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Pharmaceutical Advertising

Sweden
Håkan Borgenhäll, Kristina Ekberg and Jakob Kraus
Advokatfirman Vinge KB

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Law and Practice

Contributed by:
Håkan Borgenhäll, Kristina Ekberg and Jakob Kraus
Advokatfirman Vinge KB see p.15

Contents

1. Regulatory Framework p.4
- 1.1 Laws and Self-Regulatory Codes p.4
- 1.2 Application and Legal Value of Regulatory Codes p.4

2. Scope of Advertising and General Principles p.4
- 2.1 Definition of Advertising p.4
- 2.2 Difference Between Information and Advertising p.4
- 2.3 Restrictions on Press Releases p.5
- 2.4 Comparative Advertising p.5

3. Advertising of Unauthorised Medicines or Unauthorised Indications p.6
- 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications p.6
- 3.2 Provision of Information During a Scientific Conference p.6
- 3.3 Provision of Information to Healthcare Professionals p.6
- 3.4 Provision of Information to Healthcare Institutions p.6
- 3.5 Publication of Compassionate Use Programmes p.6

4. Advertising to the General Public p.7
- 4.1 Main Restrictions on Advertising to the General Public p.7
- 4.2 Information Contained in Advertising to the General Public p.7
- 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry p.8

5. Advertising to Healthcare Professionals p.8
- 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals p.8
- 5.2 Reference to Data Not Included in the Summary of Product Characteristics p.9
- 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics p.9
- 5.4 Restrictions on Reprints of Journal Articles p.9
- 5.5 Medical Science Liaisons p.9

6. Vetting Requirements and Internal Verification Compliance p.10
- 6.1 Requirements for Prior Notification/ Authorisation p.10
- 6.2 Compliance with Rules on Medicinal Advertising p.10

7. Internet p.10
- 7.1 Regulation of Advertising of Medicinal Products on the Internet p.10
- 7.2 Advertising of Medicines on Social Media p.10
- 7.3 Restrictions on Access to Websites p.10
- 7.4 Provision of Disease Awareness Information to Patients Online p.10

8. Inducement/Anti-bribery p.10
- 8.1 General Anti-bribery Rules p.10
- 8.2 Legislative or Self-Regulatory Provisions p.11

9. Gifts, Hospitality, Congresses and Related Payments p.11
- 9.1 Gifts to Healthcare Professionals p.11
- 9.2 Limitations on Providing Samples to Healthcare Professionals p.11
- 9.3 Sponsorship of Scientific Meetings p.11
- 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events p.12
- 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions p.12
- 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions p.12
- 9.7 Payment for Services Provided by Healthcare Professionals p.12
- 9.8 Prior Authorisations or Notifications p.13

10. Transparency p.13
- 10.1 Requirement to Disclose Details of Transfers of Value p.13
- 10.2 Foreign Companies and Companies that Do Not Yet Have Products on the Market p.13

11. Enforcement p.13

11.1 Enforcement Bodies p.13

11.2 Initiating Proceedings for Advertising Infringements p.14

11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe p.14

11.4 Relationship Between Regulatory Authorities and Courts p.14

11.5 Recent Enforcement Trends p.14

1. Regulatory Framework

1.1 Laws and Self-Regulatory Codes

The Medicinal Products Act (2015:315) establishes the general requirements on advertising of medicinal products. Advertising must be in accordance with good marketing practice, be up-to-date, objective, balanced and not be misleading. Further clarifications are found in the Swedish Medicinal Products Agency's (MPA) Regulation LVFS 2009:6 on the marketing of medicinal products for human use, which implements Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The Swedish Radio and Television Act (2010:696) contains limitations with regards to advertisements of medicinal products through, eg, teleshopping (which is prohibited), and sponsorships of TV advertisements.

Moreover, the Marketing Practices Act (2008:486) sets out rules that are applicable on all products and services, including medicinal products. According to this Act, advertising must comply with good marketing practice and all marketing claims must be accurate and therefore not misleading. The Act also regulates matters relating to, eg, comparative advertisement and special offers.

The Swedish Association of the Pharmaceutical Industry (LIF) has adopted the Ethical Rules for the Pharmaceutical Industry (the "LER Rules"), which govern advertising and information of medicinal products towards healthcare professionals and to the general public. The Information Examiner Committee (IGN) and the Information Practices Committee (NBL) are the two regulatory bodies that supervise compliance with the LER Rules. The LER rules, and the decisions from IGN and NBL, are not legally binding but they are, however, recognised by the pharmaceutical industry and should be seen as a complementing set of rules to current legislation.

The LER Rules and decisions from the committees may also be considered by Swedish courts when determining, eg, good marketing practice. The Code of Advertising and Marketing Communication Practice issued by the International Chamber of Commerce (the "ICC Rules") is also considered by the Swedish court when determining good marketing practice.

1.2 Application and Legal Value of Regulatory Codes

The LER Rules apply to members of LIF as well as to the Association for Generic Pharmaceuticals and Biosimilars in Sweden (FGL) and Innovative Smaller Life-science companies (IML).

Only members may be subject to sanctions under the LER-rules, eg, penalty fees. However, the committees of LIF can review matters relating to medicinal products from non-members although these non-members cannot be subject to any sanctions.

The LER Rules are not legally binding. However, as stated in **1.1 Laws and Self-Regulatory Codes**, the LER Rules are recognised within the pharmaceutical industry and they may be applied by courts in order to determine, eg, good marketing practice.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Regarding the definition of advertising, LVFS 2009:6 makes a reference to directive 2001/83/EC and cites the Directive's definition of advertising of medicinal products. Accordingly, advertising of medicinal products includes "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products".

Examples of what could constitute advertising under LVFS 2009:6 may be advertising of medicinal products to the general public or healthcare professionals, visits by sales persons to healthcare professionals, sponsorship of promotional meetings attended by healthcare professionals or supply of samples. From the expression "any form" it can be concluded that the definition of advertising of medicinal products is very broad.

The Marketing Practices Act defines marketing practice as "advertising and other measures in commercial activities which are intended to promote the turnover of, and access to, products, including a trader's acts, omissions, or other measure or behaviour before, during or after the sale or delivery of products to consumers or traders".

2.2 Difference Between Information and Advertising

There is no sharp line between information and advertising. Information is part of a broader scope and may fall within the relevant marketing provisions. According to the preparatory works, where there is ambiguity on whether or not a statement is to be considered as advertising, the Act should be interpreted in the light of directive 2001/83/EC.

The decisive criteria in order to distinguish between advertising and information (which, as a rule, does not fall under the advertising rules) is the purpose of the communication. The assessment of whether the communication has a promotional purpose

or not should be based on an assessment of all the relevant circumstances on a case-by-case basis. If the information does not have a promotional purpose or includes non-commercial information, it may fall outside the relevant marketing provisions.

The content in, eg, patient leaflets or information regarding patient support programmes may be considered as advertising if, for example, the information can be seen as an inducement designed to promote the prescription, supply, sale or consumption of medicinal products, ie, having a promotional purpose.

In LVFS 2009:6, examples of activities that are not covered by the term "advertising" can be found. Correspondence or material of non-promotional nature, which is necessary to answer a specific question regarding a medicinal product, is not considered as advertising. Neither is factual and informative announcements or material relating to, eg, pack changes, adverse-reaction warnings as part of general drug precautions or trade catalogues part of the term advertisement provided that this information does not include any claims of the medicinal product. Furthermore, information regarding human health or diseases, eg, disease awareness campaigns, are not covered by the term advertising provided that the information does not include any direct or indirect reference to medicinal products.

Further, mere factual and informative messages on, eg, the product packaging is not considered as advertising provided that there are no claims, (eg, regarding effects) about the medicinal product and that the information otherwise comply with relevant legislation.

With regards to vaccinations of humans against infectious diseases, the LER Rules states that such campaigns are not regarded as marketing of a certain medicinal product provided that the purpose is to provide the general public with necessary information regarding protection against infectious diseases through vaccination. Another requirement hereto is for instance that the product name, the product logotype or similar distinctive marks or features such as administration method are not included in the information.

The actual definition of advertising does not differ depending on if the information is aimed towards the general public or to health care professionals. However, lawfulness of the advertising depends on whether the advertising is aimed towards the general public or health care professionals, see **4.1 Main Restrictions on Advertising to the General Public** and **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**.

2.3 Restrictions on Press Releases

In general, Swedish legislation or self-regulatory codes do not set out any specific restrictions on what type of marketing activities that are allowed. Irrespective of type and form, any advertisement must be in compliance with the applicable advertising rules, such as the Medicinal Products Act as well as LVFS 2009:6, the Marketing Practices Act and the LER Rules.

Both IGN and NBL have in several cases concluded that press releases published by pharmaceutical companies, or which are made available by pharmaceutical companies, through a specific link targeting journalists, do not constitute advertising and thus fall outside the scope of the LER Rules. Whether or not a press release falls within the scope of the LER Rules is assessed on a case-by-case basis. If the press release is of scientific nature and is presented in a clear and objective way and does not promote the pharmaceutical company's own product and does not discredit another company's medicinal product, it will likely fall outside the scope of the LER Rules.

2.4 Comparative Advertising

Comparative advertisement is allowed under Swedish law under certain conditions.

The Medicinal Products Act includes general requirements that advertising must be up-to-date, objective, balanced and not be misleading. These requirements must be considered when a medicinal product is compared with another medicinal product. According to LVFS 2009:6, it is not permitted, in relation to advertising to the general public, to claim that a medicinal product is better, or equal to, another treatment or medicinal product.

The Marketing Practices Act includes general provisions relating to comparative advertisement between two traders. The Act implements Directive 2006/114/EC concerning misleading and comparative advertising. A trader can directly or indirectly refer to another trader or such trader's products provided that the comparison is not misleading, objectively relates to relevant, verifiable and distinguishing characteristics of the products and does not discredit the other trader's business or product.

The LER Rules contain specific rules regarding comparisons of medicinal product information towards the general public and healthcare personnel concerning, eg, effects, active ingredients and cost of treatment. Generally, the comparison must be performed in a fair way and be relevant, objective and truthful.

A comparison may not mislead the recipient. This entails that the:

- objects that are subject to the comparison are specified and, if necessary, the name of the medicinal products and generic names of the compared products are stated;
- comparisons of properties of synonymous medicinal products, or of medicinal products with the same indications, must provide a comprehensive and fair view of the compared properties; and
- comparison of certain properties may not lead to incorrect or misleading conclusions regarding properties that are not subject to the comparison.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The Medicinal Products Act prohibits advertising of medicines or indication(s) that have not been authorised for sale in Sweden. All advertising must correspond with the Summary of Product Characteristics (SmPC), as well as with the authorised indication(s), of the authorised medicinal product.

Distribution of information on unauthorised products or indication(s) and which entails a promotional purpose may be considered as unlawful pre-launch advertising or off-label advertising.

3.2 Provision of Information During a Scientific Conference

As stated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is, as a general rule, prohibited to advertise unauthorised medicines or indications in Sweden. If the information on unauthorised medicines or indications during a scientific conference is considered to have a promotional purpose in relation to, eg, a specific medicinal product, it may likely be deemed unlawful pre-launch or off-label advertising. However, if the provided information has a purely informational purpose, without any references to or claims regarding a specific medicinal product, it may be permissible. In light of the broad interpretation of advertising, such provision of information should nevertheless be performed with great care.

Furthermore, according to an opinion by LIF, information regarding pipeline drugs (ie, drug candidates that a pharmaceutical company has under discovery or development) is not accepted within commercial areas, eg, at exhibition stands at conferences.

Under the LER Rules it is, however, under certain circumstances, possible to refer to a medicinal product authorised in another country than Sweden at a conference taking place in Sweden. This requires that the event is an international scientific meeting where the majority of the participants come from countries outside Sweden. Furthermore, the marketing material must, for instance, contain information regarding in which countries the medicinal product has been authorised for sale and that it has not been authorised for sale in Sweden. In addition, LIF has stated that it is permissible under the above circumstances to present a general pipeline overview that briefly includes phase, number of products, indications and name/substance. This overview should, according to LIF, be very short and general and not constitute the major part of, eg, the exhibition stand.

3.3 Provision of Information to Healthcare Professionals

As stated above, advertising of unauthorised medicines or indications is in general prohibited. This prohibition applies to advertising to healthcare professionals, as well as advertising to the general public. Sending unsolicited information on unauthorised medicinal products or indications to healthcare professionals may thus constitute unlawful pre-launch or off-label advertising.

However, individual correspondence, accompanied by material of non-promotional nature if necessary, does not fall under the advertising provisions if it is required in order to respond to a specific query regarding a medicinal product. Accordingly, it may be allowed for a pharmaceutical company to respond to a specific query from a healthcare professional concerning, eg, off-label use. The response shall not, however, go beyond the specific query.

3.4 Provision of Information to Healthcare Institutions

As stated above, unsolicited communications with healthcare professionals may be deemed as unlawful pre-launch or off-label advertising.

However, LVFS 2009:6 provides an exemption concerning price lists, which may be of relevance. Under this exemption, factual and informative announcements and reference material relating to, eg, trade catalogues and price lists, are not considered to be advertisements provided that they do not include product claims.

3.5 Publication of Compassionate Use Programmes

Compassionate Use Programmes, ie, a treatment option that allows the use of an unauthorised medicinal product towards patients who have a disease with no satisfactory authorised

therapies, may be available in Sweden under strict conditions. The MPA is the competent authority in this regard.

There are no specific provisions relating to the publishing of a compassionate use programme or other forms of early access. As stated above, advertising of medicines or indication(s) that have not been authorised for sale in Sweden is prohibited. In the light of the broad interpretation of the term advertising, information regarding a medicinal product's use in connection with a compassionate use programme may be deemed unlawful off-label or pre-launch advertising. However, this assessment must be made on a case-by-case basis.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising to the General Public

The Medicinal Products Act explicitly prohibits advertising of prescription-only medicines (except for vaccination campaigns on human infectious diseases) towards the general public. The prohibition also includes advertising of medicinal products or indications that have not been authorised for sale in Sweden and advertising of medicinal products targeting children.

According to the LER Rules, it is, however, allowed to provide information to the general public on prescription-only medicines through the Pharmaceutical Specialities in Sweden's, Sw.Farmaceutiska specialiteter i Sverige, (FASS) website (a system used by the health care industry that provides information regarding all authorised medicinal products for human use where patients can get access to the SmPC and the leaflet), to the extent the information complies with the requirements under Swedish legislation. It is also permitted to provide information through, eg, brochures if the information is intended to be handed to a patient by healthcare personnel to facilitate the patient's correct use of the medicine.

Furthermore, to ensure public access to information on prescription-only medicines, a pharmaceutical company may provide information regarding such products on a website (pre-approved website) administered by a pharmaceutical company provided that pre-examination and pre-approval has occurred. This pre-approval system has been introduced by LIF. Any pharmaceutical company that complies with the LER Rules may apply for a pre-approval. The company is not allowed to actively market the website. Instead, the user must seek the information on its own.

Advertising of over-the-counter medicines is allowed in Sweden but subject to comprehensive regulation.

As a general rule, all advertising must be up-to-date, objective, balanced and not be misleading. It must also correspond to the SmPC.

4.2 Information Contained in Advertising to the General Public

When advertising a medicinal product that addresses the general public, it must be made clear that the message is an advertisement and that the product is a medicinal product.

The content of the advertising shall not be construed in a way that could result in the medicinal product being used in a harmful way or that could result in people not seeking appropriate care. Furthermore, the advertising must correspond to the SmPC in all respects.

According to LVFS 2006:9 and the LER Rules, the advertising must at least contain the following information:

- the name of the medicinal product and the common (ie, the generic) name if the medicinal product only contains only one active ingredient;
- information that is necessary to facilitate the correct use of the medicinal product including any necessary warnings or limitations of use. Such information can relate to the need for contact with the healthcare for a diagnosis before treatment or if treatment does not have any effect within a certain time, limitations in treatment for children and pregnant women or limitations in the duration of the treatment;
- an explicit and easy-to-read invitation to take note of the package leaflet or the outer packaging, as the case may be;
- its dosage form;
- contact information of manufacturer or applicable representative;
- information on the year of publication of the information or, if applicable, the date when the webpage was last updated; and
- if the advertising concerns an over-the-counter medicinal product that has an effect against a disease or symptoms of a disease, which requires contact with the healthcare for diagnosis or treatment or a recommendation to consult a physician prior to the use of the product.

The price of a medicinal product may be disclosed in an advertisement, but this is not mandatory.

According to LVFS 2009:6, advertising of medicinal products to the general public may not contain any information that, inter alia:

- gives the impression that it is not necessary to consult a doctor or that a surgical operation is unnecessary;

- suggests that medicine effects are guaranteed, are without adverse reactions or are better than, or equivalent to, another treatment or product;
- suggests that a person's health can be enhanced by taking the medicine;
- suggests that a person's health may be affected without taking the medicine (with the exception for vaccination campaigns);
- refers to recommendations by, eg, scientists or health professionals or other persons, who, because of their celebrity, could increase the use of the medicinal product;
- suggests that the medicinal product is equal to any foodstuffs, cosmetics or other consumer goods;
- suggests that the safety or effect of the medicinal products is due to the content being derived from nature;
- could lead to a wrong self-diagnosis, eg, by describing a case history;
- contain exaggerating or misleading claims on cure; or
- contain exaggerating or misleading visual representations of changes in the human body caused by disease or injury.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The relationship between pharmaceutical companies and patients is not specifically regulated under Swedish law. However, such interaction is covered by the applicable advertising provisions targeting the general public (in which patients are included). For instance, a pharmaceutical company is not allowed to provide free samples to patients when advertising a medicinal product.

The LER Rules contain a comprehensive set of ethical rules with regards to co-operation between pharmaceutical companies and user organisations or interest groups, such as disability and patient organisations. These rules aim to ensure that collaborations, information and training are designed in a way that the parties' independence from each other is not jeopardised or doubted from a legal or ethical point of view. This entails that any collaboration project cannot consist of the main part of the organisation's business and/or economy.

The LER Rules contain four main sections regarding collaborations that apply to pharmaceutical companies and comprise collaborations such as research, training, consultancy and market studies.

First, regarding transparency and contract, a collaboration should be regulated in a written agreement containing provisions regarding, eg, financing, rights and obligations. Any agreement hereto (both related ongoing, concluded and future collaborations) should be kept available for third parties.

Second, regarding economic and other support, such support may only be provided to specified projects. A pharmaceutical company may not provide economic or other support that:

- intends to finance the organisation's daily and regular operations;
- results in an organisation's business being unable to continue after the termination of the collaboration agreement;
- causes circumstances of dependency between the parties; and
- exceeds the costs for the activities under the collaboration.

Third, regarding consultation, when a pharmaceutical company engages a representative of an organisation for consultation, the pharmaceutical company must ensure that there is a legitimate need for the assignment. It is important to note that the engagement may not constitute encouragement to promote a product or a pharmaceutical company. Prior to the engagement, the enquiry must be made to the responsible persons within the organisation who shall decide whether to accept the assignment. A written agreement should be concluded between the organisation of the representative and the pharmaceutical company. This agreement must regulate the remuneration for the assignment, which should be reasonable in relation to the performed work and time spent. The pharmaceutical company may pay for travel, boarding and accommodation relating to the consultation assignment provided that the costs are moderate. No other benefits, remunerations or gifts may occur. In relation to public announcements, the pharmaceutical company must announce that the representative is a consultant of the pharmaceutical company.

Fourth, regarding the general rules for co-operation, collaboration must be transparent. In all information materials and invitations, it must be made clear that it is a collaborative project. These rules also apply to advertising or PR agencies.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The Medicinal Products Act and LVFS 2009:6 set out general rules for advertising of medicinal products to healthcare professionals. In particular, LVFS 2009:6 states that all advertising must include essential information that corresponds to the SmPC and the supply classification of the medicinal product. The documentation relating to the advertising must include the date it was drawn up or last revised.

The advertisement must be accurate, up-to-date, verifiable and sufficiently complete in order for the recipient to form his or her own opinion about the product's therapeutic value. Furthermore, any quotations, tables or other illustrative material from medical journals or other scientific works that are used in the advertising must include the source.

The LER Rules contain slightly more detailed rules on what information advertising must include. Provided that the FASS catalogue text or the SmPC is not reproduced, the information must, as a minimum, encompass the following data according to the LER Rules:

- the product's name;
- its dosage form and, if required, its strength (it is required to include the strength if the product, eg, is offered in different strengths);
- its active ingredients, indicated by generic name;
- a balanced statement of the product's characteristics, including particulars of the pharmacological group or other accepted group affiliations and indication/area of indications;
- warnings and restrictions in relation to the use of the product;
- name and contact information (address or telephone number or web address) of the manufacturer or of its representative who is responsible for the medicinal product information in Sweden;
- information on the year of publication or the date when the webpage was last updated if advertising occurs on the internet;
- information regarding the date the SmPC was compiled or reviewed;
- the status of the product (whether it is a prescription-only medicine or over-the-counter);
- if the product is included in the Swedish benefits system, including any restrictions, and if it is included in the benefits system, the sales price for the subsidised package (it is, however, not necessary to state the price as such); and
- a reference to fass.se for further information.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

As a main rule, advertisements of medicinal products may not contain information, such as therapeutic indications, pharmacological properties or other characteristics, which conflict with the SmPC.

However, according to a decision from NBL, references to new studies that which did not constitute the basis in the SmPC is allowed in accordance with the judgment from the Court of Justice of the European Union in case C-249/09, Novo Nordisk AS v Ravimiamet. From In light of this judgment, it can be concluded that claims in advertising may under certain conditions supplement the information in the SmPC. This is conditional upon the fact that that those claims confirm or clarify – and are compatible with – the SmPC information and do not distort it. This possibility is limited to advertising that are targeting persons qualified to prescribe or supply medicinal products.

Notwithstanding the above, advertising to the general public or to persons with no specific medical knowledge must in all parts correspond to the SmPC. It is however not necessary with to have a literal conformity between the advertising and the SmPC, but the advertising must have factual support in the SmPC.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

There are no explicit rules which address advertising of combination products or companion diagnostics. The general rule is however that advertisements of medicinal products may not contain information such as therapeutic indications, pharmacological properties or other characteristics, which conflict with or are not included in the SmPC.

5.4 Restrictions on Reprints of Journal Articles

As a main rule, information relating to human health or diseases, eg, in a form of a reprint of a journal article, will not be considered as advertising, provided that there is no direct or indirect reference to medicinal products. The same applies to correspondence, accompanied with non-promotional material, which is required to respond to a specific query from a healthcare professional regarding a medicinal product. It should, however, be noted that journal articles concerning unauthorised medicinal products or indications may constitute unlawful pre-launch or off-label advertising.

Furthermore, the LER Rules contain rules regarding the distribution of information and educational material to healthcare professionals. Such material may be provided if it is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and to the direct benefit of patient care.

5.5 Medical Science Liaisons

The general rule is that advertising of unauthorised medicines or indications is prohibited. For instance, providing unsolicited information on unauthorised medicinal products or indications to healthcare professionals may constitute unlawful pre-launch or off-label advertising. Accordingly, the lawfulness of MSLs will depend on whether the discussion of scientific information is purely informational and does not have a commercial purpose. However, if the discussions are considered to be an inducement

to, eg, prescribe off-label use for a specific product, it will be deemed unlawful. This will be assessed on a case-by-case basis.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising of medicinal products is not subject to prior authorisation from or notification to public authorities. However, according to the LER Rules, in order for the IGN to perform its task as a supervising regulatory body, pharmaceutical companies are required to send new medicinal product information to IGN, such as publications, advertisements, invitations, mailings or information on websites. This applies to information to both the general public and to healthcare professionals.

6.2 Compliance with Rules on Medicinal Advertising

There are no rules for arrangements or requirements regarding ensuring compliance with rules on medicinal advertising.

7. Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

The same rules are applicable on advertising of medicinal products irrespective of the medium used, ie, the applicable provisions are technology-neutral in this respect. Accordingly, the Medicinal Products Act, LVFS 2009:6, the Marketing Practices Act and the LER Rules will apply to advertising on the internet and social media.

Moreover, LIF has adopted an interpretative document that provides guidance on how the LER Rules should be applied on advertising in digital media, eg, through social media platforms, mobile applications and podcasts.

7.2 Advertising of Medicines on Social Media

There are no specific restrictions in relation to advertising of medicines in social media channels. Such advertisement must always comply with the Medicinal Products Act, LVFS 2009:6, the Marketing Practices Act and the LER Rules.

It should be noted that social media, in its general use, is considered to target the general public. However, certain platforms provide the possibility to target the advertising against a specific group, such as healthcare professionals. For instance, closed groups can be used on Facebook and Sponsored InMail can be used on LinkedIn.

LIF's interpretative document highlights a few aspects that should be considered in relation to advertising on social media. For example, it is stated that posting texts regarding new findings may be unlawful pre-launch advertising. Furthermore, it is stated that a pharmaceutical company is responsible for the content on the applicable social media platform. This means, for instance, that if someone is commenting on the company's post, the company is responsible to remove the comment, eg, if it concerns information regarding a prescription-only medicinal product, which may target the general public. Also, if a pharmaceutical company uses "social influencers" in its advertising, it is stated that the company is responsible for the content in the influencer's communication.

7.3 Restrictions on Access to Websites

At the moment, it is not a requirement to implement access restrictions. An identification request is adequate. However, it may be useful to include access restrictions to make sure that the advertising is not targeting the general public.

7.4 Provision of Disease Awareness Information to Patients Online

The same rules are applicable on advertising of medicinal products irrespective of the medium used, ie, the applicable provisions are technology-neutral in this respect. Information regarding human health or diseases, eg, disease awareness campaigns, are not covered by the term advertising and is thus allowed provided that the information does not include any direct or indirect reference or claim regarding medicinal products.

8. Inducement/Anti-bribery

8.1 General Anti-bribery Rules

The anti-bribery rules are set out in Chapter 10 of the Swedish Penal Code. Under these rules, it is unlawful for an employee or person performing an assignment to receive, accept a promise of or demand an undue benefit for the performance of his or her employment or duties (bribe-taking). Conversely, it is unlawful for a person to provide, promise or offer an undue benefit to any of the aforementioned persons (bribe-giving). It should be noted that it is not relevant whether the bribe is of any benefit to the receiving person. Bribe-taking and bribe-giving constitute two independent crimes, irrespective of whether one would accept the bribe, or vice versa. The rules apply to both the private and public sector.

The rules only apply if the recipient is an individual and not if the recipient is an organisation or a company. However, these entities may be subject to a corporate fine if the company direc-

tors have knowledge or should have knowledge that employees are engaging in unlawful activities without taking any action.

Lastly, both the Medicinal Product Act, LVFS 2009:6 and the Marketing Practices Act set out rules on good marketing practice. Giving a bribe to increase the sale of a medicinal product may for example violate such marketing practice and thus be unlawful under these rules.

8.2 Legislative or Self-Regulatory Provisions

The offering of benefits is generally not recognised in Sweden. Offering benefits to healthcare professionals should therefore take place with great restraint, towards recipients in both the private and public sectors. The Swedish Penal Code, which is described above in **8.1 General Anti-bribery Rules**, is interpreted against the code of conduct within the industry.

Furthermore, the LER Rules set out comprehensive provisions regarding the co-operation between pharmaceutical companies and health care professionals in relation to, eg, meetings arranged by pharmaceutical companies or healthcare companies, consultation and assignments and collaborative projects. These provisions also regulate the offering of, eg, meals, alcohol, recreational activities, donation and grants, etc. All employees, as well as senior management, in the healthcare sector and pharmaceutical companies are subject to these rules. According to the LER Rules, the basis for all co-operation is documentation, transparency, reasonability and it must benefit all parties.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

It is not allowed to offer gifts to health care professionals. However, information and educational material may be provided only if the material is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and to the direct benefit of patient care.

Items of medical utility may be provided with the purpose of educating employees and for the care of patients provided that they are of a value not exceeding SEK450 and not routinely used in the recipient's business.

Furthermore, there are comprehensive restrictions in relation to offering of, eg, goods, meals and travels towards health care professionals.

In any event, the above material may not be offered or distributed as an incentive to recommend, prescribe, purchase, sell or administer medicinal products.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to LVFS 2009:6 and the LER Rules, free samples of authorised medicinal products in Sweden may only be provided to:

- those with a pharmacy authorisation or persons responsible for medicinal products at a pharmacy;
- pharmacists at hospital pharmacies (the sample can however only be provided by a healthcare professional);
- other retailers who are authorised to sell the medicinal product; and
- to persons authorised to prescribe the medicinal product.

A pharmaceutical company may only provide a package of the smallest size and the number of samples per product to the same person is limited to one sample per year. In addition, medical samples may only pertain to new products (ie, a product that has been publicly available for less than two years). Each medical sample must be marked with the text "free medical sample, not for sale" or similar and it must be accompanied by the SmPC.

Furthermore, a medical sample may only be provided following a written, dated and signed request by the recipient and a careful check must be made to ensure that the person sending the request is authorised to prescribe or dispense the medicinal product.

A medical sample may not constitute an incentive to recommend, prescribe, purchase, sell or administer medicinal products.

9.3 Sponsorship of Scientific Meetings

A pharmaceutical company can organise or pay for meetings targeting healthcare professionals. This entails that a company may finance, eg, venue, lectures, study material and meals that are necessary to carry out the meeting.

A main and general condition for arranging or sponsoring a meeting is that the scientific and professional programme constitutes the dominant part and purpose of the meeting. The meeting may only regard the company's own business areas.

Meals should be moderate, and they may only be served in connection with the meetings. Alcoholic drinks must be limited and only be served in connection with meals (spirits may never be offered).

Travel and accommodation for participants may not be financed by the company or requested by the participants. Further, participants may not be offered fees from the pharmaceutical company and the participants are not allowed to request fees for their participation.

Pharmaceutical companies may arrange or sponsor events taking place abroad if the majority of the participants come from another country than Sweden or if relevant knowledge or experience cannot be obtained in Sweden. The choice of location and venue must be reasonable. For instance, seasonal leisure resorts and other luxurious or exclusive places should be avoided (eg, a ski resort during the winter season). The same applies to locations where major international events are being held in connection with the meeting (eg, sports events).

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to finance social or recreational activities in connection with meetings (and they may not be requested by healthcare professionals). However, simple social activities (eg, background music or local performances) are allowed if they are not organised or requested by the pharmaceutical companies.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Donations to the healthcare sector are permitted provided that they are made to support research and development. The support in this regard must be intended to be used for real research and development and it may not be given on vague grounds, eg, to a healthcare association which "works towards more research" within a certain area.

Donations may not be provided or requested with the purpose of financing healthcare professionals' or healthcare institutions' social activities or regular business operations. Furthermore, there cannot be any connection between the donation and past, present or future use, recommendation, sale or prescription of the donor's products or services. In addition, the donation may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The general limitations on gifts and other benefits as described above will, in principle, ensure that rebates and discounts cannot be provided to healthcare professionals.

There is no explicit prohibition with regards to rebates and discounts to healthcare institutions. It has occurred that county councils ("Regions") (which are handling the purchase of medicinal products) have entered into agreements with pharmaceutical companies where the company has provided a discount on a medicinal product. These agreements have been subject to criticism, in particular concerning medicinal products that are included in the Swedish benefits system.

Consequently, the Swedish government and the Swedish Association of Local Authorities and Regions (SALAR) have temporarily concluded an agreement stating that no agreements regarding discounts on medicinal products included in the Swedish benefits system may be entered into between Regions and pharmaceuticals companies. If agreements are concluded, the Government's financial contribution to that Region will decrease, with an amount corresponding to the discount.

Furthermore, there may be instances where discount arrangements may give rise to unlawful inducements, eg, if a discount applies only after a health-care provider has purchased a certain amount of products.

9.7 Payment for Services Provided by Healthcare Professionals

The LER Rules contain provisions regarding employees and executives in the healthcare sector and their engagements with pharmaceutical companies, eg, in relation to research, education, conferences, product development and their participation on advisory boards.

In order for a pharmaceutical company to engage the healthcare professional, there must be a legitimate need to carry out the assignment.

The assignment must be agreed upon in writing between the healthcare professional, its employer and the pharmaceutical company. The agreement should explicitly specify the services to be carried out and how remuneration is to be regulated. Any remuneration must be reasonable in relation to the nature of the assignment and the time spent. Any reimbursement of expenses must follow the employer's rules for travel and expenses. No other benefits, remuneration or gifts may be provided. If the healthcare professional carries out the assignment as part of normal work duties, the compensation must be paid to the employer.

In the agreement referred to above, there must be an obligation for the healthcare professional to declare that he or she is a consultant to, or a part-time employee of, the company when he or she expresses an opinion in public on a topic relating to the assignment. Also, a consultant should be urged to be transparent with his or her assignment in relation to other assignments mandated by public authorities or expert bodies.

The engagement with the healthcare professional may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

9.8 Prior Authorisations or Notifications

When engaging a healthcare professional for an assignment, consent must be obtained from the healthcare professional's employer through a written agreement, see **9.7 Payment for Services Provided by Healthcare Professionals**.

10. Transparency

10.1 Requirement to Disclose Details of Transfers of Value

The LER Rules implement the 2013 EFPIA code of disclosure whereby value transfers in the form of, eg, sponsorships, donations and remunerations for consulting services will be made public. Pharmaceutical companies acting on the Swedish market must therefore publicly disclose the persons or organisations in Sweden that have received value transfers in a given year and the total value of these value transfers.

A value transfer refers to direct or indirect transfers in cash or in kind, to or for the benefit of recipients, which are made in development or sale of a medicinal product for human use, irrespective of whether the purpose is promotional.

In relation to value transfers to healthcare professionals, the pharmaceutical company must report the name and address where the person is mainly operating, consultancy fees and expenses for assignments, eg, travel and accommodation.

In relation to value transfers to healthcare organisations, the pharmaceutical company must report the name (eg, hospital, clinic, association) of the organisation, where the organisation mainly carries out its business, donations, contributions to expenses of certain activities (eg, sponsorship costs), consultancy fees, and expenses for assignments, eg, travel and accommodation.

There is no obligation to report meals (in relation to, eg, conferences), information and education material or items of medical utility. Conference fees as well as financing of travel and accommodation in connection with meetings/conferences are not relevant for Sweden since such arrangements are no longer allowed (since 1 January 2015), see **9.3 Sponsorship of Scientific Meetings**.

The disclosure shall be made in accordance with the template in appendix 1 to the LER Rules. It must be made in Swedish, but it is recommended that it is done in English as well. The disclosure can be made in either LIF's co-operation database or on the pharmaceutical company's website. If disclosure is made on the website, a link to the report must be made in LIF's co-operation database.

Please note that, in light of the General Data Protection Regulation (EU) 2016/679 (GDPR), private companies as well as public authorities must comply with comprehensive new legal requirements on the processing of personal data. This has an impact on the publishing of value transfers. According to LIF's opinion, written consent is required from the relevant healthcare professional (eg, a consultant) in order to disclose a value transfer. With regards to healthcare institutions, eg, hospitals, clinics, organisations or a limited liability company, consent is not required according to LIF.

10.2 Foreign Companies and Companies that Do Not Yet Have Products on the Market

Disclosure must be made in accordance with rules of the national code that is applicable in the country where the recipient has its principal place of business or its seat. If any of these two are located in a country other than Sweden and if the pharmaceutical company lacks the ability to disclose the value transfer through a group company in the country of destination, the pharmaceutical company must disclose the value transfer in accordance with the LER Rules.

The above rules are applicable to pharmaceutical companies that are members of LIF, the FGL, IML and EFPIA.

11. Enforcement

11.1 Enforcement Bodies

The MPA is responsible for the supervising and enforcement of the compliance under the Medicinal Products Act and regulations issued under it, eg, LVFS 2009:6. In case of unlawful advertising, the MPA has authority to issue prohibitive injunctions combined with a conditional fine for non-compliance. Decisions by the MPA can be appealed to the Administrative Court in Uppsala.

The Swedish Consumer Agency is responsible for enforcing the general rules on advertising. The Swedish Consumer Agency is led by a Director General who is also the Consumer Ombudsman who represents consumer interests and has authority to issue prohibitive injunctions combined with a conditional fine for non-compliance with the Marketing Practices Act. Decisions by the Consumer Ombudsman can be appealed to the Patent and Market Court. The Consumer Ombudsman may also, under certain conditions, pursue legal action in court, where the Patent and Market Court and the Patent and Market Court of Appeal are the competent courts.

IGN and NBL are the self-regulatory bodies under LIF. IGN's competence comprises the review of medicinal product information and determines, on its own initiative or after complaints,

whether the pharmaceutical companies' marketing activities comply with good marketing practice. It may also refer a matter to the NBL. NBL's competence includes, eg, handling appealed matters from IGN or LIF's compliance officer and being first and last instance in matters where a public authority has filed a complaint regarding advertising of medicinal products.

The rules relating to inducements in criminal cases are enforced by prosecutors under the Penal Code in civil courts (district courts, courts of appeal and the Supreme Court).

11.2 Initiating Proceedings for Advertising Infringements

A company may file a complaint to the MPA, which may decide to initiate a supervisory matter. A company may also initiate legal actions for, eg, unfair advertising before Act before the Patent and Market Court. Furthermore, it is possible to notify IGN on advertising that is not compliant with the LER Rules.

11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe

The main sanction for violations of the advertising rules in the Medicinal Products Act is a prohibitive injunction combined with a conditional fine for non-compliance.

Furthermore, the Marketing Practices Act include numerous sanctions depending on the nature of the violation. For instance, the provisions regarding misleading advertisement may results in the following sanctions issued by the Patent and Market Court:

- prohibitive injunction, which normally is issued with a conditional fine, which according to the Court's practice generally amounts to approximately EUR100,000, however, the conditional fine may be adjusted according to the circumstances on a case-by-case basis;
- special fine (fine for disruptive marketing practices). If imposed, the amount of a market disruption charge is calculated on the basis of the trader's turnover; the amount varies, on a case-by-case basis, from approximately EUR1,000 to EUR1 million but cannot exceed 10% of the trader's yearly turnover; and
- third party damages provided that the trader has intentionally or negligently violated the prohibition on, eg, misleading marketing and that another trader or a consumer have suffered damages thereby.

An action before the Patent and Market Court may be pursued by the Consumer Ombudsman, a competitor, a consumer or a trade or consumer association.

It should also be noted that both the MPA and the Consumer Ombudsman may issue an injunction combined with a conditional fine, which the trader may accept in order to avoid legal proceedings in court.

Many matters are handled by the IGN and NBL. Both individuals and pharmaceutical companies may pursue an action before IGN. IGN's and NBL's competence derives from contractual relationships with the members. Under this authority, IGN and NBL may fine members who violate the LER Rules. Fees determined by the IGN and NBL may not exceed SEK500,000.

11.4 Relationship Between Regulatory Authorities and Courts

As stated above in **1.1 Laws and Self-Regulatory Codes**, the LER Rules are recognised by the pharmaceutical industry and the decisions from IGN and NBL may be considered by courts in relation to, eg, good marketing practice.

Proceedings initiated before IGN or NBL may be filed in parallel with a proceeding before a court or a public authority.

11.5 Recent Enforcement Trends

No deviating enforcement trends relating to the rules governing advertising of medicinal products have been noted in Sweden. However, it should be noted that the increased use of social media has led to a number of enforcement actions the past few years as well as a recent updated social media guideline by LIF. The guideline describes the most widely used digital channels in Sweden, eg, social media platforms, mobile applications and podcasts, and how they can be used to communicate to the public as well as to healthcare professionals. Since the development of digital channels is rapid, the document is continuously updated, and it is valuable for pharmaceutical companies to stay updated in relation to this document.

Advokatfirman Vinge KB is a full-service business law firm with offices in Stockholm, Gothenburg, Malmö, Helsingborg and Brussels. The firm's intellectual property and life science groups, which consists of approximately 35 lawyers, have expertise in marketing-related consultancy in specialised sectors such as the biotechnology, pharmaceuticals and med-tech industries and have extensive experience of legal market assessments, including advertising campaigns, product launches, product liability, compliance, marketing and advertising strategies. Vinge offers a full-service IP concept within three key areas: contentious, non-contentious and prosecution (patent prosecution in collaboration with patent agency firms). Biotechnology, pharmaceuticals and med-tech are a few of the key practices areas, and the team is continuously assisting both national and international pharmaceutical companies with negotiation and drafting a wide range of pharmaceutical-related agreements as well as advertising and compliance within the pharmaceutical sector.

Authors

Håkan Borgenhäll is a partner and head of the IP group at Vinge. His practice focuses on intellectual property and marketing law with a focus on contentious matters. Håkan has served as an expert in the Governmental Committee in relation to the newly proposed Swedish Patents Act. He was involved in the Swedish preparations for the proposed Unitary Patent Court (UPC) and was appointed as the Swedish Bar Association's member of the CCBE task group concerning UPC-related questions. He is the representative and author of the Swedish Bar Association's comments in relation to proposed amendments in Swedish IP laws. Håkan has been the leading counsel in some of the most important patent disputes in the last decades, including litigation-related blockbuster pharmaceuticals and SPC disputes. Håkan is a member of EPLAW, FICPI and AIPPI, and is also a member of several national IP associations.

Kristina Ekberg is a partner in the private M&A group at Vinge and head of the life sciences and health sector group. Kristina has special knowledge of and experience in advising clients within the life sciences sector, with a focus on private M&A transactions and commercial agreements.

Jakob Kraus is an associate at the firm. He is specialised in intellectual property law and life science and has experience within the biotechnology, pharmaceutical and med-tech sectors. He is continuously advising on matters relating to advertisement and compliance within, inter alia, the healthcare sector.

Advokatfirman Vinge KB

Stureplan 8
Box 1703
SE-111 87
Stockholm
Sweden

Tel: +46 (0)10 614 3000
Fax: +46 (0)10 614 3190
Email: contact@vinge.se
Web: www.vinge.se