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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?

Advertising of medicinal products in Finland is governed by the Medicines Act (395/1987, as amended) and the Medicines Decree (693/1987, as amended).

Also, the Code of Ethics (revised in 2022) ("PIF Code") issued by Pharma Industry Finland ("PIF") contains detailed provisions on the advertising of medicinal products, complementing the statutory legislation. The PIF Code has been drafted and implemented by the representatives of the pharmaceutical industry. All members of the PIF (which includes, in practice, most of the major players in the pharmaceutical industry in Finland) have undertaken to comply with the PIF Code and therefore it represents the generally accepted code of conduct of the industry.

On a general level, the Consumer Protection Act (38/1978, as amended), which is applicable to consumer advertising, the Unfair Business Practices Act (1061/1978, as amended), which is applicable to business-to-business advertising, and the Electronic Communications Services Act (917/2014, as amended), which contains provisions on electronic direct marketing, may apply to the advertising of medicinal products. With the exceptions of an action based on unfair business practices (see question 1.9 below) and comparative advertising (see question 3.4 below), these general provisions will not be described in more detail below.

1.2 How is "advertising" defined?

Advertising of medicinal products is defined as all types of publicity, advertising and promotional activities intended to promote the prescription, supply, purchase or use of medicinal products. This includes, *inter alia*, advertising directed at the general public, advertising directed at persons qualified to prescribe or supply medicinal products, sales promotion and activities of medicinal sales representatives. Also, the distribution of samples shall be considered advertising of medicinal products.

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?

Pharmaceutical companies must have a scientific service unit responsible for the information distributed on the medicinal products of the company and for the correctness of such information. Under the PIF Code, the scientific service unit must employ at least one physician or pharmacist responsible for the approval of the company's advertising measures before their publication, including events, advertisement gifts and market studies. This person must ensure that the final form of the advertising measure complies with the PIF Code and the legislation on pharmaceutical advertising.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

No, there are no legal or code requirements for companies to have specific standard operating procedures, although most companies have such in place. In terms of specific personnel, see question 1.3 above for requirements concerning scientific service units.

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?

There is no mandatory requirement for prior approval of advertisements by the Finnish Medicines Agency ("Fimea") or the PIF. However, a pharmaceutical company may voluntarily request the supervisory body acting under the PIF to inspect an advertisement directed at consumers in advance. Notwithstanding the aforementioned, it is stipulated in the PIF Code that all television and radio advertisements for medicinal products must be submitted for preliminary inspection to the PIF.

The supervisory body operating under the PIF may, in connection with the preliminary inspection, approve the contemplated radio or television advertisement as such, or with amendments, or reject it.

If a draft other than the final advertisement is submitted to the inspection, the statement of the supervisory body given in connection with the examination of such draft will not be considered the supervisory body's final opinion of the finished advertisement. The supervisory body is, however, bound to the opinion given by it on the compliance of the draft with the PIF Code.

The supervisory body must give the applicant a separate justified decision on the preliminary inspection of the advertisement, indicating the date of the decision. The applicant shall be notified of the decision immediately.

A preliminary television or radio advertisement that has been inspected can be shown for a period not exceeding three years from the date of approval.

Concerning advertising measures other than radio or television advertisements, the preliminary inspection may focus on the question of whether the measure in question complies with the PIF Code and whether it would be prohibited through subsequent supervision. The preliminary inspection decision must specify the reasons for which the advertising measure does not comply with the PIF Code.

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?

Fimea may prohibit a company from continuing or repeating advertising that violates the provisions of the Medicines Act and Decree. Fimea may also order a company to rectify improper advertising, if considered appropriate due to the safety risk of medicinal products. A conditional fine may support a prohibition or order issued by Fimea.

Fimea's decision to prohibit or rectify improper advertising may be appealed to an Administrative Court and further to the Supreme Administrative Court. The time to appeal is 30 days from the date of service of the decision. Fimea's decision must be complied with unless the Appellate Court rules otherwise.

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? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

A person that intentionally, or due to negligence, acts in violation of the Medicines Act or Decree or Fimea's prohibition or order may be sentenced for a pharmaceutical offence to fines or imprisonment of up to one year. If the act is only due to negligence, the person may be fined for a pharmaceutical infringement. Criminal proceedings are handled by the general courts and initiated by the general prosecutor.

In October 2006, Fimea prohibited a major pharmaceutical company from advertising a medicinal product with material that was not in accordance with the approved summary of product characteristics ("SmPC"). Fimea also prohibited such advertising that omits an essential detail for the medical value of the medicinal product or which refers to a clinical trial in a way that misrepresents the conclusions, extent and significance of the trial. The prohibitions were enforced with a conditional fine in the amount of EUR 2 million. In 2019, Fimea prohibited a pharmaceutical company from using starter packs as part of its marketing. The prohibition was enforced with a conditional fine of EUR 70,000.

It is not common for competitors to take direct action through courts for advertisement infringements, but it happens from time to time that a pharmaceutical company files a complaint with Fimea against a competitor (which is not a member of the PIF) and requests that it acts and prohibits the advertising of the competitor.

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

The supervisory bodies acting under the PIF monitor the appropriateness of advertising medicinal products by the PIF's member companies and compliance with the PIF Code. A supervisory body may raise a matter on such advertising on their own initiative or based on a complaint. Anyone can lodge a complaint against measures taken by the PIF's companies committed to the PIF Code falling within the scope of application of the PIF Code. The sanctions that the supervisory bodies of the PIF may issue for violation against the PIF Code include: an admonition for future reference; a request to abstain from incorrect activity; a processing charge; a compensation payment; a sanction payment (minimum EUR 1,000 and maximum EUR 100,000); and an order to rectify and correct the measures taken. In addition, a company may be ordered to pay liquidated damages (minimum EUR 20,000 and maximum EUR 300,000). The supervisory body may also submit the matter to Fimea for action if, e.g., a company continues its non-complying activity in spite of an admonition, requests to abstain from incorrect advertising or temporarily requests to abstain.

Disagreements between pharmaceutical companies concerning a violation of the PIF Code should be submitted for examination to the system set forth in the PIF Code before they may be brought to the attention of the relevant authorities. A member company that has bypassed said system can be ordered to pay liquidated damages. Liquidated damages can also be imposed if the company violates a contract made amicably with another pharmaceutical company in relation to the discontinuation of incorrect advertising.

If a case is being examined by the authorities, the supervisory body of the PIF does not issue a decision on it until such proceedings have been finalised. After a final decision by the authorities has been issued, the case can be decided by the supervisory body, considering the dimensions of the decision by the authorities as well as the eventual sanctions imposed. If the examination of the case by the authorities is considerably delayed, the supervisory body of the PIF can, exceptionally, take up the case despite the pending process with the authorities.

Fimea may handle a matter even though it is being assessed or has been decided by the supervisory body of the PIF.

According to the PIF Code, the Inspection Board or the Supervisory Commission can, upon the request of the interested party, at their discretion, impose a EUR 5,000 compensation payment for an unfounded complaint made merely for the purpose of harming the competitor, payable to the company suffering from the complaint to cover the costs incurred for the reply to the unfounded complaint.

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?

Under the Unfair Business Practices Act, practices that are contrary to good business practices or that are otherwise unfair in relation to other entrepreneurs may not be used in advertising.

Advertising must also clearly indicate its commercial purpose and the party for the benefit of whom the advertising is carried out. Furthermore, it is prohibited to use in commercial activities false or misleading expressions regarding their own or another entrepreneur's business activities that are likely to affect the demand or supply of goods or harm another entrepreneur's business activities.

An action based upon the violation of the provisions of the Unfair Business Practices Act may be initiated at the Market Court by an entrepreneur who is affected by the violating action or whose activity it may damage (e.g. a competitor). The Market Court may prohibit the continuation of the unfair practice and order suitable rectifying measures. The Market Court may also support a prohibition or rectifying measure order with a conditional fine. Finally, the losing party may be required to reimburse the opposing party's legal costs. A party may appeal a decision by the Market Court to the Supreme Court if the Supreme Court grants leave to appeal.

A competitor that has suffered damages due to the unfair practice of another entrepreneur may also sue for damages at a General Court. Finally, the public prosecutor may bring criminal charges against an entrepreneur that has deliberately, or out of gross negligence, used false or misleading expressions in advertising.

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)?

Only medicinal products referred to in the Medicines Act may be advertised or marketed as medicinal products. It is prohibited to market medicinal products lacking market authorisation in Finland.

It is not acceptable, e.g., at training events, to give specific information of non-authorised medicinal products using the contemplated trade name. However, it is acceptable to give objective information of published research results regarding non-authorised medicinal products, by using the generic name.

In case a healthcare professional has obtained information, e.g. at an international training event, of the name of a medicinal product that has not yet been authorised in Finland but will be marketed using the same name, it is acceptable upon request to inform the doctor thereof. The active advertising of such product is prohibited.

The aforementioned prohibition to market medicinal products that do not have a marketing authorisation in Finland also applies at international events arranged in Finland, according to Finnish legislation.

However, general information on a pharmaceutical company and their portfolio, as well as research activities and results, is not considered advertising (in the context of the Finnish medicines regulation) and thus is allowed. In practice, this leaves two possibilities to distribute information about non-authorised products:

1) advertising of the company itself, where the product portfolio can also mention products without marketing authorisation in Finland; and
2) information of a company's product development programmes, without any brand names, but information of the results of research programmes. No therapeutic claims are allowed.

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

It is acceptable to provide neutral information of scientific research results concerning unauthorised products and/or off-label information. However, product trade names must not be used.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

The same rules apply as in question 2.2 above. However, in case the press release is issued by a listed company and based on the statutory information liability of the pharmaceutical companies, such a press release could, in certain situations, also contain the trade name of the product, as this type of press release is outside the scope of the PIF Code.

When issuing a press release about unauthorised medicinal products and/or off-label information, the issuer must ensure that such a press release does not contain any elements of advertising whatsoever. The same limitation applies to specialised/scientific media (see the answer to question 2.1 above).

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

It is acceptable to provide information on scientific research results for medicinal products that are not yet authorised, only if the healthcare professional has explicitly requested the information; unsolicited distribution of information is, as a main rule, not allowed. Information sent to healthcare professionals upon request may not contain any trade names of unauthorised products and reference must only be made to the name of the active ingredient. Furthermore, information on the research results must be presented in a neutral and objective way.

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?

According to the Medicines Decree, product and price lists are not considered advertising. However, such product and price lists may not contain any claims concerning the medicinal product in question. This rule also applies to products approved by Fimea for named-patient/compassionate use purposes.

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?

According to Fimea, the offering of a pharmaceutical product without a valid marketing authorisation (or with a pending marketing authorisation) in tender offers is prohibited by virtue of the Medicines Act, unless the tender offer has not been specified to explicitly concern said product.

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?

It is possible to enter into consultancy agreements with healthcare professionals, for, e.g., market research purposes. It must be noted, however, that such consultancy relationships must fulfil certain criteria set forth in the PIF Code (e.g. a written agreement requirement and that the consultancy fees are on a reasonable level) and the pharmaceutical company may not engage more healthcare professionals, e.g. in market research, than is reasonably needed.

3 Advertisements to Healthcare Professionals

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

Advertising of medicinal products to persons qualified to prescribe or supply such products must include essential information on the medicinal product and its use. In particular, such advertising must include:

- essential information, in accordance with the SmPC, on the purpose of use, recommended use, effect and safety of the product;
- legal conditions of supply;
- conditions of reimbursement under the health insurance system, average treatment costs, where possible, and retail prices of different packages; and
- the date when the advertisement was prepared or revised.

All information given in advertising should correspond to the approved SmPC, be accurate, up to date, verifiable and clear enough to enable the reader to form an opinion of the therapeutic value of the product. Quotations, as well as tables and other illustrative matter taken from medicinal journals or scientific research, must be faithfully reproduced and the precise sources indicated.

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?

As a main rule, an advertisement may not contain any information that is not compliant with its content with the approved SmPC (e.g. off-label information).

However, an advertisement may refer to studies that have not been explicitly mentioned in the SmPC, provided that such studies have been appropriately published, the information is compliant with the SmPC and the reference fulfils other general requirements for advertisements as listed above in question 3.1 and below in question 3.4. Moreover, it is permissible to include the mention of these in the material for the advertising of medicinal products articles that have been accepted for publication in scientific journals, as well as the results of trials or studies submitted to the regulatory authorities in association with marketing authorisation applications. The unpublished study results must meet the same quality criteria applied to published results. Any reference to study results must be associated with explicit information on the trial arrangements (e.g. *in vivo*, *in vitro*, animal testing).

As an exception to the above, reference may also be made to such study results that have not been published, if they can be deemed to have material significance for the medication of patients. New information has material significance if it refers to a serious disease and if there is clear proof that the treatment in question is superior to the earlier treatments.

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

The PIF Code requires that pharmaceutical promotion must not contain direct and active recommendations to use the medicinal product given by scientists, healthcare professionals or celebrities.

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 are no numeral requirements to this extent. The PIF Code only stipulates that the comparison between different active ingredients must be based on scientific evidence.

Furthermore, any research results included in the material for the advertising of medicinal products must have been published in article form in a scientific journal. Moreover, it is permissible to include this in the material for the advertising of medicinal products articles that have been accepted for publication in a scientific journal, as well as trials supplied to the regulatory authorities in association with a marketing authorisation application.

The use of unpublished material, such as abstracts or posters of similar materials that have not been published in scientific journals, is, as a rule, prohibited.

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?

The Medicines Act stipulates that advertising may not provide a misleading or exaggerated picture of the formula, origin or pharmaceutical significance of a product, or be inappropriate in any other similar way.

In addition, the Unfair Business Practices Act contains general provisions regarding comparative advertising, which may be applicable to the advertising of medicinal products.

Furthermore, the PIF Code stipulates that comparisons between different medicinal products, active ingredients, excipients or other characteristics must be accurate and reliable. The graphic comparison and price comparison of the product must be clearly justifiable. The object in comparison must be clearly recognisable.

The packages and dosages used in price comparisons must correspond to each other. When the prices of products are compared, the medicinal products covered by the comparison

and their trade names must be clearly indicated. When using comparisons in advertising, the time of comparison or the date of publication must be disclosed.

Special weight must be given in the comparison to the objectivity of advertising and the correctness of information.

There are no explicit rules prohibiting a company from referring to a competitor's product or indication that has not yet been authorised in Finland. However, such information may be considered inessential from the point of view of a Finnish consumer and healthcare professional as the product is not available for sale or prescription in Finland. Consequently, it is possible that comparative advertising of this kind may be considered inappropriate.

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

Scientific material, the direct objective of which is not the promotion of the sales of a medicinal product published by the pharmaceutical industry, e.g. scientific papers and proceedings of congresses, is explicitly excluded from the scope of the advertising provisions of the Medicines Act and Decree, as well as the PIF Code. There are no specific rules on the distribution of scientific material. Distribution of scientific material is basically permitted as long as it constitutes a genuine exchange of scientific information and is not a hidden sales promotion of a medicinal product.

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?

There are no specific rules on "teaser" advertisements, and basically all advertising directed at healthcare personnel must fulfil the content requirements described above (see question 3.1). An exception to this basic rule involves "reminder advertising". Reminder advertising means advertising that is intended solely as a reminder of the name of the product. Reminder advertising may contain only the trade name of the product, the name of its active substance and the trademark of the product, as well as the holder of the marketing authorisation, marketer, importer or manufacturer and its company logo. The nature of a reminder advertisement is thus the opposite from that of a teaser advertisement, in the sense that reminder advertisements are used after a product has already become known to remind the target group of the existence of the product. It remains unclear, however, whether the provisions on reminder advertisements could also be a basis for permitting teaser advertisements.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

Promotion of a medicinal product must be based on the most recently approved SmPC. Use of Product A in combination with Product B could thus be referred to as part of the promotion of Product A. If Product B is referred to by its trade name, instead of its active ingredient, it is still recommendable to obtain consent for such reference from the marketing authorisation holder of Product B. In case the combination use is not an approved indication of Product B, promotion of Product B for such use could be considered a violation of the applicable advertising regulation.

4 Gifts and Financial Incentives

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

According to the Medicines Decree, samples of self-care medicinal products may be distributed only to persons entitled to prescribe and supply them. Samples of prescription-only medical products can be distributed only to persons entitled to prescribe medicinal products. If the marketing authorisation of the medicinal product is subject to restriction of supply, the sample can only be given to the doctor entitled to prescribe it.

Only one sample package per calendar year may be given to each person authorised to prescribe or supply the medicinal product. A sample may be distributed only on the basis of a written, signed and dated request, and pharmaceutical companies must keep records of the free samples given in each calendar year. A sample must be exactly the same as the smallest package size available on the market. Each sample must be accompanied by an SmPC.

Narcotics, including psychotropic substances and substances that mainly affect the central nervous system, must not be distributed as samples.

The PIF Code further states that during the two years following the introduction of the medicinal product to the market or the adoption of its reimbursable price, one package of each medicinal product, strength and pharmaceutical form can be given as a free sample to each recipient in one calendar year. The free medicine samples can be distributed for a maximum of two years. However, this does not apply to distribution of free samples of self-care medicinal products.

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

Under the Medicines Act, sales promotion of medicinal products to healthcare professionals, such as gifts and benefits, must be inexpensive and related to their professional activities. Hospitality at sales promotion events must be reasonable and secondary compared to the purpose of the event.

The PIF Code contains stricter rules on incentives, gifts, advertising gifts and other support measures. Under the Code, it is forbidden to give promotional gifts related to prescription-only medicinal products. While the distribution of promotional gifts related to the advertising of non-prescription medicinal products must be reasonable, such gifts must have minor economic significance for the recipient and they must have bearing on their professional operations. The value of such gifts may not exceed EUR 35 (retail price including VAT). Healthcare professionals must not be offered or otherwise provided with direct or disguised economic incentives, gifts or promotional articles constituting inducements. Making donations or awarding grants to individual healthcare professionals is only permitted for performing so-called "investigator-initiated clinical trials" with a proper study protocol, which is approved by the regulatory authority and ethics committee and otherwise meets the statutory criteria for clinical trials.

It must also be noted that offering an additional benefit may be considered a bribe if the benefit is significant and may induce the recipient to make such acquisitions that would not otherwise be justifiable for the institution.

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? If monetary limits apply, please specify.

According to the PIF Code, the above rules on incentives, gifts, advertising gifts and other support measures also apply directly and indirectly to representatives of healthcare and patient organisations (see question 4.2 above). The PIF Code stipulates that the support must be defined and targeted to support healthcare, research or training and it must not constitute an incentive for the recommendation, prescription, purchase, dispense, sale or administration of a particular medicinal product. There must always be a written agreement between the pharmaceutical company and the organisation. No monetary limits apply for such donations.

Under the PIF Code, a company can engage in sponsorship activity using the company name. However, the use of a product name is not allowed. The PIF Code also contains specific rules on the obligation to disclose economic benefits targeted at healthcare organisations or professionals. The requirements on disclosure of transfers of value set forth in the PIF Code are in line with the requirements of the EFPIA Disclosure Code.

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?

Sales promotion must not be inappropriate or such that it may endanger the trust of the general public that the prescription, use or assignment of medicinal products is independent. Consequently, arrangements where medical or educational goods and services are provided to doctors that could lead to changes in prescribing patterns will most likely be considered inappropriate.

The PIF Code further stipulates that healthcare professionals can be provided with informative and educational material and medicinal supplies under certain conditions if these do not constitute an incentive for, *inter alia*, the recommendation, prescription or sale of a particular medicinal product.

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?

Pharmaceutical companies are not permitted to grant discounts to individual pharmacies, and the wholesale price must be the same in all pharmacies. The wholesale price must include all rebates, refunds and other benefits that are granted to a pharmacy. The aforementioned restrictions do not apply to such medicinal products that may be sold in places other than pharmacies, such as nicotine replacements. It is, however, permitted for pharmaceutical companies to grant discounts to welfare and health units, e.g. hospital districts and individual hospital pharmacies.

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? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

There are no explicit rules prohibiting the provision of equipment or services to third-party institutions contingent on the purchase of medicinal products. However, it cannot be ruled out that, in some circumstances, such an arrangement may be considered unacceptable, particularly where the arrangement jeopardises the public's trust in the impartiality of prescribing or supplying medicinal products.

It is, as a main rule, forbidden to give consumers another product or benefit (giveaways) at the price of a medicinal product purchased. However, providing the consumer with, e.g., apparatus for administration in connection with the prescription or purchase of a medicinal product may be allowed, assuming the provision of this kind of benefit is indispensable for the use of the medicinal product in question and it cannot be interpreted as promotion of the product in question (see answer to question 1.2 above).

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?

The Medicines Act and Decree do not contain any specific provisions on this point. According to the PIF Code, the advertising of medicinal products must follow good practices in order to inspire truth and esteem. A refund scheme could thus possibly be considered contrary to good practice.

Furthermore, it is prohibited in consumer advertising to suggest that the effects of the product are guaranteed, or that its use is not associated with any adverse effects, or suggest without grounds to prove that the effects are equally good or better than those of another treatment or medication.

The nature of the product, whether it is a prescription-only or an over-the-counter product, does not make any difference.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

Yes. The Finnish Health Insurance Act (1224/2004, as amended) temporarily provides for conditional reimbursement of a medicinal product from public health insurance for purposes of sharing risks associated with new medicinal treatments. A decision on conditional reimbursement is associated with a confidential agreement between the Pharmaceutical Pricing Board and the marketing authorisation holder, which usually includes a provision on refund paid by the marketing authorisation holder

to the Social Insurance Institution of Finland on the basis of reimbursement paid by the latter to patients of the product in question. The decision on conditional reimbursement is valid for the maximum period of five years. It is possible to apply for a renewal. The current regulation on conditional reimbursement remains in force until the end of 2025.

Confidential risk sharing arrangements and outcomes-based schemes between marketing authorisation holders and hospitals have also become more common over recent years. In addition to outcomes-based pricing, such agreements often involve terms on discounts provided to hospitals. While such arrangements are allowed as such, it is noteworthy that giving medicinal products to hospitals for free is considered inappropriate marketing. Legislation on public procurements must also be taken into consideration when contracting with hospitals.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

Yes. Pharmaceutical companies may engage in, e.g., research collaboration with Finnish public health bodies. However, the starting point for all such cooperation is that the decision-making of authorities should not be inappropriately influenced. Authorities are expected to act in an objective manner, and their acts must also appear objective when assessed by third parties. Thus, collaboration with an authority that, for example, is responsible for the public procurement of medicinal products may be considered inappropriate if the timing of such collaboration overlaps with a decision on procurement of medicinal products of the pharmaceutical company in question.

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

Pharmaceutical companies may sponsor further or complementary training. However, according to the Finnish Medical Association, events organised by pharmaceutical companies themselves do not fulfil the requirements for post-graduate or further professional education (i.e. no Continuing Medical Education accreditation). When a pharmaceutical company sponsors a scientific event, the attendees and invitees must be clearly informed of this. Furthermore, pharmaceutical companies may participate in the expenses of further complementary training only if the company is provided with a possibility to actively distribute information of their products in the training event.

According to the Guidelines concerning Continuing Medical Education (2007) published by the Finnish Medical Association, it is further recommended that physicians and other healthcare professionals participating, e.g., as lecturers in Continuing Medical Education events sponsored by pharmaceutical companies disclose their financial and other interests (e.g. grants and awards received from the pharmaceutical industry, shareholding in pharmaceutical companies, etc.). The conflict-of-interest disclosure should be made in the programme of the event.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The Finnish Criminal Code (39/1889, as amended) contains the general anti-bribery rules regarding the giving and accepting of a bribe. The Criminal Code contains provisions on active bribery of a public official or a Member of Parliament, passive bribery of a public official or a Member of Parliament, active bribery in business, and passive bribery in business. The Criminal Code also contains provisions on aggravated forms of the mentioned crimes. The provisions of the Criminal Code apply to the interaction between pharmaceutical companies and healthcare professionals or organisations if the interaction meets the essential elements of the offence set forth in the Criminal Code.

Finland does not have a special authority focusing particularly on investigating bribery-related offences. As it is the case with other offences, the police force is responsible for investigating such offences. In cases of a more complex nature, i.e. involving organised crime, international connections or involvement of senior public officials, the investigations are normally conducted by the National Bureau of Investigation. After the investigation is complete, the case is turned to the prosecutorial service for consideration of charges. Fimea monitors advertising of medicinal products to ensure such advertising is in compliance with the Medicines Act and Decree. Also, the PIF monitors the appropriateness of the advertising of medicinal products by the PIF's member companies and compliance with the PIF Code.

The police force shall investigate when, on the basis of a report made to it or otherwise, there is a reason to suspect that a crime has been committed. Thus, the police force may start an investigation even though the matter is already subject to assessment by Fimea or the PIF. See question 1.8 on the relationship regarding the processes instituted by the PIF and competent authorities.

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?

According to the PIF Code, events organised or sponsored by the pharmaceutical industry must observe the customary local norms of hospitality. The hospitality must be reasonable and suitable to the situation, as well as secondary to the purpose of the event. Furthermore, hospitality must not exceed what typical participants in the event would be prepared to pay if they had to cover their own expenses. Hospitality should reinforce the positive public image of the pharmaceutical industry and may not endanger the public trust towards neutrality of medicine subscription and supply. The overall daily expenditure on meals (food and beverages) per participant must not exceed EUR 45 for lunch and EUR 100 for dinner.

Scientific or training events may take place abroad, provided they have sufficient scientific- or training-related justification.

The PIF Code must also be followed in pharmaceutical advertising and other operations falling within the scope of application of the Code, targeted at Finns abroad or in international congresses. In addition, local instructions and requirements should be adhered to. Please also see question 5.2 below.

The PIF Code stipulates that cooperation and hospitality with patient organisations and their representatives are covered with the same obligations applied to healthcare professionals.

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?

According to the PIF Code, the pharmaceutical industry may participate in the costs of updating or advanced healthcare training, provided the industry is given the possibility to participate in the information activity. The main focus of the event must be medical information and research or other medical training. The majority of the participant's time must be consumed by scientific programmes or training. The costs must essentially relate to scientific programmes and information, and be allocated only to professionals who receive the information. Hospitality provided in events must be limited to the persons who personally meet the criteria of event participants, except for necessary assistants who are required due to a person's state of health.

The event must take place at a location that is suitable, taking into account the scientific or training programme of the event. The event may not be organised in a "luxury" location or at a resort known for its leisure and entertainment activities. The event may also take place abroad, provided it has sufficient scientific- or training-related justification.

The cost may only include registration, travel, accommodation and meal expenses of the scientific or training event. Payment for the attendee's time is not allowed.

The event and travel time must be organised so that, excluding travel days, the majority of the participant's time will be spent on scientific programmes and training.

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?

The hospitality arrangements for scientific meetings are most likely considered advertising within the meaning of the Medicines Act and Decree, and the issues highlighted in questions 5.1 and 5.2 above must be followed in such hospitality arrangements.

Fimea may prohibit a company from continuing or repeating hospitality arrangements that violate the provisions of the Medicines Act and Decree. A conditional fine may support a prohibition or order issued by Fimea (see question 1.6).

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

Basically, yes. However, the payment should be reasonable and it should strictly relate to professional activities. Otherwise, there is a risk that such payment will be considered an inappropriate gift. In their cooperation with doctors, companies must ensure that the agreement relating to the compensation is not used to circumvent the rules and regulations on the promotion of medicinal products.

The use of healthcare professionals as a group or as individual consultants or advisers must be arranged to meet certain criteria defined in the PIF Code (e.g. a written contract is required, and consultants are liable to disclose their relationship to the company whenever writing or speaking publicly about the subject matter of the consultation relationship).

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

It is not prohibited for physicians to take part in post-marketing surveillance (see also question 5.3). According to the PIF Code, in organising market research, special attention must be paid to the protection of the privacy of the patients, as well as to the voluntary participation in such research. In addition, market research must not have an impact on the treatment of individual patients and should be based on objectiveness, and the compensation paid for the implementation of the research must be of reasonable economic value. Market research must also be limited in scope and the opinion of healthcare professionals must not be asked repeatedly. Market research may not contain any elements of advertising and the research may only be conducted on medicinal products with valid marketing authorisations.

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

See questions 2.7, 5.4 and 5.5 above. With regard to market research, it is permissible to compensate healthcare professionals for their participation; however, according to the PIF Code, the amount of the remuneration must be minor. The PIF has considered EUR 35 to be an acceptable amount of compensation, but if it is a case of extensive research that takes more time, the acceptable level of remuneration may amount to EUR 100.

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 medicinal products should encourage the appropriate use of the same, and information given in advertising must correspond to the SmPC. Advertising may not solicit the general public to an unnecessary use of medicinal products, provide a misleading or exaggerated picture of the formula, origin or significance as a medicine, or otherwise be inappropriate. In practice, this means that no gifts, charitable donations or offers, such as "two-for-one" offers, may be used in marketing of medicinal products and that price may not be used as a main argument in the marketing of a medicinal product. Products may be advertised as medicinal products only if defined as such pursuant to the Medicines Act.

Advertisements to the general public must include the product name and the name of the active ingredient, if the product contains only one active ingredient, as well as information necessary for

correct and safe use, and an explicit and easily readable request to read separate instructions. According to the PIF Code, the advertisement must also include the indication and the name of the holder of the marketing authorisation, importer or marketer.

It is prohibited to include in advertisements to the general public groundless statements regarding health or direct advertising at children or give an exaggerated or misleading picture of the effects of a medicinal product.

Advertisements to the general public must not refer to clinical trials in such a way that a false picture is given of the conclusion, extent or significance of the trials. According to the Medicines Decree, advertisements to the general public must be set out in such a way that it is evident that the message is an advertisement of medicinal products and must not include any information that:

- gives the impression that it is unnecessary to consult a doctor or that a treatment recommended by a doctor is not necessary;
- suggests that the effects of the product are guaranteed, or that its use is not associated with any adverse reactions, or suggests that the effects are equally good or better than those of another treatment or medication;
- suggests that the health of the subject can be enhanced by taking the medicinal product or that the health of the subject could be affected by not taking the medicinal product;
- is directed solely or mainly at children;
- refers to a recommendation by scientists, healthcare professionals or celebrities;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the therapeutic effect or safety of the medicinal product is based on its origins from nature;
- could easily lead to an incorrect self-diagnosis or self-cure due to a detailed representation of a case history;
- refers in inappropriate, intimidating or misleading terms to claims of recovery;
- uses inappropriate, intimidating or misleading terms, pictorial representations of changes caused in the human body by disease or injury, or of the effect of a medicinal product in the human body or its parts; or
- mentions that the medicinal product has been granted a marketing authorisation.

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

It is prohibited to market prescription-only medicinal products or products containing narcotics or psychotropic substances to the general public.

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?

Disease awareness campaigns are allowed, provided they are not, even indirectly, intended to promote the sale of medicinal products. Notwithstanding question 6.2 above, it is acceptable to provide information on prescription-only medicinal products to the general public, provided the information only contains essential information consistent with the SmPC and product leaflet. The information given can also refer to prescription-only medicinal products if the information is of an impartial and factual nature, and covers all alternative medicinal products on the market. In such cases, sufficient information on non-medicinal forms of treatment must also be given. The PIF Code contains more detailed criteria for awareness campaigns, concerning, e.g., the visual image of the awareness information and internet sites containing health awareness material.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Please see questions 2.3 and 6.3 above and question 6.5 below. In case developments as to unauthorised medicinal products or unauthorised indications are referred to, the publication should not involve any elements of advertising whatsoever.

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

Information focusing primarily on the operations of the company and corporate image advertising and business representation with no direct objective of promoting sales of medicinal products are excluded from the scope of the PIF Code. In addition, press releases based on the information that a pharmaceutical company is obliged to provide, as well as informative notices (e.g. changes in packaging or warnings about adverse effects), are not considered promotional according to the Medicines Decree.

It must be noted, however, that the advertising provisions of the Medicines Act and Decree and the PIF Code apply to all forms of advertising and promotional activities by pharmaceutical companies, and the context and subject matter are decisive in determining whether or not an activity amounts to the promotion of medicinal products. A non-promotional item may be used for a promotional purpose and therefore come within the scope of the relevant legislation and industry rules. Consequently, material issued by companies that relates to medicinal products, but which is not designed as a promotion for those, such as corporate information, press releases, financial information for shareholders and the Stock Exchange, and responses to unsolicited enquiries from the public, should be examined to ensure that it does not contravene the Medicines Act or Decree or the PIF Code.

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

The PIF Code contains guidelines on cooperation with patient organisations. In the PIF Code, it is also stated that the EFPIA Code should be applied. Providing support to patient groups is not prohibited as such. However, the (financial) support must not be used to circumvent the legislation and the PIF Code. Donations are only allowed if their purpose is to support healthcare and research, and if information regarding donations is properly documented and filed by the donor. Donations will not be accepted in cases where the nature of the cooperation may jeopardise the public trust in the impartiality of the prescription and supply of medicinal products. All donations and sponsorship, direct or indirect, should be disclosed by pharmaceutical companies to ensure transparency. It should also be noted that in the materials and publications created jointly by a

patient organisation and the pharmaceutical company, the editorial material should be based on editorial initiatives and assessments. The editorial and promotional material must be clearly separated. A pharmaceutical company must not require that it would be the only party financing the healthcare or patient organisation or any of such organisation's projects. Finally, when a pharmaceutical company sponsors, e.g., a scientific event organised by the patient organisation, this should be clearly indicated in the invitations and programmes.

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 a general rule, restrictions on advertising to consumers apply to patients as well. Giveaways or medicinal product samples cannot be distributed to consumers in sales promotion. In addition, prize-winning competitions and lotteries are prohibited. Please also see questions 6.1 and 6.2 above.

Patient instructions must always be delivered by the company to physicians or other healthcare professionals, and they must not be generally available to consumers. When delivering the material, the recipient must be informed clearly that the patient instructions are merely intended for particular patients to support the treatment prescribed to them, and are not generally distributable to all patients.

6.8 What are the rules governing company funding of patient support programmes?

Pursuant to the Medicines Act, a safety study conducted after the grant of a marketing authorisation that is performed as a non-interventional study must not be performed where the act of conducting the study promotes the use of a medicinal product. Payments to healthcare professionals for participating in non-interventional studies must be restricted to the compensation for time and expenses incurred. For example, payments should not be paid for recruiting patients for the study and no other similar additional incentives should be provided.

Pursuant to the Finnish Medical Research Act (488/1999, as amended), no payment shall be made for participating in the study to the study subjects, their guardians, close relatives, any other persons closely connected with them, or their legal representative. However, an appropriate remuneration may be paid in respect of expenses or loss of earnings or for any other inconvenience suffered as a result of the study.

Under the PIF Code, informational/educational material and medical supplies are of minor value if their value does not exceed EUR 45. See also question 5.6 above.

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 express obligation to disclose details of clinical trials in advertising.

However, the Medicines Decree stipulates that advertising materials may not omit an essential detail, the omission of which could give a false impression. Further, according to the Medicines Decree, advertising may not refer to any clinical trial in a way that misrepresents the conclusions, extent or significance of the trial.

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 (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Yes. The Medicines Act stipulates that the holder of a marketing authorisation or other entity advertising a medicinal product should make publicly available, e.g. on the company's webpage, an updated list of direct or indirect economic or other benefits it has granted to medical or healthcare associations or patient organisations. The disclosure obligation concerns both national and foreign companies that are advertising their (authorised) products in Finland.

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 (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Yes. There is a requirement in the PIF Code for companies to make publicly available transfers of value annually provided by them to healthcare organisations and healthcare professionals who have their place of business in Europe. The disclosure obligation concerns both national and foreign member companies of the PIF that are advertising their (authorised) products in Finland.

As a main rule, the economic liaisons are published by specifying the name of the recipient, while the values of the economic benefits received by the individual recipient are published for each reporting period by classifying them in certain stipulated categories, e.g. donations and grants, contributions to the costs of events and service and consultation fees. The economic benefits received by a recipient can be published by annual aggregate categories, provided that the individual sums can be presented on request.

The publication should be displayed in the Finnish language on the company's webpage, following the PIF's template. The company must provide a brief presentation of the methods used in the publication and identification of each category. The publication takes place annually within six months from the end of each reporting period. The reporting period is one full calendar year. The data must be kept publicly accessible for at least three years and stored for at least five years.

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?

Due to data protection regulations, the publication of data on individuals requires consent from the person in question. If such consent is not obtained, the data is disclosed without the name

of the person involved. However, the associations of Finnish healthcare professionals generally support the disclosure.

8 Digital Advertising and Social Media

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

No, there are no legal or code requirements for companies to have specific standard operating procedures, although most companies have them in place.

Basically, the same rules apply to internet advertising as to advertising through other media. Advertising products that are to be sold by prescription, or which contain narcotics or psychotropic substances, is prohibited unless aimed at persons entitled to prescribe those medicinal products.

According to the PIF Code, multi-page and moving banners must be implemented so that reference to the minimum and/or additional information appears, at least, on the first page after clicking one link and that such information is readable, irrespective of the movement of content.

Based on our experience, the Finnish authorities react quite expediently to internet advertising, as they do not consider them to be fulfilling the legal requirements. The companies usually agree to change their advertising after having received a notice thereof.

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?

According to the Medicines Act, electronic advertising to healthcare professionals must be implemented in such a secure manner that it cannot target the general public. Thus, if advertising is carried out through electronic media, such as an extranet or another limited access system, the advertiser must ensure that unauthorised persons cannot access it (e.g. passwords and registration requirements for physicians). A general warning, such as "information for medical professionals only", is not sufficient.

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?

The content restrictions set by the Finnish regulations regarding the advertising of medicinal products also apply to websites accessed by links. According to the guidelines on the advertising of medicinal products produced by Fimea, independent websites that may be accessed by links from a company website need to comply with the Finnish regulations, even if the independent website is in a language other than Finnish or Swedish. Consequently, it is prohibited to have a link to a website in which prescription-only medicinal products or products containing narcotics or psychotropic substances are advertised, unless the site is only accessible to persons entitled to prescribe those medicinal products (see also question 7.2). There are no specific rules based on which the company would be held responsible for reverse linking.

The holder of the marketing authorisation is responsible for compliance with the Finnish legislation of an independent website that is accessible by a link from the marketing authorisation holder's website.

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

Advertising of prescription-only medicinal products or products containing narcotics or psychotropic substances to the general public is prohibited under the Medicines Act. However, a pharmaceutical company may publish the SmPC or the package leaflet approved by an authority on the company's website, provided that the summary or the insert has not been amended or abridged.

It is deemed possible to publish user instructions of such medicinal products whose dosing requires particular knowledge or use of particular auxiliary means (e.g. user instructions for inhalers or insulin pens).

A pharmaceutical company may generally also briefly mention that a particular medicinal product or active ingredient is used for the treatment of a particular disease. Demonstration of, *inter alia*, indications, therapeutic statements, effects or other such features of the medicinal product may, however, be considered advertising, which is prohibited as regards prescription-only medicinal products.

The acceptability of published information is considered on a case-by-case basis depending on the context of the information.

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

No specific regulation exists. The same rules basically apply to social media as to advertising through other media. The PIF Code explicitly states that it applies to operations taking place on the internet, social media and other electronic communications media.

According to the PIF Code, a pharmaceutical advertisement must not give information or an impression that suggests that the consumer can shoulder the responsibility for another person's health. This provision has been applied so that, in pharmaceutical advertising, a consumer cannot recommend a medicinal product to another consumer, for example, on Facebook pages. If, e.g., the pharmaceutical company's website(s) or Facebook page allows discussions about medicinal products to take place, such discussions are under the company's responsibility. From the PIF Code's point of view, likes and shares are also problematic.

According to the PIF Code, hidden advertising of medicinal products is prohibited. This provision has been applied so that mentioning the name of a prescription-only medicinal product family in a LinkedIn post was deemed not necessary nor justified in order to raise awareness of company activities.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

No specific regulation exists. According to the PIF Code, the pharmaceutical company has a wide responsibility for pharmaceutical advertising, which also extends to functions performed in collaboration with third parties. Accordingly, discussions taken by employees in the pharmaceutical company's name in forums hosted by others are under the pharmaceutical company's responsibility. The pharmaceutical company's duty of diligence also includes instructing and training employees on these matters.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

No specific regulation exists. The hospitality rules that apply to physical meetings, congresses and symposia (see section 5 above) apply to their virtual counterparts too. However, the use of EFPIA's Conference Vetting System evaluation platform is mandatory for member companies.

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?

In 2021, an amendment to the Medicines Act, according to which the retail price of a self-care medicinal product is, at most, the retail price according to the pharmaceutical tariff and, at minimum, the wholesale price used nationwide, was accepted (applicable as of 1 April 2022). According to the preparatory works, it follows from regulation of maximum prices for self-care medicinal products that pharmacies can commence competing on prices by lowering their own margins. The possibility of lowering prices should not lead to inappropriate pharmaceutical marketing or unnecessary use of self-care medicines that is not based on users' medical needs, wherein giveaways, donations to charity and volume discounts are especially prohibited. However, informing of the discounted minimum price as part of the pharmacy's marketing is allowed, but the information on price reduction may not be presented as the first or only thing in marketing. The increased marketing interest of pharmacies also means that pharmacies can be responsible for their marketing, whereas the marketing authorisation holder cannot be held legally responsible for the marketing if the pharmacy carries out the marketing independently and the marketing authorisation holder is not in any way involved in the marketing or its planning.

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

Health technology and related mobile applications have been under discussion and it is thus expected that practice in relation to this will develop. Due to the COVID-19 pandemic, over the past two years, the focus on physical medical sales representation has shifted to remote events, resulting in issues related to distance communication and distance advertising becoming even more topical.

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

There are no general practice or enforcement trends that have become apparent in Finland over the last year or so. The service capacity of healthcare was put to the test due to the COVID-19 pandemic and clinicians' time has only been used for clinical work. This has been reflected in the pharmaceutical advertising supervisory control; there have been fewer cases than normal, and no development trends can therefore be identified.

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