Sweden

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REGULATORY OVERVIEW

1. Please give a broad overview of the structure and funding of the national healthcare system.

The healthcare system is mainly funded by tax revenues. Most hospitals and health service entities are public, although private healthcare exists.

Sweden still has a statutory monopoly for the retail business of pharmaceuticals, run by the state-owned National Corporation of Swedish Pharmacies (Apoteket AB). Apoteket AB has agreed with the Government that it has the unconditional right and obligation to offer all medicinal products (both prescription and over-the-counter (OTC) medicines) that have been authorised for sale by the Medical Products Agency or the European Medicines Agency if applicable. Only hospitals are permitted to acquire medicinal products direct from manufacturers. Apoteket AB's monopoly has been challenged in a recent case that has been referred to the European Court of Justice (ECJ) for a preliminary ruling (*Case C-438/02*). The Advocate General's Opinion was delivered on 25 May 2004 (*see Question 29*).

Those operating in the market have agreed to use a one-channel model for pharmaceutical distribution. Currently only two distributors are active on the market. In practice they act as logistic service companies and not traditional wholesalers. A pharmaceutical company can deliver its products to pharmacies and hospitals under its own management, but few companies have chosen this model.

2. Please briefly describe the regulatory environment for medicinal products/pharmaceutical products/drugs, by whatever name known (referred to below as medicinal products).

The Swedish pharmaceutical market is extensively regulated in the interest of protecting public health. The main pieces of legislation governing medicinal products are:

- The Medicinal Products Act (*SFS 1992:859*).
- The Decree on Medicinal Products (*SFS 1992:1752*).
- The Regulations and General Recommendations issued by the Swedish Medical Products Agency.

Since Sweden joined the European Union (EU) in 1995, most of the Swedish regulatory framework for medicinal products is based on EU legislation, of which Directive 2001/83/EC on the Community code relating to medicinal products for human use forms the foundation. In addition, Sweden has a number of country specific rules relating to, for example, the sale and distribution of medicinal products (*see Question 1*) and generic substitution and pricing of medicinal products (*see Questions 8 and 9*).

3. Please provide details of the key regulator of medicinal products in your jurisdiction.

Name. The Medical Products Agency (*Läkemedelsverket*) (MPA).

Contact details. Box 26
SE-751 03 Uppsala
Sweden
T +46 18 17 46 00
F +46 18 54 85 66
E *registrator@mpa.se*
W *www.mpa.se*

Areas of responsibility. The MPA is responsible for regulation and surveillance of the development, manufacture and sale of medicinal products. The MPA is also, among other things, responsible for:

- Providing information on medicines.
- Authorising and monitoring the conducting of clinical trials.
- Approving and monitoring natural remedies and other drug related products.

In addition to its national duties, the MPA participates in the co-operation at EU level including the development of new standards and requirements for medicinal products.

MANUFACTURE AND CLINICAL TRIALS

4. Is authorisation required to manufacture medicinal products? If so, please give a broad overview of the authorisation process, in particular:

- **To whom should the application be made?**
- **What criteria need to be satisfied to obtain authorisation?**

- **Are there any specific restrictions on foreign applicants?**
- **What are the key stages and timing of the process?**
- **What fee is payable?**
- **Is authorisation given for a fixed period? If so, for how long and what is the renewal procedure?**

- **Application.** A manufacturer or importer of medicinal products from third countries must obtain authorisation from the MPA before initiating any activities (*see Question 3 for contact details*).
- **Criteria.** The criteria that need to be satisfied to obtain a manufacturing authorisation are set out by the MPA. Among other things, the applicant must specify:
  - whether the application concerns medicinal products in general or specific products;
  - the pharmaceutical forms which are to be manufactured or imported; and
  - 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, and appoint a qualified person, who is responsible, among other things, for ensuring that the products are manufactured in accordance with good manufacturing practices and applicable legislation.
- **Restrictions on foreign ownership.** There are no specific restrictions on foreign ownership. However, an applicant for a manufacturing authorisation who is not resident within the EEA must appoint an agent who can represent the applicant in Sweden.
- **Key stages and timing.** An application must be in writing and contain certain information and documents. 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 will be charged. Information on fees is available on the MPA website (*www.mpa.se/humanlakemedel/humanlkm_avgifter2001.shtml*).
- **Period of authorisation and renewals.** A manufacturing authorisation is valid for a limited period of time 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 when it expires.

5. Does the regulator have powers to monitor compliance with manufacturing authorisations? If so, does it exercise those powers?

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. These inspections are carried out on a regular basis by a special unit within the MPA called the Inspectorate (*see Question 12*). The licence holder must provide necessary assistance in connection with inspections.

6. In the event of a breach of the terms of a manufacturing authorisation, what are the regulator's powers of enforcement?

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;
- If one or more of the essential conditions for the authorisation are no longer fulfilled; or
- If the annual fee has not been paid.

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.

7. Are clinical trials regulated? If so, please give an overview of the necessary consents, authorisations and procedural 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. A new MPA regulation came into force on 1 May 2004, implementing Directive 2001/20/EC (the former MPA regulation on clinical trials is still valid for trials relating to medicinal products for veterinary use).

Clinical trials should be planned, conducted and reported in accordance with the latest version of the Declaration of Helsinki and good clinical practice (GCP) (*CPMP/ICH/135/95*). Under the new MPA regulation, the sponsor is responsible for ensuring that the necessary authorisations from the MPA and an Ethics Committee are obtained. Applications must be made on the specific EudraCT application form. A valid application will normally be reviewed and decided upon by the MPA within 30 days of receipt of the application. If no objections have been made by the MPA within 60 days of receipt of a valid application, the clinical trial is deemed to have been approved by the MPA.

Potential trial subjects must receive clear and comprehensive information on the trial to enable them to make an informed decision as to whether or not to take part. Patient consent must be in writing.

Sponsors must provide adequate insurance protection for injuries caused to patients during a clinical trial 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 injuries 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 medicinal product.

PRICING AND STATE FUNDING

8. Are the prices of medicinal products regulated?

The Pharmaceutical Benefits Board (*Läkemedelsförmånsnämnden*) (PBB) must decide on the sales price for medicinal products included in the benefits scheme after negotiations with the manufacturer (*Pharmaceutical Benefits Act (SFS 2002:160)*) (*see Question 9*).

In addition, a new system for generic substitution has been introduced under which a pharmacy has a duty to substitute a drug with the least expensive drug available, provided that the following four conditions apply:

- The drug is included in the Pharmaceutical Benefits Scheme (the Pharmaceutical Benefits Board has found that the drug fulfils the specific criteria for reimbursement and a sales price has been set by the board).
- A prescription has been issued for the drug.
- There are one or more less expensive, substitutable drugs available. The MPA has been given the task to decide which drugs are substitutable.
- The less expensive, substitutable drug is available at the pharmacy where the prescription is dispensed.

The prescriber has a right to object to the substitution on medical grounds. The patient can refuse to have the drug replaced if he pays the difference between the price set for the prescribed drug and the corresponding price for the least expensive substitutable drug available.

9. In what circumstances will the cost of a medicinal product be funded or reimbursed by the state? How is pricing determined in these circumstances?

The manufacturer or seller of a medicinal product may apply for the product to be included in the national benefits scheme (*Pharmaceutical Benefits Act*). The PBB must determine whether or not the medicinal product qualifies for the benefits system and must set the price for that product. The applicant and the county councils (which bear the costs for the pharmaceutical benefits system) must be given the opportunity to participate in deliberations with the PBB before any decision is taken. The PBB will consider 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.

In short, the PBB determines whether the medicinal product's cost is reasonable in relation to the achieved health advantages. The PBB's decision can be appealed to the County Administrative Court.

Generally, only prescription drugs qualify for the reimbursement system. An OTC drug normally qualifies for the benefit scheme 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.

MARKETING

10. Is authorisation required to market prescription-only medicinal products? If so, please give a broad overview of the authorisation process, in particular:

- **To whom should the application be made?**
- **What conditions must be satisfied by the applicant?**
- **What are the key stages and timing of the process?**
- **Is there an abridged procedure?**
- **What fee is payable?**
- **Is authorisation given for a fixed period? If so, for how long and what is the renewal procedure?**

- **Application.** The MPA is responsible for granting marketing authorisations under the mutual recognition procedure (MRP) and the national procedure (*see Question 3 for contact details*).
- **Conditions.** The conditions that must be satisfied by the applicant under the national procedure, or if Sweden is the reference member state under the MRP, are set out in a regulation issued by the MPA. The applicant must show 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 on 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 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.
- **Abridged procedure.** An abridged application can be submitted for pharmacological tests, toxicological tests or clinical trials if the:
  - medicinal product is equivalent to a product already authorised and the person responsible for the latter product has consented;
  - safety and efficacy of the product is already well-established through published scientific references; or
  - medicinal product is equivalent to a product already authorised within the EU for ten years or more and which is currently marketed in Sweden.
- **Fee.** An application fee and an annual fee will be charged. Information on fees is available on the MPA website (*www.mpa.se/humanlakemedel/humanlkm_avgifter2001.shtml*).
- **Period of authorisation and renewals.** A marketing authorisation is valid for five years and is renewable for five-year periods. Renewal applications must be submitted to the MPA no later than three months before the expiry date of the existing authorisation period and include an updated:
  - safety assessment;
  - summary of the product characteristics; and
  - package leaflet.

11. Are the marketing authorisation requirements for over-the-counter (OTC) medicinal products the same as those outlined above?

Yes, the marketing authorisation requirements for OTC medicinal products are the same as those outlined above.

12. Does the regulator have powers to monitor compliance with marketing authorisations? If so, does it exercise those powers?

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 Inspectorate (*see Question 5*). The MPA may order the licence holder to prove that it still fulfils relevant requirements for a marketing authorisation.

13. In the event of a breach of the terms of a marketing authorisation, what are the regulator's powers of enforcement?

A marketing authorisation can be revoked if:

- 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 in accordance with the Product Safety Act despite an order by the MPA to do so; or
- 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.

14. Is there a procedure for mutual recognition of foreign marketing authorisations?

Sweden has an MRP based on the principle that if a marketing authorisation for a medicinal product has been granted by one member state within the EU, a second or subsequent member state will mutually recognise that authorisation within 90 days, unless there are serious grounds for supposing that the product concerned may present a health risk.

15. Are there any restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners?

Care must be taken when gifts or other benefits are offered to public as well as private medical practitioners, as the rules governing what can be received are strict. Any person who gives, promises or offers any improper remuneration to an employee in respect of his service may be held 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 code Rules Governing Drug Information issued by the Swedish Association of the Pharmaceutical Industry (LIF) also contain restrictions relating to gifts and hospitality, including a general requirement that all hospitality offered to physicians 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. In addition, representatives of the pharmaceutical industry, medical institutions and physicians in Sweden have mutually agreed on general principles to be applied to the interaction between them. The rules have been laid down in two agreements (one entered into between LIF and the Swedish Medical Association and one between LIF and the Federation of County Councils) that include provisions regarding travelling, meals and invitations. The agreements are currently being re-negotiated and new agreements are expected to come into force in 2004.

16. How are parallel imports regulated?

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 within the EEA once the product has been put on the market anywhere in the EEA by the holder, or with its consent. Therefore, medicinal products may be subject to parallel trade within the EEA, provided the parallel import is undertaken in accordance with 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:

- Directly imported product is authorised for sale in Sweden;
- Parallel imported product is authorised for sale in the exporting country;
- Exporting country is a member state within the EEA; and
- Parallel imported product is sufficiently similar to the directly imported product.

Repackaging or re-labelling of the product requires a specific manufacturing authorisation from the MPA.

The labelling and package leaflet must be designed in accordance with 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.

17. Is it possible to market medicinal products online, by e-mail and/or mail order?

Apoteket AB (*see Question 1*) has the exclusive right to distribute prescription and OTC drugs to Swedish consumers. Traditionally, medicinal products have only been sold to consumers via pharmacy retail stores belonging to Apoteket AB. However, Apoteket AB currently offers OTC drugs online to consumers living in certain municipalities of Sweden and the intention is to gradually include the rest of Sweden.

During the last year, several internet pharmacies targeted at Swedish consumers have emerged. The MPA has reported at least two of these internet pharmacies to the police, claiming that the pharmacies run a pharmaceutical retail business in Sweden, thereby committing a criminal offence under the act governing the retail monopoly of Apoteket. The cases raise interesting questions relating to, among other things, the EU rules on free movement of goods and state monopolies related to those assessed by the ECJ in the Doc Morris judgment (*case C-322/01*).

A private individual can order medicinal products via, for example, mail order or the internet, if the individual can prove that the product:

- Is ordered from within 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; and
- If it is a prescription drug, 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 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 the products are intended for personal consumption. The MPA can grant an exemption from this rule, but in practice exemptions are rarely given.

ADVERTISING

18. Are there any restrictions on advertising medicinal products (both prescription-only and OTC)?

The Medicinal Products Act includes a basic provision that all advertising of medicinal products must be kept up to date, factual, balanced and must not be misleading. This rule complements the general provisions of the Market Practices Act (*SFS 1995:450*) which is applicable to advertising for all kinds of products and services, including medicinal products. It also 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 sets out specific rules on, among other things, misleading advertising, comparative advertising and special offers.

The more detailed rules relating to pharmaceutical advertising have not yet been set out in statute, but can be found in the ethical code Rules Governing Drug Information issued by LIF (the LIF Rules). 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 list rules on, for example, comparative advertising, misleading, incomplete or unsubstantiated information and disguised promotion.

It may be noted that Directive 92/28/EEC regarding advertising of medicinal products (now Directive 2001/83/EC) has not been fully transposed into Swedish statute law. Swedish authorities have instead to a considerable extent relied on the LIF Rules and the self-regulatory system established by LIF. However, the present system is currently under evaluation. A working group set up by the government has recently proposed that more detailed rules on advertising of medicinal products be set out in the Medicinal Products Act, including an explicit prohibition on the promotion of prescription drugs to the general public. The new legislation should come into force in July 2005.

PACKAGING AND LABELLING

19. Please give a broad overview of the regulatory framework governing the packaging and labelling of medicinal products.

Requirements on the packaging and labelling of medicinal products are contained in the MPA Regulation on the Packaging and Labelling of Medicinal Products. The labelling of a medicinal product must show:

- The name, strength and pharmaceutical form of the product.
- Package size.
- Composition.
- Directions for use and storage precautions where appropriate.
- Warnings.
- Batch number.
- Expiry date.
- The name and address of the marketing authorisation holder.
- The marketing authorisation number.

Information on the correct handling of a product must be clearly worded and prominently positioned on the label. Samples of packaging and labelling text, including package inserts, must always be provided to the MPA with the submission of an application for a marketing authorisation.

TRADITIONAL HERBAL MEDICINES

20. Is the manufacture and marketing of traditional herbal medicinal products regulated in your jurisdiction? If so, please give an overview of the regime.

Swedish law contains specific rules relating to natural remedies (*naturläkemedel*). A natural remedy denotes a medicinal product in which the active ingredient or ingredients:

- Derive from natural sources;
- Have not been processed too highly; and
- Consist of part of a plant or animal, bacterial culture, mineral, salt or salt solution.

Natural remedies must also be suitable for self-medication in accordance with tested national tradition or tradition in countries close to Sweden with respect to drug usage.

The manufacture and sale of natural remedies requires authorisation from the MPA. The applicant must be able to verify the quality, safety and efficacy of the product. The quality requirements (the demands relating to the manufacturing process) correspond to the requirements for ordinary medicinal products. Safety and efficacy of the natural remedy can be verified in two different ways. The applicant can either make references to medical literature verifying a well-established traditional use of the product in Sweden or in countries close to Sweden with respect to drug usage, or prove the safety and efficacy of the natural remedy by scientific studies in the same way as is required for ordinary medicinal products.

Natural remedies are not covered by the state retail monopoly and can therefore be marketed and sold in, for example, health food stores and other kinds of stores. A list of all approved natural remedies in Sweden is published on the MPA's website at *www.mpa.se*.

INTELLECTUAL PROPERTY

21. What are the criteria for patentability?

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 in the:

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

The Patent and Registration Office administers patent applications and keeps the official patent registers.

22. What is the procedure for obtaining patent protection? In particular:

- **To whom should the application be made?**
- **What are the key stages of the process and timing?**
- **What fee is payable?**
- **For how long is protection given?**
- **What is the renewal process?**
- **In what circumstances can a patent be revoked?**
- **Is your country a party to any international conventions on patent protection?**

- **Application.** Patent and Registration Office (*Patent-och registreringsverket*) (PRO).
  Box 5055
  S-102 42 Stockholm
  Sweden
  T +46 8 782 25 00
  F +46 8 666 02 86
  W *www.prv.se*

- **Process and timing.** The inventor or 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 each patent application within three years, although the time period may vary significantly. If a patent application is rejected, the decision can be appealed to the Court of Patent Appeals (*Patentbesvärsrätten*) within two months.

- **Fee.** Continuously updated information is available on the PRO website at *www.prv.se/patent/index.html*.

- **Duration of protection.** 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 in accordance with Council Regulation 1768/92. The certificate takes effect at the end of the term of the relevant patent and is valid for a maximum of five years.

- **Renewal process.** A patent cannot be renewed.

- **Revocation.** Third parties are entitled to give the PRO notice of opposition against a patent within nine months of the date of grant of the patent. 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 attack the granted patent after the nine-month period, court proceedings must be initiated.

- **International conventions.** Sweden is a signatory to the:
  - Patent Cooperation Treaty; and
  - European Patent Convention.

23. What remedies are available in situations of patent infringement?

A patent holder who wishes to enforce its rights by initiating court proceedings against an infringer can request the Stockholm District Court to order the infringer to cease the infringement and to ensure that the relevant goods are:

- 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 interlocutory injunctions in patent infringement cases.

24. Can product brands be protected by registration as a trade mark? If so, what is the test for obtaining trade mark protection?

The brand of a medicinal product may be registered as a trade mark under the Swedish Trade Mark Act (*SFS 1960:644*)

(STMA) in the same way as any other brand. In order to be registerable, a trade mark must:

- Be capable of graphical representation;
- Be distinctive; and
- 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).

25. What is the procedure for obtaining registration of a trade mark? In particular:

- **To whom should the application be made?**
- **What are the key stages of the process and timing?**
- **What fee is payable?**
- **For how long is protection given?**
- **What is the renewal process?**
- **In what circumstances can a trade mark be revoked?**
- **Is your country a party to any international conventions on trade mark protection?**

- **Application.** Patent and Registration Office (*Patent-och registreringsverket*) (PRO).
  Box 530
  S-826 27 Söderhamn
  Sweden
  T +46 8 782 25 00
  F +46 8 666 02 86
  W *www.prv.se*

- **Process and timing.** The application must be in Swedish and include:
  - the name, address and telephone number of the applicant;
  - an illustration of the trade mark; and
  - information on the goods or services for which the trade mark will be used and the class in 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 necessary requirements are fulfilled, the PRO will examine 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 (*Patentbesvärsrätten*) within two months from the day of the PRO decision.

- **Fee.** Current fees for the registration of a trade mark can be found at *www.prv.se/varumarke/index.html*.

- **Duration of protection.** A trade mark registration is valid for ten years from the date of registration.

- **Renewal process.** A trade mark registration can be extended every ten years and can consequently be kept in force indefinitely providing that the registration fees are paid. The payment of the registration fee is considered as an application for renewal.

- **Revocation.** A trade mark registration can be revoked if:
  - 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; or
  - 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 the mark has been registered. A decision by the PRO to revoke a registration can be appealed to the Court of Patent Appeals (*Patentbesvärsrätten*) within two months from the PRO decision.

- **International conventions.** Sweden is a party to the following international conventions relating to trade marks:
  - Paris Convention for the Protection of Industrial Property;
  - Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs Agreement);
  - Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks; and
  - Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks.

26. What is the process for enforcing brand or trade mark infringement?

The holder of a trade mark registration can enforce its rights by initiating infringement proceedings at a District Court. The holder of the trade mark can ask the court to order the infringing party to cease 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 may issue interlocutory 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.

PRODUCT LIABILITY

27. Please give a broad overview of product liability law. In particular:

- **Under what laws can liability arise (for example, contract, tort, statute)?**
- **Who is potentially liable for a defective product?**
- **What is the substantive test for liability?**
- **What is/are the limitation period(s) for product liability claims?**
- **What defences are available?**
- **What remedies are available to the claimant?**

- **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*) (*produktansvarslagen*). Damages can be claimed for injuries caused by a product due to a safety deficiency (injuries 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*) (*skadeståndslagen*).
- **Who is liable?** 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.
- **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 of the medicinal product. Liability is strict (no-fault) (*Product Liability Act*).

  In tort, the claimant must prove there is a causal link between the injury and use of the medicinal product. Whereas liability under the Product Liability Act is strict, in tort the claimant normally has to prove negligence.
- **Limitation period.** The period of limitation 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 awareness, such claim reaches its statute of limitation ten years after the product was put into circulation. Claims based on the Tort Act have a limitation period of ten years.
- **Defences.** The defendant can escape liability if it can prove that (*Product Liability Act*):
  - 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; or
  - 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.
- **Remedies.** 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 lower than those in other jurisdictions.

28. Are class actions permitted for product liability claims? If so, how common are they?

Private individuals, certain non-profit organisations and certain authorities may 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 force on 1 January 2003 and no case law has been developed so far.

FUTURE DEVELOPMENTS

29. Please summarise any impending developments in the regulation of medicinal products, patent and trade mark law and product liability.

The regulatory environment for medicinal products is currently subject to several important developments, including the following:

- The Swedish retail monopoly has been challenged under the EU rules on state monopolies and free movement of goods.

The case concerned has been referred to the ECJ by a Swedish court, following the offering of OTC drugs (nicotine patches and nicotine gums) for sale in a Swedish retail store in violation of the Pharmaceutical Trade Act (*SFS 1996:1152*) (*Case C-438/02*). The case is of great general interest as it puts the existence of the Swedish monopoly into question, in particular with respect to the sale of OTC drugs. The Advocate General's Opinion was delivered on 25 May 2004.

- In October 2002, a new system for generic substitution was launched in Sweden. The MPA has recently taken the system one step further by introducing generic prescription on trial at certain clinics and pharmacies. Physicians taking part in the trial will issue prescriptions by reference to the relevant active substance, instead of the name of a particular medicinal product.
- Directive 92/28/EEC regarding advertising of medicinal products (now Directive 2001/83/EC) has not been fully transposed into Swedish statute law. Swedish authorities have instead relied on the self-regulatory system established by LIF. In June 2003, the government set up a working group which was given the task of evaluating the current system and making proposals for necessary amendments. The working group has recently proposed that more detailed rules on advertising of medicinal products be set out in the Medicinal Products Act, including an explicit prohibition on the promotion of prescription drugs to the general public. It is proposed that the new legislation will come into force in July 2005.

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