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Sweden

PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Sweden.

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SWEDEN
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

The following laws and other regulations constitute the main framework governing advertising of medicinal products in Sweden.

Central provisions on advertising of medicinal products are stated in the Medicinal Products Act (SFS 2015:315) (Sw. *Läkemedelslagen*). The act mandates that advertising of medicinal products must be up-to-date, factual, balanced and not be misleading, and that it must be consistent with good marketing practices (Sw. *god marknadsföringssed)*. Further, the Swedish Medical Products Agency ('**MPA**') has issued regulations (LVFS 2009:6) on marketing of medicinal products for human use (Sw. *Läkemedelsverkets föreskrifter (LVFS 2009:6) om marknadsföring av humanläkemedel,* '**LVFS 2009:6**'). LVFS 2009:6 holds detailed provisions that clarify and specify the central provisions of the Medicinal Products Act. Together the Medicinal Products Act and LVFS 2009:6 implement the rules on advertising in the EU Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

In addition to the specific rules on marketing of medicinal products, the Marketing Practices Act (2008:486) (Sw. *Marknadsföringslagen*) applies to advertising of all products and services, i.e., also marketing of medicinal products. In short, it requires all marketing activities to be compatible with good marketing practice and fair towards consumers and the industry. It also sets out specific rules on misleading advertising, comparative advertising and special offers.

Further, the Radio- and Television Act (SFS 2010:696) (Sw. *Radio- och tv-lagen*) prohibits advertisements of medicinal products through teleshopping (i.e., the activity of buying medicinal products advertised on television using your phone or the internet) as well as product placement and other advertisements of prescription only ('**Rx**') medicinal products. The act also prohibits advertising medical treatments available only on prescription in television broadcasts, searchable teletext and video-on-demand. Thereto, the act contains limitations on sponsorships of television advertisements.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Yes. Rules on advertising of medicinal products are stated in a self-regulatory code issued by the Swedish industry trade association, the Swedish Association of the Pharmaceutical Industry (Sw. *Läkemedelsindustriföreningen*, '**LIF**'), called the Ethical rules for the pharmaceutical industry ('**LER**'). LER is regularly updated. The most recent revision of LER was in June 2022.

Further, other self-regulatory and codes of practice initiatives that are applicable to advertising in general also apply to the advertising of medicinal products, such as The International Chamber of Commerce's Advertising and Marketing Communications Code ('**ICC Rules**').

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

LER applies to LIF member companies as well as the Association for Generic Pharmaceuticals and Biosimilars in Sweden (Sw. *Föreningen för Generiska läkemedel och Biosimilarer*, '**FGL**') and its member companies, the Association of Smaller Life Science Companies (Sw. *Innovativa Mindre Life Sciencebolag*, '**IML**') and its member companies, and the Association for Clinical Research Organizations active in Sweden (Sw. *Branschorganisationen för CRO-företag*, '**ASCRO**') and

its member companies.

b. What is the legal status of the self-regulatory codes?

LIF member companies are by their membership bound on a contractual basis to comply with LER and decisions by LIF's two disciplinary bodies, the Information Examiner Committee (Sw. *Informationsgranskningsnämnden*, '**IGN**') and the Information Practices Committee (Sw. *Nämnden för bedömning av läkemedelsinformation*, '**NBL**'). LIF member companies shall also ensure that their affiliate companies (e.g., parent companies or sister companies) observe and comply with LER in the event of activities on the Swedish market or targeted at the Swedish market. They are further obliged to enjoin their business partners to comply with LER in licence agreements and the like, even when such business partners do not act on behalf of the pharmaceutical company. A LIF member company is responsible for all activities conducted on its behalf by an intermediary. The same applies to the members of FGL, IML and ASCRO.

Further, LER is widely recognised by the pharmaceutical industry as a whole (i.e., also by non LIF members) and although not legally binding, LER is applied by courts as an expression of fair and ethical marketing.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

'**Advertising**' as such is not defined by statute in Sweden. '**Marketing**' of medicinal products is defined in LVFS 2009:6. The definition implements and shall correspond to the definition in EU Directive 2001/83/EC according to the preparatory works to the Medicinal Products Act. This means that the concept of advertising of medicinal products shall be interpreted in conformity with EU law.

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The definition of '**Marketing**' covers:

- any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. In particular it includes:
    - advertising of medicinal products to the general public;
    - advertising of medicinal products to persons authorised or entitled to prescribe or supply them;
    - visits by medical sales representatives to persons authorised or entitled to prescribe medicinal products; and
    - the supply of samples.

Package leaflets, correspondence with a non-commercial message required to respond to specific questions on certain medicinal products, warning messages on adverse reactions as part of general drug precautions as well as information on health and diseases such as disease awareness campaigns (under the prerequisite that they do not mention any medicinal product or active substances) are not covered by the definition.

Marketing of medicinal products is thus more narrowly defined than marketing in general under the Marketing Practices Act, where marketing is defined as advertising and other measures in commercial activities which are intended to promote the turnover of, and access to, products or services, including a trader's acts, omissions, or other measure or behaviour before, during or after the sale or delivery of products or services. LER is based on the broader definition of marketing in the Marketing Practices Act.

Risk minimisation information ('**RMI**') falls outside the scope of the definition of marketing. RMI is information that holders of marketing authorisations are required to communicate to healthcare professional ('**HCP**')s (or to patients through HCPs) in accordance with specific conditions in the product's approval or as required following approval, e.g., due to a safety signal. Nevertheless, RMI is subject to detailed rules in LER. The detailed LER rules state, e.g., that:

- RMI, as a principle rule, is to be provided at the workplace during working hours;
- no marketing of the relevant product for the RMI and/or other products may occur in connection with meetings classified as RMI;
- RMI may not entail funding of other cooperation activities or meetings; and
- in addition to what is stated in any procurement contract, a pharmaceutical company may carry all reasonable costs for the RMI to be provided, however, this shall be

done in compliance with the guiding principles set out in LER.

b. Does the definition apply equally to all target audiences?

There is no separation between target audiences in relation to what constitutes marketing of medicinal products. However, there is a separation between target audiences when it comes to what constitutes permissible marketing of medicinal products. As such, it is not permissible to market medicinal products to children, and there are separate rules that apply to marketing to the general public and marketing to HCPs and other professionals authorised or entitled to prescribe or supply medicinal products.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Yes. The principal rule is that press releases shall only target journalists and news editors, and pharmaceutical companies shall not share them with the general public or with HCPs. Since journalists and news editors are the primary target audience, the message should be tailored to that audience, meaning that the news story shall be predominant. In more detail, a press release shall be newsworthy, contain only a minimum amount of references to any product name and/or any active substances, and solely include such brief and balanced information on medicinal products that is necessary to convey the news message.

However, a press release can be considered marketing of medicinal products targeting the general public, since journalists and news editors are part of the general public and since press releases often are publicly available online. The relevant distinction is whether the press release, considering its overall content and purpose as well as all other relevant factors and circumstances of the case, is deemed to have a predominant commercial or non-commercial message, thus falling inside or outside the scope of marketing of medicinal products. Since advertising of Rx medicinal products to the general public is prohibited by law, strict caution should be observed for press releases including any information on Rx medicinal products.

Press releases are to some extent covered by LIF's guidelines for the use of digital channels in accordance with LER (Sw. *Användande av digitala kanaler utifrån Läkemedelsbranschens etiska regelverk*). The guidelines state inter alia that pharmaceutical companies shall not link, otherwise share or distribute press releases regarding medicinal products, nor shall press releases be shared on social media by company employees/representatives. Special regulatory frameworks may in part override this. For publicly listed pharmaceutical companies to which rules on disclosure of information to the market applies, press releases may be distributed via their own investor relations information channels. The content of such press releases shall, however, also observe the abovementioned limitations – with the strictest caution applied to press releases with any information on Rx medicinal products.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Yes. Under the Medicinal Products Act, the holder of a marketing authorisation for a medicinal product (Sw. *Innehavare av försäljningstillstånd*, '**MAH**') must employ a function with scientific competence to monitor the information relating to the medicinal product.

Further, LER stipulates that a pharmaceutical company, or its representative in Sweden, shall employ an Information Officer in marketing ethics (Sw. *Informationsansvarig marknadsetik,* '**IMA**'). The IMA must be suitable, hold a position of responsibility within the company, and complete certain courses in marketing law held by LIF. The IMA shall be the company's liaison officer in ethical matters related to informational and marketing activities.

The IMA must pre-approve all marketing materials relating to medicinal products. This pre-approval includes the IMA's certification of having examined the final marketing material and that it:

- complies with applicable rules and regulations;
- is consistent with the Summary of Product Characteristics (Sw. *Produktresumén*, '**SPC**') and with any decisions or recommendations of the Dental and Pharmaceutical Benefits Agency (the government authority administrating the Swedish system of pharmaceutical subsidies, Sw. *Tandvårds- och läkemedelsförmånsverket*, '**TLV**') relating to the medicinal product in question; and
- is a fair and truthful presentation of facts.

6. Do companies have to have material

approved by regulatory bodies prior to release?

No. However, all marketing material for a medicinal product must be in conformity with its SPC, and the SPC must be approved by the authorities. Further, pharmaceutical companies bound by LER must send IGN so called 'statutory copies' of all marketing materials. This includes new, up-to-date medicinal product information, e.g., publications, advertisements, invitations, mailings, commercial films or information on websites, within a reasonable period after the medicinal product information was put in use, though no later than 3 months thereafter. Further, please see question 9 below regarding 'pre-approved websites'.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Yes, comparative advertising is allowed subject to requirements under the general provisions in the Medicinal Products Act and the Marketing Practices Act, i.e., that any advertisement must be up-to-date, factual, balanced and must not be misleading.

Further, LER requires comparisons between a medicinal product's effects, active ingredients and cost of treatment to be objectively and accurately presented and give a fair overall picture of the compared products. This means, among other things, that the:

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

Finally, it is not allowed to discredit other companies or other medicinal products.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

In general, the provisioning of information on unauthorised medicinal products or indications will be deemed to constitute marketing and will therefore be prohibited under the Medicinal Products Act. It is possible to provide such information under certain circumstances where the information is not classified as marketing of medicinal products, e.g., individual correspondence following an unsolicited query from an HCP. Under Swedish law all marketing of medicinal products must also be in conformity with the approved SPC, which generally means a prohibition of information on unauthorised indications.

Previously, LER stipulated specific conditions under which information regarding unauthorised medicinal products and unauthorised indications could be provided at international scientific congresses held in Sweden. According to a judgement by the Administrative Court of Appeal in Stockholm on 27 September 2021, *case no. 546-21*, there is no longer leeway in the regulatory framework for marketing of medicinal products to make exemptions from the prohibition on marketing unauthorised medicinal products or indications at international scientific congresses. As a consequence of the judgement, LER has been revised. Providing information regarding unauthorised medicinal products or unauthorised indications at international scientific congresses are thus no longer exempted under LER, but is instead subject to the general prohibition as set forth above.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

Prescription only ('Rx') medicinal products

The Medicinal Products Act prohibits advertising of Rx medicinal products to the general public. Exemptions are made in the Medicinal Products Act for marketing campaigns concerning vaccination against infectious diseases. Further, certain non-commercial information, i.e., information that does not constitute advertising, on

Rx medicinal products may be provided to the general public. This includes inter alia information intended to facilitate the safe, effective and correct use of medicinal products, e.g., patient aid materials that are intended to be handed to patients by HCPs. Such information may also be given through the website Fass.se. In addition, for the purpose of ensuring the public access to requested and easily comprehensible information on Rx medicinal products, LER facilitates the possibility to provide such information on websites established and administered by pharmaceutical companies, preconditioned that the information and website have been pre-examined and approved by IGN (so called 'pre-approved website'). Other permissible non-commercial information includes factual and informative messages and reference materials such as information relating to, e.g., changes in packaging, warnings of unwanted adverse reactions or relevant price lists that do not contain any product claims.

Pre-approved websites shall, in all aspects, have as its factual basis what is stated on Fass.se and in the SPC as approved from time to time. There is, however, no requirement that the information on Fass.se and/or SPC shall be reproduced word-for-word or in its entirety on the pre-approved website.

Over the counter ('OTC') medicinal products

Under Swedish law the advertising of OTC medicinal products to the general public is allowed subject to requirements under the general provisions in the Medicinal Products Act and the Marketing Practices Act. Accordingly, any advertisement must be in conformity with the SPC, up-to-date, factual, balanced and must not be misleading.

Further, detailed requirements are provided in LVFS 2009:6 and in LER. For advertising of OTC medicinal products to the general public, the following information must be included:

- the name of the medicinal product, its dosage form and its active ingredients specified by generic name or in some other suitable way;
- the information necessary to facilitate the correct use of the medicinal product including statements of any necessary warnings or limitations that are applicable to its use;
- details of company name and contact information;
- a clear statement about the year of publication or, in the case of information on the internet, the date when the site was most recently updated; and
- an explicit and easily legible invitation to carefully study the information contained in the package leaflet or, as applicable, on the outer packaging.

As regards medicinal products that are effective against a disease or symptoms of a disease that require contact with a physician for diagnosis or treatment, the medicinal product information must further include a clear recommendation to consult a physician before using the medicinal product.

In 2020 new detailed rules in LER was introduced regarding guidelines for marketing of OTC medicinal products in digital channels, as can be seen on mobile telephones, tablets etc. The new detailed LER rules provide a so-called layered approach to communicate the required minimum information for digital advertisements in two steps. The first layer is always to include:

- the above described invitation to read the package leaflet;
- the therapeutic indication/-s; and
- a link to the second layer where the rest of the mandatory information can be found. What counts as mandatory information will vary. A concrete assessment must be made in each individual case. The requirements for the content and readability of the information, as set out above, must, however, be met.

The guidelines also cover the design of digital advertisements. The first layer of the advertisement shall be marked by a green field, as wide as the advertisement itself and at least 1/5 of the advertisement's total area. The green field must be labelled with a standardised symbol of a white cross within a white circle, and the heading 'OTC medicinal product' (Sw. *Receptfritt läkemedel*) as well as the text 'Read the patient leaflet before use' (Sw. *Läs noga bipacksedeln före användning*). The green field shall further be clickable or otherwise enable an easy passage to the second layer, via a clear and legible link.

For advertising of OTC medicinal products to the general public, the following information must not be included:

- information that gives the impression that it is not necessary to seek medical attention or to go through a surgical operation, especially if diagnosis or treatment plans are offered via correspondence;
- information that suggests that the efficacy of the medicinal product is guaranteed, that it does not result in any side effects, or is better than, or equivalent to, the effect of any other treatment or medicinal product;
- information that suggests that a person's

general well-being can be improved by using the medicinal product;
- information that suggests that a person's health may be affected by not using the medicinal product (not applicable to vaccination campaigns for infectious diseases);
- information that refers to any recommendation by scientists, HCPs or persons who, without belonging to any of these categories, could still promote the consumption of medicinal products by virtue of their position;
- information that indicates that the medicinal product is a food, a cosmetic product or some other consumer goods;
- information that suggests that the medicinal product is safe or effective because it is a natural product;
- information that could lead to an inaccurate self-diagnosis by describing a disease in detail;
- information which uses incorrect, alarming or misleading language to refer to claims of recovery stemming from the medicinal product; or
- information that uses incorrect, alarming or misleading image representations of changes in the human body caused by illness or injury, or by the effect of a medicinal product on the human body or parts of the human body.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Yes, LER provides a framework for the interaction between patient organisations and pharmaceutical companies, divided into rules for: (i) consultations; and (ii) economic (and other) support. Noteworthy, as from 1 May 2020 this framework also applies on the interaction between pharmaceutical companies and individual patients, as well as persons closely associated to patients. Below is a non-exhaustive list of restrictions and requirements in relation to such collaborations.

All collaboration shall take place in a responsible and meaningful manner, and in such a manner that the parties' independence from one another is not jeopardised or questioned from legal and/or ethical standpoints. This means inter alia that the chosen collaborative projects may not comprise an overwhelming share of the patient organisation's activity and/or economy.

All collaborations must, as a general rule, be regulated in written agreements signed by both parties. In exceptional cases, the collaboration may be documented in another appropriate way (e.g., via a written decision, minutes, or an invitation to the company activity etc.). The agreement must clearly state, e.g., the scope and purpose of the project and each party's rights and obligations. Such agreements must always be readily available for a third party. Information about the collaboration shall also be available in the database on collaborations administered by LIF (Sw. *LIFs Samarbetsdatabaser*) for the duration of the project. All projects are published for 3 years.

Moreover, there are rules on gifts, informational and educational materials, and items of medical utility as well as for patient support programs.

For economical (and other) support, further rules apply, e.g.:

- support may only be provided for specific projects and may not be used to finance the ordinary work of the patient organisation, or any other work which would give rise to a situation of dependency for the organisation;
- if the collaboration relates to the financing of events, meetings or gatherings, the invitation should be sent to the organisation's operations manager, who then decides if and who should be in attendance; and
- no independent social activities may be provided or financed by the pharmaceutical company.

For consultations, further rules apply, e.g.:

- the number of consultants should not be higher than what is necessary for the project;
- there must be a legitimate need for the assignment;
- the purpose of the consultation may not be to educate or unduly influence the consultant/-s;
- if the assignment is to provide a lecture/patient story to HCPs or the general public, the consultant may only lecture/tell about his/her own or a related's disease and possible care and not about specific medicinal products, treatments or vaccinations, i.e., the lecture may not constitute a patient testimonial;
- the consultation may not be part of an incentive to choose a specific medicinal product; and
- monetary compensation must be reasonable

in comparison to the work being provided.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Advertising of medicinal products targeting HCPs must include all essential information consistent with the SPC as approved from time to time. Information with no factual basis in the approved SPC, such as unauthorised indications, is prohibited. In addition to information directly taken from the SPC, or which can be derived from it, other information may be used. This is under the condition that such information supplements the SPC, by confirming or specifying information in it, and that such supplementary information is in conformity with the information in the SPC.

Further, advertising of medicinal products is supposed to promote the appropriate use of them by presenting information that is up-to-date, objective and balanced. No advertisements should be misleading, and all advertisements should be in accordance with good marketing practices for medicinal products and good business practices in general.

Advertising must also be identifiable as advertising. This means that advertisements disseminated to HCPs through media containing scientific or other editorial material must be presented in such a way that it will be readily recognised as advertisements. It must always be clear and evident when information material is financed by a pharmaceutical company. Written product information must clearly indicate the name and contact details (address/telephone number/website address/email) of the manufacturer or its representative responsible for the medicinal product information in Sweden.

All medicinal product information must be up-to-date and must contain a clear statement about the year of publication. Information as to the quality and efficacy of a medicinal product shall be capable of substantiation by means of documentation, e.g., any written or visual presentation containing reports on scientific facts and discoveries. Documentation to which reference is made in medicinal product information shall be of a high scientific standard. Medicinal product information that contains quotations, numerical data, diagrams etc. taken from a scientific study must clearly contain information about relevant sources and references to the documentation. Documentation must be cited in a balanced and fair way. This requirement means, e.g., that if the results of a study are contradicted by the results of another study they cannot be cited without reservation.

Information concerning medicinal products for which the relevant SPC is available at any time via Fass.se must, in the event the SPC is not reproduced, contain at least the following particulars:

- the name of the medicinal product;
- its dosage form and, if required, its strength;
- its active ingredients, specified by generic name which must be positioned close to the name of the medicinal product where this first appears as a headline or eyecatcher;
- a balanced statement of product characteristics; this description shall contain required particulars about pharmacological group or other accepted group affiliation, together with indication or area of indications;
- required warnings or restrictions as regards the use of the medicinal product;
- details of company name and contact information;
- a clear statement about the year of publication or, in the case of information on the internet, the date when the site was most recently updated;
- information about the date on which the SPC was compiled or reviewed;
- the status of the product (e.g., Rx or OTC);
- the product's status relating to the Swedish system of subsidies for medicinal products. If the medicinal product is included in the system of subsidies; the sales price for the subsidised packages (which may be stated by a reference to Fass.se according to the point below), as well as clear indication of any limitations in a decision by TLV to include the product in the system of subsidies; and
- a reference to Fass.se for further information.

In the event the current SPC for a medicinal product is not available at any time via Fass.se, written information concerning the medicinal product must contain the adopted SPC in full.

Further, information on clinical trials, or copies of journals etc. will be considered advertising under Swedish law and, as such, must be in line with the rules described elsewhere in this legal guide and be accompanied by the minimum information above. However, also mentioned elsewhere in this guide, the provision of certain information will not be considered advertising if sent as a result of an unsolicited request

by an HCP (please see questions 3a and 8 above). There is no explicit requirement to send a minimum of information along with the requested information.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Gifts are generally prohibited and shall not be provided, offered or promised to HCPs. However, LER stipulates a few exemptions from the prohibition, namely:

- Informational and educational materials can be provided if the total value does not exceed SEK 450 (incl. VAT) and under the conditions that the material is directly relevant to the practice of the recipient and directly beneficial to the care of patients.
- Items of medical utility can be provided for purposes of educating employees and for the care of patients if the total value does not exceed SEK 450 (incl. VAT) and the item is not such which is routinely used in the recipient's business.

Gifts allowed according to the above may never be supplied, offered or promised as an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Yes, subject to strict restrictions under statutory requirements. Free samples of medicinal products that have been authorised for sale in Sweden can only be provided to:

- persons qualified to prescribe the product (only those medicinal products that are included in the prescriber's right to prescribe can be provided);
- persons with a pharmacy authorisation;
- persons responsible for medicinal products in pharmacies;
- other retailers authorised to sell medicinal products; and
- pharmacists of hospital pharmacies (the sample can only be distributed to pharmacists appointed by the healthcare organisation ('**HCO**')).

Provisioning of medicinal product samples shall be done with great restraint and may only take place under the following conditions:

- only a limited number of samples of each medicinal product may be submitted to the same recipient each year;
- each sample delivery requires a written, dated and signed request from the party ordering the sample;
- a careful examination to ensure that the recipient is authorised to prescribe or dispense the medicinal product is required;
- requests must be saved to be displayed at the next inspection by MPA;
- only one package of the smallest available size must be supplied on each occasion;
- each sample shall be marked with the text 'free medicinal product test, not for sale' or any other wording having the same meaning and the expiry date;
- each sample shall be accompanied by a copy of the SPC;
- medicinal products that are considered narcotics in accordance with MPA's regulations (LVFS 2011:10) may not be provided as samples; and
- samples may not be used in the treatment of humans or animals.

LER imposes even stricter requirements stating that samples must be distributed in a very restricted manner, at most one per product per year to one and the same person. Samples of Rx medicinal products for human use can only be of new products (publicly available for less than two years). New strength or dosage form without a new indication is not considered to be a new product in this regard.

Samples may never constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Sponsorship of scientific meetings and congresses is allowed but is subject to extensive restrictions in LER.

Sponsorship of individual HCP's passive attendance to scientific events is subject to a general prohibition. The Swedish position is that the HCP's employer is responsible for its employees' training and development

of skills and carries the responsibility for related costs. Pharmaceutical companies may, in return for a reasonable counter performance, offer sponsorship to specific activities or meetings that have a connection to the pharmaceutical company's own business area. By connection is meant that the pharmaceutical company has products or conducts research within a specific therapy area. Sponsorship may only regard actual costs for a clearly defined activity or meeting. Sponsorship of regular activities, participation fees, travels and accommodation may not be given by pharmaceutical companies, or be requested by HCPs.

Sponsorship of actively participating HCPs, in the meaning engaged as speakers, panel debate members or the like, is allowed but restrictions apply. LER provides substantial regulations relating to the organisation of meetings with HCPs or an economic organisation divided into amongst other meetings arranged by or in cooperation with pharmaceutical companies, and meetings arranged by or on behalf of healthcare or an economic association. Below is a non-exhaustive list of restrictions and requirements in relation to such collaborations.

Sponsorship, as for all cooperation between pharmaceutical companies and healthcare, must abide by the six fundamental principles laid out in LER. The sponsorship must be based on trust and withstand examination and scrutiny with regard to the risk of jeopardizing trust. Further, the sponsorship must be mutually beneficial, transparent, proportional, permeated by moderation, and clearly documented in writing. In addition, the following basic principles apply to all cooperation with HCPs:

- benefits or other types of remuneration, or actions which are in breach of LER or the intentions thereof may not be offered or requested;
- moderate meals may be offered. The value of a lunch should not exceed SEK 350 (incl. VAT) per person. The value of a dinner shall not exceed SEK 950 (incl. VAT) per person;
- alcohol may only be served restrictively, and only at meals. Spirits may never be offered, and non-alcoholic alternatives must always be made available;
- recreational activities may not be financed by pharmaceutical companies. Simple social activities, such as background music or local performances, playing at the venue in connection with the meeting shall not be considered as offered by pharmaceutical companies if it has neither been organized, requested nor paid for by the pharmaceutical company;
- travel should be planned so that arrival and departure are as close to the assignment as reasonably practicable. For air travel, economy class should be selected. Duly justified exceptions may be made for travels outside of Europe with a duration of over 6 hours. Additionally, if possible, travel time may not exceed the total length of the meeting, including potential side event;
- only participants in the meeting may be invited. Accompanying individuals may not participate; and
- pharmaceutical companies may only arrange or sponsor meetings outside of Sweden or the Öresund region if the majority of the participants come from countries other than Sweden or if corresponding knowledge or experience cannot be provided in Sweden. The selection of location and venue for the meeting shall be reasonable in relation to the purpose of the meeting, and leisure resorts during season, places known for their exclusivity and locations hosting major events shall be avoided, e.g., locations for winter sports during ski season. The same applies to locations at which major international events are being staged at the same time as, or in connection with, the conference, e.g., sports events. Neither shall pharmaceutical companies sponsor conferences held at such locations.

For meetings arranged by or in cooperation with pharmaceutical companies, further rules apply, e.g.:

- the scientific and professional programme must be the purpose of the meeting;
- pharmaceutical companies may only invite to meetings where the program has a connection to the pharmaceutical company's own business areas. The pharmaceutical company is responsible for the content being compliant with LER;
- sponsoring of ordinary activities and internal activities of healthcare providers or associations are prohibited;
- invitations may be sent to relevant employees, i.e., the main target group of the meeting, with a copy of the invitation to the HCP's operations manager (or the person appointed by him/her). Invitations should also be sent to relevant pharmaceutical committees. Exemptions to the invitation procedure may be made in case of open advertising of physical meetings in printed or

web based media and for remote participation in such meetings or remote attendance in other meetings which are directed to a large target group;
- the content of the invitation is subject to restrictions such as a requirement that potential provision of product information be clearly indicated on the invitation;
- the meeting shall be held at the participants' workplace, or in the vicinity of the participants' workplace, or as close to such locality as possible, unless special circumstances warrant otherwise;
- pharmaceutical companies may finance the venue, speakers, study materials, meals and similar as is necessary to carry out the meeting. Travel and accommodation for individual participants may not be paid for by pharmaceutical companies or requested by individual participants. The service of booking of travel and accommodation may, however, be provided by pharmaceutical companies, but all related expenses shall be passed on in full; and
- participants in meetings may not be offered a fee by pharmaceutical companies and participants do not have the right to receive or request a fee for participating.

For meetings arranged by or on behalf of healthcare or an economic association that organizes employees in the healthcare sector, further rules apply, e.g.:

- the scientific and professional programme must be the purpose of the meeting;
- pharmaceutical companies may only offer sponsorship to meetings that have a connection to the company's own business areas;
- sponsorship of the ordinary activities and internal activities of healthcare or associations may not occur, such as training for an individual clinic, planning conferences, or staff parties;
- sponsorship of meetings where the meal is the only actual cost cannot be requested or offered;
- the party arranging the meeting shall well before the meeting, communicate the names of the sponsor;
- the income generated to healthcare or an association generated by sponsorships can only cover actual, documented, reasonable and direct costs that are necessary in order to carry out the professional parts of a meeting, e.g., expenses for speakers, venues, moderate meals, or the cost for training materials;
- travel, accommodation, and participation fees may not be paid for by pharmaceutical companies or requested by individual participants, nor may the service of booking of travel and accommodation be provided by pharmaceutical companies;
- the pharmaceutical company should request a complete budget for the meeting; and
- the financial outcome of the meeting shall be reported to the pharmaceutical companies sponsoring the activity, including exhibitors, within three months after the activity is completed. If the revenues from all sponsors generate a surplus to the organizer, a refund shall, as a rule, be made to the companies that have participated as sponsors.

The abovementioned rules shall also apply to meetings and conferences taking place abroad, if the sponsorship is directed to the Swedish market. Local rules for meals (e.g., the so called "Host Country Principle" in the EFPIA Code of Practice) take precedence over LER. However, in the absence of local rules or guidance the Swedish values for meals apply.

If a pharmaceutical company sponsors or participates in an international meeting arranged by a third party, or in any other way cooperates with a third party regarding the arrangements of such a meeting, the meeting must in addition be approved trough e4ethics prior to the pharmaceutical company's sponsorship or participation. The requirement only applies to meetings arranged in an EFPIA country which attracts more than 500 participants (healthcare professionals) from at least 5 EFPIA countries. Virtual meetings are exempt from this requirement.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

LER states that recreational activities in relation to scientific conferences arranged or sponsored by pharmaceutical companies are not allowed. Simple social activities, such as background music or local performances, playing at the venue in connection with the conference, shall not be considered as offered by pharmaceutical companies if it has neither been organized, requested nor paid for by the pharmaceutical company.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Yes, it is possible to pay for consultations and assignments provided by HCPs, e.g., participation in advisory boards and market research. However, such payments risk being considered improper inducements and are strictly regulated in LER. The primary rule is that consultations and assignments may never constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Further, all interaction with HCPs must comply with the general rules for cooperation (please see question 14 above). Transfers of value must also be recorded (please see question 18 below).

The remuneration paid to HCPs for their services in consultations and assignments shall be reasonable in relation to the content of the work and the time spent. Where applicable, reimbursement of expenses shall be paid in accordance with the employer's rules for travel and expenses. No other benefits, remuneration or gifts may occur. Compensation for work carried out as a part of normal work duties shall be paid to the employer.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Yes, grants and donations are permitted within strict boundaries. Detailed rules are provided for in LER. First and foremost, all cooperation must comply with the general rules for cooperation (please see question 14 above).

Secondly, grants and donations to healthcare are only allowed if they are made to support research and development. Grants and donations may never be offered or requested to fund healthcare's internal or regular activities and pharmaceutical companies' grants and donations may not be requested or offered for the finance of recreational activities.

Thirdly, grants and donations to healthcare shall not be connected to past, present or potential future use, recommendation, sale or prescription of the donor's products or services, and may not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Finally, the donor shall keep a register of the grants and donations given and the donation or grant shall be transparent and be well documented.

In general, it does not matter if the grant or donation is monetary or in kind, if the result is a monetary gain. What constitutes a monetary gain can, e.g., be calculated based on potential savings for the HCP or the HCO in which the HCP is employed.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Yes, pharmaceutical companies are required to disclose details of transfers of value to HCPs or HCOs. This is mandated in LER, where it is stipulated that any direct or indirect transfers of value that are made to or for the benefit of the recipient must be clearly documented and publicly disclosed.

Below follows a brief description of what the companies must report and how:

- disclosure should be made annually and comprise a full calendar year. Companies are strongly recommended to report transfers of values on the last weekday in May and should report the transfers by 30 June at the latest. The details shall remain public for a period of three years;
- disclosure should be made in accordance with a template created by LIF and available via their web page;
- disclosure can either be performed via LIF's co-operation database or on the pharmaceutical company's website. If the company's website is used, a link to the website shall be placed in LIF's co-operation database;
- disclosure shall, in general, be performed in accordance with the rules of the national code that applies to the country where the recipient has its principal place of business or its seat. If the recipient is situated in another European country than Sweden, and if the pharmaceutical company cannot disclose the transfer of values through a member of its group of companies in the country of the

recipient, the pharmaceutical company shall disclose the transfer of value according to LER;
- disclosure should be made in Swedish. However, pharmaceutical companies are encouraged to also disclose the information in English;
- details on transfers of value shall be documented by the pharmaceutical company and be maintained for a period of at least 5 years following the expiry of each reporting period; and
- depending on the circumstances of the situation, reporting can be made on an individual level or an aggregate level.

Transparency requirements for foreign companies and/or companies that do not yet have products on the market:

- the rules on transparency in LER apply to all companies bound by LER that target or are active on the Swedish market. Foreign companies and companies awaiting a marketing authorisation may therefore be covered by the rules in LER; and
- it is the duty of the Swedish marketing companies to ensure that the rules in LER are observed by parent companies and sister companies in the event of activities on the Swedish market or targeted at the Swedish market. It is also the duty of the Swedish marketing companies to enjoin business partners to comply with LER in license agreements or similar.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

A competent authority's involvement in authorising advertising in advance would most likely be considered illegal censorship under the Swedish Constitution. However, the provisioning of certain non-commercial information, relating to Rx medicines, on the internet may only be provided on websites that are authorised by IGN, so called 'pre-approved websites' (please see question 9 above).

The Medicinal Products Act and Marketing Practices Act applies to all advertising that is directed to the Swedish market, including on the internet and through social media. Thus, all requirements and restrictions on advertising of medicinal products mentioned elsewhere in this legal guide will also apply to advertising on the internet (including social media) for medicinal products. Further, in 2020 LIF issued guidelines for marketing of OTC medicinal products via digital channels on mobile phones and tablets (please see question 9 above). Moreover, LIF has issued guidelines for the use of digital channels in accordance with LER (Sw. *Användande av digitala kanaler utifrån Läkemedelsbranschens etiska regelverk*).

In general, the same rules apply in relation to necessary and prohibited information, please see question 9 above regarding advertising directed at the general public and question 11 above regarding advertising directed at HCPs. Websites must clearly indicate their intended target audience (HCPs or general public) and the presentation (content, links, etc.) must be adapted to it. Medicinal product information on the internet must contain a clear statement about the date when the site was most recently updated, as well as a designation that makes it possible to identify the information as advertisement without difficulty. Pharmaceutical companies are responsible for all content in the digital channels they use, including comments on their posts or for posts made by so called influencers that the company might employ. LER's guidelines also provide guidance on the use of specific social media, e.g., Facebook and Twitter. The disciplinary bodies of LIF, i.e., IGN and NBL, have found that exemptions may apply to internet banners – recognising the difficulties in providing the required minimum information on the banner itself. However, the disciplinary bodies uphold a strict position on the requirements to provide minimum information and for it to be easily legible, especially when it comes to short video clips.

As advertisements on Rx medicinal products must only be disseminated to HCPs, access restrictions apply. The mechanism commonly used, which is recognised as compliant by LIF's disciplinary bodies IGN and NBL, is any form of self-verification where the viewer confirms that she or he is an HCP. However, it is not certain whether such systems would be approved by a court of law.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

Yes, the anti-bribery provisions in the Swedish Penal

Code (1962:700) apply to all interaction between pharmaceutical companies on the one hand, and HCPs and HCOs on the other. The provisions mainly provide as follows:

- an employee or contractor may not receive, accept a promise of or request an improper benefit for carrying out an employment or assignment (passive bribery);
- it is not permitted to provide, promise or offer an improper benefit to an employee or contractor for carrying out an employment or assignment (active bribery);
- it is not permitted to receive, accept a promise of or request an improper benefit in order to influence a person who exercises public authority or decides on public procurements, or to provide, promise or offer an improper benefit in order for the recipient to influence the decision maker when exercising public authority or deciding on a public procurement (trading in influence); and
- a businessman must act with caution when providing cash or other assets to its representatives, agents, cooperation partners and other representatives to ensure that the funds are not used for bribes (negligent financing of bribery).

The rules on anti-bribery in the Penal Code do not entail a legal definition of what constitutes an "improper benefit". A court shall consider all factors relevant to the circumstances of the case at hand to decide on what is an improper benefit.

Further, LER holds several rules on all interaction between pharmaceutical companies on the one hand, and HCPs and HCOs on the other hand, including inducements as mentioned under questions 13-17 above. The rules on anti-bribery are interpreted against the content of the industry code.

Additionally, the Swedish Anti-Corruption Institute (Sw. *Institutet Mot Mutor*) issues a national code of practice for business conduct, the Code to Prevent Corruption in Business (the '**IMM Code**'). The IMM Code is in principle stricter than the anti-bribery provisions in the Penal Code, and the outspoken purpose of the code is that it should provide businesses with guidance so that they are able to determine what constitutes a permitted or an improper benefit. The IMM Code also provides guidance for companies on matters relating to preventive measures to be adopted against corruption and in matters regarding control measures that need to be adopted in relation to intermediaries in order to avoid bribery.

The provisions mainly provide as follows:

- all kinds of gifts, rewards and other benefits, even those without real direct financial value, e.g., memberships in exclusive clubs or prestigious awards, may constitute an improper benefit;
- it is forbidden to provide any benefits to those who exercise public authority or decide on public procurements;
- there are other categories for which particular restrictiveness should be observed such as employees or contractors at public entities, even if they do not participate in the exercise of public authority or in public procurements, or in sectors where integrity is particularly sensitive and in which particular interests must be protected; and
- no matter the recipient, certain forms of benefits are improper and should not be provided, e.g., (i) monetary gifts and loans of money; (ii) goods and services for private purpose and private discounts on goods and services; (iii) access to vehicles, boats and holiday homes; (iv) holiday trips; (v) offers that are perceived as generally unethical, e.g., purchase of sexual services and strip club visits; and (vi) benefits that may result in the giver gaining a hold over the recipient.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The statutory rules applying to the offering of benefits or inducements to HCPs are the anti-bribery provisions in the Swedish Penal Code (1962:700), please see question 20 above.

On top of the anti-bribery provision, detailed rules on the offering of benefits or inducements to HCPs can be found in LER, please see questions 12-18 and 20 above. Additional self-regulation can be found in the IMM Code, please see question 20 above.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

Public courts (anti-bribery, statutory rules on inducements).

The Patent and Market Court, the Patent and Market Court of Appeal (the Supreme Court – theoretically) (marketing practices under the Marketing Practices Act).

MPA (supervisory authority under the Medicinal Products Act).

The Administrative court in Uppsala, the Administrative Court of Appeal in Stockholm and the Supreme Administrative Court (appeals of MPA decisions).

IGN and NBL (self-regulation; marketing and inducements).

The Swedish Consumer Agency (supervisory authority under the Marketing Practices Act).

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

A company can initiate infringement proceedings against competitors before the Patent- and Market Court, if the competitor's marketing is in violation of any part of the Marketing Practices Act, such as the general clause prohibiting unfair advertisement.

A company can also report a violation of the Medicinal Products Act or of LVFS 2009:6 to MPA, which in turn can issue a prohibitive injunction against the competitor's advertisement. MPA decisions are appealed to the Administrative Court in Uppsala, the Administrative Court of Appeal in Stockholm and the Supreme Administrative Court.

Further, companies bound to comply with the self-regulatory system established by LER (please see question 2 above) may turn to the disciplinary bodies IGN and NBL. Companies not bound to comply with LER can in individual cases agree to subject themselves to the procedures before IGN and NBL and their disciplinary regime. IGN and NBL monitor pharmaceutical companies' adherence to statutory law, LER and good marketing practices. A company can report a competitor's infringement of good marketing practices to IGN or NBL. For most types of cases, IGN is the first instance and NBL the instance of review to which the aggrieved party can appeal an undesired outcome in IGN. If the complaint concerns a pre-approved website (which is approved by IGN) (please see question 9 above) it can be reported to NBL directly.

Finally, an infringement of the Marketing Practices Act can be reported to the Swedish Consumer Agency which can issue a prohibitive injunction against the infringer.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

A violation of the Medicinal Products Act will often result in a prohibitive injunction subject to fines. MPA also has the power to issue provisional orders, requesting information and documents, as well as injunctions to take corrective measures, where both may be subject to fines. Besides an injunction subject to fines, several other measures are available to the Swedish Consumer Agency and the courts, depending on the nature of a violation of the Marketing Practices Act. For example, misleading advertisement and special offers may result in market disruption fees up to 4 % of the trader's annual turnover in the financial year preceding that in which the infringement ceased or in which the trader was served with the writ of summons and damages suffered by third parties. However, this is generally not applicable when it comes to breaches of the general clause on unfair marketing.

If a company's online marketing is in violation of the Medicinal Products Act and sanctions cannot be imposed with other means, MPA may issue an injunction ordering a company, a hosting service provider or an internet provider to insert a warning message that is clearly displayed on the website where the marketing occurs. Such an injunction may be subject to fines.

The self-regulatory bodies NBL and IGN can order payment of disciplinary fines up to SEK 500,000 for violation of good business practices. The fines are paid to LIF. IGN or NBL may in cases of gross violations, in addition to the fine, instruct the company to issue a corrective public statement.

Criminal sanctions can be taken against individuals guilty of giving or taking bribes or other similar criminal offences. Additionally, for such criminal offences a company may be imposed with a criminal corporate fine. The maximum amount of the fine is SEK 10 million for small companies and SEK 500 million for large companies. Large companies are defined as either a company whose securities are traded on a regulated market, or a company that fulfills more than one of the following conditions: has an average number of employees that exceeds 50 people, has had a balance-sheet total of over SEK 40 million the last two years, has had a net-turnover total of over SEK 80 million the last two years. Small companies are defined as companies that are not large companies.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

MPA, as the supervisory authority in the pharmaceutical sector, acts independently from the self-regulatory bodies NBL and IGN. However, MPA can report cases to the self-regulatory bodies, or review the decisions of the self-regulatory bodies by its own initiative. Courts and other authorities, such as MPA, can ask NBL to make a guiding statement about a question. Nothing prevents cases to be investigated concurrently by both MPA and IGN or NBL.

The decisions and statements of IGN and NBL are not legally binding per se, but they are binding on a contractual basis for the parties mentioned under question 2 above, and courts may use LER and the decisions of IGN and NBL to determine what is considered good marketing practices in the context of medicinal products marketing.

The decisions of MPA and of the courts are binding vis-à-vis the involved parties, and the court decisions may serve as precedents. The self-regulatory bodies must follow the developing case-law and not make conflicting decisions in individual cases or in their general guidance statements. However, the self-regulatory bodies are free to impose a stricter perspective than law, as the starting point for LER is that in the event of conflict between applicable provisions according to law, LER, the EFPIA Code of Practice, or the IFPMA Code of Practice, the most restrictive provision shall apply.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

2023 has offered several cases in IGN and NBL revolving around the outer boundaries of what qualifies as marketing and is thus subject to LER and what falls outside the scope of marketing. For example, several cases have centred around whether advertisements constitute marketing or so-called institutional advertising (i.e., promoting the company in general rather than a specific product of the company), instructional material or informational material. One of the more interesting cases to this end focused on an advertisement by the only Swedish manufacturer of Covid-19 vaccine. The advertisement in question was published in Sweden's third largest daily newspaper. Due to the content of the advertisement, i.e., the positive and value-based description of the vaccine's characteristics, IGN assessed the advertisement as marketing in scope of LER rather than institutional advertising not in scope of LER. The assessments by IGN and NBL of whether a particular advertisement qualifies as marketing or not are made *in casu*, wherefore caution is advised before drawing general conclusions. Nevertheless, a trend towards IGN and NBL expressing an extensive interpretation of marketing is indicated which emphasizes the importance of carefully designing any institutional advertising, informational material or instructional material to remain as such and not qualify as marketing.

One noteworthy enforcement trend in IGN and NBL case law is the focus on marketing via digital channels and social media, mirroring the overall conversion into digital marketing. The trend has been evident since 2020. In 2020 several cases involved sponsoring of tv shows and short videoclips online, meanwhile 2021 offered several cases regarding information about medicinal products on internet banners. The trend continues through 2022 and 2023 focusing on marketing via internet banners and TV as well as via social media (e.g., Facebook and Instagram). One interesting case from 2023 revolved around the display time of the required minimum information in a videoclip on Facebook and Instagram marketing an OTC medicinal product. According to NBL, the minimum information must be displayed for a duration long enough to enable the viewer to assimilate the information. It is thus not sufficient to display the minimum information for a shorter period of time with the option for the viewer to pause the video to read the information, or to loop the video providing the viewer the option to rewatch the video to read the information.

Another interesting enforcement trend is the relationship between MPA and IGN and NBL. During 2023, this relationship has been displayed by MPA initiating cases in NBL by filing complaints claiming that pharmaceutical companies violate LER in their advertisements (e.g., claims have been made in advertisements that does not have support in the SPC). On multiple occasions, NBL has found the complaints to be justified and that the advertisements are in fact violating LER, demonstrating the interplay between MPA as supervisory authority and IGN and NBL as self-regulatory bodies.

Yet another noteworthy enforcement trend is the focus MPA has put on advertisement of products containing different types of Cannabidiol ("**CBD**"). Several recent cases with products containing CBD have been investigated by MPA and resulted in prohibitive injunctions under penalty of fines. Of particular interest is two cases which, among others, revolves around the

jurisdiction of MPA. In both cases, products containing CBD were sold via internet by companies domiciled in the Netherlands. MPA considered both cases to fall within its jurisdiction. The Administrative Court in Uppsala upheld MPA's assessment in the *Administrative Court in Uppsala case no. 4526-20* and the *Administrative Court in Uppsala case no. 1702-21*. The latter judgement was appealed to the Administrative Court of Appeal in Stockholm. The Administrative Court of Appeal in Stockholm upheld the appealed judgement in *Administrative Court of Appeal in Stockholm case no. 4211-22*. In addition to clarifying the jurisdiction of MPA, the two cases – along with the *Administrative Court in Uppsala case no. 8495-19*, which also concerns products containing CBD – further emphasize the extensive definition of what constitutes a medicinal product under Swedish law and is thus subject to the requirements under the Medicinal Products Act. MPA's focus on CBD products is further displayed by the *Administrative Court in Uppsala case no. 2513-22*, in which MPA successfully applied to the administrative court to impose a fine of SEK 90,000 on a company selling CBD products due to violating a prohibitive injunction.

One final enforcement trend that can be seen from IGN and NBL is the particular focus on warning about adverse reactions. More specifically, IGN and NBL have in many cases highlighted the need to warn about restrictions or potential adverse reactions during pregnancies if the advertisement targets women in fertile age.

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