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The International Comparative Legal Guide to:

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A practical cross-border insight into pharmaceutical advertising

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1 General – Medicinal Products

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

Chapter VII of the Medicinal Products Act of 4 December 1992 as well as chapter 13 of Medicinal Products Regulation of 18 December 2009 govern advertising of medicinal products. The provisions of the Marketing Control Act of 9 January 2009 that concern advertising are also relevant for medicinal products.

In addition to the above-mentioned formal legislation, the Association of the Pharmaceutical Industry in Norway (LMI) has issued two guidelines, "Rules for marketing medicinal products" and "Rules for marketing veterinary products", which offer more specific provisions than the formal legislation. LMI has also published a guideline on the cooperation between the pharmaceutical industry and patient organisations.

Furthermore, LMI has also entered into agreements with the four Regional Health Enterprises, which own the public hospitals in Norway, and various associations, (including the Norwegian Medical Association, the Norwegian Association of Pharmacists, the Norwegian Nurses Organisation and the Norwegian Federation of Organisations of Disabled People), which also contains relevant provisions in regards to marketing of medicinal products.

LMI's guidelines and the agreements with the above-mentioned organisations are formally binding only to members of LMI, but the provisions are largely considered industry practice.

1.2 How is "advertising" defined?

Section 13-2 of the Medicinal Product Regulation defines advertising as:

"[A]ny form of written and oral description, picture, as well as hand out of free samples of medicinal products for humans and animals, as well as herbal medicinal products, which are designed for the purpose of increasing the sale or use/application."

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

No mandatory "sign off" arrangement for companies exists. A company is responsible for providing its sales representatives with adequate training in order to communicate scientific information precisely and completely, *cf.* section 13-9 of the Regulation. Furthermore, pursuant to section 13-11 of the Regulation, the marketing authorisation holder shall establish a professional information service and designate a responsible person in charge of:

- submitting a copy of all written material;
- ensuring that advertising is in compliance with the Regulation and existing provisions;
- verifying that sales representatives are given adequate training and fulfilling their duties according to the Regulation;
- providing the Norwegian Medicines Agency and LMI's self-regulatory body with information necessary for these to perform their supervisory tasks;
- ensuring that decisions and orders from the Norwegian Medicines Agency and the self-regulatory body are complied with immediately; and
- ensuring filing of promotional material for at least two years.

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

There are no such requirements in Norway.

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

No such approval is required, nor is there any explicit legal basis for Norwegian authorities to require approval in advance.

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

Pursuant to section 13-10 of the Regulation, the Norwegian Medicines Agency can demand the advertisement stopped if the advertisement is in breach of the Regulation. Such a demand may also include the issuing of a corrective statement to all who have received the advertisement. In cases of repeated breach, the Agency also has the power to issue a ban on advertisement for a specific medicinal product for a certain period of time, and even permanently.

The Agency's decisions to restrict advertisements are administrative decisions and subject to appeal to the Ministry of Health and Care. These decisions may also be brought before the ordinary courts.

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

In principle, violations of the Medicinal Product Act, as well as those of the Regulation, are subject to criminal sanctions. According to section 31, the sanctions range from fines to imprisonment for up to three months.

In practice, two sets of sanctions are used:

- The Norwegian Medicines Agency, which is responsible for the enforcement of the Act and the Regulation, may in cases of repeated breach order temporary or permanent bans on advertising, see question 1.6. Permanent bans are rare, but in events of repeated breaches a typical prohibition period would be three months.
- The other way to impose sanctions is through fines issued by the Committee for Information on Medicinal Products (the Committee), a self-regulatory board consisting of members from both the Norwegian Medical Association (NMA) and LMI. Fines typically range between NOK 50,000 and 150,000, but according to the statutes of the Committee, fines up to NOK 300,000 may be ordered. Both competitors and the Norwegian Medicinal Agency may file complaints regarding advertisements to the Committee. It is also not uncommon that the Secretary of the Committee files complaints on advertising to the Committee.

Finally, a company may initiate legal action if the company or its product(s) have been affected by the illegal advertising.

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

In principle, the two processes operate independently of each other, thus neither the Agency nor the Committee are bound by the other party's previous assessment. The Agency will however in practice often take into account the fact that the Board has reached a decision in a specific case and may refrain from handling the case, and *vice versa*.

As described under question 1.7, the Agency may also lodge a complaint to the Committee, against a company.

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

In cases of unfair competition between tradesmen, competitors may file complaints to the Council dealing with unfair marketing practices (NKU), a self-regulatory body consisting of, *inter alia*, the Confederation of Norwegian Enterprises (NHO). Competitors may also initiate legal proceedings on the basis of unfair competition.

Unfair competition towards consumers is supervised by the Consumer Ombudsman, and breaches may be subject to sanctions such as prohibitions, orders, daily penalties and fines. Actions from the Consumer Ombudsman are rare in this area.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

The Regulation section 13-3 third paragraph only allows for advertising of medicinal products that are approved and hold a marketing authorisation. According to the same provision, advertising for products sold via so called "special exemptions" (products without a marketing authorisation in Norway and used under the sole responsibility of a healthcare professional) is also prohibited. In LMI's Rules for marketing of medicinal products ("LMI's Rules"), it is also stated that advertising must not take place before an approved price has been issued by the Norwegian Medicines Agency.

The permissibility of providing such information to healthcare professionals would thus depend on whether or not the action can be considered as advertising. Due to the definition of advertising in the Regulation, all information on such products considered to be of a promotional nature would therefore be prohibited, while information of non-promotional nature would fall outside the scope. Information about unauthorised products of a non-promotional nature (e.g. ongoing research projects) may therefore be discussed and made available at scientific meetings. In the event that a company sponsors the meeting, there is an increased risk of such information being considered unlawful advertising.

The position is the same regarding off-label promotion. According to section 13-2 second paragraph, all advertising must be in accordance with the Summary of Product Characteristics. A prohibition on off-label advertising is also specified in LMI's Rules.

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

As indicated under question 2.1, information of a purely non-promotional nature may be published. For instance, information on unauthorised medicines and off-label information may therefore be published in scientific journals. Independent journalists may also write about such medicines, although press articles considered as disguised advertisements are prohibited. Promotional statements in press publications could also be deemed as advertising.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

This would depend on whether the information is considered promotional. Press releases are therefore not precluded from being considered advertising, and due to the definition of "advertising",

such press releases are likely to be considered advertising. However, information which must be disclosed in accordance with corporate legislation, etc. is permitted.

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

Providing information on unauthorised products to healthcare professionals will, under normal circumstances, be considered as advertising, and therefore prohibited. If the healthcare professional requests information of his own initiative, it is, however, permitted to provide such information. The condition is, however, that the answer is limited to meet the particular request.

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

This decision has not led to any amendments in either legislation or industry guidelines in Norway.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Due to the definition of advertising in the Regulation, providing such information would likely be deemed advertising and consequently be prohibited.

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

LMI's Rules for marketing of medicinal products exempt limited market researches such as phone interviews or e-mail/online-based questionnaires on certain conditions. Provided that the market research is not a form of disguised advertising, market researches could also apply to unauthorised products or unauthorised indications.

However, due to the definition of advertising in the Regulation, there is a risk that such market research may also be considered advertising and thus in violation of the Regulation. Whether this is allowed would likely depend on, *inter alia*, the scale of the market research as well as the questions posed.

Pursuant to LMI's Rules for marketing of medicinal products, several conditions must be fulfilled in order for healthcare professionals to participate in market research:

- A written agreement made in advance, describing in detail the services and conditions for payment.
- A legitimate need for the services must have been identified prior to requesting the service and entering into an agreement.
- The criteria for selecting consultants must be directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the healthcare professionals in question meet those criteria.
- The number of healthcare professionals engaged for the assignment/service must be reasonable in terms of meeting the identified needs.
- The company must maintain records of agreements and contracts made with healthcare professionals. The results of the services must only be used in accordance with the agreement.
- The engagement of healthcare professionals shall not be an inducement to recommend, prescribe, purchase, sell or administer a specific medicinal product.
- The compensation paid shall be reasonable and represent a fair market value.

3 Advertisements to Healthcare Professionals

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

According to section 13-7, advertising directed at healthcare professionals must include:

- Name, dosage form and strength.
- Name of all active substances (which must be presented in a clear font and in a clearly visible place).
- The marketing authorisation holder (and possibly the manufacturer).
- Authorised indications.
- Contraindications.
- Adverse effects, precautionary measures and interactions.
- Dosage.
- Package size(s).
- Prescription class, as well as rules for prescription and delivery.
- Approved price per date and provisions for reimbursement.

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

According to section 13-3 of the Regulation, the advertisement shall be sober-minded and factually-based, and promote rational use according to current rules for prescription. Advertisements shall not give misleading or exaggerated views of the properties and medical value of a drug, nor lead to use of the drug which is not medically substantiated.

For advertisements to healthcare professionals, additional documentation on the properties and effects of the product may be included, but must be made by referring to scientific material available to the recipient (e.g. professional journals, reference books and published congress reports). Journals that are not professionally quality assured and company internal research reports are not allowed. Documentation referred to must also include the date of the documentation or the date of the latest revision.

Within these parameters, studies can be referred to despite not being included in the SmPC, provided that the information is compatible with the information in the SmPC. It is required that information from studies is presented accurately and shall not exceed the conclusions of the original author.

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

According to section 13-5 of the Regulation, advertising to the general public shall not contain endorsements from physicians, dentists, veterinarians, fish health biologists or any other healthcare professionals.

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

There is no such general requirement in Norway. However, information as to the qualities and effects of a drug must always be capable of substantiation by means of scientific documentation, and as referred to under question 3.2, only certain scientific material may be referred to.

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

Comparative advertisement is not specifically governed by the Regulation. The general rules on comparative advertisement in the Marketing Control Act will therefore apply.

The Marketing Control Act section 25 prohibits actions between businesses that are in breach of good business practice, while section 26 prohibits misleading advertising. Both provisions are relevant with regard to comparative advertising.

The specific requirements pertaining to comparative advertising are set in the Regulation on comparative advertisement. Pursuant to section 2 of this regulation, comparative advertising means any advertising which directly or indirectly refers to a competitor or products or services offered by a competitor.

Section 3 of the regulation sets out the relevant criteria for comparative advertising:

- it is not misleading;
- it compares goods or services meeting the same needs or intended for the same purpose;
- it objectively compares one or more materials, relevant, verifiable and representative features of those goods and services, which may include price;
- it does not discredit or denigrate the trade marks, trade names, other distinguishing marks, goods, services, activities, or circumstances of a competitor;
- for products with designation of origin, it relates in each case to products with the same designation;
- it does not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products;
- it does not present goods or services as imitations or replicas of goods or services bearing a protected trade mark or trade name; and
- it does not create confusion among traders, between the advertiser and a competitor or between the advertiser's trade marks, trade names, other distinguishing marks, goods or services and those of a competitor.

LMI's Rules on advertising for medicinal products also include rules on comparative advertisement, stating that comparative advertisement must not be misleading and must be based on comparable and relevant product characteristics. Both the manufacturer's own and the competitors' products must be presented in a balanced, fair and objective manner.

In principle, as long as the comparison is within the requirements in section 3 above, it should be permissible to use the brand name of another company in comparative advertisement.

Comparisons with a product not authorised in Norway, is likely not allowed due to the prohibition on advertising products without a marketing authorisation, see question 2.1. Since such a product is not relevant to the Norwegian market, such a comparison could also be deemed to violate the requirement of comparing relevant features.

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

The distribution of scientific papers and/or proceedings of congresses to healthcare professionals are generally allowed under Norwegian law. However, depending on the context, unsolicited distribution of scientific papers, etc. which concern the company's medicinal products could be considered advertising, and thus be subject to the same rules.

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

Such advertisements would still be considered advertising of medicinal products, and would not meet the necessary specifications on advertisement of medicinal products, see question 3.1.

So-called "teaser advertisements" are only allowed towards healthcare professionals, and must only contain the trade name, the generic name of the active substance and the name of the marketing authorisation holder.

4 Gifts and Financial Incentives

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

Pursuant to section 13-8 of the Medicinal products Regulation, samples may be provided to healthcare professionals on the following terms:

1. Samples may only be distributed to medical doctors, dentists, veterinarians and fish health biologists. Samples of prescription-only medicinal products may only be given to those who have the right to prescribe the product in question.
2. Samples may only be given in response to a written and signed requisition.
3. Only one sample may be distributed to each medical doctor, dentist, veterinarian or fish health biologist every year. If the medicinal product comes in different forms or strengths, only one sample of each may be issued. The sample must be the smallest available package.
4. Each sample must be labelled: "Free pharmaceutical sample – not for sale".
5. Herbal medicinal products shall, according to current legislation, be labelled: "Herbal medicinal products".

6. A complete copy of the Summary of Product Characteristics (SmPC) must be provided together with the sample.
7. Samples of unauthorised medicinal products shall not be given.
8. Samples of medicinal products in prescription class A or medicinal products containing substances classified in accordance with international conventions as psychotropic substances or narcotics shall not be given.
9. Each pharmaceutical company shall keep records of all provided samples. Such records shall be kept for two years and upon request be forwarded to the pharmaceutical authorities.

LMI's Rules also include a statement that samples of medicinal products must not be distributed for the purpose of achieving a recommendation, prescription, purchase, delivery, sale or administration of a particular medicinal product, and furthermore that samples of medicinal products may not be distributed for more than two years after a product has been introduced onto the Norwegian market.

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

According to Section 387 of the Criminal Code any person who requests or receives, or gives or offers to give, an improper advantage in relation with a position, office or assignment, may be held liable for corruption.

While the Criminal Code is intended for the clearly reprehensible cases, and thus not applicable in any cases of improper advantages, a similar provision is found in the Act on Healthcare Personnel section 9. Pursuant to this provision, healthcare personnel are prohibited from accepting gifts, commissions, services or payments which are suited to influence them in an improper manner. The prohibition is further specified in the appurtenant Regulation on gifts etc. to healthcare personnel. These rules formally only apply to healthcare professionals.

Despite already strict restrictions in the legislation, the Association of the Pharmaceutical Industry (LMI) practises a ban on gifts or other financial benefits to healthcare professionals.

The ban does not concern information and educational material, providing that the material is of limited value, is directly relevant to the occupation of the recipient, and is of direct benefit in the treatment of patients. Likewise, medical utilities are also exempted, providing that they are of limited value, have a bearing on the recipient's profession, and are not a part of the recipient's usual professional activities, such as consumables and other products that are required in the performance of the healthcare professional's position. By limited value, the current limit decided by LMI is NOK 400.

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

Gifts or donations to healthcare organisations are not specifically regulated in legislation, but the restrictions of section 387 of the Criminal Code would apply. However, LMI's Rules only allow donations to institutions or organisations if they are made with the purpose of supporting medical research and treatment. Documentation concerning the donation is to be kept by the company, and the donation must not involve the recommendation, prescription, purchase, delivery, sale or administration of a particular medicinal product.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Such goods and services intended to affect prescription are not permissible, see question 4.2.

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

The rules on advertising and inducements in Norway do not prevent the offering of a volume-related discount, although in certain cases, such arrangements could be contrary to competition law.

However, section 6 of the Medicinal Product Act prohibits discounts which are not determined at the time of the sale of a medicinal product.

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

Offering additional services or equipment that is contingent on the purchase of medicinal products risks being regarded as an improper benefit intended to influence the procurement decisions of the institution. In practice, such offers could be considered as a gift to the institution, and would likely be deemed as being in violation of LMI's requirement that donations shall not be an inducement to purchasing a particular medicinal product, see question 4.3. If the procurement is subject to a tender offer, such an arrangement could also be contrary to the tender terms. Such an arrangement could also have implications with regard to competition law.

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

There are no explicit provisions in the Regulation or in LMI's Rules which explicitly prohibit such refund schemes.

The Norwegian Medicinal Agency has protested in at least one instance where a refund scheme was offered, and where a "money back guarantee" for the patient regarding a prescription drug was promoted, not directly towards the patients, but towards physicians and pharmacists. The campaign was nevertheless deemed as advertising towards the patients, which is not allowed for prescription drugs.

Refund schemes intended for consumers are thus likely to be considered advertising, and therefore not allowed for prescription medicines.

Based on this, a refund scheme could in principle be acceptable for OTC-products. However, it is likely that offering a refund scheme could be considered contrary to promoting rational use of medicinal products, and thus be in violation of section 13-3 of the Regulation.

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

Such sponsorship is considered a benefit according to section 9 of the Healthcare Personnel Act, and is specifically mentioned in the appurtenant regulation.

If it is suited to influence the healthcare professional in an improper manner, it would be illegal for the healthcare professional to accept it, see question 4.2.

Offering to pay for continuing medical education would regardless of this also be considered as a gift to the individual health professional or his employer, who would otherwise have to cover the necessary expenses himself. As described under questions 4.2 and 4.3, LMI's Rules do not permit such gifts.

Between LMI and the Regional Health Authorities, it is explicitly stated in the agreements that it is not permitted to enter into agreements on sponsoring seminars that give eligible or approved hours to continuing medical education.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

As described under question 4.2, the Healthcare Personnel Act section 9 and the appurtenant regulation prohibit gifts etc. suited to influence healthcare personnel in an improper manner. Fully or partially covering of expenses related to seminars and conferences is mentioned as one of the examples of the term "gift" in the regulation. Healthcare personnel are therefore not allowed to receive hospitality that is suited to influence them in an improper manner.

LMI operates with more specific rules. According to item 9.4 of LMI's Rules, hospitality shall be limited to travel, meals, and overnight accommodation, as well as any necessary attendance fees, all of which must be of a reasonable scope and level, not exceeding what healthcare personnel would have paid if they were to pay for the expenses themselves.

With regard to meals, LMI operates with established rates, currently 70% of the State's representation rates for dinners and 40% for lunches.

Conferences outside Norway are specified in item 9.2 of LMI's Rules. Companies must not arrange or sponsor arrangements located outside Norway unless:

- the arrangement has been approved in advance by the Committee Secretariat of the Committee for Information on Medicinal Products; and
- the majority of those invited are from countries other than Norway, and the destination appears reasonable given the departure point of the attendees; or
- the location of the arranger or expertise makes it more reasonable to hold the arrangement outside Norway.

The provision also states that it is not permitted to sponsor or pay for healthcare personnel to travel to or attend events abroad held by third parties.

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

In general, the same rules at stated under question 5.1 would apply to healthcare professionals' attendance at scientific meetings. Pursuant to LMI's Rules item 13, payment in order to gain access to healthcare professionals' time is not allowed. However, this does not preclude using a healthcare professional as a consultant, see question 5.4.

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

No explicit rules on responsibility for the companies exist. With regard to hospitality, etc., section 9 of the Health Personnel Act would apply to healthcare professionals, while the Criminal Code section 387 would apply to both the company and the healthcare professional, see question 4.2.

With regard to content, a pharmaceutical company may be responsible for the content of the lecturer's material if it is considered advertising.

As also described under question 1.7, the Committee for Information on Medicinal Products has the power to issue fines for members of LMI in the event of breach of LMI's Rules.

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

According to LMI's Rules item 14.01, healthcare professionals may be used as consultants/advisors on e.g. advisory boards, and such participation may involve remuneration. The following criteria apply:

- A written contract or agreement must be entered into in advance, in which the assignment/service to be provided and the conditions for payment of compensation are described in detail.
- A legitimate need for the services must have been identified prior to requesting the service and entering into an agreement.
- The criteria for selecting consultants must be directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the healthcare professionals in question meet those criteria.
- The number of healthcare professionals engaged for the assignment/service must be reasonable in terms of meeting the identified needs.
- The pharmaceutical company shall maintain records of agreements and contracts made with healthcare professionals.

The results of the services provided/assignments carried out shall be used only in accordance with the contract/agreement that has been made.

- The engagement of healthcare professionals to carry out assignments/provide services shall not be an inducement to recommend, prescribe, purchase, sell or administer a specific medicinal product.
- The compensation paid for the assignment carried out/service provided shall be reasonable and represent a fair market value.

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

This is also permissible. The criteria under question 5.4 will apply.

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

This is also permissible. The criteria under question 5.4 will apply. In this regard, LMI's Rules item 14.03 states that limited market surveys, such as one-off phone interviews or e-mail/internet questionnaires are excluded from the scope of these provisions, provided that the healthcare professionals are not consulted regularly (either in terms of a number of surveys or to respond to the individual survey) and that the remuneration for participation is minimal.

6 Advertising to the General Public

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

Advertising of non-prescription medicines to the general public is allowed, cf. section 13-5 of the Regulation, but certain limitations apply. Including recommendations from health professionals is permitted, and illustrations must not exaggerate properties of the drug, nor be misleading or use severe effects (i.e. depict a body altered by disease or injury). Nor is reference to severe diseases allowed.

Furthermore, distributing gifts or free samples of medicinal products is prohibited when this is done in relation to advertising.

Advertisements to the general public must also always be depicted so that it is clear that it is advertising, and that the advertised product is clearly identified as a medicinal product.

Section 13-6 further sets out certain requirements on mandatory information which must be included, e.g. the product name, the active ingredient and necessary instructions for proper use, as well as a list of specific prohibitions.

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

Pursuant to section 13-5 of the Regulation, advertising prescription-only medicines to the general public is prohibited. However, this prohibition does not extend to prescription-only vaccines for people who are part of a vaccination campaign that has been approved by the authorities.

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

Information on health related questions or disease (disease awareness campaigns) from the industry is allowed, *cf*. section 13-1 of the Regulation, provided that there is no direct or indirect referral to a specific medicinal product.

The Norwegian Medicines Agency has issued a guideline on the requirements placed on such information:

- The information emphasised must be related to health and diseases, not information regarding treatment options. The information must also support that it is healthcare professionals together with the patient who shall find suitable treatment for the patient.
- The information may refer to different treatment options, and even mention medicines as one of several treatment options. However, mentioning trade names or active ingredients is not allowed.
- Groups of medicines may be mentioned, but only at a high ATC-level (i.e. within ATC-levels 1 and 2).
- For information on diseases where there is only one option or a few options for treatment, it is important that the information focuses not on treatment, but on health, disease and information on where the patient may seek advice, since such campaigns may easily direct the patient towards one particular medicinal product.
- Health and disease information shall not promote the use of one or several specific medicines.
- The information shall be specific, updated, verifiable, adequately comprehensive, balanced and easy to understand. The name of the originator must be mentioned.

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

Due to the definition of "advertising" in section 13-2 of the Regulation, a press release concerning a prescription-only medicine could be deemed "advertising" by the Norwegian Medicines Agency, depending on the actual content of the press release. Actively sending a press release to a non-scientific journal will likely be considered a promotional activity, i.e. with "purpose of increasing the sale or use/application", and therefore not allowed, *cf*. question 6.2.

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

Annual Reports are addressed to, e.g., shareholders and investors to provide information about company activities, and not with the intent of increasing sales or use of medicinal products. Such reports will therefore under normal circumstances not be considered "advertising".

Corporate brochures describing medicinal products could, depending on the content, be considered advertising. Whether this is the case must be determined by various factors, such as e.g. how the products are described, to whom the brochures are directed, the language used, etc.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

Arranging and funding meetings with patient organisations by a pharmaceutical company may fall under the scope of "advertising" in the Regulation, depending on how the meeting is organised, the focus of the meeting, the communication given and the purpose of the funding. If the activity is considered advertising, the rules stated under question 6.1 will apply.

Furthermore, as mentioned under question 1.1, the LMI has a specific guideline on the cooperation between the pharmaceutical industry and patient organisations, which is largely based on EFPIA's Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations. The guideline states, *inter alia*, that companies may not offer financial support or secretarial services to support the administration of the patient organisation, that no more than 15% of the income of the organisation may come from the pharmaceutical industry, that the industry only can fund up to 50% of any given project. The guideline also emphasises transparency and the independence of the patient organisation.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

As described under question 6.1, offering gifts in connection with advertising of medicinal products is prohibited. It is also specifically prohibited to give samples of medicinal products to the general public, including patients.

There are otherwise no explicit restrictions on offering gifts to patients, but due to the broad definition of "advertising" in the Regulation, giving items to patients could, depending on the nature of the gift and the circumstances, fall within the scope of the rules governing advertising.

7 Transparency and Disclosure

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

There is no obligation for the company to disclose details of clinical trials. However, all such research projects in Norway are subject to pre-approval by the Regional Ethics Committee, cf. the Act on Health Research section 9 and certain limited information on the study, e.g., the project description, will be disclosed in a public portal. The public hospitals under the Regional Health Authorities and the Directorate of Health cooperate on a patient-friendly portal informing about ongoing clinical trials at the hospitals.

Clinical trials that are a part of an application for a marketing authorisation are, in general, subject to the Freedom of Information Act, but such studies will largely be considered confidential. Information about a study which is not considered confidential may be disclosed to the general public upon request.

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

No such requirement exists in the legislation, but requirements exist in industry codes, see question 7.3.

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

Chapter 15 of the LMI's Rules contains several provisions on transfer of value to healthcare personnel and healthcare organisations, which are mandatory for all pharmaceutical companies which are members of LMI. The provisions largely implement EFPIA's Disclosure Code, and refer to this Code in cases of doubt or need of more information.

Transfers of value that concern only over-the-counter medicines taking place within the framework of ordinary sale of medicinal products, or refer to veterinary products, are excluded, as are disclosures concerning the value of free samples, meals in a professional context at approved rates and ordinary information and marketing costs.

The duty to report transfers of value applies from 1 January 2015, shall take place for one calendar year at a time, and must take place within six months of the end of a reporting period. Reporting must take place on the company's website, and according to the Rules, companies "undertake to make it possible for LMI to create a link to a joint reporting website". Reporting shall be done in Norwegian, but companies are encouraged to report in English as well.

The report must be publicly available for three years after being published, and be maintained for five years after the reporting period has expired.

Reporting shall either be done at an individual or aggregated level, cf. section 15.04 of the LMI Rules, which corresponds to article 3 of EFPIAs Disclosure Code.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

In order to publish information at an individual level, the Norwegian Personal Data Act requires that consent must be obtained prior to the individual disclosure taking place. In the event that such consent to disclosure cannot be obtained, LMI's Rules state that the transfer of value shall be reported at an aggregated level.

8 The Internet

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

Advertising of medicinal products on the Internet is subject to the same rules as advertising in any other media. The Medicinal Products Act and the Medicinal Product Regulation and LMI's Rules are therefore also applicable to such advertisements. In addition, provisions which apply to internet advertising in general will also apply to medicinal products. For instance, the Marketing Control Act contains a provision prohibition e-mail advertising without prior consent from the recipient.

The Norwegian Medicines Agency has also decided that twice a year companies must send an overview of their own webpages as well as pages they support, to the Committee for Information on Medicinal Products. This also includes advertising in social media.

The Agency also considers that the use of banner advertising on webpages shall comply with the provisions relating to "reminder" advertising, ref. question 3.7.

The supervision of websites in Norway is rather efficient due to the notification requirement.

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

The Agency considers that as a minimum requirement it is necessary that the starting webpage contains information which is allowed to be disclosed to both the general public and healthcare professionals alike, and that webpages for healthcare professionals are strictly separated from other webpages, preferably also including a "warning" to proceed to such pages only if you are healthcare personnel, combined with an active confirmation from the user.

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

There are no specific rules on linking to and from websites, and thus the permissibility must be determined with basis in the existing rules on pharmaceutical advertising. As a starting point, ordinary linking to independent websites under normal circumstances will likely not be deemed problematic. If the linked-to webpage contains information which could be problematic with regard to the rules if stated by the company on their webpage, it is recommended that the company uses a "disclaimer" stating that the linked webpage is outside the control of the company and no responsibility for the information disclosed there will be assumed.

However, if the linking is done as part of a promotional activity or in order to attempt to circumvent the rules on pharmaceutical advertising, a company could in principle be held responsible for the content on the independent website.

A company will not be held responsible for reverse linking undertaken by an independent party.

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

Information disclosed on webpages for the general public, which are considered advertising, must be in compliance with the rules on advertising to the general public, see question 6.1. Information which is not considered advertising, such as corporate information, contact information, etc., may be placed freely on the website. Health information may also be placed, provided the rules outlined under question 6.3 are adhered to.

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

As stated under question 8.1, the rules on advertising on the internet also apply to social media. The Consumer Ombudsman has also published a guideline on advertising in social media in general, and this guideline would also be applicable to medicinal products.

9 Developments in Pharmaceutical Advertising

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

The most significant development in 2015 was the revocation of the prohibition on television advertisements, which became effective on 1 January 2016.

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

The highly anticipated white paper on medicinal products, published by the Ministry of Health and Care in 2015 was adopted by Parliament in February 2016. Among the topics discussed in the white paper was how industry patient information brochures, which are supplied to the patient after the doctor has prescribed, should be classified. The pharmaceutical industry has requested that such brochures should not be considered advertising. The Ministry did not support this initial view, but suggested that the industry should be invited to cooperate with the authorities to construct patient directed information on medicinal products.

The majority of the Parliament Committee that evaluated the white paper, expressed a more positive, yet ambiguous view, stating that the industry should have a larger role in the work for more correct use of medicinal products. It can therefore be expected that there will be some further development on this particular topic in 2016.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The most notable trend is that the NMA has started to publish their supervisory reports from inspections on industry meetings on their website, regardless of whether there has been a breach of the rules. The comments submitted from the company on the reports are also published, as well as any administrative decisions. Previously, the NMA usually only published the administrative decisions.

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Haavind

Haavind was established in 1893 by Jan Groos Helmer. Today, Haavind is among the largest law firms in Norway, with approximately 100 lawyers, based in Oslo. The firm assists both national and foreign clients from the public and private sectors operating in various industries, including technology and telecommunications, construction and offshore, real estate, healthcare and life sciences, banking and finance, energy and food.

The Health and Life Sciences practice includes a high level of expertise among its lawyers, and offers a wide variety of services ranging from complex and comprehensive services to minor assignments on e.g. regulatory affairs, contracts and intellectual property rights. The firm enjoys a strong reputation amongst companies in the pharmaceutical industry, and represent on a regular basis several prominent pharmaceutical companies operating both in Norway and abroad.

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