview of the structure and funding of the national healthcare system.**

The responsibility for health and medical care in the Swedish healthcare system is shared between the state, county councils and municipalities, and mainly funded by tax revenues. Most hospitals and health service entities are public, although private healthcare exists.

New regulations have entered into force during 2009 to abolish Apoteket's previous monopoly over retail trade of medicinal products to consumers in Sweden and permit entry of new players on the Swedish pharmacy market. The MPA approves and monitors the establishment and operations of pharmacies under the Act on trade with pharmaceuticals (*SFS 2009:366*).

Further, from 1 November 2009, other types of retailers (for example, grocery stores and convenience shops) can sell over-the-counter (OTC) medicinal products, subject to regulations issued under the Act on Trade with Non-Prescription Medicines (*SFS 2009:730*).

Before the reform of the pharmacy market in July 2009, most pharmaceutical companies operating on the Swedish market used a "one-channel" model for pharmaceutical distribution. Despite the reform, there are still only two main distributors on the Swedish market, although this is likely to change in the near future. In addition, before the reform, the distributors acted as logistic service companies and not as traditional wholesalers. Pharmaceutical companies can deliver their products to pharmacies and hospitals directly, but few choose to do so. Further, in view of the recent reform of the pharmacy market, new players are expected to enter the wholesale market.

- In what circumstances are the prices of medicinal products regulated?**

The Dental and Pharmaceutical Benefits Agency (*Tandvårds- och läkemedelsförmånsverket*) (DPBA) decides on the sales price for medicinal products included in the benefits scheme after negotiations with the manufacturer (*Pharmaceutical Benefits Act (SFS 2002:160 revised by SFS 2009:373)*).

A system for generic substitution was introduced in 2002 under which a pharmacy has a duty to substitute a medicinal product with the least expensive medicinal product available, provided the following four conditions are fulfilled:

- The medicinal product is included in the Pharmaceutical Benefits Scheme (that is, the DPBA has found that the medicinal product fulfils the specific criteria for reimbursement and a sale price has been set by the DPBA).
- A prescription has been issued for the medicinal product.

- One (or more) less expensive and substitutable medicinal products are available. The MPA issues a list of substitutable medicinal products.
- The prescribing physician can object to the substitution of a medicinal product on medical grounds. The patient can also refuse to have the substitute medicinal product if he pays the price difference between the prescribed medicinal product and the substitutable medicinal product.

The company which markets a medicinal product can apply for the product to be included in the national benefits scheme under the Pharmaceutical Benefits Act. The DPBA:

- Is authorised to determine whether or not the medicinal product qualifies for the benefits system.
- Sets the price for the medicinal product.

The applicant and the county councils (which carry the costs of the pharmaceutical benefits system) can participate in deliberations with the DPBA before a decision is made. The DPBA considers a number of principles within the healthcare system, including:

- Care on equal terms.
- Giving priority to those in greatest need of care.
- Cost-effectiveness.
- The suitability of the medicinal product.
- The marginal utility of the medicinal product.

The DPBA generally determines whether the medicinal product's cost is reasonable in relation to the achieved health advantages. The DPBA's decision can be appealed to the Administrative Court.

Only prescription medicinal products usually qualify for inclusion in the national benefits scheme. An OTC medicinal product normally qualifies only if it is needed for the treatment of a long-term illness demanding continuous treatment for at least one year, or recurrent treatment for at least three months per treatment period.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

The reimbursement system means that the cost of medicinal products is gradually reduced for the individual patient over a 12-month period. The patient carries the full cost if the total expenditure for medicinal products does not exceed SEK900. The costs are then gradually reduced by subsidies. The maximum aggregated amount an individual patient can be liable to pay during a 12-month period is SEK1,800. As at 1 November 2010, US\$1 was about SEK6.7.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- To which authority must the application be made?
 - What conditions must be met to obtain authorisation?
 - Are there specific restrictions on foreign applicants?
 - What are the key stages and timing?
 - What fee must be paid?
 - How long does authorisation last and what is the renewal procedure?
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Application

A manufacturer or importer of medicinal products from third countries must obtain authorisation from the MPA before initiating any activities.

Conditions

The MPA has set the conditions which must be satisfied to obtain a manufacturing authorisation. Among others, the applicant must specify:

- Whether the application concerns the manufacture or import of a specific medicinal product, certain kind(s) of medicinal products or medicinal products in general.
- The pharmaceutical forms that are to be manufactured or imported.
- The place where the products are to be manufactured and controlled.

The applicant must also have at its disposal suitable and sufficient premises, equipment and control facilities. The applicant must appoint a qualified person, who is responsible for, for example, ensuring that the products are manufactured according to Good Manufacturing Practices (GMP) and applicable legislation.

Restrictions on foreign applicants

There are no specific restrictions on foreign ownership. However, an applicant for a manufacturing authorisation who is not resident within the EU or the European Economic Area (EEA) must appoint a local representative.

Key stages and timing

An application must be in writing and contain certain information and documentation. The procedure for granting the authorisation must not exceed 90 days from the day on which the MPA received the application. The applicant can appeal a rejection by the MPA to the Administrative Court.

Fee

An application fee and an annual fee are applicable. Information on fees is available on the MPA website (www.lakemedelsverket.se).

Period of authorisation and renewals

A manufacturing authorisation is valid for certain or indefinite time, and on the condition that the annual fee has been paid. The MPA carries out inspections at the premises on a regular basis.



6. What powers does the regulator have to:

- Monitor compliance with manufacturing authorisations?
 - Impose penalties for a breach of a manufacturing authorisation?
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The MPA can monitor compliance with the manufacturing authorisation and applicable law by:

- Carrying out inspections.
- Taking samples.
- Examining any document relating to the object of the inspection, including GMP.

Inspections are carried out on a regular basis by a special unit within the MPA, the Department of Inspection. The Department of Inspection conducts about 300 inspections each year. These relate to manufacturers, wholesalers and other entities developing, storing and distributing medicinal products. The licence holder must provide necessary assistance in connection with the MPA's inspections.

A manufacturing authorisation can be revoked if the licence holder:

- Breaches any requirement of particular importance for the safety or quality of the medicinal product.
- No longer fulfils one or more of the essential conditions for the authorisation.
- Has not paid the annual fees.

The MPA can also temporarily debar a qualified person from his appointment, if the person does not fulfil his duties.

A decision by the MPA to revoke a licence or debar a qualified person from his duties can be appealed to the Administrative Court.

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- Which legislation and regulatory authorities regulate clinical trials?
 - What authorisations are required and how is authorisation obtained?
 - What consent is required from trial subjects and how must it be obtained?
 - What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?
 - What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?
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Clinical trials are regulated by a number of regulations, including the Medicinal Products Act, the Decree on Medicinal Products and regulations on clinical trials issued by the MPA (which

implement Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive)). In addition, the ethical rules for the pharmaceutical industry issued by the Swedish Association of the Pharmaceutical Industry (*Läkemedelsindustriföreningen*) (LIF Rules) contain specific rules on the conduct of clinical trials.

Clinical trials must be planned, conducted and reported according to the latest version of the Declaration of Helsinki and the Note for Guidance on Good Clinical Practice (GCP) (*CPMP/ICH/135/95*). Under the MPA regulations, the sponsor must ensure that the necessary authorisations from the MPA and the competent Ethics Committee are obtained. Applications must be made on the specific EudraCT application form. A valid application is normally reviewed and a decision issued by the MPA within 60 days of receipt of the application.

Potential clinical trial subjects must receive clear and comprehensive information on the trial to enable them to make an informed decision on whether or not to take part in the trial. Patient consent must be in writing. Any personal data collected in the clinical trial must be processed according to the Data Protection Act and the Swedish Patient Data Act (*SFS 2008:355*). If the clinical trial includes genetic analysis, this testing must be pre-examined by the Data Inspection Board (*Datainspektionen*).

Sponsors must provide adequate insurance protection for injuries caused to patients during a clinical study. Public hospitals must take out insurance for patient injuries under the Patient Injury Act (*SFS 1996:799*), including injuries occurring during participation in a clinical trial. However, this only covers injuries caused by medical treatment, not those caused by the medicinal product itself. Therefore, the primary function of insurance taken out by sponsors for clinical trials is to provide economic compensation for injuries caused by the investigational medicinal product.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- To which authority must the application be made?
 - What conditions must be met to obtain authorisation?
 - What are the key stages and timing?
 - What fee must be paid?
 - How long does authorisation last and what is the renewal procedure?
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Application

The MPA is responsible for granting marketing authorisations under the mutual recognition procedure (MRP), the decentralised procedure (DPC) and the national procedure. Applications can also be submitted to EMEA under the centralised EU system.

Conditions

The conditions that must be satisfied by the applicant under the national procedure, or if Sweden is the reference member state (RMS) under the MRP or the DCP, are set out in regulations issued by the MPA. The applicant must demonstrate that the medicinal product is of satisfactory quality, safety and efficacy, and does not have any harmful effects disproportionate to its intended effect.

Key stages and timing

An application is needed for each single pharmaceutical formulation and strength. The application should be made on a specific form supplied by the MPA, which is identical to the form used in the MRP. The MPA has 210 days to assess the application starting from the date a complete application is filed. If the application is rejected, the applicant can appeal to the Administrative Court.

Fee

An application fee and an annual fee apply. Information on fees is available on the MPA website (*see box, The regulatory authorities*).

Period of authorisation and renewals

A marketing authorisation is valid for five years and is renewable. A renewed authorisation is normally unlimited in time. Renewal applications must both:

- Be submitted to the MPA no later than six months before the expiry date of the existing authorisation period.
- Include an updated and consolidated version of the documentation regarding quality, safety and efficacy.

The existing marketing authorisation is valid during the processing of the renewal application.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- Which medicinal products can benefit from the abridged procedure (for example, generics)?
- What conditions must be met?
- What procedure applies and what information can the applicant rely on?

Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) has been fully transposed into Swedish legislation through amendments of the Medicinal Products Act. As a result, if an applicant can demonstrate that the relevant medicinal product is a generic of a referenced medicinal product, which is or has been authorised for not less than eight years in an EEA member state, the applicant can refer to the results of pre-clinical or clinical trials conducted in relation to the reference medicinal product. Under the Notice to Applicants (NTA) Volume 2A, reference must be made to the dossier of a reference product for which a marketing authorisation has been granted in the EU, based on a complete dossier under Articles 8(3), 10a, 10b or 10c of the Code for Human Medicines Directive.

In a ruling of March 2006, the Swedish Supreme Administrative Court confirmed that the innovative pharmaceutical industry has standing to appeal decisions by the MPA relating to marketing authorisations granted for a generic product based on the abridged procedure. Before this judgment, the owner of the reference product, who was not a party to the generic marketing

authorisation matter before the MPA, was not entitled to appeal against the MPA's decision. Swedish courts had previously dismissed appeals filed by the innovative industry because of a lack of standing. As a result of the Supreme Administrative Court's decision, it appears that the following should also be sent to the owner of the reference product, immediately after any grant of market authorisation for a generic product:

- The generic marketing authorisation granted for Sweden by the MPA.
- Instructions on how to appeal.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

A medicinal product can only be placed on the Swedish market when marketing authorisation has been issued or recognised by the MPA or when an authorisation has been granted for the entire EU.

11. What powers does the regulator have to:

- Monitor compliance with marketing authorisations?
- Impose penalties for a breach of a marketing authorisation?

The MPA can monitor compliance with applicable law by:

- Carrying out inspections.
- Taking samples.
- Examining any document relating to the object of the inspection.

Inspections are carried out on a regular basis by the Department of Inspection at the MPA (*see Question 6*). The MPA can also order the licence holder to prove that it still fulfils relevant requirements for a marketing authorisation. The licence holder has a duty to provide necessary assistance in connection with the MPA's inspections.

A marketing authorisation can be revoked temporarily or permanently if any of the following apply:

- The holder fails to prove, on an order by the MPA, that it continues to fulfil relevant requirements for the authorisation.
- The holder breaches any of the specific conditions relating to the authorisation.
- The holder does not recall the product despite an order by the MPA to do so.
- For any other reason, one or more of the essential conditions for the authorisation are no longer fulfilled.

A decision by the MPA to revoke a marketing authorisation can be appealed to the Administrative Court.



12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Under intellectual property law, a patent or trade mark can only be relied on to stop parallel imports from outside the EEA. Intellectual property rights are exhausted in the EEA once the product has been put on the market anywhere in the EEA by the holder, or with its consent. Therefore, parallel trade in medicinal products within the EEA is possible, provided the parallel import is undertaken according to applicable regulations and case law.

The sale of parallel imported medicinal products requires an authorisation from the MPA. An authorisation is granted if the following conditions are fulfilled:

- The directly imported product is authorised for sale in Sweden.
- The parallel imported product is authorised for sale in the exporting country.
- The exporting country is a member state within the EEA.
- The parallel imported product is sufficiently similar to the directly imported product.

A marketing authorisation for a parallel imported product is granted for five years and can be extended for an indefinite period.

Repackaging or re-labelling of the product requires a specific manufacturing authorisation from the MPA. The labelling and package leaflet must be designed according to the MPA Regulation on Packaging and Labelling of Medicinal Products (*LVFS 2004:8*), including a requirement that information be written in Swedish. Foreign text on packages may be accepted if it does not conflict with the Swedish text. The name of the parallel imported product must also be approved by the MPA.

If the marketing authorisation for the parallel imported product expires in the exporting country, or if the marketing authorisation for the directly imported product in Sweden is revoked for quality, efficacy or safety reasons, the Swedish marketing authorisation for the parallel imported product expires.

13. Please briefly outline the restrictions on marketing practices such as gifts or “incentive schemes” for healthcare establishments or individual medical practitioners.

Great care must be taken when gifts or other benefits are offered to public or private medical practitioners, as what can be received is strictly regulated. Any individual who gives, promises or offers any improper remuneration to an employee in relation to his services may be guilty of bribery under the Criminal Code. Bribery is broadly interpreted and cash benefits, such as vouchers, hotel visits, gifts to relatives and club memberships, are generally considered improper. Benefits directly related to, and constituting a natural and useful part of the employee's service (for example, samples, serious and short study tours or courses, and ordinary working lunches) are not normally considered improper, provided they fulfil the applicable requirements.

The LIF Rules (*see Question 7*) also contain restrictions relating to gifts and hospitality. They include a general requirement that all hospitality offered to healthcare personnel attending meetings arranged by a company must be of such a kind and on such a scale that there is no risk that the recipients will let themselves be influenced by them in the execution of their professional duties.

The LIF Rules, last amended on 21 May 2010, include, among others:

- Strict rules concerning cost sharing between pharmaceutical companies and the participant or his employer for travel, food, accommodation and conference fees.
- Detailed provisions on the drafting and submission of invitations to scientific conferences, congresses or other meetings.

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

The pharmacy market has been reformed (*see Question 2*). Since 1 July 2009, new players can enter the Swedish pharmacy market as a result of the abolition of Apoteket's exclusive right to sell prescription and OTC medicinal products to Swedish consumers. In addition, since 1 November 2009, retailers other than pharmacists (for example, grocery stores and convenience shops) can sell OTC medicinal products.

Traditionally, medicinal products have only been sold to consumers through pharmacy retail stores belonging to Apoteket. However, pharmacies now offer on its website OTC and prescription medicinal products to consumers living in Sweden.

A private individual can order medicinal products from outside Sweden by, for example, mail order or the internet, if the individual can prove that the product:

- Is ordered in the EEA.
- Is approved both in Sweden and its country of origin.
- Is intended for personal use.
- Has been purchased from a pharmacy.
- Does not contain more than one year's worth of consumption.

If the product is a prescription medicinal product, the individual must also prove that he received the prescription from a person authorised to issue prescriptions within the EEA.

The import of medicinal products from a non-EEA country requires a Swedish marketing and/or manufacturing authorisation or a particular import licence. It is illegal to order medicinal products from a non-EEA country through the internet or mail order without an import licence, regardless of whether the products are intended for personal consumption. The MPA can grant an exemption, but in practice, exemptions are rarely given.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
 - What types of medicinal product cannot be advertised?
 - What restrictions apply to advertising that is allowed?
 - If advertising over the internet is treated differently, please identify the differences.
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The Medicinal Products Act includes a basic provision that all medicinal products advertising must be up to date, factual, balanced and not misleading. Advertising medicinal products must also be compatible with good marketing practice. In addition, the Medicinal Products Act was amended on 1 May 2006 to include more detailed rules on pharmaceutical advertising. Directive 92/28/EEC on the advertising of medicinal products for human use (Medicinal Advertising Directive) is now fully transposed into Swedish law (incorporated in the Code for Human Medicines Directive (see *Question 1*)). Therefore, the following are not allowed:

- Advertising of medicinal products that are not authorised for sale in Sweden.
- Advertising aimed at children.
- Advertising aimed at the general public of medicinal products that are only available on prescription (except for campaigns for vaccination against human infection diseases).

Further, the general provisions of the Market Practices Act (*SFS 2008:486*) apply to the promotion of all kinds of products and services, including medicinal products. It contains a general requirement that all marketing must be both:

- Compatible with good marketing practice.
- Fair towards consumers and the industry.

The Market Practices Act also sets out specific rules on, among others, misleading advertising, comparative advertising and special offers.

The LIF Rules (see *Question 13*) also contain detailed provisions for pharmaceutical advertising. Although not legally binding, the LIF Rules are widely recognised by the pharmaceutical industry and applied by courts as an expression of fair and ethical marketing. The LIF Rules include prohibitions on, among others, promotion of prescription medicinal products to the general public, off-label promotion and pre-launch marketing. They also contain rules about, for example, comparative advertising, misleading, incomplete or unsubstantiated information and disguised promotion.

Under the LIF Rules, for the purpose of ensuring public access to requested and easily comprehensible information on prescription medicinal products, this information may, under certain conditions, be provided by pharmaceutical companies on pre-examined and approved websites (*Förhandsgodkänd hemsida*).

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
 - What information must the packaging and/or labelling contain?
 - What other conditions must be met (for example, information being stated in the language of your jurisdiction)?
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The relevant requirements are contained in the MPA Regulation on the Labelling and Package Inserts for Medicinal Products (LVFS). The labelling of a medicinal product must, among others, show the following information in Swedish:

- The name, strength and pharmaceutical form of the product.
- A declaration of the active ingredients.
- The formula, weight, volume or dose quantity of the product.
- The method of administration.
- Directions for use and storage precautions where appropriate.
- A specific warning that the product should be kept out of reach of children.
- Other relevant warnings.
- A specific reference to the package insert.
- Expiry date.
- Batch number.
- The name and address of the market authorisation holder.
- The marketing authorisation (MA) number.

The name and strength (if there is more than one strength) of the product must be written in Braille on the outer package. Certain information must be clearly and specifically worded, and prominently positioned, on the label, including:

- The name of the product.
- Storage and user instructions.
- Important warnings.

It is not permitted to include text, symbols or pictures of a promotional nature on the label or the package insert. Samples of packaging and labelling text, including package inserts, must be provided to the MPA when submitting an application for a marketing authorisation.



TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

Directive 2004/24/EC on traditional herbal medicinal products (Traditional Herbal Medicines Directive) has been implemented in the Medicinal Products Act and the MPA Regulation for Products Containing Traditional Herbs LVFS (2006:3).

A simplified registration procedure has been introduced for traditional herbal medicinal products. The requirements on the chemical-pharmaceutical documentation relating to safety and quality are equal to that of conventional medicinal products. However, for the requirement of efficacy, it is sufficient to demonstrate that the product in question or a corresponding product has been used for medicinal purposes for a period of at least 30 years at the time of the application, including at least 15 years of use within the EU. The therapeutic indications are limited to self-medication that does not require a physician's diagnosis, prescription or supervision of treatment. The products must only be intended for oral consumption, external application and/or inhalation.

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?

For a medicinal product to be patentable, all of the following must apply to it:

- It must be susceptible to industrial application (the invention must, among others, be capable of being reproduced with the same result).
- It must be novel (the invention must not already be available to the public anywhere in the world).
- It must involve an inventive step (an invention must not, having regard to the state-of-the-art, be obvious to a person skilled in the art).

In addition, certain biotechnical inventions may be patentable.

The following cannot be patented:

- Methods for surgical or therapeutic treatment, or diagnostic methods, practised on humans or animals. However, this does not prevent the granting of patents for products, including substances and compositions of substances, for use in methods of this type.
- Inventions, the use of which would be contrary to morality or public order.

The Patents Act (1967:837) and the Patents Regulation (1967:838) apply.

19. How is a patent obtained? In particular:

- To which authority must the application be made?
- What fee must be paid?
- What are the key stages and timing?
- Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?

The authority

The Swedish Patent and Registration Office (PRO) (*Patent och Registreringsverket*) (www.prv.se) administers patent applications and maintains the official patent register.

Fee

The applicant must pay a filing fee and supplementary fees for, among others, each patent claim in addition to the first ten. If the patent is granted, a granting fee and annual fees must be paid. Current fees can be found on the PRO website (*see above, The authority*).

Process and timing

The inventor or its successor-in-title can apply for a patent with the PRO. The description, patent claims and abstract must be in Swedish. The PRO aims to process applications within two years, although the time period can vary significantly. If a patent application is rejected, the decision can be appealed to the Court of Patent Appeals (*Patentbesvärsrätten*) within two months.

20. How long does patent protection last? How is a patent renewed or patent protection extended? If the patent itself cannot be extended, can the organisation's monopoly rights be extended by other means, such as supplementary protection certificates or (regulatory) data exclusivity periods?

A patent is effective for 20 years from the day the patent application was filed. An annual fee must be paid after the grant of a patent, or the patent lapses.

Supplementary protection can be granted for medicinal products for a period of up to five years (Regulation (EEC) 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (Medicinal Products Supplementary Protection Certificate Regulation)).

21. In what circumstances can a patent be revoked?

Third parties can give the PRO notice of opposition to a patent within nine months of the date of grant. If an individual wishes to challenge the granted patent after the nine-month period, court proceedings must be initiated.

The patent can be revoked if one of the following applies:

- The patent was granted even though the conditions in the Patents Act are not fulfilled.

- The patent relates to an invention the description of which is not sufficiently clear to enable a person skilled in the art to carry out the invention with the guidance of the description.
- The patent comprises subject matter not appearing in the application as filed.
- The scope of patent protection has been extended after the grant of the patent.

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

A patent is infringed when an individual, without the consent of the patent holder, for example produces, offers for sale, or commercially exploits the patented invention. The patent safeguards the exclusive right to commercial exploitation of the patented invention.

A patent holder claiming patent infringement can submit an application for a summons to the Stockholm District Court. The prosecutor can institute criminal proceedings in certain circumstances.

The remedies available under the Patents Act are:

- Penalties (fines or up to two years' imprisonment).
- Injunctions (under penalty of a fine, including preliminary injunctions).
- Damages.
- Forfeiture of property in relation to which a violation has occurred, or profits from such a violation and so on.
- Corrective measures (such as recollection of property from the channels of commerce).
- Liability for costs to spread information about a judgment in a patent case.

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

The brand of a medicinal product can be registered as a trade mark under the Swedish Trade Mark Act (*SFS 1960:644*) in the same way as any other brand. To be registrable, a trade mark must fulfil all the following requirements:

- It must be capable of graphical representation.
- It must be distinctive.
- It must not be descriptive.

Registration is not allowed, if for example, the mark is intended to mislead the public or is confusingly similar to an earlier trade mark.

The MPA also examines the name of the medicinal product in connection with, for example, the marketing authorisation approval.

24. How is a trade mark registered? In particular:

- To which authority must the application be made?
 - What fee is payable?
 - What are the key stages and timing?
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The authority

The PRO administers trade mark applications and maintains the official trade mark register (*see Question 19*).

Fee

The applicant must pay a filing fee and a supplementary fee for, among others, each class in addition to the first. The current fees can be found on the PRO website (*see Question 19*).

Process and timing

The application must be written in Swedish, unless the PRO in an individual case decides otherwise, and must include, among others:

- The name and address of the applicant.
- An illustration of the trade mark.
- Information on the goods or services for which the trade mark will be used and the class to which these goods or services belong.

If the formal requirements are fulfilled, the PRO examines whether there are any obstacles to the registration of the mark (for example, if the mark is confusingly similar to an earlier trade mark or business name). If no obstacles are found, it takes about three months to obtain trade mark registration. However, the time period can vary significantly. The registration is published in the *Swedish Trade Mark Gazette (Svensk varumärkestidning)*. Oppositions can be filed within two months of registration. If an application is rejected, the decision can be appealed to the Court of Patent Appeals within two months.

25. How long does trade mark protection last? How is a trade mark renewed?

A trade mark registration is valid for ten years from the date of registration. The registration can be extended every ten years and can remain in force indefinitely, provided the renewal fees are paid.

26. In what circumstances can a trade mark be revoked?

Third parties can give the PRO notice of opposition to a trade mark within two months of the date of registration. If someone wishes to challenge the trade mark after the two-month opposition period, court proceedings must be initiated.

A trade mark registration can be revoked in any of the following circumstances:

- The conditions for registration under the Trade Marks Act were not fulfilled at the time of registration and have still not been met.



- The trade mark is found to be deceptive, contrary to public order, or liable to cause general offence.
- The trade mark is no longer distinctive.
- The trade mark has not been in use on the market for an uninterrupted five-year period (unless the trade mark owner can provide an acceptable explanation for non-use).

Invalidity proceedings can remove a trade mark from registration for all or some of the goods for which it was registered.

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

A trade mark is infringed when an individual, without the consent of the trade mark holder, in the course of business markets products under a mark confusingly similar to the registered trade mark.

A trade mark holder claiming trade mark infringement can submit an application for a summons to the District Court. In certain circumstances, the prosecutor can institute criminal proceedings.

The remedies available under the Trade Marks Act are the same as those under the Patents Act (see *Question 22*).

In addition to the provisions of the Trade Marks Act, the Market Practices Act and extensive case law from the Market Court offer protection for a trade mark holder against misleading and otherwise unlawful use of its trade marks.

28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

There is no such requirement.

29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

There is no such requirement.

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

Sweden is a signatory to the following international conventions relating to patents:

- Patent Cooperation Treaty 1970.
- European Patent Convention 1973.

Sweden is a signatory to the following international conventions relating to trade marks:

- World Intellectual Property Organisation (WIPO) Paris Convention for the Protection of Industrial Property 1883.
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989.

Sweden is also a signatory to the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).

PRODUCT LIABILITY

31. Please give an overview of medicinal product liability law, in particular:

- Under what laws can liability arise (for example, contract, tort or statute)?
 - What is the substantive test for liability?
 - Who is potentially liable for a defective product?
-

Legal provisions

A patient who suffers personal injury from using a particular medicinal product can bring an action under the Product Liability Act (*SFS 1992:18*). Damages can be claimed for injuries caused by a product due to a safety deficiency (that is, the injuries were caused because the product was not as safe as may reasonably be expected). A patient can also bring a claim under the Tort Act (*SFS 1972:207*).

The Pharmaceutical Insurance Association (*Läkemedelsförsäkringen*) (LFF) provides a voluntary no-fault insurance scheme for its members through the insurance company LFF Service AB. The insurance covers damages caused by adverse effects of pharmaceuticals purchased at a pharmacy in Sweden, received in the healthcare system and adverse effects of investigational medicinal products in clinical trials. A vast majority of pharmaceutical companies conducting business in Sweden are members of the LFF.

Substantive test

Under the Product Liability Act, to be entitled to compensation the claimant must prove that the injury is caused by the medicinal product due to a safety deficiency and that there is a causal link between the injury and safety deficiency.

Under the Tort Act, the claimant must prove that there is a causal link between the injury and use of the medicinal product. No-fault liability does not apply (as it does under the Product Liability Act), so the claimant must usually prove negligence.

Under pharmaceutical insurance, a personal injury with preponderant probability that has been caused by a pharmaceutical and which could not reasonably have been predicted by the prescribing physician is covered by the insurance.



A manufacturer, importer or any individual who, by affixing its company name, trade mark or other distinguishable sign to a product, identifies himself as the producer, can be held liable for damages.

32. What are the limitation periods for bringing product liability claims?

The limitation period for a claim based on the Product Liability Act is three years after the party suffering the damage became aware of, or should reasonably have become aware of, the damage and the identity of the person liable. Regardless of the injured or damaged party's state of awareness, this claim reaches its limitation ten years after the product was put into circulation. Claims based on the Tort Act have a limitation period of ten years.

33. What defences are available to product liability claims?

The defendant can escape liability under the Product Liability Act if it can prove any one of the following:

- There is no causal link between the injury and use of the medicinal product.
- It did not put the product into circulation in the course of its business.
- It is probable that the defect that caused the damage did not exist at the time when the product was put into circulation.
- The defect is due to compliance of the product with mandatory regulations issued by the public authorities.
- The state-of-the-art defence applies, meaning that the state of scientific and technical knowledge at the time when it put the product into circulation was not enough to enable the discovery of the existence of the defect.

In tort, the defendant can escape liability if, for example, it can prove that there is no causal link between the injury and use of the medicinal product, or that it did not cause the injury by a wilful or negligent act.

34. What remedies are available to the claimant?

A company held liable under the Product Liability Act or in tort must pay damages for injury caused. There is no upper limit for the amount of damages, but damages paid as a result of a court action are generally low compared to those in other jurisdictions.

35. Are class actions allowed for product liability claims? If so, are they common?

Private individuals, certain non-profit organisations and certain authorities can initiate a group claim under the Group Claims Act (*SFS 2002:599*) if, among others:

- Several common disputes exist.
- The action cannot be equally, or more effectively, processed in another way.

THE REGULATORY AUTHORITIES

Medical Products Agency (MPA) (*Läkemedelsverket*)

T +46 18 17 46 00
F +46 18 54 85 86
E registrator@mpa.se
W www.lakemedelsverket.se

Main areas of responsibility. The MPA is the Swedish national authority responsible for regulation and surveillance of the development, manufacture and sale of medicinal products. Its main task is to ensure that patients and healthcare professionals have access to safe and effective medicinal products, and that the drugs are used in a rational and cost-effective manner. The MPA's operations are largely financed through fees.

Dental and Pharmaceutical Benefits Agency (DPBA) (*Tandvårds och- läkemedelsförmånsverket*)

T +46 8 568 420 50
F +46 8 568 420 99
E registrator@tv.se
W www.tv.se

Main areas of responsibility. The DPBA's main task is to ascertain if a medicinal product (or medical device) should be included in the medicinal product benefits scheme and so be reimbursed by society. From 1 July 2008, the DPBA is also responsible for questions concerning subvention of dental care.

Association of the Pharmaceutical Industry (*Läkemedelsindustriföreningen*)

T +46 18 17 46 00
F +46 18 54 85 86
E info@lif.se
W www.lif.se

Main areas of responsibility. The Association of the Pharmaceutical Industry (LIF) is the trade association for the research based pharmaceutical industry in Sweden. LIF has issued the Ethical Rules of the Pharmaceutical Industry (see *Questions 13 and 15*).

- The representative of the group is suitable to conduct the group action.
- Certain other requirements are met.

The group claim covers group members who announced within a certain period that they want to be included in the claim. The members are not part of the trial, but the judgment is binding for all group members.

The Group Claims Act came into force on 1 January 2003 and no pharmaceutical case law has been developed so far.

36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?

Punitive damages are not allowed for product liability claims.



REFORM

37. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

The Swedish pharmacy market has recently been reformed (see *Question 2*). Since 1 November 2009, the final stage of the reform permits retailers other than pharmacies to sell OTC medicinal products. The overall aims of the reform are to:

- Give consumers better access to medicines, a higher level of service and a better range of services.
- Create price pressure on non-prescription and prescription medicines.

The reform's objectives are expected to be achieved through exposing the market to competition by allowing the entry of new

players on the market. A number of state-owned pharmacies have been divested to encourage new entrants to the market. It is expected that the reform will also affect competitive conditions on the wholesale market.

In May 2008, the Competition Authority was appointed by the government to monitor developments in the reform of the pharmacy market.

In relation to the pharmacy market's reform, the DPBA has the responsibility to review the pricing of medicines and how the pricing system can be developed. The price and reimbursement system is currently subject to review. In a recent report, the DPBA has proposed the implementation of an international reference pricing system as a complement to the current system, to obtain additional price pressure on the market. The report generally focuses on downward pressure on prices of pharmaceutical products. No decision has been made in this regard.

CONTRIBUTOR DETAILS



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Areas of practice. Competition, distribution, marketing and regulatory issues in the pharmaceutical sector; other heavily regulated sectors such as medical devices, food and cosmetics. Pharmaceuticals including clinical trials, parallel import/exports, supply quota, pharmaceutical information, marketing and market research, reimbursement, pricing and pharmaceutical insurance issues.

Recent transactions

- Representing pharmaceutical companies in relation to issues brought before the Information Practices Committee and national authorities.
- Numerous litigation, concerning reimbursement, substitution, regulatory data protection and pharmaceutical advertisement.



SOPHIE DUCATÉ

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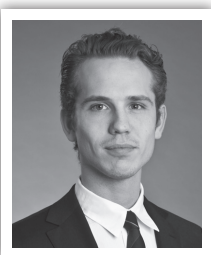
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W www.mannheimerswartling.se

Areas of practice. Focus on heavily regulated products such as medicinal products, medical devices, food, cosmetics and borderline products. Anti-trust; advertising; branding and therapeutic information; hospitality; anti-corruption issues; counterfeiting issues; pricing.

Recent transaction

Advising Bracco Imaging on the acquisition of Initios Medical AB.



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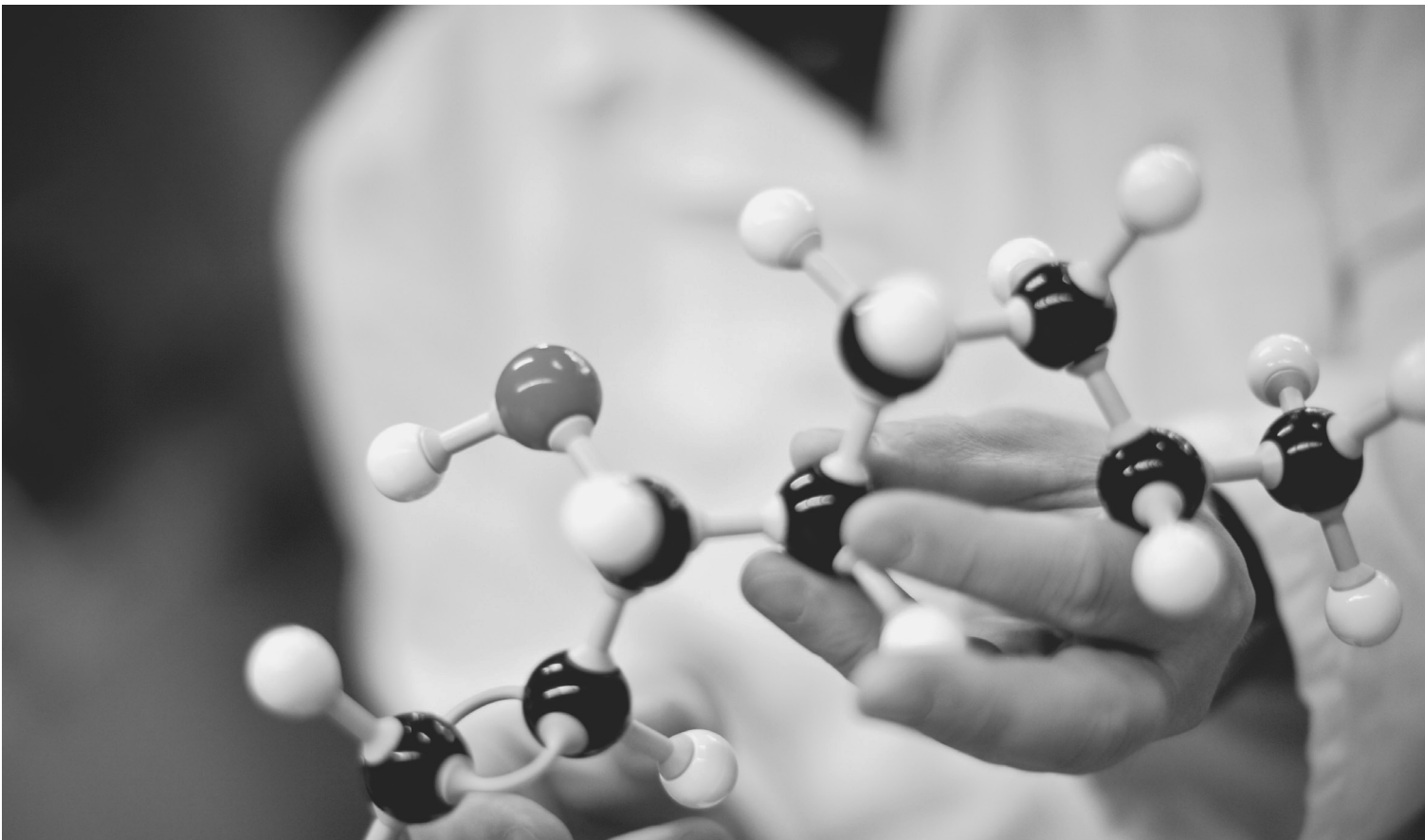
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Areas of practice. Focus on heavily regulated products such as medicinal products, medical devices, food, cosmetics and borderline products.

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Health Care & Life Sciences

ADVISING OUR CLIENTS THROUGHOUT THE PRODUCT LIFECYCLE; FROM EARLY STAGE DISCOVERY THROUGH PRODUCT LAUNCH AND SALES AND MARKETING

With extensive international industry experience, our team takes a multidisciplinary approach to navigating the complex issues that face both multinational corporations and smaller companies with individual entrepreneurs within the pharmaceutical, biotechnology, and medical device sectors as well as the nutrition and food industries. Highly skilled attorneys coupled with our understanding of the complex life science commercial business enables us to provide practical solutions to the diverse range of issues facing the industry today including:

- Regulatory matters
- Market authorizations
- Procurement, Pricing and Reimbursement
- Substitution
- Clinical trial issues
- Strategic Alliances and Partnerships (Licensing transactions, Sponsored Research Collaborations, Co-promotion, and Distribution agreements)
- Competition and anti-trust matters
- Intellectual property protection and litigation
- Global manufacturing issues
- Development and implementation of Global Compliance Programs (Anti-bribery, policy development, implementation, and oversight).
- Drug safety and risk management
- Data privacy
- Review and guidance relative to advertising and promotion rules
- Policy and legislative guidance

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