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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2012

9th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

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Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design
F&F Studio Design

GLG Cover Image Source
Stockxchng

Printed by
Information Press
June 2012

ISBN 978-1-908070-30-2
ISSN 1743-3363

Strategic Partners

AEJE ECLA

MIX
Paper from responsible sources
FSC® C011748

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Sweden

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1 General - Medicinal Products

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

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. Advertising of medicinal products must also be compatible with good marketing practice. Further to this basic provision, the Act also contains detailed rules on the advertising of medicinal products. Thus, advertising of medicinal products which are not authorised for sale in Sweden is not permitted. Advertising of medicinal products must also not be aimed at children and advertising of medicinal products available only on prescription must not be aimed towards the general public, with the exception of campaigns for vaccination against human infection diseases. Further, the Swedish Medical Products Agency has issued a regulation clarifying and specifying the rules governing the advertising of medicinal products for human use in Sweden.

Additionally, the general provisions of the Market Practices Act are applicable to advertising of all kinds of products and services, including medicinal products. Sweden adopted a new Market Practices Act which entered into effect in July 2008. The Market Practices Act 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.

Detailed rules relating to pharmaceutical advertising can also be found in the Ethical Rules for the Pharmaceutical Industry issued by the Swedish Association of the Pharmaceutical Industry (LIF), last amended 8 December 2011. 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, advertisement of prescription drugs to the general public, off-label advertisement and pre-launch marketing. They also list rules with respect to e.g. comparative advertising, misleading, incomplete or unsubstantiated information and disguised advertisements.

1.2 How is "advertising" defined?

There is no definition of the term "advertising" in the Medicinal Products Act. However, in the draft legislation to the bill the Government held that the term "advertising" in the new provisions of the Medicinal Products Act (in force since May 1, 2006) refers to the term "advertising" as described in Directive 2001/83/EC.

The Market Practices Act defines promotion (*marknadsföring*) as "commercial advertising and other measures undertaken in the course of business intended to promote the disposal and supply of goods, including a business proprietor's acts, omissions or other measures before, during or after the sale or delivery of products to consumers and other business proprietors", whereas the LIF Rules (*cf.* question 1.1 above) apply to any information, regardless of media, which is provided by the pharmaceutical industry in connection with marketing operations directed towards health professionals or the general public.

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 by a pharmaceutical company of a scientific article covering the company's own products will be considered as a marketing activity if addressed to a physician or the general public (despite the fact that such article may, as such, be of a non-promotional nature).

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

No such arrangements are required in Sweden. However, under the LIF Rules, pharmaceutical companies are obliged to send new, up-to-date drug information to the Pharmaceutical Industry's Information Examiner (IGM), such as publications, advertisements, invitations, mailings, TV advertisements or information on websites. On request, the IGM may provide general advice on measures that have not yet been implemented. Such advice constitutes non-binding advance decisions.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

No, there are no such requirements.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No such approval is required in Sweden. Swedish authorities may

not require this as such a procedure would be considered a violation of the Swedish Freedom of the Press Act. However, the revised LIF Rules now provide for a possibility to ensure the public access to requested and easily comprehensive information on prescription drugs on websites established and administered by pharmaceutical companies. Such information may be provided solely on condition that pre-examination has taken place and resulted in an approval by the Swedish Pharmaceutical Industry's Information Examiner (IGM). A so-called pre-approved website shall, in all aspects, have as its factual basis the information stated on Fass.se and the summary of product characteristics as approved from time to time by the Medical Products Agency for the drug at issue. Further requirements are, *inter alia*, that a pre-approved website's content shall provide to the public access to patient-suited information regarding the drug in order to facilitate the correct use of the same.

Pre-examination and approval by IGM is also required in respect of campaigns for vaccination of humans against infectious diseases regarding promotion on radio, TV and in other advertisements. The pre-examination of such vaccination campaigns shall be performed for the purpose of ensuring that such marketing is in full compliance with the LIF Rules and other applicable marketing legislation.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The Swedish Medicinal 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 can issue a prohibitive injunction subject to fines upon non-compliance, or refer the case to the NBL (see below). Decisions by the MPA can be appealed to the County Administrative Court. The MPA may also notify the Consumer Ombudsman who is authorised to issue prohibitive injunctions subject to fines upon non-compliance, or to initiate action in the Market Court or the Stockholm District Court (depending on the sanctions sought) under the Market Practices Act. Decisions by the Stockholm District Court can be appealed to the Market Court, whereas decisions by the Market Court cannot be appealed against.

A great majority of all cases regarding the advertising of medicinal products never go to court, but are handled by the 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. A decision by the IGM can be appealed to the NBL.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? 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 normal sanction under the Medicinal Products Act for failing to comply with the rules governing advertising would be a prohibitive injunction subject to fines upon non-compliance.

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. An action before the Market Court or the Stockholm District Court can be initiated not only by the Consumer Ombudsman, but also by a competitor, a consumer/patient or a trade or consumer association.

As outlined above, most cases regarding advertising of medicinal products are handled by the two self-regulatory bodies: the IGM; and the NBL. The IGM monitors the market and may open a case without a formal complaint, or refer a case to the NBL. Private individuals and pharmaceutical companies, including competitors, are also entitled to bring an action before the IGM. The IGM and the NBL have contractual authority to fine member companies who violate the LIF Rules. The maximum fine is SEK 500,000.

1.8 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The competent authority (MPA) and the self-regulatory bodies (IGM/NBL) function independently of each other. The MPA may, at its own discretion, choose to notify and request the NBL to take action in a certain matter or, alternatively, take action itself. IGM/NBL are free to try a matter even if the same is also investigated by the MPA. Not only the IGM/NBL, but also the MPA apply the LIF Rules as applicable statute law which also explicitly refers to fair marketing practice.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Unfair competition based on unlawful marketing measures is governed by the Market Practices Act, the LIF Rules and the Medicinal Products Act (*cf.* questions 1.1-1.6 above).

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? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product's variants not authorised)?

As outlined above, the advertising of medicinal products which are not authorised for sale in Sweden is explicitly prohibited.

Additionally, under Article 2 of the LIF Rules, drug information is permitted only for medicinal products authorised for sale in Sweden. Further, the information must 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 the IGM/NBL, as well as by the MPA. Information on medicines which do not fall within the definition of promotion, but is protected by the constitutional right of freedom of speech, however, can still be discussed and distributed to health professionals prior to an authorisation. Thus, information on unauthorised medicines may be made available at e.g. scientific meetings, as long as the information does not constitute advertisement. 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 advertisement.

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 advertisement 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?

For a long time press releases intended for journalists and news editors have been deemed not to fall within the definition of advertisement, but been protected by the constitutional right of freedom of speech. Press releases about unauthorised medicinal products have thus been deemed permitted, provided that the information cannot be considered as disguised advertisement for the medicinal product.

However, in a recent decision by the MPA, a change in the MPA's attitude towards press releases can be noticed. In the decision the MPA argued *inter alia* that a press release containing anything other than an accurate reproduction of the packaging in accordance with article 62 of the Directive 2001/83 is deemed to have a promotional purpose and also that a distinction between journalists and other members of the general public is irrelevant. The decision has been appealed and is currently subject to judicial review in the County Administrative Court and until the court renders its judgment the question regarding to what extent it is possible for companies to issue press releases is somewhat uncertain.

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

The dispatch of information on an unauthorised medicine to health professionals will normally constitute unlawful pre-launch marketing. It is permitted to provide information in response to a specific request from a physician, however, on the condition that the answer is limited to meet the particular question.

2.5 How has the ECJ judgment in the Ludwigs case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in Sweden?

To our knowledge, the Ludwigs case has not led to any changes in the Swedish legislation or the MPA's guidelines.

2.6 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 marketing approval is likely to be regarded as unlawful pre-launch marketing.

2.7 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The LIF Rules contain a section on market research whereby a number of criteria are stipulated. These criteria must all be satisfied in order for the collaboration to be considered as "Market research". By "Market research" the LIF Rules mean e.g. questionnaires, interviews and focus groups. The criteria to satisfy encompass e.g. that the market research is implemented by an independent company/institute, in which the client pharmaceutical company does not have any ownership or profit interest and that the design of the research is intended only to gather information or opinions and attitudes, not to influence respondents or convey sales-promotional contacts.

3 Advertisements to Health Professionals

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

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

- the name of the medicinal product;
- its dosage form and, if required, its strength;
- names of its active ingredients, stated by a 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;
- required warnings or limitations applicable to the use of the medicinal product; and
- information about the date on which the documentation and SmPC were compiled or reviewed, the status of the product and if the product is part of the benefits system (incl. possible restrictions) and the sale price.

Further, the advertisement must clearly show the name, as well as the address or telephone number or web address of the pharmaceutical company responsible for the marketing of the medicinal product in Sweden, 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 are 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 support statements contained in the advertisement. It shall also state the date of the establishment or revision of the advertisement material. The information provided shall be correct, up-to-date, verifiable and as detailed as possible in order for the recipient to get an opinion of the product's value for treatment.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not in the SmPC?

Under Article 4 of the LIF Rules, all information on medicinal products must be truthful and may not contain any presentation in words or pictures that directly or indirectly is intended to mislead. In addition, under Article 8 of the LIF Rules, information regarding the quality and efficacy of a medicinal product must be able to be substantiated. Thus, any claim must be supported by scientific documentation. Furthermore, documentation to which reference is made in information on medicinal products must be of a high scientific standard. Under the condition that the above requirements are met, an advertisement may refer to studies not in the SmPC.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

As a general rule, it is required that the co-operation between pharmaceutical companies and healthcare professionals is managed with good judgment and preserved credibility. In addition, such co-operation may not constitute any incentive for the healthcare professional to recommend, prescribe, purchase, supply, sell or administer specific drugs. In addition, the Swedish Medical Association has issued rules for their members regarding advertisement. These rules provide that physicians shall not present themselves as guarantors for any particular medicinal product. Thus, it is not permitted to have healthcare professionals endorse specific medicinal products in promotional materials.

3.4 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

There is no such general requirement in Sweden. It should be noted, however, that information as to the qualities and effects of a drug shall always be capable of substantiation by means of scientific documentation.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in Sweden?

There is no particular provision on comparative advertisement in the Medicinal Products Act. However, under the general provision of the act, advertising shall be kept up-to-date, factual, balanced and must not be misleading.

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 must 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 incorrect or misleading conclusions regarding properties not covered by the comparison.

Comparisons between drugs and groups of drugs may not be included on pre-approved websites (*cf.* answer to question 1.5 above).

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

Section 18 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 trademark, trade name or other distinguishing marks of a competitor.

It follows from the LIF Rules that drug information is permitted only for medicinal products authorised for sale in Sweden. Therefore, the possibility to refer to a competitor's product which has not yet been authorised for sale in Sweden is very limited and would only be possible in a context which is not considered as marketing (*cf.* question 2.1 above).

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

The distribution of scientific papers and/or proceedings of congresses to doctors is permitted under Swedish law. It is important to note, however, that the unsolicited distribution of a scientific paper or similar material 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 an article may, as such, be of a non-promotional nature). Thus, the rules and regulations governing advertising of medicinal products must be paid attention to.

3.7 Are "teaser" advertisements permitted that 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 be at risk of being regarded as unlawful prelaunch 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 the MPA Regulation LVFS 2009:6 on the marketing of medicinal products for human use and the LIF Rules (and MPA Regulation LVFS 1995:25 on the distribution of medicinal samples), free samples of medicinal products that have been authorised for sale in Sweden can be provided to persons qualified to prescribe the product, to those with a pharmacy authorisation, to the responsible persons for medicinal products in pharmacies, to other retailers authorised to sell medicinal products, as well as pharmacists of hospital pharmacies (in the latter case, the sample may only be distributed by the healthcare professional). 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 "medicinal sample, not for sale" and the expiry date, and it should be accompanied by a copy of the SmPC. The sample may not be used for the treatment of human beings or animals. Finally, it is not permitted to distribute free samples of medicinal products listed as narcotics by the MPA.

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 the public, as well as private medicinal 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 principle under the bribery rules, be related to and constitute a natural and useful part of the physician's medicinal practice (e.g. scientific literature). As a rule of thumb, the market value of a benefit according to said bribery rules should not exceed SEK 100, but a higher value may under certain circumstances be acceptable. Donations of money must never be granted to medicinal practitioners. It should be noted, however, that the LIF Rules contain a very strict limitation according to which no gifts which are not related to the physician's medicinal practice are allowed.

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 medicinal institutions under certain conditions. The donation should be made for a specific purpose relating to and constituting a natural and useful part of the medicinal 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 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

Medicinal and educational goods and services intended to affect prescription patterns are likely to be considered unethical.

4.5 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.

4.6 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 risks being regarded as an improper benefit intended to influence the procurement decisions of the institution. This is so in particular if the additional benefit is addressed to a private individual at the institution. Such arrangement could also have competition law implications.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

Under the Sale of Goods Act, a company may have a duty to refund the purchaser if the product does not have the specified qualities. There is a risk, however, that the offering of specific refund schemes or money-back guarantees would be held to infringe the general requirement under the LIF Rules that all marketing must be in compliance with good trade practice, and/or the MPA Regulation LVFS 1995:25 and 2009:6 on the distribution of medicinal samples. It cannot be excluded that such offers would be considered to constitute an unlawful inducement or to create a "dependence" on the relevant drug in an unethical way. The above rules apply regardless of whether the product is a prescription-only medicine or an OTC medicine.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Financial support to the healthcare sector is a sensitive issue in Sweden and great care must be taken in order not to challenge the integrity and independent relationship between the pharmaceutical industry and the medicinal profession. The offer to sponsor continuing medicinal education should never be addressed to individual physicians, but should always be targeted to and approved by the employer or principal concerned.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

As pointed out in question 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 are also applicable 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, medicinal institutions and physicians in Sweden have mutually agreed on general principles to be applied to the interaction between them. The rules governing hospitality have also been further clarified in case-law from the NBL and the IGM.

The possibility of offering hospitality abroad is limited. The choice of location for an event must be reasonable in relation to the purpose of the event. Locations at which major international events are being staged at the same time as, or in connection with, the arrangement shall be avoided. Pharmaceutical companies must not contribute financially to events that are located in such places.

Generally, companies may not arrange or provide financial support for arrangements held abroad unless: (i) the majority of those invited come from other countries and considering the origin of most of those invited it is reasonable from a logistical or security perspective to organise the arrangement abroad; or (ii) considering the relevant resources or experts who are the subjects of the arrangement, it is reasonable to organise the arrangement in another country. Moreover, the choice of location for an arrangement must be reasonable in relation to the purpose of the arrangement, which implies that locations that are known for leisure activities or other exclusivity, such as winter sports, motor and golf competitions, shall be avoided. Under the new and revised LIF Rules the LIF Compliance Officer may decide whether a location is considered acceptable or not. A decision by the Compliance Officer may be appealed to the NBL.

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 invitation should be addressed to the employer or principal, rather than to the individual physician. In case of offers from a pharmaceutical company to attend an international scientific meeting, they shall be made only to the employer or principal. The company may offer to pay the enrolment fees and up to 50% of the expenses for 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. The company must not pay the participant for his time or offer any other kind of fee for his participation. Guests or relatives of the physician must not be invited or paid for. No payment for the attendance as such may be offered.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

Cf. answers to questions 5.1 and 5.2.

5.4 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 reasonable honoraria/fee corresponding to the time and effort he has put into the assignment, including compensation for relevant travel and accommodation costs. Agreements must be made in writing between the company, the physician and the physician's employer.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

It is permitted under Swedish law to engage physicians to take part in post-marketing surveillance studies. The physician may be paid a reasonable honoraria/fee corresponding to the time and effort he has put into the assignment, including compensation for relevant travel and accommodation costs. Agreements must be made in writing between the company, the physician and the physician's employer. The conduct of post-marketing surveillance studies (phase IV studies) is governed by the rules and regulations applicable to clinical trials, including the Medicinal Products Act and the MPA Regulation LVFS 2011:19.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

Doctors may be compensated for taking the time to participate in market research by e.g. answering questionnaires or similar surveys relating to treatment and medicinal products. It is important, however, that the remuneration is reasonable and corresponds to the time and effort actually put into the assignment. However, the remuneration must not exceed SEK 1,000.

5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

Under the LIF Rules pharmaceutical companies are encouraged to publically announce which sponsorships are provided and which donations or fringe benefits are given to the healthcare sector and pharmacies.

In addition, LIF has entered into a separate agreement with the Swedish Medical Association regarding the sponsorship of trade associations (e.g. specialist associations) by pharmaceutical companies. Information about such sponsorships must be made available in LIFs joint co-operation database. This applies regardless of whether the activity sponsored is on-going, finished or will take place in the future.

Economic or other support to organisations or interest groups shall only be given to specified collaborative projects or activities. Such support must be regulated in written agreements and a short version of such agreements should be made available in the LIF Co-operation Database when the project or activity is on-going and at least for one month after the project or activity is concluded.

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 question 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 question 1.1 above.

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

As mentioned above, there is an explicit prohibition in the Medicinal Products Act on the advertising of prescription-only medicines to the general public (with the exception of vaccination campaigns against human infection diseases).

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. As regards information on prescription drugs on websites, please refer to question 1.5 above.

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 the NBL that a distinction shall be made between three types of information: non-commercial medicinal 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 advertisement, but as the NBL recognises that a pharmaceutical company may still have a commercial interest in initiating e.g. a disease awareness campaign, NBL feels 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 medicinal treatment (i.e. the medicinal products) available, or else the campaign risks being considered as a disguised advertisement 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?

For a long time press releases intended for journalists and news editors have been deemed not to fall within the definition of advertisement, but been protected by the constitutional right of freedom of speech. It has thus been deemed permitted to issue press releases about prescription-only medicines also to non-scientific journals.

However, in a recent decision by the MPA, a change in the MPA's attitude towards press releases can be noticed. In the decision the MPA argued *inter alia* that a press release containing anything else but an accurate reproduction of the packaging in accordance with article 62 of the Directive 2001/83 is deemed to have a promotional purpose. The decision has been appealed and is currently subject to judicial review in the County Administrative Court and until the court renders its judgment the question regarding to what extent it is possible to issue press releases is somewhat uncertain.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Descriptions of products and research initiatives as background information in Annual Reports are generally permitted. Such information is normally addressed to shareholders, investors, etc. and does not fall under the rules governing the advertising of medicinal products.

Corporate brochures are generally regarded as marketing material. Such brochures may as a rule contain general descriptions of products and research initiatives. However, depending on, among other things, the route of distribution (e.g. potential investors or the general public), the kind of language used and the level of detail in the product and research descriptions, the corporate brochure may be held to constitute drug advertising and, accordingly, be subject to the rules governing the advertising of medicinal products (including the prohibitions on pre-launch marketing and advertisement of prescription drugs to the general public, etc.).

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The co-operation with and funding of patient support groups is subject to LIF's Ethical Rules as to Co-operation between LIF Member Companies and User Organisations. The Ethical Rules cover cooperation with all kinds of user organisations (e.g. disability organisations, patient organisations, organisations for the relatives and associations for senior citizens) and stipulate, among other things, that agreements between a user organisation and a pharmaceutical company shall always be made in writing and be available to third parties, that financial support may only be given for special projects or activities, that the co-operation shall be conducted in such a manner that the parties' independent positions in relation to each other cannot be questioned and that it shall always be clearly evident from any information materials, etc. that the parties are co-operating.

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 also applicable to advertisements 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). The supervision by the IGM and the NBL of Swedish websites has so far been rather efficient. As regards information on prescription drugs on websites, please refer to question 1.5 above.

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?

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 also applicable to advertisements 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). The supervision by the IGM and the NBL of Swedish websites has so far been rather efficient. With regard to information on prescription drugs on websites, please refer to question 1.5 above.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Information which may be accessed by link from a company-sponsored website implies responsibility for the linking company in respect of the accuracy of said information. A company will not be liable for any reversed linking undertaken independently by another party.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

With regard to information aimed at the public, pharmaceutical companies may only publish information on prescription-only medicines by way of linking to Patient-FASS (*cf.* question 6.2 above).

8 Developments in Pharmaceutical Advertising

8.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The rules relating to pharmaceutical advertising in the Medicinal Products Act remain unaltered. The LIF Rules were revised as of 8 December 2011. A new Market Practices Act entered into force during 2008.

8.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No, there are not.

8.3 Are there any general practice or enforcement trends that have become apparent in Sweden over the last year or so?

Great focus has been put on all kinds of sponsoring, travels and events both under the Criminal Code and under the LIF Rules and a number of investigations have been initiated regarding financial support by the industry to the healthcare side.

It can also be noted that a review of the Swedish bribery legislation has recently been made. The review has resulted in stricter rules including *inter alia* prohibition against negligent funding of a bribe. The new rules are expected to enter into force 1 July 2012.

8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

Some smaller amendments were made to the LIF Rules in 2011 in order to implement the amendments to the EFPIA Codes, although the LIF Rules did to a large extent already meet the requirements in the amended Codes.

Acknowledgment

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