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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2004

A practical insight to cross-border Pharmaceutical Advertising work

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Chapter 29

Sweden

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1 General- medicinal products

1.1 What laws and codes of practice govern the advertising of medicinal products in your country?

The Medicinal Products Act includes a basic provision that all advertising of medicinal products shall be kept up to date, factual, balanced and must not be misleading. This rule complements the general provisions of the Market Practices Act. The latter Act is applicable to advertising for all kinds of products and services, including medicinal products, and 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 more detailed rules relating to pharmaceutical advertising have not yet been laid down in statute law, but can be found in the ethical code Rules Governing Drug Information issued by the Swedish Association of the Pharmaceutical Industry (LIF). 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 with respect to *e.g.* 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 considerably extent relied on the LIF Rules and the self-regulatory system established by LIF. The Government has recently set up a working group which has been given the task to evaluate the current system and make proposals for necessary amendments, however. Potential new legislation can be expected in year 2005 at the earliest.

1.2 Must advertisements be approved in advance by a regulatory or industry body before use?

No.

1.3 What are the penalties for failing to comply with the rules? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The Swedish Medical Products Agency (MPA) monitors the pharmaceutical market, including the advertising and other marketing activities of pharmaceutical companies. The MPA may take action in cases of non-compliance and normally seeks a voluntary solution. If an amicable solution is not found, the MPA may notify the Consumer Ombudsman who is authorized to initiate action in the Market Court under the Market Practises Act. The MPA may also refer the case to the NBL (see below), which may issue a decision on the case under the LIF Rules.

The Market Practices Act provides for several remedies/sanctions depending on the nature of the violation. The specific rules on *e.g.* misleading advertisements and special offers carry a sanction of both prohibitive injunction (subject to fines upon non compliance), market disruption fees between SEK 5,000-5,000,000 and third party damages, whereas only prohibitive injunction is available in cases of violation of the general clause on unfair marketing. Depending on the sanction sought, an action under the Market Practices Act may be brought either before the Market Court or before the Stockholm District Court. Such action can be initiated not only by the Consumer Ombudsman, but also by a competitor or a trade or consumer association.

A great majority of all cases regarding the advertising of medicinal products never go to court, but are handled by LIF through its two self-regulatory bodies, the Pharmaceutical Industry's Information Examiner (IGM), who is a physician, and the Information Practises Committee (NBL), which is a court-like body. IGM monitors the market and may open a case without a formal complaint, or refer a case to NBL. Private individuals and pharmaceutical companies, including competitors, are also entitled to bring an action before IGM. A decision by IGM can be appealed to NBL. IGM and NBL have contractual authority to fine member companies who violate the LIF Rules. The maximum fine is SEK 250,000. IGM issues approx 80-130 decisions per year, whereas NBL makes a review of approx 40 cases per year.

2 Providing information prior to authorisation of medicinal product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

According to Article 2 of the LIF Rules, drug information is only permitted for medicinal products authorised for sale in Sweden. Further, the information may not contain indications or dosages other than those approved by the MPA, unless otherwise specified by the MPA.

The prohibitions on pre-launch marketing and off-label use are strictly reviewed by IGM and NBL. Information on medicines which does not fall within the definition of promotion but is protected by the constitutional right of freedom of speech can still be discussed and distributed to health professionals prior to an authorisation, however. Thus, information on unauthorised medicines may be made available at *e.g.* scientific meetings, as long as the information does not constitute promotion. The fact that a meeting is sponsored by the company responsible for the product will clearly increase the risk that the information be considered as unlawful promotion.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information on unauthorised medicines may be published in scientific journals and independent journalists may write about such medicines, provided that the information cannot be considered as disguised promotion for the product.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

Press releases intended for journalists and news editors do not fall within the definition of promotion, but are protected by the constitutional right of freedom of speech. Press releases about unauthorised medicines are thus permitted.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Advertising/promotion is a very wide concept in Sweden and a great deal of the information that emanates from a pharmaceutical company on its own products is regarded as marketing material. Not only traditional adverts or promotion brochures fall within this definition, but also *e.g.* the unsolicited distribution of a scientific article covering the company's own products will be considered as a marketing activity when it is addressed to a physician (despite the fact that such article may, as such, be of a non-promotional nature). The dispatch of information on an unauthorised medicine to health professionals will thus normally constitute unlawful pre-launch marketing. It is permitted to provide information in response to a specific request from a physician, however, on condition that the answer is limited to meet the particular question.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

The provision of information to institutions prior to the attainment of a marketing approval is likely to be regarded as unlawful pre-launch marketing.

3 Advertisements to health professionals

3.1 What information must appear in advertisements directed to health professionals?

Written information shall, if the FASS catalogue text or the SmPC is not reproduced, contain at least the following data:

- the name of the medicinal product,
- its formulation and, if required, its strength,
- names of its active ingredients, stated by generic name, as well as quantities of such ingredients,
- a balanced statement of the product characteristics, including particulars on pharmacological group or other accepted group affiliation and indication or area of indications and
- required warnings or limitations applicable to the use of the medicinal product.

Further, the advertisement must clearly show the name as well as the address or telephone number of the manufacturer concerned, or of his representative in Sweden. If the advertisement contains quotations, numerical data or diagrams taken from a scientific study, or makes a comparison between drugs that is based on such a study, reference shall always be made to the documentation. Otherwise, it is not normally necessary to make references to documentation that supports statements contained in the advertisement.

3.2 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison?

According to Article 12 of the LIF Rules, comparisons between effects, active ingredients, costs of treatment *etc* of drugs must be objectively and truthfully presented and give a fair overall picture of the compared products. This means among other things

- that objects included in the comparison must be selected in a correct manner and be clearly specified (including the complete name and generic designation, if necessary),
- that the facts which the comparison is intended to clarify and the limitations of the comparison be clearly presented,
- that comparisons of properties of synonymous drugs, or of drugs with the same indications, shall give a comprehensive and fair picture of the properties compared and
- that the presentation should not induce to incorrect or misleading conclusions regarding properties not covered by the comparison.

If required for clarity, the complete name and generic designation of the compared drugs should be stated. The use of another company's trade mark would risk constituting a trade mark infringement, depending on the way it is used.

Section 8a of the Market Practices Act also includes

general requirements on comparative advertisements stipulating, among other things, that a comparison must not discredit or denigrate a competitor or take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor.

3.3 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

A "teaser" advertisement alerting the reader that information on something new will follow will risk being regarded as unlawful pre-launch marketing (even though the name of the product is not mentioned), in particular if the advertisement is part of other information activities drawing attention to the new product.

4 Gifts and financial incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

According to MPA Regulation LVFS 1995:25 on the distribution of medical samples, free samples of medicinal products that have been authorised for sale in Sweden can be provided to persons qualified to prescribe the product and to the head of a pharmacy. The sample may only be supplied in response to a written request, which has been signed and dated. The request must be kept and filed by the company. The company must also carefully check that the person sending the request is authorised to prescribe or dispense medicinal products.

Samples shall be distributed only with great restraint. Only one package of the smallest size shall normally be supplied on each occasion and the number of samples of each product each year to the same recipient must be limited. The sample must be marked with "medical sample" and the expiry date, and it shall be accompanied by a copy of the SmPC unless information on the product has been published in FASS. The sample may not be used for the treatment of human beings or animals.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

Great care must be taken when gifts or other benefits are offered to public as well as private medical practitioners, as the level of acceptance concerning benefits is extremely low in Sweden. 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. Gifts which risk influencing professional decisions will also infringe the LIF Rules. The assessment whether a gift is improper or not shall be based on all available facts including (i) to whom the gift is offered, (ii) in what context the gift is offered, (iii) the type and value of the gift and (iv) the presentation of the offer. The gift should, as a general rule, be related to and constitute a natural and useful part of the physician's medical practice (e.g. scientific literature). As a rule of thumb, the market value of a benefit should not exceed SEK 100, but higher value may under certain circumstances be acceptable.

The rules regarding benefits etc are currently subject to review and stricter rules are expected to come into force later this year.

Donations of money must never be granted to medical practitioners.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

Gifts and donations of money or equipment may be granted to hospitals or other medical institutions under certain conditions. The donation should be made for a specific purpose relating to and constituting a natural and useful part of the medical practice. It must never be made for the purpose of unlawfully inducing the institution to purchase, recommend or use the donator's products. The principal of the institution must approve of each donation. The contribution should be appropriately documented and a written receipt should always be issued.

4.4 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

The Swedish rules on advertising and inducements do not prevent the offering of volume related discounts to institutions. Such arrangements may in certain circumstances have competition law implications, however.

4.5 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

The offering of additional services or equipment that is contingent on the purchase of medicinal products risk being regarded as an improper benefit intended to influence the procurement decisions of the institution. This is in particular so if the additional benefit is addressed to a private individual at the institution. Such arrangement could also have competition law implications.

4.6 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed?

It is permitted under Swedish law to offer a refund scheme to a medical institution in case the product does not work. The company may in fact have a duty under the Swedish Sales Act to refund the purchaser if the product does not have the specified qualities.

5 Hospitality and related payments

5.1 What rules govern the offering of hospitality to health professionals?

As pointed out in Section 4.2 above, the level of acceptance concerning benefits is very low in Sweden and great care must therefore be taken when hospitality is offered to public as well as private health professionals. The prohibitions on bribery and bribe-taking under the Swedish Criminal Code can be applicable also to the offering of hospitality.

The LIF Rules include 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 thereby 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, which include provisions regarding travelling, meals, invitations etc. The contents of the agreements and the LIF Rules have also been further clarified in case-law from NBL and IGM. New and stricter rules are expected to come into force later this year.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

It is as a general rule permitted to pay for expenses incurred by a physician in connection with attending a scientific meeting, on condition that the employer or principal of the physician has approved of this. The company may offer payment for enrolment fees, plain meals and moderate travel and accommodation costs, but must not arrange or pay for any irrelevant side arrangements. Social activities and entertainment like theatre, golf etc must not be offered, regardless of whether the meeting is arranged in Sweden or abroad. The duration of the stay must not exceed the time necessary to accomplish its purpose. Guests or relatives of the physician must not be invited or paid for.

5.3 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

It is as a general rule permitted under Swedish law to engage physicians to give lectures at scientific meetings, participate in advisory boards or research or to provide other expert services. The physician may be paid a honoraria/fee corresponding to the time and effort he has put into the assignment, including compensation for relevant travel and accommodation costs. Agreements concluded with staff physicians require prior authorization by the employer or a superior. There is no legal obligation for the company to document agreements and necessary approvals in writing, but such documentation specifying the services, remuneration etc is strongly advisable.

6 Advertising to the general public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

It is permitted to advertise non-prescription medicines to the general public in accordance with the regulatory framework mentioned in Section 1.1 above. The LIF Rules fall into two different parts; one applicable to information/advertisements aimed at health professionals and one governing information/advertisements aimed at the general public. The latter part of the LIF Rules includes similar rules and restrictions as those outlined in Section 1.1 above.

6.2 Is it possible to advertise prescription only medicines to the general public? If so, what restrictions apply?

Article 102 of the LIF Rules prohibits advertising for prescription only medicines to the general public, with a few exceptions. It is thus permitted to provide information from Patient-FASS and to provide aids (*e.g.* patient brochures) intended to be given to patients by health professionals in order to facilitate the correct use of their medicines.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

It follows from established case-law from NBL that a distinction shall be made between three types of information; non-commercial medical information (protected by the right of freedom of speech), product information (governed by applicable marketing law) and therapy and educational information. Therapy and educational information is regarded as a mixture between the two first-mentioned information categories. Such information does not constitute promotion, but as NBL recognises that a pharmaceutical company may still have a commercial interest in initiating *e.g.* a disease awareness campaign, NBL feel at liberty to apply the LIF Rules by analogy, in relevant parts, to such information campaigns. Thus, disease awareness campaigns are permitted but must comply with the general requirements of fair and trustworthy information, objectivity *etc* under the LIF Rules. It is important that the information is focused on the disease and not on the medical treatment (i.e. the medicinal products) available, or else the campaign risks being considered as disguised promotion for a prescription drug.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

Press releases intended for journalists and news editors do not fall within the definition of promotion, but are protected by the constitutional right of freedom of speech. It is thus permitted to issue press releases about prescription only medicines also to non-scientific journals.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertising of medicinal products is subject to the same rules as advertising in any other Swedish media. Thus, the Medicinal Products Act, the Market Practices Act and the LIF Rules are applicable also to promotions published on the Internet. The NBL has taken the view that a website falls within its jurisdiction if the site is aimed at the Swedish market (*i.e.* the country of destination principle). It is unclear whether the implementation of Directive 2000/31/EC on Electronic Commerce into

Swedish law, operating the rule of origin principle, will affect this position. The supervision by IGM and NBL of Swedish websites has so far been rather efficient.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

According to established case-law from NBL, a pharmaceutical company may divide its website into different sites intended for *e.g.* health professionals, the general public and the press. The visitor should be clearly informed of to whom each of the sites is addressed, but no pass words or other particular security arrangements are required to ensure that the general public do not in fact visit the site intended for health professionals.

8 General- medical devices

8.1 What laws and codes of practice govern the advertising of medical devices in your country?

The Market Practices Act is applicable to the advertising of all kinds of products and services, including medical devices (*cf.* Section 1.1 above). There are currently no Swedish laws or codes of practices that govern the advertising of medical devises in particular. The SLF Code of Ethics that is expected to enter into force in spring 2004 (cf. Section 8.2 below) is likely to include certain guidelines relating to advertising of medical devices, however.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

Payments and hospitality offered to physicians in connection with the promotion of medical devices are subject to the same strict rules as outlined in Sections 4 and 5 above with respect to medicinal products. The prohibitions on bribery and bribe-taking under the Swedish Criminal Code are applicable to the medical device industry and the pharmaceutical industry alike. There is no self-regulation system in place for the medical device industry like the one governing the pharmaceutical industry (*i.e.* the LIF Rules and the two agreements between LIF and the Medical Association and the Federation of County Councils, respectively). The Swedish Association of Suppliers of Medical Devices (SLF) is currently working on a Code of Ethics, however, intended to specify the conditions for interaction between the medical device industry and health care professionals. The Code is expected to enter into force in spring 2004 and will include provisions on, for example, product training and education, conference support, hospitality, gifts and donations.

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We advise clients throughout all phases of a product's life cycle. Our experience includes research and development agreements, technology licensing, strategic joint ventures and projects, clinical trials, market authorisations (including data exclusivity and the abridged procedures), labelling, distribution, pricing and reimbursement, generic substitution, parallel imports, marketing, branding and therapeutic information, sponsorship and compliance programmes. We regularly advise clients in matters before the Swedish Pharmaceutical Industry Information Examiner (IGM) and the Information Practice Committee (NBL) as well as the courts and other authorities.

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