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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2015

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A practical cross-border insight into pharmaceutical advertising

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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 (SFS 1992:859) 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 infectious diseases. Further, the Swedish Medical Products Agency ("MPA") has issued a regulation clarifying and specifying the rules governing the advertising of medicinal products for human use in Sweden, LVFS 2009:6.

Additionally, the general provisions of the Market Practices Act (SFS 2008:486) are applicable to advertising of all kinds of products and services, including medicinal products. 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 ("LER Rules") issued by the Swedish Association of the Pharmaceutical Industry ("LIF"), last amended as of 1 March 2015. Although not legally binding, the LER Rules are widely recognised by the pharmaceutical industry and applied by courts as an expression of fair and ethical marketing. In addition, members of LIF are contractually bound by the LER Rules, and the Medicinal Products Act states that all marketing of medicinal products for humans must correspond with good practice for such marketing, which the LER Rules reflect. The LER 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" under the Medicinal Products Act refers to the term "advertising" as defined in Directive 2001/83/EC.

The Market Practices Act defines promotion (Sw. *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 LER 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 healthcare professionals or the general public.

The concept of "advertising/promotion" is very broad 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 promotional 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 healthcare professional or the general public (even if the article is, as such, 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 LER 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 and information on websites. LIF has appointed two IGMs, one covering measures aimed at the general public ("IGM Consumer") and one covering measures aimed at the healthcare sector ("IGM Profession"). Thus, drug information aimed at the general public shall be sent to IGM Consumer and drug information aimed at the healthcare sector shall be sent to IGM Profession. 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 (SFS 1949:105). However, the LER Rules provide for the possibility to ensure 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 IGM. A so-called pre-approved website shall, in all aspects, have as its factual basis the information stated on Fass.se (the online version of the FASS catalogue issued by LIF) and the summary of product characteristics ("SmPC") as approved from time to time by the MPA for the drug at issue. Further requirements are, *inter alia*, that a pre-approved website's content shall provide access to patient-suited information regarding the drug to the public in order to facilitate its correct use. Pre-examination and approval by the 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 LER 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 MPA monitors the pharmaceutical market, including advertising and other marketing activities of pharmaceutical companies. It 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 Information Practices Committee ("NBL"). 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. Neither court can assist on the issue of a corrective statement.

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 IGM, who is a physician; and the NBL, which is a court-like body. As noted above, as of 2013, LIF has appointed two IGMs: IGM Consumer, covering measures aimed at the general public; and IGM Profession, covering measures aimed at the healthcare sector. A decision by the IGM can be appealed to the NBL. Both the IGM and the NBL can request that the pharmaceutical company places a corrective advertisement in the media determined by the IGM or 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 and 5,000,000 and third party damages, whereas only prohibitive injunction is available as a remedy 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 (*cf.* questions 1.3 and 1.6 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. Also private individuals and pharmaceutical companies, including competitors, are entitled to bring an action before the IGM. The IGM and the NBL have contractual authority to fine member companies who violate the LER Rules. The maximum fine is SEK 500,000 in each instance (IGM and NBL). As mentioned above, if the IGM or NBL finds that the violation of the LER Rules is serious, the IGM or NBL is entitled, in addition to the fee, to request that the pharmaceutical company places a corrective advertisement on the media determined by the IGM or the NBL.

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. The 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 LER Rules as applicable statute law which also explicitly refers to fair marketing practice (*cf.* question 1.1 above).

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 LER Rules and the Medicinal Products Act (*cf.* questions 1.1-1.7 above).

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare 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 variants not authorised)?

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

Additionally, under Chapter 1 Article 2 of the LER 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 does 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 healthcare professionals prior to an authorisation. Thus, information on unauthorised medicines may be made available at e.g. scientific meetings, provided that the information does not constitute advertisement. The fact that a meeting is sponsored by the company responsible for the medicinal product will clearly increase the risk that the information be considered as unlawful advertisement.

Information on a medicinal product which is authorised for sale in other countries than Sweden may be distributed at international scientific conferences held in Sweden. However, the conference must be an international event with a majority of the participants from countries other than Sweden. The drug information must include details about the countries in which the drug has received market authorisation, as well as the fact that it has not been granted such authorisation in Sweden. Also off-label indications can be presented at international scientific conferences held in Sweden subject to certain conditions.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Information on unauthorised medicines and off-label information may be published in scientific journals and independent journalists may write about such medicines or information, 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 unauthorised medicines and/or off-label information? If so, what limitations apply?

For a long time, press releases aimed at journalists and news editors were deemed not to fall within the definition of advertisement and were protected by the constitutional right of freedom of speech. Press releases about unauthorised medicinal products were thus considered permissible, provided that the information could not be considered as disguised advertisement for the medicinal product.

However, in a decision from September 2011 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 was appealed to the County Administrative Court, which in a judgment in February 2013 upheld the MPA's decision. The court did not consider the typical nature of a press release and thus its non-commercial purpose. Moreover, the court disregarded the fact that a press release is aimed at journalists, referring to the fact that there were no technical barriers for the public to access the information. The County Administrative Court's judgment was appealed to the Administrative Court of Appeal, which dismissed the appeal in November 2013. It held that journalists should be considered to belong to the general public and therefore, information on non-authorised medicinal products could not be aimed at journalists.

The Administrative Court of Appeal's judgment conflicts with long-standing practice and has been appealed to the Supreme Administrative Court, where it was decided in June 2014 not to grant leave of appeal. This means that the question regarding to what extent it is possible for companies to issue press releases about unauthorised medicines and off-label information is settled by the Administrative Court of Appeal.

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

The dispatch of information on an unauthorised medicine to healthcare professionals will normally constitute unlawful pre-launch marketing. It is permitted to provide information in response to a specific request from a healthcare professional, 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 on unauthorised medicines or indications 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 authorisation is likely to be regarded as unlawful pre-launch marketing.

2.7 Is it possible for companies to involve healthcare 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 LER Rules contain a section on market research, where a number of criteria are stipulated. These must all be satisfied in order for the collaboration to be considered as "Market research". By "Market research" the LER Rules mean e.g. questionnaires, interviews and focus groups. The criteria encompass e.g. that the company/institute performing the research undertakes to comply with the ethical rules for market research issued by ICC/ESOMAR, that the design of the research is intended only to gather information or opinions and attitudes and not to influence respondents or convey sales-promotional contacts, and that the respondents are treated in the strictest confidence and in accordance with the Data Protection Act (1998:204). Any remuneration for participation in market research must be proportionate to the time invested (*cf.* question 5.6 below).

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare 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;
- the names of its active ingredients, stated by a generic name, as well as the 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;
- 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 reimbursement system (including possible restrictions) and the sale price;
- the name and either the address, telephone number or web address of the pharmaceutical company responsible for the marketing of the medicinal product in Sweden, or of its representative in Sweden;
- the date of publication or, in the case of internet information, the date when the site was most recently updated;
- the date of the last SmPC revision;
- whether the product is an over-the-counter or prescription product;
- whether the product is included in the Swedish benefits scheme (and if so, the price per subsidised package and any limitations in the subsidy decision); and
- a reference to Fass.se.

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 supports statements contained in the advertisement. 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 mentioned in the SmPC?

Under Chapter 1 Article 4 of the LER Rules, all information on medicinal products must be truthful and may not contain any presentation in words or pictures that directly or indirectly are intended to mislead. As a consequence of this, a general restriction is that a product may not be claimed to not have any side effects or risk of toxicity, abuse or addiction. In addition, information regarding the quality and efficacy of a medicinal product must be able to be substantiated. Any claim must be supported by scientific documentation of a high scientific standard. Under the condition that the above requirements are met, an advertisement may refer to studies not mentioned in the SmPC.

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

Under Chapter 1 Article 8 of the LER Rules, healthcare professionals may not participate in medicinal product information, offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment. In addition, the Swedish Medical Association has issued rules for its members regarding advertisement. These rules provide that physicians shall not present themselves as guarantors for any particular medicinal product. In conclusion, 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 may be 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 must 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 Chapter 1 Article 12 of the LER 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 could, however, risk constituting a trademark infringement, depending on how it is used.

Section 18 of the Market Practices Act also includes general requirements on comparative advertisements and stipulates, 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 LER 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 healthcare professionals?

The distribution of scientific papers and/or proceedings of congresses to healthcare professionals is permitted under Swedish law. However, it is important to note 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 healthcare professional (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 apply.

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 risks being regarded as unlawful pre-launch marketing (even if the name of the product is not mentioned), especially 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 healthcare professionals with samples of medicinal 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 LER Rules (as well as the MPA Regulation LVFS 1995:25 on the distribution of medicinal samples for veterinary use), free samples of medicinal products that have been authorised for sale in Sweden can be provided to persons qualified to prescribe the product, those with a pharmacy authorisation, the responsible persons for medicinal products in pharmacies, and 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 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 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 healthcare professionals? If so, what restrictions apply?

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 Criminal Code (SFS 1962:700). The LER Rules prohibit gifts to the healthcare sector, with the exception of:

- information and educational material of low value, direct relevance to the recipient's professional practice and of direct benefit to patient care; or
- items of medical utility for the education of employees and for patient care, if of low value and not routinely used in the recipient's business.

Donations to the healthcare sector are only permitted when made to support research and development. They must be transparent and well-documented, and the donor must keep a registry of made donations. Donations may never be offered or requested for the funding of e.g. social activities or the routine practice of healthcare professionals. In addition, donations to the healthcare sector may not be linked to any prior, current or future use, recommendation, sale or prescription of the donor's products or services, and may not constitute incentive to recommend, prescribe, buy, offer, sell or administer specific pharmaceuticals.

4.3 Is it possible to give gifts or donations of money to healthcare organisations 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?

It is prohibited to give gifts to the healthcare sector under the LER Rules (*cf.* question 4.2 above).

Proportional donations of money or equipment to hospitals or other medicinal institutions may be made to support research and development (*cf.* question 4.2 above).

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals 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 and unlawful.

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. However, such arrangements may, in certain circumstances, have competition law implications.

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 (SFS 1990:931), a company may have a duty to refund the purchaser if the product does not have the specified qualities. However, there is a risk that the offering of specific refund schemes or money-back guarantees would be held to infringe the general requirement under the LER Rules that all marketing must be in compliance with good business practice, and/or the MPA Regulation LVFS 1995:25 and 2009:6 on the distribution of medicinal samples. Depending on the content and wording, such refund schemes may be considered acceptable pay-per-performance agreements or be considered unlawful inducement. Whereas, the above rules apply regardless of whether the product is a prescription-only medicine or an OTC medicine, the pay-per-performance structure in practice will be applicable only to prescription-only medicines.

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 healthcare professionals, 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 healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

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, healthcare professionals. The prohibitions on "giving a bribe" and "taking a bribe" under the Swedish Criminal Code are also applicable to the offering of hospitality.

The LER Rules include five basic principles applicable to all cooperation between pharmaceutical companies and healthcare professionals. The principles are the benefit principle, the transparency principle, the proportionality principle, the moderation principle and the documentation principle. In addition, there is a general requirement that all hospitality offered to healthcare professionals 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. 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, or motor and golf competitions, shall be avoided. Under the LER 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.

LIF has issued thresholds for hospitality and meals provided to a healthcare professional. The value of a lunch should not exceed SEK 250 (incl. VAT) per person. The value of a dinner should not exceed SEK 700 (incl. VAT) per person. For hospitality abroad, local rules take precedence. In the absence of local rules or guidance, the Swedish levels apply.

5.2 Is it possible to pay for a healthcare professional 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?

A pharmaceutical company may pay for the venue, speakers, study materials, meals and similar as is necessary to carry out the meeting but not for enrolment fees, travel and accommodation for individual healthcare professionals, as this is strictly prohibited.

The company may never 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 may not pay the participant for his/her time or offer any other kind of fee for his/her participation. Guests or relatives of the healthcare professional may not be invited or paid for.

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 healthcare professionals to attend?

Cf. answers to questions 5.1 and 5.2 above.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

It is, as a general rule, permitted under Swedish law to engage healthcare professionals to give lectures at scientific meetings, participate in advisory boards or research or to provide other expert services. It should be noted that the LER Rules contain a requirement that the healthcare professional should be engaged in an advisory board only if he/she can contribute with knowledge in a particular area where such knowledge cannot be obtained within the company. The healthcare professional may be paid a reasonable honoraria/fee corresponding to the time and effort he has put into the assignment. Compensation for relevant travel and accommodation costs should be in accordance with the employer's rules for such expenses. Agreements must be made in writing between the company, the healthcare professional's employer and the healthcare professional.

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

It is permitted under Swedish law to engage healthcare professionals to take part in post-marketing surveillance studies. The healthcare professional may be paid a reasonable honoraria/fee corresponding to the time and effort he has put into the assignment. Compensation for relevant travel and accommodation costs should be in accordance with the employer's rules for such expenses. Agreements must be made in writing between the company, the healthcare professional's employer and the healthcare professional. The conduct of post-marketing surveillance studies (phase IV studies) is governed by the Medicinal Products Act, the MPA regulation on security reporting on medicinal products for human use, LVFS 2012:14 (and LVFS 2012:15 regarding medicinal products for veterinary use), and the LER Rules and a thereto belonging policy document.

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

Healthcare professionals 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. In any event, the remuneration may not exceed 2.5% of the current base amount/KPI (SEK 1,112.50 in 2015).

Importantly, market research should not contain any promotional material.

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, though not to children, in accordance with the regulatory framework mentioned in question 1.1 above.

The LER Rules are divided into two parts: one applicable to information/advertisements aimed at healthcare professionals; and one governing information/advertisements aimed at the general public. The latter part of the LER 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 infectious diseases).

Chapter 1 Article 102 of the LER Rules prohibits advertising of prescription-only medicines to the general public. However, it is permitted to provide information from Patient-FASS and to provide aids (e.g. patient brochures) intended to be given to patients by healthcare 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 the NBL considers that a pharmaceutical company may still have a commercial interest in initiating e.g. a disease awareness campaign, and therefore feels at liberty to apply the LER 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 LER 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 aimed at journalists and news editors have been deemed not to fall within the definition of advertisement and protected by the constitutional right of freedom of speech. It has thus been thought permitted to issue press releases about prescription-only medicines also to non-scientific journals.

However, in a decision from September 2011 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 was appealed to the County Administrative Court and then the Court of Appeal; both of which upheld the MPA's decision. The courts did not consider the typical nature of a press release and thus its non-commercial purpose. Moreover, the courts disregarded the fact that the press release was aimed at journalists, referring to the fact that there were no technical barriers for the public to access the information. The Court of Appeal's judgment conflicts with long-standing practice and has been appealed to the Supreme Administrative Court, where it was decided in June 2014 not to grant leave of appeal. This means that the question regarding to what extent it is possible for companies to issue press releases about unauthorised medicines and off-label information is settled by the Administrative Court of Appeal.

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 the funding of, patient organisations?

The cooperation with and funding of patient organisations is subject to the LER Rules, which cover cooperation with all kinds of user organisations (e.g. disability organisations, patient organisations, organisations for the relatives and associations for senior citizens). The LER Rules stipulate, among other things, that agreements between a user organisation and a pharmaceutical company should 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 cooperating.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Under the LER Rules, pharmaceutical companies must comply with the 'Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases' entered into between the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), the Juvenile Products Manufacturers Association ("JPMA") and the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Thus, all on-going and completed clinical trials must be registered on a publicly available database such as the WHO's clinical trial portal http://apps.who.int/trialsearch/. The registration should include, among other things, information on: brief title; trial description; trial phase; trial type; trial status; trial purpose; intervention type; condition or disease; key eligibility criteria, including gender and age; the location of the trial; and contact information.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

There is no specific legislation in this regard.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The LER Rules implement the 2013 EFPIA Code on Disclosure of

Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations without variation. Transfers of value made from 1 January 2015 and onwards must be disclosed in Swedish and voluntarily in English. Disclosure shall be made in a designated section of the online cooperation database of LIF, or on the company's website as a complement.

8 The Internet

8.1 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 LER 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, see question 1.5 above.

8.2 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 healthcare professionals?

Long-standing case law from the NBL/IGM provides that no website security is required provided that it is clear from the website that it is aimed at healthcare professionals and not the general public.

It should be noted that the County Administrative Court in the case referred to in question 6.4 above pointed to the fact that there were no technical barriers to anyone taking part of the press release. Thus, the court seems to consider that some kind of website security is required in order to make sure that the information will not be regarded as aimed at the general public. However, this goes against all previous case law from the NBL/IGM and the Supreme Administrative Court has not yet rendered its judgment.

8.3 What rules apply to the content of independent websites that may be accessed by a 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 that 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.

8.4 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).

8.5 Are there specific rules, laws or guidance controlling the use of social media by companies?

The LER Rules apply to the use of social media. In addition, LIF has issued guidelines on compliance of the use of social media in light of the LER Rules.

9 Developments in Pharmaceutical Advertising

9.1 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 LER Rules were revised as of 1 March 2015, introducing a strict ban on gifts for the healthcare sector (*cf.* questions 4.2 and 4.3 above) and prohibiting the sponsoring of enrolment fees, travel and accommodation for individual healthcare professionals (*cf.* question 5.2 above).

Further, in June 2015 the Supreme Administrative Court decided not to grant leave of appeal in the press release case (*cf.* question 2.3 above).

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

No developments are expected.

9.3 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, travel and events both under the Criminal Code and the LER Rules, and a number of investigations have been initiated regarding financial support by the industry to the healthcare side.

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