

<b>PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES</b>
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<b>GENERAL</b>
<b>1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.</b>
<p>All marketing is generally governed by the Swedish Market Practices Act (Sw. Marknadsföringslagen SFS 2008:486), including the advertising of medicinal products and medical devices. The overall rule is that marketing must be compatible with good marketing practice and fair towards consumers and the industry. The Market Practices Act covers, inter alia, issues of misleading and comparative advertising and special offers.</p> <p>Regarding pharmaceuticals, the Swedish Medicinal Products Act (Sw. Läkemedelslagen SFS 2015:315) provides that all advertising of medicinal products must be up to date, factual, balanced, not misleading and in accordance with good marketing practice. The Medicinal Products Act contains rules on advertising of medicinal products related to prescription or over-the-counter status, the targeted audience and authorisation status. The Swedish Medical Products Agency (MPA) has issued Regulation (LVFS 2009:6) on marketing of medicinal products for human use (MPA Regulation LVFS 2009:6) to clarify these rules further.</p> <p>In addition, the Ethical Rules for the Pharmaceutical Industry (LER Rules), issued by the Swedish Association of the Pharmaceutical Industry (LIF), contain detailed rules on pharmaceutical advertising. The LER Rules are regularly revised (most recently on 17 June 2022; effective as of 1 July 2022). Although not legally binding, the LER Rules are recognised by the pharmaceutical industry and healthcare sector alike and are applied by courts as a standard of fair and ethical marketing. Members of the association are also contractually bound by the industry code. The LER Rules cover a range of issues, including pre-launch and off-label advertisement, advertising of prescription medicines, comparative advertising, information standards and disguised advertising.</p> <p>With regard to medical devices, Regulation (EU) 2017/745 on medical devices (MDR), states, inter alia, that in the labelling and advertising of medical devices, it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by certain listed measures.</p> <p>In addition, the Swedish Association of Local Authorities and Regions, LIF, Swedish Medtech and Swedish Labtech have issued cooperation rules for interactions between the publicly funded healthcare sector and the pharmaceutical industry, the medical technology industry and the laboratory technology industry (Cooperation Rules). Members of any of these trade associations are contractually bound by the Cooperation Rules but, irrespective of whether a company is a member or not, the healthcare industry must apply these rules to all companies within sectors that operate in or target the Swedish market.</p>
<b>2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?</b>
<p>The Market Practices Act generally defines marketing (Sw. <i>marknadsföring</i>) as "advertising and other measures in the course of business activities which are intended to promote the sale of and access to products including a trader's actions, omissions or other measure or behaviour before, during or after sale or delivery of products to consumers or traders". The Market Practices Act is applicable to both advertising of medicinal products and medical devices.</p> <p>The Medicinal Products Act does not contain any separate definition of "advertising". The legislative bill preceding the Medicinal Products Act, however, refers to the definition provided in Directive 2001/83/EC on the community code relating to medicinal products for human use.</p> <p>The LER Rules moreover apply to any information, regardless of medium, provided by the pharmaceutical industry in connection with marketing operations directed at healthcare professionals or the general public. Also, generally, what constitutes "advertising" or "marketing" is very broad in Sweden and most information on medicinal products emanating from a pharmaceutical company could be considered marketing material.</p>
<b>3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any,</b>

<b>between any self-regulatory process and the supervisory and enforcement function of the competent authorities?</b>
<p>As described above, the Market Practices Act applies to both medicinal products and medical devices.</p> <p>The Swedish Consumer Agency is responsible for supervising the relevant provisions of the Market Practices Act and the Consumer Ombudsman (Sw. Konsumentombudsmannen) can initiate proceedings at the Swedish Patent and Market Court.</p> <p>The MPA is the competent supervisory authority for compliance with the Medicinal Products Act and connected regulations. Cases on the advertising of medicinal products in Sweden are regularly handled by Swedish courts, the MPA and other competent authorities, but a great number of these matters are also handled by the two self-regulatory bodies the Swedish Pharmaceutical Industry's Information Examiner (Sw. Informationsgranskningsnämnden or "IGN") and the Information Practices Committee (Sw: Nämnden för Bedömning av Läkemedelsinformation or "NBL"), who have the task of auditing and assessing any violation of the LER Rules.</p> <p>The competent authority, the MPA, and the self-regulatory bodies, the IGN and NBL, function independently of one another. The MPA may, at its own discretion, choose to take action itself or to notify the NBL in a given matter. The IGN and NBL are also free to try a matter that is, in parallel, investigated by the MPA.</p> <p>With regard to medical devices, the MPA is the competent supervisory authority for compliance with the MDR and supplementary national legislation and regulations. It could be noted that there is currently not much case law with respect to marketing of medical devices in Sweden.</p>
<b>4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?</b>
<p>The Market Practices Act applies to the marketing of all types of products, including food supplements and special nutritional products.</p> <p>It could also be noted that even if a product falls within the definition of other product types, such as food supplements and special nutritional products, the way it is marketed may mean that the product is classified as a medicinal product (and fall under said legal framework on marketing of medicinal products). This may e.g. be the case where marketing of the product (especially the substances it contains) includes information or claims that it has characteristics to prevent, ease or treat diseases.</p>
<b>CONSUMER MARKETING</b>
<b>5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?</b>
<p>According to the Medicinal Products Act and the MPA regulation LVFS 2009:6, marketing of prescription medicinal products to the public is prohibited. Further, it is stated in the LER rules that information to the general public regarding prescription medicinal products shall be supplied only to the extent permitted by the MPA's provisions and in accordance with applicable laws and regulations. The only exemption from this prohibition is for certain campaigns to the general public for vaccines against infectious diseases.</p> <p>Regarding medical devices, there is no specific restrictions in the applicable legal framework as regards e.g. the targeted audience of the marketing.</p>
<b>6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?</b>
<p>Internet and social media advertising of medicinal products and medical devices are subject to the same rules as advertising in any other media in Sweden.</p>

As regard medicinal products, it could be noted that the NBL has taken the view that a website falls within its jurisdiction if the site is aimed at the Swedish market (under the country of destination principle), and the self-regulatory bodies are rather efficient in their supervision of websites.

It could also be noted that, recognising the increased use of digital channels for marketing of pharmaceuticals to the public, and that the way information is presented may need to be adapted to new formats and ways of consuming media, LIF has issued new guidelines on the marketing of non-prescription medicinal products on digital platforms. The guidelines apply to advertisements that are intended to be displayed on digital platforms where the viewers' field of vision is limited, i.e. smart phones and tablets, and provide how such information could be designed.

**7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?**

No, requiring a pre-approval of this kind would generally be contrary to the Swedish constitutional right to protection of press freedom and freedom of expression.

It could be noted however, that the LER Rules include provisions on granting the public on demand access to easily comprehensible information on prescription only medicines through websites managed by pharmaceutical companies. These provisions include that such information may only be provided if pre-approved by the IGN and must, in all parts and on a factual basis, rely on Fass.se (the main public informational source regarding pharmaceuticals in Sweden) and on the product's Summary of Product Characteristic (SmPC).

**8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?**

The main rule is that the advertising of medicinal products that are not authorised for sale in Sweden is prohibited. Equally, it is prohibited to advertise indications or dosages or other variations that are not approved in Sweden. The MPA and the IGN/NBL strictly monitor the Swedish market to ensure compliance with these prohibitions.

Note however that purely informational material on medicinal products that does not qualify as marketing, and that is protected by the constitutional right of freedom of speech, may be distributed to and discussed with healthcare professionals pre-market authorisation. Information on unauthorised medicinal products may thus be made available at e.g. scientific meetings, provided that it does not constitute disguised advertising.

**9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?**

The Market Practices Act contains some general provisions regarding comparative advertisements. Among other things, a comparison may only objectively refer to material, relevant, verifiable and distinguishing characteristics of the products, may not discredit or denigrate a competitor or take unfair advantage of the reputation of a competitor's trademark, trade name or other distinguishing symbol.

Moreover, the LER Rules provide detailed guidance in this regard. Hence, medicinal product information that includes comparisons between effects, active ingredients, costs of treatment etc. must be presented in such a way that the comparison as a whole is fair. The object(s) included in the comparison must be selected in a fair way, must be relevant and must be presented objectively and truthfully.

A fair comparison requires, among other things, that:

- the objects included in the comparison should always be clearly specified; thus, if required for sake of clarity, the complete name and generic designation of the compared medicinal products should be stated (though it should be noted that the use of another company's trademark could constitute trademark infringement);
- the facts which the comparison is intended to clarify and the limitations inherent in the comparison must be stated in such a way that the comparison is not likely to mislead;
- the comparison of properties of synonymous medicinal products, or of medicinal products with the same indications, shall give a comprehensive and fair picture of the properties compared; and
- the comparison of certain properties should not induce incorrect or misleading conclusions regarding properties not covered by the comparison.

As regards the issue of referring to a competitor's unauthorised medicinal product or indication, such reference would be included in the general prohibition provided above and hence not be permissible in the marketing context (see question **Error! Reference source not found.**).

#### **DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS**

**10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?**

In the context of advertising pharmaceuticals, the Medicinal Products Act and the MPA Regulation LVFS 2009:6 refers to healthcare professionals as persons authorised to prescribe or dispense medicinal products. Advertising to healthcare professionals is subject to a number of rules governing its form and content. Among other things, the Medicinal Products Act requires that such advertising must be objective, balanced, and in accordance with good market practice and not misleading.

The LER Rules (Section 1) also contains detailed rules on the marketing of medicinal products targeted at physicians, dentists, pharmacists or other personnel within Swedish healthcare system or the distribution of medicinal products. Among other things, medicinal product information must include accurate, objective, meaningful and balanced facts dealing adequately with the favourable and unfavourable properties of the medicinal product.

The Cooperation Rules does not include a specific definition of healthcare professionals, but it is stated that the regulation covers all employees (defined as hired person, student in training or internship, contractor or consultant) and managers in healthcare (defined as all publicly funded healthcare in county councils, regions and municipalities as well as private operations with care agreements or according to the Swedish Act on System of Choice in the Public Sector (Sw: *Lag (2008:962) om Valfrihetssystem*)). The Cooperation Rules include provisions on how the industry may arrange meetings to provide information to employees and managers within healthcare for marketing purposes (Section 2 of the "Specification").

**11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?**

As mentioned in the response to Question **Error! Reference source not found.**, all advertising and promotional activity are subject to the same rules, regardless of what media that is used.

Note however that both the LER rules and the Cooperation Rules provide that meals may, as a main rule, not be provided or required during remote meetings.

Also, as regard the LER Rules which is technology-neutral, LIF has issued a special guideline on the use of digital channels in relation to the LER Rules.

Further, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have issued a Joint Guidance on Virtual and Hybrid International Medical Congresses (the Guidance). At the date of writing (12 March 2024), no local guidelines equivalent to the Guidance have been issued in Sweden by LIF, and the Guidance should therefore be consulted regarding virtual meetings and congresses.

**12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?**

Yes. The LER Rules ban pharmaceutical companies from having healthcare professionals contribute to the medicinal product information, act as a guarantor for a particular product or recommend a certain treatment. Correspondingly, the Swedish Medical Association (Sw. *Sveriges läkarförbund*), a union in which the majority of Swedish medical doctors are members, has issued rules on advertising of healthcare services that prevent its members from contributing to medicinal product information aimed at the general public, and to promotional material as guarantors for a particular medicinal product or a product developed by a third party which is associated with healthcare services.

**13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of**

**money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Under the MPA Regulation LVFS 2009:6, free samples of medicinal products authorised for sale in Sweden may, under the circumstances provided below, be provided to persons qualified to prescribe the product, licensed open-care pharmacies, managers of open-care pharmacies and designated pharmacists at hospital pharmacies. The supply of samples of medicinal products to any other recipient is explicitly prohibited.

Medicinal product samples may only be supplied in a very restrictive manner and if the following conditions are met:

- only a limited number of samples of each medicinal product is provided to the same recipient per year;
- each sample delivery is preceded by a written, dated and signed request by the recipient;
- it has been thoroughly investigated that the recipient is qualified to prescribe or expedite the medicinal product in question (and orders are kept and filed);
- no sample is greater than the smallest available package size;
- each sample is labelled with 'free medicinal product sample, not for sale' or similar; and
- each sample is accompanied by a copy of the product's SmPC.

No samples may be used in the treatment of humans. The distribution of samples of medicinal products categorised as narcotics by the MPA is not allowed.

Under the LER Rules, a maximum of one sample per year may be provided to one and the same person. Samples of prescription medicines may only concern new medicines that have been publicly available for up to two years (note that a new strength or dosage form without a new indication is not considered to be a new product). Lastly, medicinal product samples may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Regarding samples of medical devices, the European industry organisation MedTech Europe's Code of Ethical Business Practice (the Code) could be used for guidance in this regard. The Code for example, specifies that the quantity of samples provided must not exceed the amount reasonably necessary for the healthcare professional to acquire adequate experience and that appropriate records of the provided samples shall be maintain (eg, recording proof of delivery and receipt of return of any unused samples).

It can also be noted that in the guideline on gifts to clinics and healthcare personnel issued by Swedish Medtech and Swedish Labtech (see further below), it is mentioned that what is stated in the guideline concerning gifts should not be confused with the opportunity for the industry to provide appropriately selected product samples. Also, there is the possibility for the industry to provide medical devices to healthcare for product evaluation purposes. In such cases, the products must always be provided to a healthcare department, not to individual employees.

Giving gifts, donations or other kind of benefits to healthcare professionals is governed by the general provisions on anti-bribery in Sweden. In this regard, the Swedish Criminal Code (Sw: *Brottsbalken SFS 1962:700*) stipulates that a person who provides, promises or offers an improper benefit to an employee for carrying out their service may be held responsible for bribery. The same holds true for an employee who for this purpose receives, accepts a promise of or requests an improper benefit. The provisions of the Criminal Code do not specifically regulate improper benefits received/offered by or to healthcare organisations or personnel, but as this applies to the public and private sector as a whole and great care should be taken when gifts or other benefits are offered to such organisations and personnel. Also, note that in assessing what constitutes an improper benefit under Swedish anti-bribery legislation, relevant industry standards are one of the factors which should be considered.

The LER Rules provide that gifts may not be supplied, offered or promised to healthcare professionals with the exception of the following circumstances: (1) information and educational material of low value that is of direct relevance to the recipient's professional practice and of direct benefit to patient care; or (2) items of medical utility for the purpose of educating employees and to enhance patient care, if of low value and not routinely used in the recipient's practice.

None of the above may be supplied, offered or promised to healthcare professionals as an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products. The threshold for 'low value' is currently set at SEK450 (approx. €40) in a LIF board decision.

It is important to note that adherence to the LER Rules and the monetary threshold for gifts do not exclude criminal liability. There may be situations where the provision of a gift worth less than SEK450 is considered bribery.

With regard to the medical device sector, provisions relating to gifts are not specifically regulated in the Cooperations Rules. Reference is instead made to the Code. Swedish Medtech and Swedish Labtech have also issued a separate guideline on gifts to clinics and healthcare personnel that is based on the Code. This guideline, for example provides that gifts must:

- be of low value, as perceived by the receiver;
- be connected to the healthcare personnel's profession, be of benefit to patients or left in purely educational purposes;
- not be considered influencing the healthcare personnel's behaviour;
- not be given to an individual healthcare personnel, other than on retirement or similar; and
- not be monetary or include alcohol.

**14. What rules govern the offering of hospitality to healthcare professionals?**

As provided above, provision of any kind of benefit to healthcare professionals will be governed by the Swedish general anti-bribery legislation. Consequently, acts of improper hospitality may be considered bribery under the Criminal Code.

The offering of hospitality from a pharmaceutical company/representative to healthcare professionals is also governed by the LER Rules. LIF has also issued thresholds for meals and hospitality provided to healthcare professionals. The value of a lunch or dinner may not currently exceed SEK350 (approx. €31) and SEK950 (approx. €83) per person, respectively, including VAT.

The offering of hospitality from a medical device company/representative is governed by the Cooperation Rules.

**15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?**

Both the LER Rules and Cooperation Rules provide for a limited scope of making donations to the healthcare sector. Given under what circumstances donations may be made, it lies in its nature that they should not be considered as a promotional tool.

According to the LER Rules, donations may only be made for the purpose of supporting research and development and if the following requirements are fulfilled:

- the donation is made in a transparent and well-documented manner;
- the donor keeps a register of received donations;
- the donation is not linked to any prior, current or future use, recommendation, sale or prescription of the donor's products or services;
- the donation does not constitute an incentive to recommend, prescribe, buy, offer, sell or administer specific medicinal products; and
- the donation is not in any way offered or requested for the funding of internal or routine operations or recreational activities of the healthcare organisation.

According to the Cooperation Rules, donations may not be given for internal activities or regular operations of the healthcare sector. Donations may never be requested or offered to finance social activities. Donations to the healthcare sector may only be given for research and development (R&D) and provided that the donation is transparent, well documented, and in accordance with the Cooperation Rules and its intentions. Donations may not be linked in any way to past, present or potential future use, recommendation, sale or prescription of the donor's products or services.

**16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?**

Both the LER Rules and Cooperation Rules provide that companies may arrange or sponsor scientific or educational meetings for healthcare participants given that certain circumstances are met. For example, the industry may only offer meetings and sponsorship of events that have a connection to the company's

<p>own area of operations. The scientific and professional programme must make up the dominant part and the purpose of the relevant meeting. If there will be any product information, it must be clearly stated in the invitation. Companies may generally pay for the venue, speakers, study materials, relevant meals, etc. as necessary to carry out the meeting. The rules may vary depending on whether the meeting is organised by the company or by healthcare. In both instances, it is prohibited for the company to pay for enrolment fees, travel expenses and accommodation for healthcare professionals.</p>
<p><b>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</b></p>
<p>Interactions with and support of patient organisations are subject to a specific chapter in the LER Rules. All types of interest organisations, including patient organisations, disability organisations, senior citizen associations and organisations for relatives, are encompassed. The following fundamental principles serve as guidance for all collaboration between pharmaceutical companies and organisations:</p> <ul style="list-style-type: none"> <li>• respect for each other and each other's roles;</li> <li>• reciprocity in relationships;</li> <li>• openness and transparency to the outside world;</li> <li>• restriction of the choice of collaborative fields; and</li> <li>• the independence of the collaboration partners must be safeguarded.</li> </ul> <p>Interactions between the medical device industry and patient organisations are not specifically covered by the Cooperation Rules, or the Code. It could however be noted that MedTech Europe has published the Patient Organisation Guidelines to support member companies when interacting with patient organisations.</p>
<p><b>18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?</b></p>
<p>The use of a third-party service provider in the performance of promotional activities are not specifically regulated under Swedish law. However, all applicable marketing rules of course needs to be adhered to also in these set ups and ultimately, a company can be held responsible for any unlawful marketing of its products where the marketing is carried out by a third party in the company's name or on its behalf.</p>
<p><b>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</b></p>
<p>There is no specific legislation in Sweden requiring pharmaceutical or life sciences companies to make information publicly available about transfers of value provided by them to healthcare professionals. However, the LER Rules directly ratify the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and apply to all companies within the pharmaceutical sector that target or are active in the Swedish market. Transfers of value made during each calendar year must therefore be disclosed annually in Swedish (and preferably also in English) in the form provided in Appendix 1 of the LER Rules in a designated section of LIF's online co-operation database or on the company's own website.</p>
<p><b>ENFORCEMENT</b></p>
<p><b>20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?</b></p>
<p>The Market Practices Act provides for several remedies or sanctions depending on the nature of the violation. The possible sanctions include prohibitive injunction subject to fines, market disruption fees and third-party damages. The minimum amount of market disruption fees is SEK10,000 (approx. €880) and the maximum amount is four per cent of the trader's annual turnover. If information on the trader's annual turnover is not available, the maximum amount of market disruption fees is an amount in SEK corresponding to €2m. An action on advertising infringement may be brought before the Patent and Market Court by the Consumer Ombudsman, by a trader affected by the marketing or by an association of consumers, traders or employees. There are examples in Sweden where action has been taken against pharmaceutical companies.</p> <p>Failing to comply with the rules on advertising under the Medicinal Products Act will normally result in a prohibitive injunction subject to fines. The responsibility for supervision and enforcement lies with the competent authority, namely the MPA.</p>

Responsibility for compliance with the LER Rules lies with IGN/NBL. A great number of matters are regularly handled by the IGN and NBL. The IGN and the NBL have contractual authority to fine LIF members for violating the LER Rules a maximum of SEK500,000 (approx. €44,000). Where a violation is gross, the IGN or NBL may, in addition, instruct the pharmaceutical company to make a corrective statement.

Responsibility for compliance with MDR and related regulations also lies with the MPA. The MPA has authority to impose fines on actors who conducts misleading claims (up to SEK100,000,000 (approx. €87,900)).

With regard to medical devices, an assessment of whether a member company has violated the Cooperation Rules is made by an external review board comprising lawyers active in other sectors as well as representatives from the medical profession and the Swedish Association of Local Authorities and Regions. If a violation is considered to have taken place, the review board proposes if action will be taken against the company. Decisions on actions are finally made by Swedish Medtech's board. Available sanctions include warning and exclusion from the trade organisation.

Authorities and courts sometimes disseminate decisions and judgment, depending on public interest in the specific case. In any event, decision or judgement of the MPA or the courts constitute an official document and as a main rule all information contained in such decisions and judgments is public information. This means that anyone can request access to, or copies of, an official document.

Decisions from IGN/NBL as well as Swedish Medtech's board are publicly available on LIF's and Swedish Medtech's websites, respectively.

**21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?**

As described above, an action on advertising infringement under the Market Practices Act may be brought before the Patent and Market Court by the Consumer Ombudsman, by a trader affected by the marketing or by an association of consumers, traders or employees.

The responsibility for supervision and enforcement for advertising medicinal products under the Medicinal Products Act, as well as medical devices under the MDR, lies with the competent authority, namely the MPA. Anyone may (by name or anonymously) submit a complaint to the MPA regarding a company's promotional activities in violation of the said regulations.

As also described above, a great number of matters relating to marketing of medicinal products are regularly handled by the two self-regulatory bodies the IGN and NBL. The IGN monitors the market and may, without a formal complaint, open or refer a case to the NBL. Private persons and companies (including competitors) may bring actions on advertising transgressions before the IGN.

**FUTURE DEVELOPMENTS**

**22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

N/A.