Distribution and marketing of drugs in Finland: overview

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DISTRIBUTION
Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation
To be distributed in Finland a drug must have a marketing authorisation granted nationally by the Finnish Medicines Agency (FIMEA) or, alternatively, centrally by the EU Commission after evaluation by the European Medicines Agency (EMA).

Exceptions
As exceptions to this, compassionate use of a product is allowed under certain circumstances, and the EU scheme for licensing parallel imports is also followed.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

Some products have been authorised by the Finnish Medicines Agency (FIMEA) under the compassionate use exception, for example, zanamivir for the treatment of certain influenza of pandemic nature.

Article 5(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) has been implemented in Finland under:

- Chapter 4, section 21(f) of the Medicines Act (395/1987).
- Section 10(b) of the Medicines Decree (693/1987).

Accordingly, the preconditions for the pre-launch use of a product are that either:

- No other means are available to treat an individual patient or an available treatment would not yield the desired result.
- No authorised drug is available to treat a group of patients or population, or to prevent an illness, and there are particularly notable reasons for granting the special authorisation.

The decision on pre-launch use is subject to any advice issued by the European Medicines Agency’s Committee for Medicinal Products for Human Use.

In addition, when a product is supplied pre-launch, the supplier must ensure that the user of the product receives sufficient instructions on the product’s correct and safe use and storage, as well as other necessary instructions.

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

Structure
Marketing authorisations can be granted through any of the national, mutual recognition, decentralised or centralised procedures. The common EU application form is used in all of these procedures.

National decision making takes place following consideration of the application at the regular co-ordination and quality assurance meetings. The processing time of the application varies depending on the procedure followed.

Regulatory authority
The Finnish Medicines Agency (FIMEA) is responsible for the licensing of drugs in Finland.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

The mutual recognition procedure based on Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) has been implemented in Finland. Accordingly, an authorisation granted by another member state can be recognised by the Finnish Medicines Agency (FIMEA).

Parallel imports are subject to their own procedure. The product in respect of which parallel importation is to take place must have a marketing authorisation in Finland. Similarly, the product to be imported must have an authorisation in the country of acquisition, which must be an EU member state. In processing the application, FIMEA confirms these matters with the relevant authorities. A sample package stating the country of acquisition and a proposal for labelling and packaging leaflets must be attached to the application.

5. Is virtual drug distribution possible from your jurisdiction?

The Finnish drugs delivery chain is linear, in that manufacturers and wholesalers can only sell products to each other or to licensed pharmacies, while licensed pharmacies or their separately authorised virtual equivalents (see Question 12), in turn, are the only places for consumers to purchase drugs.

However, on implementation in Finland of Directive 2011/62/EC amending Directive 2001/83/EC on the Community code relating...
to medicinal products for human use, as regards the prevention of
the entry into the legal supply chain of falsified medicinal products
(Falsified Medicinal Products Directive), as of 1 January 2014 the
brokering of drugs has become possible under Section 34a of the
Medicines Act. Accordingly, sales of authorised drugs, other than
wholesale distribution, that do not include the physical handling of
the product and take place on behalf of another legal or natural
person, are now allowed under certain conditions. The broker
engaging in these activities must have a permanent address within
the EU area. If in Finland, the broker must present a notification to
the Finnish Medicines Agency (FIMEA) to register its operation
before pursuing its activities. FIMEA publishes a list of all
registered brokers on its website and can impose additional
regulations concerning such brokering. No brokers have so far been
registered in Finland, nor has additional regulation relating to
brokering of drugs been set out by FIMEA.

The virtual wholesaling of drugs is not addressed by the Finnish
legislation. While it has not been explicitly prohibited, the reception
and distribution of orders requires a wholesale licence issued by
FIMEA under the Medicines Act. Best practice guidelines for these
wholesale activities are set out in FIMEA Regulation No. 5/2013,
which follows the EU Guidelines 2013/C 68/01 on Good
Distribution Practice of Medicinal Products for Human Use (CDP
Guidelines). Accordingly, a holder of the wholesale licence must
appropriately confirm the quality of its products on reception. If the
distributed products never physically enter the Finnish jurisdiction,
making such an acceptance inspection would not be possible,
meaning that virtual distribution would violate the wholesalers’
duty of care and would therefore be inconsistent with Finnish
legislation.

6. What is the procedure to appeal (legal remedy) a licensing
decision?

Licensing decisions can be appealed under the general provisions
concerning appeals in administrative matters. In accordance with
the Administrative Judicial Procedure Act, an appeal must be filed
at the Administrative Court within 30 days from the date on which
the decision was served to the appellate. The decision of the
Administrative Court can be appealed to the Supreme Administrative Court, subject to a leave of appeal granted by the court.

7. What are the costs of obtaining licensing?

The government fees for marketing authorisations are set out in
Decree 252/2014 of the Ministry of Health and Social Affairs. In the
national procedure, the costs for obtaining a marketing authorisation
for a product concerning a new pharmaceutical compound, combination product or biologically similar product are:
- EUR3,000 for the first authorisation.
- EUR8,000 for subsequent medicine forms and strengths.

For generic products, applications in which reference to
documentation of the original authorisation holder is made with its
consent and mixed-type abridged applications referred to in Article
10(3) of Directive 2001/83/EC on the Community code relating to
medicinal products for human use (Code for Human Medicines
Directive), the fee is EUR8,000 for each authorisation or
registration.

In a mutual recognition and decentralised procedure in which
Finland is a concerned member state (CMS), the fee is:
- EUR10,000 for the first authorisation for a product concerning a
new pharmaceutical compound, combination product or
biologically similar product.
- EUR6,000 for subsequent medicine forms and strengths.

For generic products, applications in which reference to
documentation of the original authorisation holder is made with its
consent and mixed-type abridged applications referred to in Article
10(3) of the Code for Human Medicines Directive, the fee is
EUR6,000 for each authorisation or registration.

In a mutual recognition and decentralised procedure in which
Finland is the reference member state (RMS), the processing fee is
EUR12,000 including all forms and strengths of the trade name
authorised.

For authorisation concerning parallel imports, the fee is:
- EUR1,900 for the first country.
- EUR1,100 for subsequent countries.

Distribution to consumers

8. What are the different categories of drugs for distribution?

There are two main categories of drugs:
- Prescription drugs.
- Over-the-counter drugs.

9. Who is authorised to distribute prescription drugs and over-
the-counter drugs to consumers?

Prescription drugs
Prescription drugs can only be distributed by pharmacies, hospital
pharmacies and dispensaries. The required pharmacy licences are
granted by the Finnish Medicines Agency (FIMEA). The number of
licences granted annually is based on an objectively assessed need
for new pharmacies in each geographic area.

Over-the-counter drugs
Over-the-counter drugs can only be distributed by pharmacies. However, homeopathic products and nicotine products can also be
distributed by other entities, such as retail stores.

10. What drugs can an attending physician distribute and
under what circumstances?

Under the Medicines Act, only licensed pharmacies are allowed to
distribute drugs to patients. However, the attending physician can
give the patient a starter pack of the prescribed medication should
this be necessary for the immediate start of the treatment. Such
packs must be given free of charge.

11. Who is authorised to prescribe prescription drugs to
consumers?

Under the Act on Health Care Professionals (559/1994),
preparation may only be prescribed by qualified physicians
and dentists, or students of medicinal and dental sciences
temporarily acting in the position of a physician/dentist, to the
extent the drugs are prescribed for their own patients. Qualified
nurses and midwives also have a limited right to prescribe certain
drugs for their own patients provided that the medicine in question
is on a list approved by the physician in charge of the health centre

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12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

**Conditions**

Under the Medicines Act, distance selling is allowed in Finland, as of 1 February 2011. However, only a licensed pharmacist providing its main service in person can provide drugs virtually, and it requires an internet page where all the information about the products is available to customers. When opening a virtual pharmacy, the Finnish Medicines Agency (FIMEA) must be notified in advance. There are currently more than 100 legally established virtual pharmacies in Finland.

Under FIMEA Regulation 2/2011, there are strict conditions for the storage and delivery of drugs, including that:

- The consistency of the storage conditions described in the marketing authorisation must be documented and the products and their delivery controlled by a pharmacist.
- The drugs cannot be delivered before the pharmacist has ensured that the customer has received all the necessary information on the use of the product.
- If the drug mainly affects the central nervous system, only the smallest packages can be sold online.
- If a prescription is required for the drug, it must be written by an authorised physician (in Finland) and must be included in the Finnish system of electronic prescriptions. This excludes all foreign prescriptions.

**Cross-border sales**

Cross-border sales of non-prescription drugs are allowed if carried out by registered virtual pharmacies. The conditions for this follow the content of Directive 2011/62/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Falsified Medicinal Products Directive), which has been implemented in Finland as from 1 January 2014. According to Section 52b of the Medicines Act, the pharmacy responsible for the online service must ensure that the marketing of the drug in question complies with the laws in the country of destination. It must also display on its website a hyperlink to FIMEA’s website where a list of registered Finnish virtual pharmacies is presented, as well as the common European logo referred to in the Falsified Medicinal Products Directive. In addition, the general provisions on the distance sale of goods under the Consumer Protection Act apply also to distance sale of drugs.

13. What regulatory authority is responsible for supervising distribution activities?

The Finnish Medicines Agency (FIMEA) supervises the manufacture, import and distribution of drugs. After licences have been granted, the supervision takes place mainly through inspections. FIMEA can conduct necessary inspections in cooperation with the European Medicines Agency (EMA).

The National Supervisory Authority for Welfare and Health (VALVIRA) supervises the prescription of drugs to consumers in accordance with the Act on Health Care Professionals. The main focus is on advance supervision taking place through licensing.

14. What is the procedure to appeal (legal remedy) a distribution decision?

Under the Medicines Act, orders given by an inspector in connection with an inspection cannot be appealed, but a request for rectification can be presented to the Finnish Medicines Agency (FIMEA). The request must be made in writing and presented to FIMEA within 30 days from the date on which the order was given. The decision issued by FIMEA can later be appealed.

The decisions of FIMEA and the National Supervisory Authority for Welfare and Health (VALVIRA) can be appealed in accordance with the general procedure concerning administrative appeals as defined in the Administrative Judicial Procedure Act. The appeal is addressed to the Administrative Court. The decision of the Administrative Court can then be appealed to the Supreme Administrative Court if leave of appeal is granted.

15. What are the legal consequences of non-compliance with consumer distribution laws?

Non-compliance with the provisions of the Medicines Act relating to, for example, the import, storage, sale or distribution of drugs, is punishable by fine as a medicines infringement. Criminal liability under medicines offences can also follow, mainly for intentional misconduct, in which case the penalty is either a fine or a maximum of one year’s imprisonment.

The Finnish Medicines Agency (FIMEA) also has the right to prohibit the import, manufacture, distribution, sale or other release for consumption of a drug if it becomes apparent that the conditions for granting the marketing authorisation no longer exist or if the requirements and obligations concerning the manufacture or import of the drug are no longer met. Similarly, it can suspend the distribution, sale or other release to consumption of a drug and order its withdrawal from the markets if there is reason to suspect that the product is counterfeit or otherwise defective.

For non-compliance by healthcare professionals in relation to the distribution of drugs, the possible legal consequences include:

- A written warning issued by the National Supervisory Authority for Welfare and Health (VALVIRA).
- VALVIRA suspending the licence of the persons in question, or otherwise prohibiting them from acting in the position of a healthcare professional for the duration of the examination of the matter.

**Wholesale distribution**

16. What is the legal regime regarding wholesale distribution of drugs?

The wholesale distribution of drugs is regulated under:

- The Medicines Act.
- The Medicines Decree.
- The Finnish Medicines Agency (FIMEA) regulation No. 5/2013 on good distribution practice of medicinal products.

In Finland, the wholesale of drugs can only be carried out under a licence granted by FIMEA. To obtain a licence, applicants must
have appropriate facilities, equipment and personnel for their operations and for the storage of drugs. Wholesalers must also have a defined "responsible person" who ensures that all action is taken in line with the applicable legislation. The responsible person must be a qualified pharmacist.

The wholesale of drugs can be made to:

- Pharmaceutical manufacturers.
- Other pharmaceutical wholesalers.
- Pharmacies.
- Subsidiary pharmacies.
- Military pharmacies.
- Hospital pharmacies or dispensaries.
- Veterinary surgeons for the purposes of veterinary medication.

Drugs that are not restricted to sales to pharmacies (that is, nicotine and homeopathic products) can also be sold to other retailers. Active pharmaceutical ingredients can also be sold to other businesses for production purposes and to universities, institutions of higher education and other scientific research institutions for research purposes.

In Finland, the distribution of drugs is operated through a single channel (or direct-to-pharmacy) system. This means that nearly all pharmaceutical companies make exclusive distribution agreements with only one wholesaler at a time and their products are therefore available only through that channel. In the single channel system, the wholesales of drugs are mainly responsible for the storage and distribution of drugs under their agreements with the pharmaceutical companies, and pharmaceutical companies set the prices of their products to pharmacies.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

**Regulatory authority**

The Finnish Medicines Agency (FIMEA) supervises wholesale and distribution activities. When necessary, it can co-operate with the European Medicines Agency (EMA).

**Supervision**

Supervision is mainly through inspections, during which the inspecting official has the right to take copies of necessary documentation, collect samples and take photographs in the premises of the wholesaler. The inspector can give orders concerning necessary improvements, which must be executed immediately.

**Rights of appeal**

Orders given by the inspector in connection with an inspection cannot be appealed but a request for rectification can be presented to FIMEA. The request must be made in writing and presented to FIMEA within 30 days from the date on which the order was given.

Decisions made by FIMEA can be appealed in turn in accordance with the general procedure for administrative appeals under the Administrative Judicial Procedure Act. The appeal is addressed to the Administrative Court. The decision of the Administrative Court can later be appealed to the Supreme Administrative Court if leave of appeal is granted.

18. What are the legal consequences of non-compliance with wholesale distribution laws?

The Finnish Medicines Agency (FIMEA) can revoke in part or in full a licence for the manufacture or wholesale of drugs if any of the requirements for granting the licence are no longer met or if an obligation essential to safety or quality has not been met. Non-compliance with the provisions of the Medicines Act relating to, for example, the import, storage, sale or distribution of drugs, is punishable by fines as a medicines infringement. Criminal liability under medicines offences can also follow, mainly for intentional misconduct, in which case the penalty is either a fine or a maximum of one year's imprisonment. See Question 15.

**MARKETING**

**Promotion**

19. What is the general legal regime for the marketing of drugs?

**Legal regime**

The marketing of drugs is regulated under the Medicines Act and Medicines Decree. In addition, general legislation applicable to all marketing must be considered when undertaking marketing activities, such as:

- The Consumer Protection Act (when targeted at consumers).
- The Unfair Business Practices Act (when targeted at businesses).

**Limits to marketing activities**

All promotional activities must be conducted on a transparent basis and encourage the appropriate use of drugs. All necessary information on a product must be given in accordance with the valid marketing authorisation, and the provision of misleading information is prohibited.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

Pharma Industry Finland has its own Code of Ethics (PIF Code), which contains detailed regulations on marketing, and has been drafted and implemented by the representatives of the pharmaceutical industry. The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice on the Promotion of Medicines influenced the drafting of the PIF Code. All members of the Pharma Industry Finland (in practice most major innovative pharmaceutical companies acting in Finland) have undertaken to comply with the code. Therefore, the code can be considered to constitute customary regulation of the industry and complements the applicable legislation.

**Marketing to consumers**

21. What is the legal regime for marketing to consumers?

**Legal regime**

For the general legal regime, see Question 19.

**Products**

Only products authorised in Finland can be marketed, while the marketing of prescription-only drugs to consumers is prohibited.
22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

Permitted marketing activities have not been separately defined in the applicable regulations. However, the general limits must be considered when undertaking marketing activities (see Question 19). Marketing materials must include the trade name of the product as well as its active ingredient if the product only contains one active ingredient. Necessary information on the correct and safe use of the drug (such as indications, possible adverse effects or patient safety issues) must also be presented in accordance with the summary of product characteristics as well as a specific and clear request to carefully read the separate instructions for the use of the drug. Advertising must not give in any manner an exaggerated or misleading impression on the effect of the drug, or information that may lead to its incorrect use. In addition, under the Pharma Industry Finland Code of Ethics (PIF Code), marketing must not involve price competition.

Prohibited claims are further specified in Section 25b of the Medicines Decree. Accordingly, marketing directed at the general public must not contain material that:

- Gives the impression that visiting a physician or that any treatment recommended by a physician is not necessary.
- Suggests that the effects of taking the medicine are guaranteed or that there will be no adverse effects or that the effects are as good as or better than those of another treatment or medication.
- Suggests that the health of a person may be improved by a drug, or that changes may occur in a person’s state of health if the drug is not taken (with the exception of certain vaccination campaigns).
- Is directed solely or primarily at children.
- Refers to recommendations made by scientists, healthcare professionals or public figures.
- Suggests that a drug is a foodstuff, cosmetic or other consumer product.
- Suggests that the efficacy of a drug or its safety is based on the product’s natural origin.
- Could, in self-care, lead to an incorrect diagnosis or treatment on account of the inclusion of a detailed case description.
- Refers to claims of recovery with inappropriate, alarming or misleading expressions.
- Contains inappropriate, alarming or misleading pictorial representations of the changes that a disease or injury causes to the human body or of the effect of a drug on the human body or part thereof.
- States that the drug has been granted a marketing authorisation.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, “buy-one-get-one-free”)?

Distribution of free samples to the public is prohibited. Similarly, giving discounts on drugs is prohibited, so that “buy-one-get-one-free” type offers would not be allowed. Offering other kinds of giveaways (such as other products or benefits) for non-prescription drugs is allowed but, under the Pharma Industry Finland Code of Ethics (PIF Code), this should not encourage the unnecessary purchase or use of drugs or endanger the appropriate communication of the correct and safe use of the product to consumers.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

The same rules apply to internet advertising as to advertising through other media. Marketing or advertising of products which are to be sold by prescription, or which contain narcotics or psychotropic substances, are prohibited, unless aimed at persons entitled to prescribe those drugs. Where prescription drugs are marketed to those entitled to prescribe them, appropriate measures must be taken to ensure that the general public is not able to access such marketing material. Such a limited access system can be created by, for example, using passwords and other registration requirements.

Should a link to an independent webpage be presented on the company sponsored webpage, the page linked to must also comply with the relevant Finnish regulations, even if available information would be presented in a language other than Finnish or Swedish. A marketing authorisation holder is responsible for the content of an independent webpage that is accessible through a link displayed its own webpage.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The Finnish Medicines Agency (FIMEA) is primarily responsible for supervising drugs marketing activities. The Consumer Ombudsman also supervises marketing activities based on the Consumer Protection Act. The Supervisory Commission for the Marketing of Medicinal Products (PIF Supervisory Commission), as well as two inspection boards under its supervision, acting under Pharma Industry Finland, supervise their member companies' compliance with the Pharma Industry Finland Code of Ethics (PIF Code). Inspection board 1 supervises marketing targeted at consumers, while inspection board 2 supervises marketing to healthcare professionals and monitors the activities of medical sales representatives.

Supervision

Under the Medicines Decree, holders of a marketing authorisation for a drug must, on request, submit to FIMEA:

- The material used in marketing and an account of the recipients of the material.
- The method of its distribution and the starting date for the distribution.
- Other information and documentation that may be needed for the supervision of marketing activities.

The examination of cases by the PIF Inspection Boards is initiated by the board's own control initiatives, complaints by PIF's member companies, or based on preliminary inspections. Cases examined by the supervisory commission are, in turn, initiated on the basis of appeals by a party to the case, referrals by one of the inspection boards or requests of opinion.

If a case is already being examined by the authorities, neither the supervisory commission nor the inspection boards can proceed with the examination in accordance with the PIF Code. Instead, the matter is examined afterwards in light of the authorities' decision.
Companies can request a preliminary inspection of their marketing material by the inspection board to ensure its compliance with the PIF Code. Radio and TV advertisements of drugs are subject to obligatory preliminary inspection under the PIF Code. The company must comply with the opinion of the inspection board. For other materials, if a decision rendered by the inspection board is not followed, the matter can be taken up by the board through its own supervisory proceedings if deemed necessary.

Rights of appeal

Decisions made by FIMEA can be appealed in accordance with the general procedure concerning administrative appeals under the Administrative Judicial Procedure Act. The appeal is addressed to the Administrative Court. The decision of the Administrative Court can later be appealed to the Supreme Administrative Court if leave of appeal is granted. Within Pharma Industry Finland, the decisions of the inspection boards can be appealed to the supervisory commission.

26. What are the legal consequences of non-compliance with consumer marketing laws?

Under the Medicines Act, the Finnish Medicines Agency (FIMEA) can forbid the continuation or renewal of marketing and order the company in question to correct marketing if this is considered necessary in terms of patient safety. This prohibition or order can be enforced with a conditional fine.

A person that intentionally or due to gross negligence acts in violation of the Medicines Act or Medicines Decree or FIMEA’s prohibition or order can be sentenced to fines or imprisonment of up to one year. For acts due to negligence, the person is subject only to fines.

Under the Pharma Industry Finland Code of Ethics (PIF Code), if a promotion is found to be non-compliant, the PIF member may in more minor cases be issued an admonition for future reference accompanied with a reasonable deadline by which the marketing materials must be revised. The request to cease an activity concerns more severe cases of breach, where the company must refrain from this activity immediately after the request to do so has been served. In such a case, the material in question must be immediately withdrawn from the market. In addition, at their discretion, the inspection boards or the supervisory commission can impose a fine ranging from the minimum of EUR1,000 to the maximum of EUR100,000 on a company that has violated the PIF Code. In the case of continuing misbehaviour, the inspection boards or the supervisory commission can also submit the case to the review of authorities or impose a contractual penalty on the company that has violated the code ranging from EUR20,000 to EUR300,000.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

Promotional activities targeted at healthcare professionals are strictly regulated. All benefits and gifts must relate to the professional activities and be moderate in nature. Under the Medicines Act, the holder of the marketing authorisation or other entity undertaking marketing activities must also maintain a publicly available list on all economic and other supportive measures (direct and indirect) it has taken in favour of health-related associations and patient organisations.

28. Are there any restrictions on marketing to professionals?

Marketing activities

All benefits and gifts to healthcare personnel must be inexpensive and relate to their professional activities. Companies must not offer or otherwise give direct or indirect financial incentives or inducements to healthcare professionals. Sales promotions must not be inappropriate or potentially endanger the general public's trust that the prescription, use, or assignment of drugs is independent. Additional benefits can be considered a bribe if they are significant and could induce the recipient to make acquisitions that would not otherwise be justifiable for the person or institution in question.

Prohibited types of marketing activities have not been further specified in the medicines legislation or other applicable regulation. However, compensation for participating, for example, in a non-interventional study must be of reasonable economic value. In addition, under the Pharma Industry Finland Code of Ethics (PIF Code), any study results included in the material for the marketing of drugs must have been published in article form in a scientific journal. The use of unpublished materials, such as abstracts, posters or similar materials that have not been published in scientific journals, is prohibited. However, as an exception, reference can be made to unpublished study results if this new information refers to a serious disease and there is clear proof that the new treatment is superior to the earlier treatments. The unpublished study results must in any case meet the same quality criteria applied to published results and involve explicit information on the trial arrangements (for example, in vivo, in vitro, animal testing). In addition, the use of such material is subject to the consent of the responsible investigator and additional information on the contents of that material must be given on request.

Frequency

The PIF Code incorporates the Code for the Good Medical Sales Representation Practices. Although the code states that the ultimate decision on the arrangement of medical sales representation events is taken by the management of the relevant healthcare unit, certain general principles to follow are provided. For example:

- Visits must be organised in advance.
- Companies must follow the instructions given by the healthcare unit regarding the booking of visits, for the avoidance of unnecessary contacts that might disturb their operation.
- Sales representation activities must be fitted in as a flexible part of the working day of the healthcare unit and the physicians working there, so that they enhance proper pharmacotherapy without disturbing the operation of the unit or the patients.

Medical sales representation activities can be arranged in the healthcare unit premises or elsewhere. If arranged in the premises of the healthcare unit, they must take place in the physician's consulting room, the medical staff's common room or other similar premises assigned by the healthcare unit for presentation purposes to allow for the presentation to take place in privacy, without disturbing the other activities of the healthcare unit.

 Provision of hospitality

Hospitality at meetings with groups of professionals must be reasonable and secondary to the purpose of the event. According to the PIF Code, events organised or sponsored by the pharmaceutical industry must be consistent with the customary local norms of hospitality. Catering and other hospitality measures must be moderate and suit the occasion, and not compromise the objectivity of physicians in prescribing drugs or endanger the public trust in the neutrality of medicine subscription and supply. In
addition, hospitality must not exceed what typical participants in the event would be prepared to pay if they had to cover their own expenses.

29. What information is it legally required to include in advertising to professionals?

Advertising of drugs to healthcare professionals must only contain essential information on the drug and its use. In particular, such advertising must include:
- Essential information, in accordance with the summary of product characteristics, 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.
- The date when the advertisement was prepared or revised.

All information given in marketing must:
- Correspond to the approved summary of product characteristics.
- 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 their precise sources indicated.

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

The Medicines Act stipulates that marketing must 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 that may be applicable to the marketing of drugs. The Pharma Industry Finland Code of Ethics (PIF Code) stipulates that comparisons between different drugs, 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 of the comparison must be clearly recognisable. The packages and dosages used in price comparisons must be comparable to each other. When the prices of products are compared, the drugs covered by the comparison and their trade names must be clearly indicated. When using a comparison in marketing, the time of the comparison or the date of publication must be disclosed. The comparison must give special weight to the objectivity of the marketing and the correctness of the information.

31. What other items, funding or services are permitted to be provided to professionals?

Discounts
Pharmaceutical companies are not permitted to grant discounts to individual pharmacies, and the wholesale price must be the same for all pharmacies. The wholesale price must include all rebates, refunds and other benefits that are granted to a pharmacy. These restrictions do not apply to drugs that can be sold in places other than pharmacies, such as nicotine replacements. However, it is permitted for pharmaceutical companies to grant discounts to welfare and health units, such as hospital districts and individual hospital pharmacies.

Free samples
Samples of drugs can be distributed only to the persons entitled to prescribe and supply them. If the prescription is subject to restrictions on supply, the sample can be given only to a physician entitled to prescribe that product. Only one sample per recipient per year can be given of each strength and composition of a drug. A sample can 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 the smallest package size available on the market. Each sample must be accompanied by a summary of product characteristics. Narcotics, including psychotropic substances and substances that mainly affect the central nervous system, cannot be distributed as samples.

Sponsorship of professionals
Under the Pharma Industry Finland Code of Ethics (PIF Code), making donations or giving grants to individual healthcare professionals is prohibited. As an exception to this, grants for investigator-initiated clinical trials with an appropriate study protocol, which have been approved by the regulatory authorities and ethics committee and which otherwise comply with the requirements set in the legislation for clinical trials, are allowed.

From 1 January 2014, the PIF Code obliges companies to carefully document and publish information on all economic benefits targeted at healthcare professionals, including all direct and indirect transfers of economic value either in cash or other forms of benefit.

Other items, funding or services
Healthcare professionals must not be offered or otherwise provided with any kind of indirect economic incentives or inducements. See Questions 27 and 28.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority
The Finnish Medicines Agency’s (FIMEA) and Pharma Industry Finland’s role in supervising pharmaceutical marketing also applies to marketing targeted at companies or other entities (see Question 29).

Supervision
Under the Medicines Act, the National Supervisory Authority for Welfare and Health (VALVIRA) and the regional state administrative agencies supervise the prohibition on healthcare professionals accepting gifts or benefits that are contrary to the medicines legislation.

Rights of appeal
See Question 25.

33. What are the legal consequences in case of non-compliance with professional marketing laws?

See Question 26.
**ENGAGEMENT WITH PATIENT ORGANISATIONS**

34. **What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?**

Pharmaceutical companies can give financial support to patient organisations and engage in other kinds of cooperation with them by, for example, arranging promotional events.

The patient organisation's logo can be used in the company's own operations solely based on the written consent of the organisation covering the purpose and means of use of the materials. Pharmaceutical companies must not try to influence the contents of the materials published by a sponsored patient organisation for the promotion of its own commercial interests. In addition, a pharmaceutical company cannot be the only founding member of a patient organisation or require it to be the sole funder of the organisation or of a certain significant form of its activities.

Under the Medicines Act and the Pharma Industry Finland Code of Ethics (PIF Code), a holder of a marketing authorisation or other entity undertaking marketing activities must also maintain a publicly available list on all economic and other supportive measures (direct and indirect) it has provided to health-related associations and patient organisations (see Question 3).

**REFORM**

35. **Are there any plans to reform the law on the distribution and promotion of drugs in your jurisdiction?**

No significant reforms are expected in the near future in the field of distribution and promotion of drugs in Finland.

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