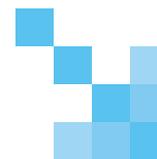


# Sweden



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## 1. 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.

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, the foundation of which is 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 and Directive 2004/28/EC amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (New Medicines Legislation)). The main pieces of legislation regulating medicinal products are:

- 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.

In addition, Sweden has a number of country specific rules relating to, for example, the sale and distribution of medicinal products, generic substitution and pricing of medicinal products.

## PRICING AND STATE FUNDING

### 2. 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.

Sweden has a statutory monopoly for the retail sale of pharmaceuticals, run by the state-owned National Corporation of Swedish Pharmacies (*Apoteket AB*). Apoteket AB has the unconditional right and obligation to supply all medicinal products, both prescription and over-the-counter (OTC) medicines, with the exemption of nicotine replacement products, natural remedies and certain medicinal products for external use, that have been authorised for sale by the Medical Products Agency (or the European Agency for the Evaluation of Medicinal Products (EMA) if applicable) as regulated in an

agreement between itself and the government. Only hospitals are permitted to buy medicinal products direct from manufacturers. The pharmacy monopoly is currently being reviewed.

Most pharmaceutical companies operating on the market use a one-channel model for pharmaceutical distribution. Currently, two distributors mainly exist on the Swedish market. In practice, they act as logistic service companies and not as traditional wholesalers. Pharmaceutical companies are free to deliver their products to pharmacies and hospitals directly, but few have chosen to do so.

### 3. In what circumstances are the prices of medicinal products regulated?

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

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

- The drug is included in the Pharmaceutical Benefits Scheme (that is, the DPBA has found that the drug fulfils the specific criteria for reimbursement and a sale price has been set by the DPBA).
- A prescription has been issued for the drug.
- One (or more) less expensive and substitutable drugs are available. The MPA issues a list of substitutable drugs.
- The less expensive, substitutable drug is available at the individual pharmacy where the prescription is dispensed.

The prescription-issuer has the right to object to the substitution of a drug on medical grounds. The patient can also refuse to have the drug replaced if he pays the price difference between the prescribed drug and the least expensive substitutable drug available.

The manufacturer or seller of 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 and sets the price for that product. The applicant and the county councils (which carry the costs for the pharmaceutical benefits system) are given the opportunity to participate in deliberations

with the DPBA before any 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 drug.
- The marginal utility of the drug.

In short, the DPBA 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 County Administrative Court.

Generally, only prescription drugs qualify for inclusion in the national benefits scheme. An OTC drug 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.

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**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)?**

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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 (about US\$131). After that, the costs are gradually reduced by subsidies. The maximum aggregated amount an individual patient can be liable to pay during a 12-month period is SEK1,800 (about US\$262).

## MANUFACTURING

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**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 Medical Products Agency (MPA) (*Läkemedelsverket*) before initiating any activities.

### Conditions

The MPA has set the conditions which must be satisfied to obtain a manufacturing authorisation. Among other things, 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 (among other things) 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 County Administrative Court.

### Fee

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

### Period of authorisation and renewals

A manufacturing authorisation is initially valid for five years and on the condition that the annual fee has been paid. The MPA carries out inspections at the premises on a regular basis, after which the authorisation is normally renewed. If not, the licence holder must apply for an extension of the authorisation before its expiration.

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**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 carry out inspections, take samples and examine any document relating to the object of the inspection to monitor compliance with the manufacturing authorisation and applicable

law, including GMP. These inspections are carried out on a regular basis by a special unit within the MPA, called the Department of Inspection. About 300 inspections are conducted by the Department of Inspection each year. These relate to manufacturers, wholesalers and other entities developing, storing and distributing medicinal products. The licence holder has a duty to 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 County 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)?

Clinical trials are governed 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 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 is responsible for ensuring 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, such testing must be pre-examined by the Swedish 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?

### Application

The MPA is responsible for granting marketing authorisations under the mutual recognition procedure (MRP), the decentralised procedure 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 decentralised procedure, 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.

The MPA can grant an individual licence (valid for a particular patient) or a general licence (covering the needs of a specific clinic) for the sale of a non-approved medicinal product. The application for this licence is made by a pharmacy (not the manufacturer),

and requires a physician to issue a prescription for the relevant medicinal product. A licence is normally valid for one year and is renewable.

### 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 County Administrative Court.

### Fee

An application fee and an annual fee apply. Information on fees is available on the MPA website (see [www.lakemedelsverket.se](http://www.lakemedelsverket.se)).

### 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 be submitted to the MPA no later than six months before the expiry date of the existing authorisation period, and 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 has been fully transposed into Swedish legislation through amendments of the Medicinal Products Act, which came into force on 1 May 2006. As a result, if an applicant can demonstrate that the relevant medicinal product is a generic of a reference medicinal product, which is or has been authorised for not less than eight years in an EEA member state, the applicant is entitled to 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 according to Articles 8(3), 10a, 10b or 10c of Directive 2001/83.

The Swedish Supreme Administrative Court has in a ruling of March 2006 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 market-

ing 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. It is our understanding that, as a result of the Supreme Administrative Court's decision, any generic marketing authorisation granted for Sweden by the MPA should be sent also to the owner of the reference product along with instructions on how to appeal, immediately after the grant of the market authorisation for the generic product.

## 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 carry out inspections, take samples and examine any document relating to the object of the inspection to monitor compliance with applicable law. 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 County 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 will be 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, 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 will expire.

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

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Great care must be taken when gifts or other benefits are offered to public or private medical practitioners, as the rules regulating what can be received are strict. Any person who gives, promises or offers any improper remuneration to an employee in respect of his services may be guilty of bribery under the Swedish Criminal Code. Bribery is broadly interpreted and cash benefits, such as vouchers, hotel visits, gifts to relatives and club memberships, are normally 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 normally not considered improper.

The ethical rules issued by the Swedish Association of the Pharmaceutical Industry (*Läkemedelsindustriföreningen*) (LIF), Ethical rules for the pharmaceutical industry (LIF Rules) 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 23 May 2008, include, among other things, strict rules regarding cost sharing between pharmaceutical companies and the participant or his employer for travel, food, accommodation and conference fees, as well as detailed provisions about the drafting and submission of invitations to scientific conferences, congresses or other meetings.

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

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Apoteket AB (see [www.apoteket.se](http://www.apoteket.se)) (see Question 2) has the exclusive right to distribute prescription and OTC drugs to Swedish consumers, with the limited exemption of nicotine replacement products, natural remedies and certain medicinal products for external use, which may be sold in food stores and so on. Traditionally, medicinal products have only been sold to consumers through pharmacy retail stores belonging to Apoteket AB. However, Apoteket AB now offers both OTC and prescription drugs online to consumers living in Sweden on its website.

In recent years, several internet pharmacies targeting Swedish consumers have appeared. The MPA has reported several of them to the police, claiming that they are running a pharmaceutical retail business in Sweden, which is a criminal offence under the statute governing the retail monopoly of Apoteket AB. The cases raise interesting questions relating to, among other things, the EC rules on free movement of goods and state monopolies as considered by the ECJ in the *Doc Morris* judgment (*Case C-322/01*).

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 drug, 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 via the internet or mail order without an import licence, regardless of whether or not the products are intended for personal consumption. The MPA can grant an exemption from this rule, 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?

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 (now Code for Human Medicines Directive (*see Question 1*)) is now fully transposed into Swedish statute law. Therefore, advertising medicinal products that are not authorised for sale in Sweden is not allowed. Medicinal products advertising cannot be aimed at children and advertising medicinal products that are only available on prescription cannot be aimed towards the general public, except for campaigns for vaccination against human infection diseases.

Additionally, the general provisions of the Market Practices Act (*SFS 1995:450*) apply to the promotion of all kinds of products and services, including medicinal products. It contains a general requirement that all marketing must be compatible with good marketing practice and fair towards consumers and the industry. The Market Practices Act also sets out specific rules on, among other things, 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 other things, promotion of prescription drugs 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 the public access to requested and easily comprehensible information on prescription drugs, such information may, under certain conditions, be provided by pharmaceutical companies on pre-examined and approved websites.

## 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)?

The relevant requirements are contained in the MPA Regulation on the Labelling and Package Inserts for Medicinal Products. The labelling of a medicinal product must, among other things, 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, and 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.**

On 2 May 2006, a new MPA regulation for products containing traditional herbs came into force in Sweden, implementing Directive 2004/24/EC on traditional herbal medicinal products. All products currently classified as natural remedies (*naturläkemedel*) containing herbs must be re-approved as conventional medicinal products or registered as traditional herbal medicinal products.

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.

Natural remedies have so far not been covered by the state retail monopoly and it has therefore been possible to market and sell these products in health food stores and other outlets. Re-classification of natural remedies as conventional medicinal products or traditional herbal medicinal products will bring the natural remedies within the scope of the retail monopoly. The government has, however, granted an exemption for all existing natural remedies that have to be re-classified. The MPA is currently reviewing the applications for re-classification which have been submitted in accordance with the new regulation. The products subject to re-classification have been granted a temporary market authorisation until the process is concluded.

## PATENTS

### 18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

For a medicinal product to be patentable, it must:

- Be susceptible to industrial application. The invention must, among other things, be capable of being reproduced with the same result.
- Be novel. The invention must not be available to the public anywhere in the world.
- 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.

The basic statutory provisions on patents are found in the:

- Patent Act (*SFS 1967:837*).
- Patent Regulation (*SFS 1967:838*).

### 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?

#### The authority

The Patent and Registration Office (PRO) (*Patent-och registreringsverket*) (see [www.prv.se](http://www.prv.se)) administers patent applications and keeps the official patent registers.

#### Fee

An application fee and an annual fee are applicable. 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 three 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 (*Patentbesvärsträtten*) within two months.

### 20. How long does patent protection last? How is a patent renewed or patent protection extended?

A patent is valid for 20 years from the date of filing the application. The holder of a patent for a medicinal product can apply for a supplementary protection certificate under Regulation (EEC) No. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products. The certificate takes effect at the end of the term of the relevant patent and is valid for a maximum of five years.

### 21. In what circumstances can a patent be revoked?

Third parties are entitled to give the PRO notice of opposition to a patent within nine months of the date of grant. The patent can be revoked, for instance, if the patentability requirements have not been fulfilled or if the granted patent covers features not reflected in the patent application. If someone wishes to challenge the granted patent after the nine-month period, court proceedings must be initiated.

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

A patent is infringed when somebody, without the consent of the patent holder, 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 who wishes to enforce his rights by bringing court proceedings against an infringer can request the Stockholm District Court to order the infringer to stop the infringement and to ensure that the relevant goods are:

- Taken into custody.
- Altered.
- Destroyed.
- Handed over to the patent holder against payment.

The patent holder can also claim damages. If certain criteria are met, the court can issue interim injunctions in patent infringement cases.

## 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*) (STMA) in the same way as any other brand. To be registrable, a trade mark must:

- Be capable of graphical representation.
- Be distinctive.
- Not be descriptive.

The mark must not be excluded under section 14 of the STMA (including situations where registration is not permitted, for example, where trade marks include national or international signs, deceptive words or works protected by copyright).

### 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?

#### The authority

Applications must be made to the PRO (*see Question 19*).

#### Fee

Current fees for the registration of a trade mark 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 other things:

- The name, address and telephone number 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.

The PRO examines whether an application contains all required information and that the necessary fees have been paid. If all 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 held by another legal or natural entity). If no obstacles are found, it takes about three months to obtain a trade mark registration. 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 refused, an appeal can be lodged with the Court of Patent Appeals within two months from the day of the PRO decision.

### 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 trade mark registration can be extended every ten years, so it can remain in force indefinitely provided that the registration fees are paid.

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

A trade mark registration can be revoked if any of the following apply:

- The conditions for registration under the STMA 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. A decision by the PRO to revoke a registration can be appealed to the Court of Patent Appeals within two months of the PRO decision.

### 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 somebody, without the consent of the registered trade mark holder, in the course of business markets its products under a mark confusingly similar to the registered trade mark. The trade mark holder can enforce its rights by bringing infringement proceedings at a District Court. It can

ask the court to order the infringing party to stop the infringement and for any of the following:

- The infringing mark to be altered or removed.
- The relevant goods to be destroyed.
- The goods to be surrendered to the trade mark holder against payment.

The trade mark holder can also claim damages. Provided certain criteria are met, the court can issue interim injunctions in trade mark infringement proceedings.

In addition to the provisions of the STMA, 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.

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

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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.
- World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- 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.

## PRODUCT LIABILITY

### 29. 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 (in other words, the injuries were caused because the product was not as safe as may reasonably have been expected). A patient can also bring a claim under the Tort Act (*SFS 1972:207*).

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

#### Substantive test

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. Liability is strict (no-fault) under the Product Liability Act.

In tort, 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) and so the claimant normally has to prove negligence.

#### Liability

A manufacturer, importer or any person 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.

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

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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, such a 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.

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### 31. What defences are available to product liability claims?

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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.

### 32. What remedies are available to the claimant?

A company held liable under the Product Liability Act or in tort will have to 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 compared to those in other jurisdictions.

### 33. 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 other things:

- Several common disputes exist.
- The action cannot be equally, or more effectively, processed in another way.
- The representative of the group is suitable to conduct the group action.
- Certain other requirements are met.

The group claim will cover group members who announced within a certain period that they want to be included in the claim. The members will not be part of the trial, but the judgment will be 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.

## REFORM

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

The Swedish pharmacy monopoly is currently being reviewed and is currently subject to deregulation (see *Question 2*).

A Government Official Report regarding the restructuring of the pharmaceutical market (*SOU 2008:4*) was published in January 2008. The Government Official Report suggests a deregulation of

## THE REGULATORY AUTHORITIES

### Medical Products Agency (MPA) (*Läkemedelsverket*)

**T** +46 18 17 46 00  
**F** +46 18 54 85 86  
**E** [registrator@mpa.se](mailto:registrator@mpa.se)  
**W** [www.lakemedelsverket.se](http://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](mailto:registrator@tv.se)  
**W** [www.tv.se](http://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 regarding subvention of dental care.

### Swedish Association of the Pharmaceutical Industry (*Läkemedelsindustriföreningen*)

**T** +46 18 17 46 00  
**F** +46 18 54 85 86  
**E** [info@lif.se](mailto:info@lif.se)  
**W** [www.lif.se](http://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 Swedish pharmaceutical monopoly (Apoteket AB), both of the market for prescription and OTC medicinal products. A number of questions including pricing and the number of state owned pharmacies which will be sold to private operators still remain unclear.

The deregulation is divided into different stages. The proposed deregulation has already led to actual deregulation in two respects. As of May 2008, nicotine replacement products can also be sold in retail shops other than pharmacies, and from September 2008 hospital pharmacies can be operated by parties other than Apoteket.

To facilitate the deregulation, a Government Bill (*2007/08:87*) suggesting the formation of a service company and a parent

company for Apoteket AB, which will oversee the restructuring of Apoteket AB, has been presented. The service company will take over the responsibility for the IT structure, including various registers and data systems in order to provide these services to new parties in the Swedish pharmaceutical market.

The proposed changes are expected to be implemented in July 2009. A Government Bill presenting the proposal regarding the restructuring of the pharmaceutical market is expected in January/February 2009, and a decision of the Swedish Parliament in March/April 2009.

#### CONTRIBUTOR DETAILS

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