



PHARMA INDUSTRY FINLAND CODE OF ETHICS

Pharma Industry Finland · 2014

UNOFFICIAL TRANSLATION:

In cases of discrepancies, the original Finnish Code of Ethics is valid.

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FOREWORD

The Finnish Medicines Agency, Fimea, is the authority in charge of controlling the marketing of pharmaceuticals. These operations are complemented by the voluntary self-regulation of the pharmaceutical industry. The self-regulation is based on Pharma Industry Finland's (PIF) Code of Ethics which is a detailed set of norms on the pharmaceutical marketing and information targeted at both the consumers and the healthcare professionals.

The compliance with the PIF Code is guided and monitored by the independent Supervisory Commission for the Marketing of Medicinal Products and the two Inspection Boards operating under its umbrella. Without a credible self-regulation system, the pressure for stronger statutory controls by the regulatory authorities would increase.

Both pharmaceutical information and pharmaceutical marketing must provide a reliable picture of medicines and their effects. Correct pharmaceutical information is a precondition for the correct use of medicines. It promotes people's health and their working and operating capacity, providing them with the best and most cost-effective therapies from the healthcare service system perspective. At the same time, it creates conditions for the continuous improvement of treatment practices.

Disseminating information on medicines is the obligation and an important societal duty of the pharmaceutical companies. Pharmaceutical information must be updated and objective under all circumstances in order for the patient's care to take place, avoiding further heavier therapies.

The pharmaceutical information must provide guidance to the healthcare professionals so that the newest and best possible treatment practices can be introduced. As the role of the consumer is enhanced, proper pharmaceutical information becomes more underlined. In order for the therapy to be successful, the consumer must receive all the available information relevant to the case. Consumers must be offered reliable information in an easily approachable form.

Therefore, the PIF Code must guide and support the behaviour of the consumers and the materialisation

of pharmacotherapies prescribed by the healthcare professionals. The objective is to combine the good therapy with continuously improving efficacy and patient safety.

The PIF Code has again been renewed to meet the present needs as well as the society's future needs. That's why the Code has now been complemented to also include the publication of economic liaisons and cooperation between the pharmaceutical industry and the healthcare professionals. The new practice makes the economic cooperation between these parties transparent, not only in Finland but also in Europe as a whole. For the trade organisations, the adopted changes mostly mean more detailed definition of existing practices since the information subject to publication has already been in the public domain.

According to the new PIF Code, the PIF member companies will publish in the year 2016 the fees and economic benefits paid to healthcare professionals and organisation during the preceding year 2015.

The cooperation between the healthcare professionals and the pharmaceutical industry is indispensable to develop healthcare, to create medical innovations as well as to ensure medicine safety. The pharmaceutical industry wants to strengthen the public trust in this cooperation. The expert work performed by the healthcare professionals plays a significant role throughout the life of a medicine. It is important that the patients and other stakeholders have easy access to the main information about the cooperation with the healthcare professionals, especially as concerns the economic liaisons.

The PIF Code is jointly adopted by the pharmaceutical companies, and the adherence to the Code is based on their responsible and voluntary commitment. The PIF Code highlights the joint will to act ethically, sustainably and responsibly complying with the jointly agreed ground rules.

Jussi Merikallio
Managing Director

I SCOPE OF APPLICATION AND DEFINITIONS

1 § Relationship to other regulations. The principles behind this PIF Code of Ethics are based on pharmaceuticals, marketing, consumer and competition legislation, on the International Code of Marketing Practice as well as on the Codes of Pharmaceutical Marketing Practice published by EFPIA (European Federation of Pharmaceutical Industries and Associations) and IFPMA (International Federation of Pharmaceutical Manufacturers Associations). In formulating this PIF Code, the following EU legislation has also been taken into account: the Directives 2001/83/EC and 2004/27/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use; the Council Directive 89/552/EEC and 2007/65/EC on the coordination of certain provisions laid down by law, Regulation or administrative action in Member States concerning the pursuit of television broadcasting activities; the Directive 2005/29/EC of the European Parliament as well as the Council Directive 84/450/EEC relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising. In its operations, the company must also comply with the regulations imposed by the personal data protection legislation.

The instructions on pharmaceutical sales representation are based on the Code and recommendations jointly issued in 2007 by PIF and the Association of Finnish Local and Regional Authorities. The full document is attached to this Code. The source material for the document included the 2007 recommendation by the then National Agency for Medicines (today Finnish Medicines Agency Fimea) for the quality criteria for sales promotion of medicines.

2 § Binding force of PIF's Code of Ethics. Besides the legislation and the orders and guidelines issued by the Authorities, the PIF Code of Ethics must be followed in marketing of medicinal products, co-operation between pharmaceutical companies and patient organisations as well as in health awareness information and other dissemination of information on health and diseases.

In their international marketing operations, the pharmaceutical companies must meet the minimum level of the requirements imposed by the EFPIA and IFPMA Codes.

The PIF Code of Ethics must also be followed in pharmaceutical marketing and other operations falling within the scope of application of the Code, targeted at Finns abroad or in international congresses. Besides the PIF Code, the instructions issued by EFPIA's local

organisations as well as the requirements imposed by the local authorities must also be adhered to in such events whereas the Supervisory Commission and Inspection Boards only apply the PIF Code.

3 § Definitions 'Pharmaceutical company' refers to a medicine marketer, importer, marketing authorisation holder or other entrepreneur engaged in pharmaceutical marketing, committed to complying with the PIF Code.

'The marketing of medicinal products' refers to any information, order acquisition or incentive measures, with the purpose of promoting the prescription, supplying, purchase or use of medicines. Such measures include, for instance, advertising targeted at consumers as well as the advertising and sales promotion targeted at healthcare professionals, the operation of medical sales representatives and the distribution of medical samples.

'Healthcare professionals' refers to the persons whose work envisages the prescription or dispensing of medicines. The professionals entitled to prescribe or dispense medicines include physicians, dentists, veterinarians, senior pharmacists and pharmacists. Moreover, nurses, opticians and dental hygienists have a limited right to prescribe certain medicines.

'Consumer' refers to persons other than those entitled to prescribe or dispense medicines.

Healthcare organisations include

- healthcare, medical and scientific associations, societies and organisations as well as
- companies and other corporations through which one or several healthcare professionals provide their services.

'Patient organisations' are NGOs (organisations of public utility), their local and regional associations and central organisations established and focusing on a certain condition, disease or disability or a group thereof. Their members are mainly patients and their caretaking family members, and they represent or promote the interests of the patients or their caretakers.

'Medicine' is defined as per Section 3 of the Medicines Act (1987/395): "Medicinal product means a product or substance intended for internal or external use to cure, alleviate or prevent a disease or its symptoms in humans or animals. Medicinal products are also considered to include substances or combinations of substances used internally or externally that can be used to restore, correct or modify the vital functions of humans or animals through pharmacological,

immunological or metabolic influence or to determine the state of health or the reason for a disease.”

‘Prescription-only medicine’ refers to a medicinal product which can only be dispensed by the pharmacy against a prescription.

‘Self-care medicine’ refers to a medicinal product which can be dispensed without a prescription.

4 § Scope of application. The PIF Code covers all measures taken by the pharmaceutical companies in the marketing of their medicines, distribution of information or in similar activities.

The PIF Code also covers the interaction of the pharmaceutical companies with healthcare professionals and patient organisations in relation to pharmaceutical research and other issues. The scope of application also includes the dissemination of health awareness information and other information related to health or diseases.

The Code applies to information distributed both on a personal basis and through the communication media. Therefore, the scope of application of the PIF Code also includes any operations taking place on the Internet, social media and other electronic communications media.

Articles 124–130 of the present Code refer to the obligation of the pharmaceutical companies to publish information on their economic liaisons.

The PIF Code also covers the marketing of veterinary medicines where applicable.

The scope of application of the PIF Code of Ethics does not comprise:

- a) products other than medicinal products;
- b) the summary of product characteristics SPC, the package labels and leaflets;
- c) the replies to specific questions about the medicine and the non-commercial material eventually related to the reply;
- d) informative notifications related to aspects such as changes in packaging, warning about adverse effects, marketing authorisations or price adopted by the Authorities, if the direct objective of such material is not the promotion of the sales of a medicine;
- e) the company’s product and price lists which do not contain any claims related to the medicinal products;
- f) general statements related to health and diseases, if the direct objective of such material is not the promotion of the sales of a medicine;
- g) scientific material published by the pharmaceuticals industry, if the direct objective of such material is not the promotion of the sales of a medicine;
- h) information focusing primarily on the operations of the company, as well as corporate image marketing and business entertainment, with no direct objective of promoting the sales of a medicine;
- i) press releases based on the statutory information liability of the pharmaceuticals companies;
- j) starter packs; and
- k) public information on vaccination campaigns adopted by the Authorities.

II GENERAL PRINCIPLES

5 § Responsibility for compliance with the PIF Code of Ethics. The pharmaceutical company is always responsible for all the corporate functions covered by the Code complying with it. The responsibility of the pharmaceutical company also extends to functions performed in collaboration with third parties. The company must ensure that this third party complies with the PIF Code of Ethics.

6 § Precondition related to the marketing authorisation. It is not permissible to market medicines other than those with a valid marketing authorisation.

7 § Nature of marketing. The information provided in and through pharmaceutical marketing must be appropriate. The information must present the various impacts resulting from the use of the medicine from many angles, thereby guiding the recipient of the information towards the correct and safe use of the medicine. The information on the medicine must be updated and based on the latest knowledge. The commercial nature of pharmaceutical marketing must not be concealed, and it must be clearly recognisable as marketing.

The marketing of a medicine must be based on the most recent adopted summary of product characteristics (SPC).

The marketing material must not fail to mention such material facts, the omission of which may give an erroneous impression of the medicine, its composition, origins, medical significance or quality.

Marketing may not refer to a clinical trial in such a way as to give an erroneous impression of the outcome, scope or significance of the trial.

Without justified reason, the marketing of medicinal products must not use the word 'safe' or suggest that the product has no adverse effects or that its use is not associated with the risk of dependency.

A medicine must not be marketed as a novelty after one year of its introduction to the market. Likewise, the change in the price, reimbursement status, indication, package size or other similar aspect must not be marketed as a novelty after one year from the implementation of such changes.

The information provided in pharmaceutical marketing must be reliable and it must not contain any verbal or visual presentation or other effects that may be misleading.

The information on a medicine must be given in such a manner as to allow for the recipients to familiarise themselves with the information in the advertisement without difficulty.

It is not the purpose of this Code to prevent the exchange of medical or other scientific information.

8 § Reminder advertisements. If the sole purpose of the medicine advertisement is to be a reminder of the name of the medicine, the advertisement cannot include anything else than the following:

- name or trade name of the medicine;
- name of the active pharmaceutical ingredient (API);
- trademark of the medicine; and
- name and logo of the holder of the marketing authorisation, marketer, importer or manufacturer.

The name of the medicine refers to its trade name, accompanied by the strength and pharmaceutical form.

9 § Good practice. In marketing of medicinal products and other operations covered by the scope of application of the Code, the companies must follow a good practice that inspires trust and respect. Offensive or tasteless expressions must not be used. The marketing of medicinal products and other operations must not use words or images that degrade, offend or shed mistrust towards any professional or patient group, product or pharmaceutical company. The marketing must not contain violence, sexual

behaviour or criminal actions, or any reference to them without a direct association with the approved indication of the medicine.

Marketing of medicinal products and other operations must promote the good public image of the pharmaceutical industry. The operations must not undermine people's trust in the impartiality of medicine prescribing and dispensing.

10 § Comparisons. The comparisons between different medicines, active pharmaceutical ingredients, excipients or other characteristics must be matter-of-fact and reliable. The visual and price comparisons between products must be clearly justified. The objects of comparison must be clearly specified. The price comparisons must include mutually comparable packages and dosages. Price comparisons must clearly indicate the medicines involved and their trade names.

Comparisons between active ingredients must be based on scientific evidence.

If comparisons are used, the time when the comparison was made or a study report was published must be indicated.

The requirement of matter-of-factness and correctness of information is particularly underlined as far as comparisons are concerned.

In the marketing of non-prescription medicines to consumers, special attention must be paid to the restriction under Article 19, item 1 b) of the present PIF Code of Ethics.

11 § Scientific service unit. The pharmaceutical companies must have a scientific service unit responsible for the information distributed on the medicines of the company and for the correctness of such information as well as on the control of the non-intervention studies under Article 36 hereunder.

The scientific service unit must have at least one physician, pharmacist with a Bachelor's or Master's Degree with sufficient expertise and experience, responsible for the compliance of the company operations with the PIF Code of Ethics. This person must ensure that the final form of the measures taken comply with the present PIF Code and with the legislation.

The responsible person at the scientific service unit must be fully acquainted with the respective provisions contained in the PIF Code of Ethics.

12 § Events organised or sponsored by the pharmaceutical industry. The main focus of the events must be on pharmaceutical information and

research or other medical training. The major part of the time spent by the participants in these events must consist of scientific programme or training.

The substantial part of the expenses incurred for the events must be related to the scientific programme or training.

The participants must always be provided with a written programme of the event in advance.

When the company organises or sponsors an event, the sponsorship must always be clearly disclosed.

The pharmaceutical companies can contribute to the expenses of further or continuing training events only when the companies are reserved sufficient opportunities to actively distribute information.

The event must be organised in a venue that is purposeful in view of the programme. The events must not be organised in venues that are renowned for their entertainment offer or luxury. The event can be organised abroad if there is a valid scientific or training-related justification to do so.

The event itself and the travels must be organised so that, excluding the travelling days, most of the time spent by the participants involves a scientific programme or training.

The events focusing on prescription-only medicines must be targeted at healthcare professionals.

If persons employed by the public healthcare services are provided with the opportunity to participate in events organised or sponsored by the pharmaceutical industry during their working hours, the invitation to the event must be addressed to the healthcare unit in question, considering the guidelines and regulations which apply to the allocation of support by external parties within that healthcare unit.

See also Articles 124-130 on the publication of information on economic liaisons.

13 § Hospitality in the events. In events or sessions organised or sponsored by the pharmaceutical industry, the usual local norms of hospitality shall be followed. The hospitality can extend only to the registration costs related to the event, as well as to the travelling, accommodation and meal expenses. The hospitality must be reasonable, suitable to the situation as well as secondary to the purpose of the event. In events for the marketing of prescription-only medicines, the hospitality must not be extended to persons other than healthcare professionals.

An exception to the stipulations in Paragraph 1, the representatives of pharmaceutical companies can, however, participate as guests in the evening programmes organised in association with medical events, training sessions of specialist societies and

corresponding scientific or training events, the day-time scientific or training programmes of which the pharmaceutical companies have sponsored, if the following six criteria are met:

- several companies are sponsoring the scientific or training programme;
- the sponsorship allocated to the organisation of the scientific or training programme is justified in volume;
- the hospitality related to the evening function is reasonable and suitable in view of the situation, and the eventual entertainment element is secondary;
- the eventual participation fee charged for the evening programme is the same for all attendants;
- no single company is the designated sponsor of the evening programme; and
- no medicines are marketed during the evening programme.

The healthcare professionals must not be paid or offered payment for the mere reason of dedicating their time to an event organised or sponsored by the pharmaceutical company.

The obligation to arrange for hospitality or for other benefits, such as economic compensations, must not constitute the precondition for the organisation of an appropriate information event.

The hospitality must not extend any further than what the typical guest to the event would be prepared to pay for a corresponding event.

The overall daily expenditure on meals (food and beverages) per participant must not exceed

- 45 euro for lunch and
- 100 euro for dinner.

14 § Market research. Market research also comprises opinion polls. Market research can be used to obtain information, e.g., about medicinal behaviour, use of medicines and treatment practices, with the objective of promoting patient safety and the correct use of medicines.

Market research cannot include any marketing elements.

Market research must not focus on a medicinal product which has not obtained the marketing authorisation.

In organising market research, special attention must be paid to the protection of the privacy of the patients and other objects of the research. The questions must respect the objectiveness principle. Market research must not have an impact on the treatment of individual patients.

The market research projects must be limited in their extent, such as one-off telephone interviews or mail, email or web-based questionnaire studies. The opinion of the healthcare professionals must not be repeatedly probed, considering both the frequency of the contacts in general as well as the number of contacts related to individual surveys.

The compensation paid for the implementation of the research must be of reasonable economic value.

15 § Use of experts. It is allowed to use healthcare professionals as experts or advisors, either as a group or on an individual basis. The following principles also apply to the use of patient organisations as experts. This provision does not apply to the market research under Article 14 of the present Code.

Among other roles, these parties can

- act as speakers in meetings or training sessions or chair such events;
- participate in medical or scientific research projects or clinical trials; or
- participate in meetings of advisory committees in cases where the participation is subject to a fee or the travelling expenses of the participants are remunerated.

The following criteria must be met in the arrangements involving these expert and other services:

- a) The service must be preceded by a written agreement specifying the nature of the services offered and the grounds for the compensation payable in line with subparagraph g).
- b) The need for service is clearly recognised before the services are solicited and eventual agreements are signed.
- c) The expert selection criteria are directly related to the recognised service need, and the persons in charge of the expert selection have sufficient expertise to assess whether the healthcare professionals in question meet such criteria.
- d) The number of experts engaged in the assignment does not exceed a reasonable number required to meet the service need.
- e) The pharmaceutical company party to the agreement keeps records of services provided by experts.

- f) The use of the expert as a service provider is not an inducement to recommend, prescribe, purchase, dispense, sell or administer a particular medicinal product.
- g) The fee payable for the services is reasonable and in line with the valid market price of such services. Nominal expert arrangements must not be used as a pretext for compensation paid to the experts.

In their expert agreements with healthcare professionals, the pharmaceutical companies must include a clause whereby the expert is obliged to always state that they are or have been in a contractual relationship with the company when publicly writing or speaking about the issue focused on by the agreement or otherwise related to the company. Likewise, the companies providing part-time employment to healthcare professionals who continue to exercise their profession are invited to ensure that such a person is obliged to disclose their employment relationship with the company whenever they write or speak in public about the issue constituting the object of this employment relationship or otherwise related to the company. Information on linkages must always be given, irrespective of the nature or arranger of the event.

The pharmaceutical companies are invited to include a clause in their co-operation agreements with patient organisations stating that the patient organisation is obliged to disclose their current or past contractual relationship with the company every time a representative of the organisation publicly writes or speaks about an issue focused on by the agreement or otherwise related to the company.

The pharmaceutical companies must also pay attention to Articles 124-130 on the obligation to publish information on economic liaisons.

16 § Dating of marketing material. Pharmaceutical marketing material must indicate the date (month and year) in which the material was compiled, or the latest revision was made.

III CODE FOR THE MARKETING OF MEDICINAL PRODUCTS

1. Code for the good marketing practice – consumers

17 S Pharmaceuticals marketed to consumers. Only non-prescription medicines can be marketed to consumers.

However, it is permissible to distribute public information on a vaccination campaign approved by the competent Authorities.

Under the present Code, information on prescription-only medicinal products can be targeted at consumers if such information only contains data consistent with the summary of product characteristics (SPC) or the package leaflet.

In questions related to personal health, the consumers must be advised to turn to their attending physician or other healthcare professionals.

It is prohibited to market medicinal products containing narcotics or psychotropic substances (as referred to in the international conventions on narcotics and psychotropic substances) to consumers.

Disguised advertising of medicines is prohibited.

18 S Minimum information in an advertisement for a medicine. An advertisement for a medicine must contain at least the following information:

- a) name of the medicinal product and the pharmaceutical substance if the medicine in question only contains one active ingredient;
- b) indication of the medicinal product;
- c) necessary information for the correct and safe use of the medicine as well as any special precautions of use, interactions and adverse effects significant for the medicine safety;
- d) explicit advice to read the package leaflet or the user instructions contained in the package;
- e) name of holder of marketing authorisation, importer or marketer; and
- f) in the marketing of veterinary medicines, also the approved target species of the medicine, as well as the maximum residue limits (MRL).

As an exception to the above, reminder advertisements referred to under Article 8 above are permitted.

19 S Prohibited information. A pharmaceutical advertisement must not give information or impression which

- a) gives an impression that consulting a physician or the treatment recommended by the physician is not necessary for a disease that would normally require medical care;
- b) suggests that the effects of the medicine are guaranteed and that they are not associated with any adverse effects, or that the effects are equal or superior to those of another treatment or medication;
- c) suggests that the medicine would improve the users' normal good health, or claim without justification that their health would deteriorate without the use of the medicinal product. An exception to this are the vaccination campaigns referred to in Article 4 subparagraph 3 k;
- d) is targeted at under 18-year-olds;
- e) suggests that the medicinal product is a nutritive product, cosmetic preparation or other consumer good;
- f) suggests that the efficacy or safety of the medicinal product is based on its natural origins;
- g) is liable to lead, in self-medication use, to wrong diagnosis or treatment due to a detailed case report contained in it;
- h) refers to recovery allegations through inappropriate, intimidating or misleading expressions;
- i) uses inappropriate, intimidating or misleading expressions or visual presentations of the changes caused by the disease or trauma in the body, or of the effects of the medicinal product in the body or in a part thereof;
- j) contains a reference to the medicine having a marketing authorisation; or
- k) suggests that the consumer can shoulder the responsibility for another person's health.

Misleading or inappropriate expressions are allegations or other expression or advertisement elements which

- emphasise the presence or lack of such ingredients in the product as have no material pharmacological or health-promotion significance;
- exaggerate or over-dramatize symptoms or their alleviation;

- give a misleading or one-sided picture of the effect of the product; or
- strongly divert the consumer's attention from the subject matter of the advertisement.

20 § Use of study results and the use of sources.

The study results and the respective sources used in pharmaceutical marketing must be reliable, and they must not be used to give a wrong or misleading impression of the medicine or its medical significance. If requested, the company must present the source material used. Reference to the source material must be made so that the source can be identified without difficulty.

21 § Special groups. Pharmaceutical marketing must not exploit the non-expertise or distress of consumers or consumer groups.

Special prudence must be applied to the use of children in pharmaceutical advertisements. Marketing of medicines intended for children's use must be targeted at adults.

22 § Use of prestige or celebrity. Pharmaceutical marketing must not contain direct and active recommendations to use the medicine, given by scientists, healthcare professionals or celebrities.

23 § Sponsorship. A company can engage in sponsorship only through its business name or logo.

Sponsorship refers to activities with the purpose of supporting one or several persons, companies, events or parts thereof either financially or otherwise, helping them to reach their scientific, artistic, sports or other objectives. Such support gives the sponsor certain rights to use the object of the sponsorship in the interest of the sponsor's business operations.

When sponsoring TV or radio broadcasts, the sponsorship element must be clearly and understandably separated from the rest of the programme offer or programme intros through the showing of the company name or logo. The name or logo of the company must be shown immediately before the programme or at its end (sponsor logo).

Sponsorship must not encourage the viewers to purchase the sponsor's or a third party's products. For the rest, sponsorship is subject to the marketing guidelines contained in the present Code.

24 § Prohibited methods in consumer marketing. Pharmaceutical marketing must not contain prize-winning competitions or lotteries targeted at consumers.

The basic rule is: it is forbidden to give the buyer of a non-prescription medicine another product or benefit (so-called giveaway) at the same price.

It is forbidden to distribute free samples of medicinal products to consumers.

2. Code for the good marketing practice – healthcare professionals

25 § Objective of information on a medicine.

The objective of the information given on a medicine is to maintain and promote the professional expertise of the healthcare professionals related to the use of medicines, as well as to promote patient safety.

26 § Targeting of pharmaceutical marketing measures.

The marketing of prescription-only medicines must be targeted only at persons entitled to prescribe or dispense the medicine. The other healthcare professionals may be given only guidance and training on the correct and safe use of the prescription-only medicines.

Non-prescription medicines can be marketed to all healthcare professionals.

A pharmaceutical company must not deliver advertising or other direct marketing material to persons who have declared they do not want it.

27 § Contents of information on a medicine. All information on a medicine must always contain the following:

- information in line with the latest adopted summary of product characteristics (SPC), essential for the prescription of the medicine;
- statutory dispensing conditions of the medicine;
- reimbursement terms and average therapy costs whenever possible; and
- retail prices of various packages sizes, if possible.

An exception to the above, reminder advertisements referred to under Article 8 above are permitted.

Marketing material made available at exhibition stands or distributed to the participants in international events may refer to medicinal products or indications of products with no marketing authorisation in the country where the event is organised if

- a) this material is accompanied with information on the countries where the product or indication has a marketing authorisation, and the material shows clearly that the product or indication has

- no marketing authorisation in the country where the event takes place;
- b) the information on the medicine is accompanied with a clarification notice of the fact that the information differs in accordance with the marketing authorisations in force in each separate country; and
- c) this is permitted by the national legislation of the place where the event takes place.

28 § Special requirements related to information on a medicine. The information on a medicine must

- be accurate, correct and verifiable;
- give objective and impartial information on the beneficial and adverse effects of the medicine;
- be clear and easily understandable; and
- be sufficiently complete so that the reader can form an opinion on the therapeutic value of the medicinal product.

29 § Results of clinical trials. Any study results included in the material for the marketing of medicinal products must have been published in article form in a scientific journal. Moreover, the pharmaceutical marketing material can make use of papers accepted for publications in a scientific journal and research documentation appended to the marketing authorisation application.

It is not permissible to use abstracts, posters or similar materials that have not been published as papers in scientific journals.

As an exception to the above, reference can be made to study results not meeting the criteria in Paragraph 1 if they can be deemed to have material significance for the medication. New information has material significance if it refers to a serious disease and if there is clear proof that the new therapy is superior to the earlier treatments.

The unpublished study results must meet the same quality criteria applied to published results. The principal investigator must have given the consent to the publication. If the pharmaceutical marketing refers to unpublished study results, additional information on the contents must be given upon request.

30 § Sources of information in the marketing of medicinal products. Reference to the materials used as the source of the information in the marketing of medicinal products must be made in a manner allowing the identification of the source without difficulty. Quotations, tables, figures and other corresponding illustrative material must be reproduced accurately so that the subject contents are not changed.

If the information is based on material related to another medicine or pharmaceutical form, the information must not unjustly lead to the assumption that the material would refer to the medicine or pharmaceutical form being marketed.

As concerns the use of results of clinical trials in the marketing of medicinal products, see Article 29 of the Code for detailed instructions.

31 § Information liability. If the practical use of the medicine reveals new important aspects, information thereof must be given in an appropriate manner, also considering the information obligation under the Medicines Act.

Pharmaceutical information on new serious adverse effects, contraindications, limitations of indications or withdrawal of production batches or medicines must be given in writing. The expression "Erittäin tärkeä – Mycket viktig" (Extremely important) or similar phrases can be used only in such contexts.

32 § Incentives, gifts, advertising gifts and other support measures. It is forbidden to give promotional gifts related to prescription-only medicines. The distribution and offer of promotional gifts related to the marketing of self-care medicines must be reasonable. The promotional gifts must have minor economic significance for the recipient, and they must have a bearing on their professional operations.

Healthcare professionals must not be offered or otherwise provided with direct or disguised economic incentives, gifts or promotional articles constituting inducements.

It is prohibited to support the leisure activities of healthcare professionals or their associations.

33 § Informative and educational material and medicinal supplies. The healthcare professionals can be provided with informative and educational materials provided that such materials:

- are of minor value;
- are materially related to the professional activities of the recipient; and
- can be directly utilised in patient work.

The materials must not constitute an incentive for the recommendation, prescription, purchase, dispensing, sales or administration of a particular medicinal product.

The medicinal supplies intended for the training of healthcare professionals and used as an aid in patient work can be given to them if they are of minor value and do not compensate for the current expenses related to the recipients daily operations.

34 § Medical samples. Free samples of medicines can be given only to persons entitled to prescribe or dispense them, who factually prescribe or dispense the medicinal product in question, therefore benefiting from the opportunity to familiarise themselves with the product in question. 'Medicine sample' refers to the smallest package size of the medicinal product available on the market. 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 the maximum of two years. The above restriction does not apply to the distribution of free samples of self-care medicines.

A prescription-only medicine sample can only be given to a person authorised to prescribe such medicines. If the prescription of a medicine is subject to a dispensing restriction, such a sample can only be given to a physician who is entitled to prescribe such medicines. Dosage devices can also be given to other persons. Narcotics, including psychotropic substances as well as substances with primary effects on the central nervous system, must not be distributed as free samples.

Free starter packages must not be used for the marketing of medicinal products.

A free medicine sample will be delivered against a written request provided with a signature and date. Each sample must be accompanied with a respective summary of product characteristics (SPC).

The pharmaceutical company must keep records of the free samples of medicines given in each calendar year. These records must be kept until the end of the year following the calendar year to which the record liability refers. Upon request, the records must be submitted to the Supervisory Commission for the Marketing of Medicinal Products or to Inspection Board II subject to it.

35 § Donations and grants for the support of healthcare or research. Donations, grants and benefits in kind offered to institutions, organisations or associations are permitted (unless covered by other provisions of the PIF Code) if

- their members are healthcare professionals or if they provide healthcare services or engage in research; and
- their purpose is to support healthcare or research.

The donor or the issuer of the grant must document and keep records of the information related to donations and grants.

The donations or grants must not constitute an incentive for the recommendation, prescription, purchase, supply, sales or administration of a particular medicinal product.

Making donations or awarding grants to individual healthcare professionals is only permitted

- for performing so-called researcher-driven clinical trials with a proper research plan;
 - approved by the regulatory authority and ethics committee; and
 - otherwise meeting the statutory criteria of clinical trials.

The holder of the marketing authorisation of a medicinal product or other marketer of medicine must keep publicly available and updated records of their direct and indirect financial or other similar support given to medical or healthcare associations.

The pharmaceutical companies must also pay attention to Articles 124–130 on the obligation to publish information on economic liaisons.

36 § Non-intervention studies on medicines with a marketing authorisation. Non-intervention studies refer to trials where the medicinal product is prescribed in the usual manner in line with the conditions of the marketing authorisation. The treatment strategy chosen for an individual patient is determined in advance in the study plan but is based on the normal treatment practice. The decision on the prescription of a medicine is independent from the inclusion of the patient in the study. The patients are not subject to any extra diagnostic or other follow-up procedures. Epidemiological methods are used for the analysis of the information collected.

Prospective non-intervention studies, with individual healthcare professionals collecting data from existing patient records, are allowed under the following conditions:

- a) The study is made for a scientific purpose.
- b) The study is accompanied with a written study plan and with written agreements between the healthcare professionals or places of research and the company financing the study. The agreements must specify the nature of the services provided and the criteria of the compensation payable for the services.
- c) The compensation payable for the services is reasonable, reflecting the valid market price of such services.

- d) The Personal Data Act is followed in connection with the study.
- e) The study does not constitute an incentive for the recommendation, prescription, purchase, supply, selling or administration of a particular medicinal product.
- f) The company's scientific service unit has approved the study plan, monitoring the progress of the study.
- g) The company must analyse, or have another party analyse, the results of the study, and the scientific service unit must be provided with the respective summary within a reasonable time. The scientific service unit maintains records of these summaries, stored for a reasonable period of time. The summary report must be sent to all healthcare professionals participating in the study and, upon request, also to the use of the competent bodies of the Supervisory Commission. If the results of the study are important for the evaluation of the risk-benefit relationship of the medicinal product, the summary report must also be immediately sent to the competent Authorities.
- h) The medical sales representatives can participate in the implementation of the study in an administrative capacity only, under the control of the scientific service unit. The scientific service unit must ensure that the medical sales representatives have received proper training for the implementation of the study.

Corresponding principles must also be followed, as applicable, to the epidemiological studies, register studies and other studies of retrospective nature.

3. Code for good medical sales representation practice

37 § Medical sales representation. The term 'medical sales representation' refers to the meetings, mainly taking place on the initiative of the pharmaceutical companies, between their medical sales representatives and healthcare professionals. Their objective is to disseminate information on the medicinal product presented, in order to promote the sales of the product in question. The present Code must be complied with, as applicable, also in medical sales representation events at pharmacies and within the private healthcare services when targeted at healthcare professionals.

A medical sales representation event provides the healthcare professionals involved in practical work with high-quality and updated information on medicines and their correct use. In addition to marketing, the medical sales representative transmits information on the results of the clinical trials on the medicine being presented, to promote the correct use of the medicinal product in question.

In accordance with the legislation, the medical sales representatives must convey all the significant information disclosed to them regarding the use of the medicine focused on, especially its eventual adverse effects.

38 § Medical sales representatives. In order to ensure the correct communications, the pharmaceutical company must ensure that the person transmitting the information has the sufficient basic knowledge to be able to convey as complete information as possible on the medicinal product presented.

39 § Enhancing proper pharmacotherapy. The activities of the medical sales representatives 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.

However, the ultimate decision on the implementation of medical sales representation events is taken by the management of the healthcare unit in question.

The persons entitled to prescribe or dispense medicines can decide independently whether they participate in sales representation events taking place outside working hours. When such events are being organised, the stipulations on the obligations of civil servants and employees of public corporations must be taken into consideration. Hospitality or other benefits offered must not jeopardise the public trust in the authorities, civil servants or employees of public corporations.

40 § Good medical representative conduct. In line with Appendix 1 of the PIF Code, the pharmaceutical companies and healthcare units should respect the following principles of good medical representative conduct in the respective events:

- a) The medical sales representations must be based on advance agreements on the visit timetable.
- b) The healthcare unit must issue clear instructions as to where and how the pharmaceutical companies can book free representation times, also indicating the respective contact persons. The instructions must be based on solutions that are purposeful from the perspective of the unit's operation.

The instructions must contain information as to the person and the procedure (by phone, by email) and times of booking the medical sales representation times. Instructions specific to each unit should be given to the pharmaceutical companies, for example, through Pharma Industry Finland.

- c) The medical sales representation activities taking place in the healthcare unit premises must be arranged 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. The medical sales representations can also be arranged in premises other than those of the healthcare unit.
- d) Reasonable time must be reserved for the medical sales representation events, and the parties should, as far as practicable, respect the agreed starting and ending hours. Eventual cancellations of the presentations must be made in good time.
- e) Medical sales presentation must be based on the therapy-approach: the medicines presented must be necessary in view of the work of the physicians participating in the event, considering, e.g., their experience and speciality, the novelty of the medicinal product being presented or the new research data on the medicine. In their work, the medical sales representatives must focus primarily on the medicinal product scheduled for the event in question.
- f) The information about the medicine given at the medical sales representation event must correspond to the latest adopted summary of product characteristics (SPC) and be accurate, correct, reliable as well as sufficiently complete and clear. The material used in the presentation must give a true and fair overall picture of the medical significance of the medicinal product being presented. In particular, the medical representation event must comply with Article 7, 26, 29 and 30 of the PIF Code of Ethics.
- g) During their visits, the medical sales representatives must provide their clients with the summary of product characteristics (SPC) of each medicine presented as well as the respective price and reimbursement data, or make the information available to them through other means.
- h) The events and the hospitality offered must comply with the general guidelines concerning the receiving of hospitality by civil servants as well as with the present Code.
- i) The use of starter packs in the marketing of medicinal products is prohibited.

IV CODE FOR THE CO-OPERATION BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS

41 § Prohibition of marketing of prescription-only medicines. The marketing of prescription-only medicines to consumers is prohibited. This prohibition also applies to the co-operation with the patient organisations.

42 § Agreement on support provided. A written agreement between the pharmaceutical company and patient organisation must be made on the financial support or any other significant sponsorship, direct or indirect. The agreement must specify the amount of the funding provided or describe the other type of support, indicating the purpose of the sponsorship. The pharmaceutical company must have a clear procedure for the approval of such agreements.

The agreements with the patient organisations are covered in more detail by Article 15.

The pharmaceutical companies must also pay attention to Articles 124–130 on the obligation to publish their economic liaisons.

43 § Patient organisation's logo and other materials. The pharmaceutical company can use the patient organisation's logo or other material in its own operations only upon a written consent of the patient organisations, covering the purpose and means of use of the materials.

44 § Materials published by the patient organisation. The pharmaceutical company must not try to

influence the contents of the materials published by the sponsored patient organisation in a way promoting its own commercial interests.

45 § List of the sponsored organisations. The pharmaceutical company must maintain an updated and publicly accessible list of the sponsored patient organisations, specifying the direct and indirect financial or other similar support given to the organisations. The list must include a brief description of the nature of the sponsorship and specify the financial value of the direct or indirect value.

The pharmaceutical companies must also pay attention to Articles 124–130 on the obligation to publish their economic liaisons.

46 § Transparency. The pharmaceutical company must ensure that the support provided by it will be disclosed in an appropriate manner in connection with the sponsored activities.

47 § Principle of multiple sponsorship. A pharmaceutical company cannot be the only founding member of a patient organisation or require being the only financier of a patient organisation or a significant form of its activities.

V CODE FOR HEALTH AWARENESS INFORMATION AND OTHER INFORMATION ON HEALTH AND DISEASES TARGETED AT CONSUMERS

1. Health awareness information

48 § Objectives and nature of health awareness information. The objective of health awareness information is to encourage the consumer to maintain their own and their close ones' good health, help them to recognise diseases, their symptoms and risk factors as well as guide the consumer to acquire additional information about the promotion of health and treatment of diseases. The premise of the disease-awareness information must be the disease itself and its diagnostics, rather than the presentation of various therapy options.

Health awareness information must be matter-of-fact by nature, reliable, high-quality and in good taste so that the information supports the positive image of the pharmaceutical industry. Written in clear terms and expressions, the language used must be comprehensible to the consumers. The premise must be the targeting information at an audience possessing the knowledge of an average reader. The information must cover the essential factors related to the disease.

49 § Balanced picture of the disease. In health awareness information, the impacts of the disease

must be described realistically. The consumers should not be frightened and the consequences of the diseases must not be overly dramatized. Health awareness information must not entice the consumers to unjustified use medicines or to seek unnecessary treatment.

50 § Prohibition of marketing of prescription-only medicines. Health awareness information must not contain marketing of medicines to consumers. In other words, it must not promote the use of any particular medicinal product or products. The marketing of prescription-only medicines, including disguised advertising, is categorically prohibited.

51 § Impartial presentation of therapy options. Information on the various therapy options can be given as part of the health awareness information. In that case, the information must cover all therapy options, including the eventual pharmacotherapies and other factors potentially influencing the treatment or prevention of the disease in question, such as changes in living habits.

No therapy option must be presented in such a way as to encourage the consumers to turn to a physician for a particular medicine prescription. Therapy options must be presented in an equal and neutral manner,

without highlighting any specific option. The choice of the therapy best suited to an individual patient always takes place as collaboration between the patient and the physician. Health awareness communications must in no way direct the choice between different therapy options.

Health awareness information may also include information on the prescription-only medicines used for the treatment of the disease, complying with the latest adopted summary of product characteristics (SPC). Should information about pharmacotherapies be given, all medicines used for that particular disease must be mentioned. If the trade names of medicinal products are mentioned, the names of all products must be given in an equitable manner.

The criteria for neutral and unbiased presentation of the therapy options include the following:

- a) No comparisons between various therapy options are made.
- b) No single therapy option is accentuated, for example, through the choice of words, colours or images, or by using different fonts, highlights or other similar tools and elements.
- c) The positive features of no single therapy option are accentuated, highlighting the negative features of the other options.
- d) No categorisation of the therapy options is made without justifiable cause, for example classifying them into leading or most recent products that are widely presented and into other or older options with a more limited presentation.
- e) No single therapy option is recommended in the articles written by healthcare professionals or in patient narratives; and
- f) The technical user instructions, such as dosing information, are either given for all products or not given at all.

If there is only one therapy option for the disease in question, the health awareness information must be realised with special care, in order not to interpret such information as disguised marketing of a prescription-only medicine to consumers. The description of dosage equipment usable for the medicinal products of one single pharmaceutical company only can also qualify as disguised marketing.

52 § Correctness of information and use of research findings. The information given must always be updated and true, and never apt to mislead the consumers.

If the health awareness information include reference to the results of a clinical trial, such data must always

have been published in an article form in a scientific journal.

The sources for general health and disease awareness information must primarily include research other than that by the pharmaceutical company.

The information given together with the study results must be equitable and neutral. Therefore, the health awareness information must not include research-based data that would direct the choice towards a particular therapy option. Moreover, the eventual references to Current Care Guidelines must be neutral so that they would not direct towards a particular therapy option. When referring to particular Current Care Guidelines, the source must be indicated, always giving the latest updated version in the quotation.

53 § Use of tests. The use of various tests measuring the consumers' state of health is allowed in health awareness communications if such tests are scientifically validated and have been published in a scientific journal.

54 § Use of prestige and celebrity. Health awareness information must not contain direct and active recommendations to use the medicine, given by scientists, healthcare professionals or celebrities.

55 § Use of children and other special groups. Special prudence must be applied to the use of children in health awareness information. Health awareness information must not be targeted at children, not even when paediatric diseases are concerned.

Health awareness information must not exploit the non-expertise or distress of consumers in an inappropriate manner.

56 § Competitions and lotteries. If competitions are associated with health awareness information, the eventual prizes must be of reasonable value. When organising the competitions, the stipulations and instructions of the Consumer Protection Act and ensuing orders and guidelines must be taken into account.

57 § Visual image of health awareness information. The visual image (including illustrations or colours) of health awareness information must not be same as the image used in the marketing of the prescription-only medicine used for the pharmacotherapy of the disease in question to healthcare professionals. The use of the same visual image is seen as disguised marketing of the prescription-only medicine to consumers. Moreover, the use of package images is prohibited.

58 § Reference to further information. Health awareness information may refer the consumers to further information on the disease in question (including the Authorities, physicians, healthcare nurses and other healthcare professionals, pharmacies or other healthcare units as well as patient organisations).

59 § Health awareness campaigns. If health awareness information is channelled through several media, or the material is composed of various elements, one single TV spot or outdoor advertisement may be limited in content, if the necessary additional information is available from other sources, such as the Internet or patient guidebook, and the more limited material makes reference to such additional information. If, for example, the TV spot refers to an Internet site, such a site must meet the criteria imposed on health awareness information. This also applies to all other materials and events associated with the health awareness campaign.

60 § Special stipulations concerning Internet sites. If the Internet site containing health awareness information includes links, the following principles must be followed in the preparation of the linked pages:

- a) The link must not lead directly to information including pharmaceutical marketing;
 - b) There can either be links to the sites of all parties offering pharmacotherapy options, or alternatively, no links to any such parties' sites;
 - c) The links must always lead to the homepage of the company, not to their product pages;
 - d) No links to foreign pages must be given, with the exception of the company's international homepage with no prescription-only medicine marketing;
 - e) If the material includes a link to the summary of product characteristics (SPC) or package leaflet of one medicine, there must also be links to the SPCs or package leaflets of all medicinal products used for the treatment of the disease in question;
- The links to the homepages of patient organisations and similar parties are allowed if they do not include marketing of prescription-only medicines to consumers.
- g) The material must not include links suggesting that the consumer send a message from the site to a third party.

All Internet sites targeted at Finnish-speakers, with the address formulated as "www.disease.fi" (such as www.migraine.fi), must always meet the criteria set for the dissemination of health awareness information as defined in the present Code. This will also apply to the health awareness sites accessible

through a link from the homepage of the pharmaceutical company.

61 § Name and responsibility of the company. The health awareness information must always clearly indicate the pharmaceutical company responsible for such information. The company's contact data can also be given.

As far as the material produced is concerned, the pharmaceutical company is always responsible for the compliance with the present Code, even when resorting to the assistance of a third party. For example, no articles written by healthcare professionals or their interviews or patient narratives must advertise any particular therapy option. Moreover, the health awareness information must not include information suggesting that the consumer take the responsibility for another person's health.

Health awareness information can give neutral general information about the pharmaceutical company in question.

2. Patient instructions distributed as support material with therapies prescribed by physicians

62 § Purpose of patient instructions. Pharmaceutical companies can produce patient instructions about the use of a particular prescription-only medicine, distributable by physicians and other healthcare professionals to patients with prescriptions of said medicines. In such a case, the patient instructions act as support material for the pharmacotherapy prescribed for the patient, and are not deemed to be consumer marketing of prescription-only medicines, provided that the principles under Articles 62–65 are respected.

63 § Contents of patient instructions. The information contained in the patient instructions must be neutral, unbiased, true and matter-of-fact. The patient instructions may contain general information about the disease in question and about its treatment, as well as "package-leaflet-like" information about the prescription-only medicine and its correct and safe use. Patient instructions must not contain any marketing elements, such as comparisons of different therapy options or advertising-type highlighting of the medicinal product or its properties.

64 § Visual image of patient instructions. The patient instructions may use the same colours as the package of the medicinal product in question, or show its image.

65 § Distribution of patient instructions. Patient instructions must always be delivered by the company to physicians or other healthcare professionals, and

they must not be generally available to consumers, for example in physicians' waiting rooms or the pharmaceutical companies' homepages. When delivering the material, the recipient must be informed clearly that the patient instructions are merely intended for particular patients to support their treatment prescribed to them, and are not generally distributable to all patients.

VI MONITORING OF THE COMPLIANCE WITH THE CODE, PRELIMINARY INSPECTION, SANCTIONS AND OTHER STIPULATIONS

1. Supervisory Commission and Inspection Boards

66 § Competence. The compliance with the PIF Code of Ethics is monitored and guided by the Supervisory Commission and two Inspection Boards subjected to it.

67 § Competence of Inspection Board I. Inspection Board I supervises all pharmaceutical marketing targeted at consumers, co-operation between the pharmaceutical industry and patient organisations as well as health awareness information and other information on health and diseases targeted at consumers. Inspection Board I will take up a pharmaceutical company's marketing or other measure upon a complaint. Moreover, Inspection Board I can take up a case falling within the scope of application of the Code if it suspects that the case at hand includes distinct non-compliance with the PIF Code of Ethics, constitutes a risk to the reputation of the pharmaceutical industry or misleads the consumer.

68 § Competence of Inspection Board II. Inspection Board II monitors the measures targeted at the healthcare professionals that fall within the scope of application of the PIF Code of Ethics. Inspection Board II solves the disputes based on complaints brought to its attention. In matters of principle, Inspection Board II can initiate proceedings under the present Code on its own initiative.

69 § Transferring the case to the Supervisory Commission. The PIF Code of Ethics: Inspection

Board I and II will transfer the case to the Supervisory Commission if the company in question

- continues the operations in violation of the Code despite an admonition for future reference or a request to abstain from incorrect activities;
- violates against a decision issued in the preliminary inspection;
- disregards the system under the PIF Code of Ethics;
- breaks the mutual agreement made with another pharmaceutical company to end non-complying activities;
- fails to rectify the incorrect operations as ordered by the Inspection Board or Supervisory Commission; or
- continues the incorrect operations despite the temporary request to abstain from the activities. In this case, the violation against the temporary request to abstain is equal to the violation of the actual request to abstain from incorrect marketing.

70 § Competence of the Supervisory Commission. The Supervisory Commission examines the appeals against the decision made by the Inspection Boards. Moreover, the Supervisory Commission also examines the cases referred to it by the Inspection Boards under Article 69. If a case referred to the Supervisory Commission under Article 69 is already pending at the Supervisory Commission, it will examine the case directly.

Upon the request of PIF, the Supervisory Commission can issue opinions on marketing or individual marketing measures on the basis of the PIF Code of Ethics and the EFPIA or IFPMA Codes in force at each given time.

2. General rules on the initiation of cases

71 § General. Anyone can lodge a complaint with the Inspection Board against measures taken by companies committed to this PIF Code of Ethics, falling within the scope of application of the Code. The parties can also lodge an appeal with the Supervisory Commission against decisions of the Inspection Board.

The cases at the Inspection Boards are initiated through its own control initiative, complaints or preliminary inspections.

The cases examined by the Supervisory Commission are initiated on the basis of appeals by a party to the case, referrals by one of the Inspection Boards, or requests of opinion.

72 § Relationship to procedures by the Authorities. A dispute between pharmaceutical companies related to a violation of the PIF Code of Ethics must be solved following the order and system prescribed by the PIF Code of Ethics, before submitting the case to the Authorities.

If the case is already pending with the competent body of the Authorities, it will not be solved by the Supervisory Commission or Inspection Boards whilst it is pending. Once a legally valid and final decision by the Authorities has been issued, the case can be solved taking the dimensions of the decision by the Authorities and eventually imposed sanctions into consideration.

If the examination of the case by the competent bodies of the Authorities is considerably delayed, the Supervisory Commission or the Inspection Board can, exceptionally, take up the case despite the pending process at the Authorities.

73 § Language of the proceedings. The proceedings under the Code of Ethics are the same as the one used in the marketing measure. Only the appendices to the complaints or appeals can be submitted in another language.

74 § Delivery of the documents. The documents submitted to the Inspection Boards or Supervisory Commission can be sent by mail, fax or email.

75 § Limitation period. Any breach against the PIF Code of Ethics must be submitted to the complaint of the system under the PIF Code within one year from the breach.

MUTUAL NEGOTIATIONS BETWEEN COMPANIES COMMITTED TO THE CODE

76 § Mutual negotiations. The companies committed to the PIF Code must try to solve their disputes primarily in amicable negotiations. The companies can make an agreement to end the incorrect activities. However, they cannot agree to consent to the non-compliance with the Code.

Negotiations between the companies are not needed if

- the case is about the marketing of non-prescription medicines to consumers. However, the companies are also here encouraged to settle their disputes primarily between themselves.
- the company continues the operations in violation of the Code despite an admonition or a request to abstain from incorrect activities;
- the company violates against a decision issued in the preliminary inspection;
- the company disregards the system under the PIF Code of Ethics;
- the company breaks the mutual agreement made with another pharmaceutical company to end non-complying activities; or
- the company fails to rectify the incorrect activities as ordered by the Inspection Board or Supervisory Commission.

When the company contacts the other pharmaceutical company to solve the dispute, it must

- specify the items in the measure covered by the scope of application of the PIF Code that it wants to have eliminated or changed; and
- make reference to the Articles of the PIF Code justifying the claim.

3. Complaints to the Inspection Board and appeal to the Supervisory Commission

77 § A complaint to the Inspection Board. A complaint can be brought to the Inspection Board unless the companies can agree on the case within seven business days from the first verifiable contact. The company can make a complaint earlier than this if it is impossible to agree on the dispute. The complaint with the Inspection Board must be made within 30 days from the first verifiable contact, on pains of the case becoming void. Under exceptional circumstances,

however, the companies can verifiably agree to extend the 30-day deadline by the maximum of 14 days if the deadline for the complaint is July or if the company's first verifiable contact takes place in July.

The company must inform the other company of the complaint lodged. Such information must be given in a verifiable manner before the complaint is sent to the Inspection Board. The advance information is not necessary if the case at hand concerns the marketing of non-prescription medicines to consumers or in situations where the company

- continues the operations in violation of the Code despite an admonition or a request to abstain from incorrect activities;
- disregards the system under the PIF Code of Ethics;
- breaks the mutual agreement made with another pharmaceutical company to end non-complying activities; or
- fails to correct the incorrect activity as ordered by the Inspection Board or Supervisory Commission.

78 § Appeal to the Supervisory Commission.

Appeal against the decision taken by the Inspection Board or by the Chairperson and Secretary of Inspection Board under Article 87 Paragraph 4 can be lodged with the Supervisory Commission through an application to that effect. The period of appeal is 14 days of the date in which notice of the written decision was served. The Supervisory Commission must examine the appeal without delay.

Despite the appeal or application for enforcement ban, the decision of the Inspection Board must be adhered to until the Supervisory Commission has issued its decision in the case. For a particular reason and upon an application of a party to the case, the Chairperson and the Secretary of the Supervisory Commission can jointly order that the decision of the Inspection Board will not be enforced before the decision of the Supervisory Commission (enforcement ban).

A particular reason may, for example, be that the decision of the Inspection Board is based on an evident misinterpretation of the Code or that the Inspection Board has otherwise followed an incorrect procedure in its decision-making.

79 § Appeal. The decisions of the Supervisory Commission are not appealable.

REQUIREMENTS IMPOSED ON COMPLAINTS AND APPEALS

80 § Requirements imposed on complaints and appeals. The complaint to the Inspection Board or the appeal to the Supervisory Commission must be made in writing. The complaint or appeal must be signed by a person authorised to sign for the company.

The complaint or appeal must be clear and sufficiently specified, containing all relevant information related to the complaint or appeal. The complainant or appellant has the burden of proof of the alleged non-compliance with the PIF Code. If the case at hand concerns the reliability of the sources used for the measures falling within the scope of application of the PIF Code of Ethics, the pharmaceutical company in question must prove the reliability of the source material. The appeal addressed to the Supervisory Commission or the reply given to an appeal must not make reference to such materials as were not presented for the examination of the Inspection Board, unless there are particularly weighty reasons to do so.

If the complaint or the appeal is ambiguous or incomplete, the complaint or the appeal must be complemented, if so requested, during the preparation of the case. If so requested by the secretary of the Inspection Board or Supervisory Commission, the company concerned must submit the material in question (including the materials of the medical sales representative). The additional material must be submitted to the Inspection Board or Supervisory Commission within five days from the service of the request.

If the complaint or the appeal is not supplemented despite the request to that effect, or it remains too ambiguous or incomplete to constitute the basis for examination, the complaint or appeal will be dismissed without examining its merits. A separate decision will be made regarding the dismissal.

4. Procedures followed at the meetings of the Inspection Boards and the Supervisory Commission

81 § Hearing of experts and requests for opinions. The Supervisory Commission and the Inspection Boards can hear experts and ask for opinions.

82 § Minutes and decisions. Minutes will be kept of the Supervisory Commission and Inspection Board meetings.

The minutes must record, at least, the attending Members, the agenda, the decisions made and dissenting opinions as well as a list of the documents appended to the minutes. Any decisions in the minutes must include the respective motivations.

A separate written decision is made on the issues on the agenda of the meeting. The decisions include the complaint made, the measure inspected or its written description, the replies and opinions obtained, the grounds given, the information on the Members participating in the decision as well as the dissenting opinions.

The Chairperson (or Vice Chairperson if the former is absent from the meeting) and the Secretary of the Supervisory Commission or Inspection Board sign the decisions which are served to the parties either by mail or in electronic form.

83 § Disqualification. As concerns the disqualification of the Chairpersons and Members of the Supervisory Commission and Inspection Board, the stipulation on the bias of Arbitrators will apply. Moreover, in order to maintain reliability, the Chairperson or Member must disqualify themselves if they have been employed full-time in one of the companies involved in the case during the past five years. The person representing the pharmaceutical industry in the Supervisory Commission must be unbiased in each separate case examined.

SPECIAL PROVISIONS CONCERNING THE INSPECTION BOARDS

84 § Composition of Inspections Board I: Inspection Board I has five Members or their personal Substitutes and the Secretary as well as a Member with expertise in veterinary medicine or his/her personal Substitute. The veterinary expert Member only participates in the examination of issues under his/her expertise area.

85 § Composition of Inspection Board II: Inspection Board II has four Members or their personal Substitutes and the Secretary as well as a Member with expertise in veterinary medicine or his/her personal Substitute. The veterinary expert Member only participates in the examination of issues under his/her expertise area.

The Board of Pharma Industry Finland will appoint the Members of the Inspection Boards. The PIF Self-care medicines committee makes the proposal on the Members of Inspection Board I. Both Inspection Boards elect one Member as their Chairperson and one as the Vice Chairperson for the term of the Board.

Pharma Industry Finland will appoint the Secretaries of the Inspection Boards.

The term of the Members and Substitute Members of Inspection Board I and II is four calendar years. At the end of each the term, one Member and the respective Substitute Member resign in turn.

The Member or Substitute can be re-elected for the maximum of three subsequent terms.

If a Member resigns from the Inspection Board in the middle of the term or becomes otherwise permanently disqualified, the PIF Board will appoint a new Member to Substitute for that Member until the end of the term of office.

86 § Secretary. The Secretary keeps the minutes of the meetings. The Secretary has no vote in decision-making. If the Secretary is disqualified or prevented from examining the case, the Substitute will attend to the tasks.

87 § Convening and quorum. The Inspection Board convenes when necessary, summoned by the Chairperson or the Vice Chairperson. A written complaint must be taken up without delay.

The Inspection Board constitutes a quorum when the Chairperson or Vice Chairperson or at least two Members or Substitute Members are present.

The decisions of the Inspection Board will be taken by simple majority. If the votes are even, the Chairperson casts the decisive vote.

However, the Chairperson and Secretary of the Inspection Board can decide that a case under Article 77, Paragraphs 1 and 2 will lapse if

- the deadline of 30 days has expired; or
- the information on the complaint initiating the case at the Inspection Board has not been served in a verifiable manner to the other company.

88 § Hearing. Before issuing an admonition, a request to abstain from incorrect measures or imposing a sanction payment, the Inspection Board must hear the companies concerned.

The Inspection Board must ask a reply to a written complaint from the parties whose rights are involved in the case and who have not yet had the opportunity to express their views in this context. The reply can be given by mail, fax or in electronic form, within the timeframe ordered by the Secretary. The deadline must not be shorter than seven days or exceed 14 days, save for exceptional reasons. The case can be examined irrespective of the failure to give a reply.

If the reply proposes a new examination that would influence the decision, the Inspection Board or its Secretary must request, within a brief period of

time, that the complainant issue a written opinion on the reply. The deadline must not exceed seven days, save for exceptional reasons.

The replies given can be sent to the other parties of the case for their information.

89 § Scope of the examination. Inspection Board I must examine the measure in full, issuing the opinion on the compliance of the activities with the PIF Code of Ethics when the case to solve is about

- marketing targeted at consumers;
- co-operation between the pharmaceutical industry and patient organisations;
- health awareness information and other information targeted at consumers and related to health and diseases.

Inspection Board II must examine the marketing or medical sales representation measure targeted health-care professionals only to the extent of the complaint in the case, issuing its opinion on the compliance of the operations with the Code. At its discretion, Inspection Board II may also examine a marketing measure more thoroughly than was requested in the complaint. In matters of principle where Inspection Board II initiates proceedings under the present Code on its own initiative, it can examine the marketing measure to extent it finds appropriate.

The Inspection Boards make their decisions on the complaints based on the material provided by the parties. They are not obliged to acquire other information on the case at hand.

90 § Principles and the interpretation of the Code. The Inspection Board can ask for the Supervisory Commission's opinion on the principles of decision in the case as well as on the correct interpretation of the PIF Code of Ethics. After receiving the opinion, the Inspection Board must make the decision in the case without delay.

91 § Temporary request to abstain from incorrect activity. If an essential incorrectness is detected in other measures falling within the scope of application of the PIF Code, the Chairperson and the Secretary of the Inspection Board can jointly issue a temporary request to abstain from incorrect marketing or other incorrect activities. The decision must be adhered to without delay and until the Inspection Board makes the decision in the case. In order to keep the temporary request to abstain from incorrect marketing in force, the Inspection Board must convene within 30 days to make a decision in the case which constituted the subject for the temporary request.

SPECIAL PROVISIONS CONCERNING THE SUPERVISORY COMMISSION

92 § Composition of the Supervisory Commission. The Supervisory Commission has a Chairperson, five Members or their personal Substitutes, as well as the Secretary and Veterinarian or his/her personal Substitute. The Veterinarian included in the composition of the Supervisory Commission will only participate in the examination of cases of his/her area of expertise.

The PIF Board will appoint the Members of the Supervisory Commission. Moreover, the Board of PIF also appoints five persons employed by pharmaceutical companies, among whom one person will be separately chosen to join the examination of the case at hand at any given time. A personal Substitute Member will also be elected for the persons employed by the pharmaceutical industry. The Substitute of the Member employed by a pharmaceutical company is the PIF General Manager.

PIF also appoints the Secretary of the Commission, and the Substitute of the Secretary.

The term of the Chairperson, Members and their personal Substitutes of the Supervisory Commission is four calendar years. At the end of each term, one Member and the respective Substitute resign in turn. The Member or Substitute can be re-elected for the maximum of three subsequent terms.

If a Supervisory Commission Member resigns in the middle of the term or becomes otherwise permanently disqualified, the PIF Board will elect a new Member to substitute for him/her until the end of the current term.

93 § Secretary. The presenting official of the Supervisory Commission, the Secretary keeps the minutes of the meetings. The Secretary has no vote in decision-making. If the Secretary is disqualified or prevented from examining the case, the substitute will attend to the tasks.

94 § Convening and quorum. The Supervisory Commission will convene when summoned by the Chairperson. If the Chairperson is prevented, the Supervisory Commission convenes upon the summons of the Vice Chairperson.

The Secretary will make a proposal to the concerned pharmaceutical companies, suggesting a qualified member employed by a pharmaceutical company to examine the case. If either of the pharmaceutical companies concerned is opposed to the proposal of the Secretary, a Substitute Member will be convened. If a qualified person employed by a pharmaceutical company, impartial to the case at hand, is not available for the meeting, the PIF General Manager will be summoned.

The summons to the meeting must be sent to the Members no later than seven days prior to the meeting. A Member recognising his/her own bias must inform the Secretary of the Supervisory Commission of such circumstances without delay, and the Secretary will summon the Substitute Member.

The Supervisory Commission constitutes a quorum when the Chairperson or the Vice Chairperson and at least two Members or Substitute Members are attending. The decisions of the Supervisory Commission will be taken by simple majority. If the votes are even, the Chairperson casts the decisive vote.

95 § Hearing. Before making the decision, the Supervisory Commission must hear the companies concerned if they have not yet had the chance to express their opinion in the case at hand. If necessary, the Supervisory Commission can hear the Inspection Board. The hearing can take place by mail, fax or in electronic form.

The reply must be given within a short timeframe determined by the Secretary of the Supervisory Commission. The deadline must not be shorter than seven days or longer than 14 days, except under exceptional circumstances. The Supervisory Commission can examine the case despite a failure to give a reply.

The replies given can be sent to the other parties of the case for their information.

96 § Scope of the examination. The Supervisory commission will make the decisions about the appeals and the issues referred to it by the Inspection Boards on the basis of the material provided by the parties or the Inspection Board. It is not obliged to acquire other information on the case at hand. The Supervisory Commission can also examine the measure beyond the scope of the appeal if the case at hand is one taken up by the Inspection Board on its own initiative.

97 § Enforcement ban. For a particular reason and upon an application of a party to the case, the Chairperson and the Secretary of the Supervisory Commission can jointly order that the decision of the Inspection Board will not be enforced before the decision of the Supervisory Commission is issued (enforcement ban). A particular reason may, for example, be that the decision of the Inspection Board is based on an evident misinterpretation of the Code or that the Inspection Board has otherwise followed an incorrect procedure in its decision-making.

5. Preliminary inspection of measures targeted at consumers

98 § Preliminary inspection. The pharmaceutical company can ask the Inspection Board I to perform a preliminary inspection on a marketing or other measure targeted at consumers.

The Inspection Board must be supplied with the marketing or other measure to be inspected as well as the basic information on the medicinal product approved by the Authorities.

The basic information includes, for example, the summary of product characteristics (SPC), package leaflet and, if necessary, the package. If the marketing or other measure refers to other material, the Inspection Board must also be supplied with that material.

If the advertisement is a spot that can be shown on the TV or radio, the applicant must also complement the application with the manuscript of the planned spot or the finalised spot.

If the TV or radio spot refers to an Internet site containing health awareness information, the site in question is also covered by the voluntary inspection.

99 § Obligatory preliminary inspection. An exception to the rule of voluntary action under Article 98, the TV or radio spots advertising self-care medicines must be submitted to preliminary inspection. The pharmaceutical company is obliged to arrange the preliminary inspection referred to in this Paragraph.

Even though the TV or radio spot covered by the preliminary inspection obligation would refer to an Internet site, the webpages are not covered by the obligatory preliminary inspection.

If a TV or radio spot already approved by the Inspection Board is changed so that the contents of the spot are not materially influenced, the spot need not be submitted to a repeated preliminary inspection. Such changes may include the change or addition of the company or product logo, deleting the word "new" or "novelty", or a change of the package image or colour or a reference to the Internet site. Before publication, the spot with such changes will be sent to the Secretary of the Inspection Board for information. The Secretary must inform the company within seven days from receiving information of the spot whether the Inspection Board must perform an inspection.

100 § Procedure of the obligatory preliminary inspection. In the preliminary inspection of TV and radio spots, the Inspection Board may

- approve the planned spot without changes;
- approve the spot with changes; or
- fail the planned spot.

If necessary, the Inspection Board can hear the applicant before making the decision.

If a draft other than the final spot is submitted to the inspection, the opinion given on the draft spot is not the Inspection Board's final stand to the finalised spot. However, the Inspection Board is tied to its opinions related to the compliance of the spot manuscript with the Code.

The Inspection Board will issue a separate, motivated and dated decision of the preliminary inspection to the applicant. Notice of the decision must be served to the applicant immediately.

A TV or radio spot inspected and approved by the Inspection Board can be broadcasted as such for the maximum of three years from the date of approval.

101 § Broadcasting of TV and radio spots. The pharmaceutical company is obliged to comply with the decision issued during the obligatory preliminary inspection procedure.

102 § Procedure in other preliminary inspections. The preliminary inspection of other marketing measures or other measures targeted to consumers can focus on the question whether the measure complies with the PIF Code of Ethics and whether it could be prohibited in subsequent supervision.

If only a part of a more comprehensive marketing or other measure is subjected to preliminary inspection, the decision of the inspection does not signify the final approval of the entire measure but the stand is only limited to the aspects emerging in this examination.

The preliminary inspection decision must specify the reasons for which the marketing measure does not comply with the Code.

If the Inspection Board notices that a finalised marketing or other measure is either contrary to the decision made during preliminary inspection or otherwise in violation against the Code, the Inspection Board can examine the case in terms of normal subsequent supervision.

103 § Preliminary inspection charge. The applicant must pay a preliminary inspection charge, set by the PIF Board annually together with the adoption of the PIF budget.

6. Sanctions

104 § Sanctions. If the marketing or other measure of a company committed to the PIF Code of Ethics does not comply with it, the Inspection Board or the Supervisory Commission may decide to impose a sanction to the pharmaceutical company, in the form of

- an admonition for future reference
- a request to abstain from incorrect activity
- a processing charge
- a compensation payment
- a sanction payment
- order to rectify and correct the measures taken.

Moreover, the Supervisory Commission can impose a contractual penalty.

The Inspection Board and Supervisory Commission may impose a sanction for the violation of the Code even though the pharmaceutical company in violation thereof would already have given up such measures.

The sanctions under the Code do not impact one pharmaceutical company's obligation to compensate the other company for the damages caused by the violation of the Code.

105 § Admonition. When the non-compliance with the Code is of minor importance, the Inspection Board or the Supervisory Commission can give the company concerned an admonition. The admonition must be associated with a reasonable deadline by which time the advertisement or other marketing material must be revised. In this case, the pharmaceutical company can, within the set timeframe, complete an agreed campaign or finish the printed marketing materials.

106 § Request to abstain from incorrect marketing. When the non-compliance with the Code is not of minor importance, the Inspection Board or the Supervisory Commission can request the company concerned to abstain from incorrect marketing. In this case, the pharmaceutical company must abstain from the non-complying activities immediately after having received the respective request in either oral or written form. Moreover, the eventual marketing material must be immediately withdrawn from the market.

107 § Sanction payment. At their own discretion, the Inspection Board or the Supervisory Commission can impose a sanction payment on the non-complying company. The minimum of the sanction payment is 1 000 euro while the maximum is 100 000 euro. The sanction payment must be proportional to the nature and extent of the violation as well as to the eventual

benefits gained by the company through such violation. When estimating the extent of the violation, the predictable information measures following from the marketing measure must also be taken into consideration. The payment associated to the request to abstain from incorrect marketing must be higher than the one imposed together with an admonition.

If the pharmaceutical concerned is a veterinary medicine, this can be taken into consideration, whenever necessary, as a factor in favour of a lower sanction payment.

The sanction payment cannot be imposed in the same case which results in a contractual penalty.

108 § Correction of incorrect activities. If it is deemed possible to correct the activities, the Inspection Board or the Supervisory Commission can order that the non-complying measure be rectified in the same way as the incorrect information was distributed. The Inspection Board or Supervisory Commission can also issue this order on their own initiative. The order must specify the minimum requirements related to the contents of the rectification as well as the timeframe for the corrective action. In considering the rectification of incorrect measures, the Inspection Board or the Supervisory Commission must consider the extent and quality of the incorrect operation as well as the eventual negligence of the PIF Code of Ethics.

109 § Contractual penalty and other sanctions.

If the company

- despite the admonition, request to abstain from incorrect marketing or temporary request to abstain, continues the activities violating the present PIF Code of Ethics;
- violates against a decision issued in the preliminary inspection of radio and TV spots;
- disregards the system under the PIF Code of Ethics;
- breaches the mutual agreement made with another pharmaceutical company to end incorrect operations;
- fails to rectify the incorrect operations as ordered by the Inspection Board or Supervisory Commission;

the Supervisory Commission can

- a) submit the case to the regulatory Authorities for their eventual measures; or
- b) at its discretion, impose a contractual penalty ranging from a minimum of € 20,000 to the maximum of € 300,000 on the company that has violated the PIF Code.

When quantifying the contractual penalty, the Supervisory Commission must consider the extent of the

operations in violation of the PIF Code of Ethics, the medias used, eventual negligence of the Code and other similar aspects. If the incorrect marketing takes place on television, this constitutes a particular factor increasing the amount of the contractual penalty.

110 § Conciliation. The sanction can be conciliated if, determined under the PIF Code, it would lead to an unreasonable situation. The consideration of the reasonableness must include the weighing of the entire contents of the measure, the positions of the parties, the circumstances prevailing before and after the activities, the eventual benefits drawn by the parties of the case as well as other similar measures.

111 § Compensation payment. The Inspection Board or the Supervisory Commission can, on the request of the company concerned, order a compensation payable by the company that has made an unfounded complaint with the sole purpose of causing harm to the competitor. The compensation is paid to the company falling victim of an unfounded complaint to compensate for the costs incurred. The compensation payment amounts to 5 000 euro.

112 § Processing charge. The Supervisory Commission or the Inspection Board can impose a processing charge payable for each handling of the case by the company causing the case to be examined. As a general rule, the charge is imposed on the party that has been found to engage in activity that is contrary to the Code. The complainant company cannot be imposed the processing charge if the activities examined are found to be non-compliant with the PIF Code of Ethic. However, the processing charge can also be imposed on the complainant company if the complaint has been found unjustified or the complainant company has asked that the examination of the case be dismissed.

Pharma Industry Finland PIF will decide on the amount of the processing charge on an annual basis. The purpose of the processing charge is to cover the costs incurred by the supervisory system for the examination of the case. The charge can be diminished or augmented for a particular reason related to the expenses incurred for the processing. Moreover, the processing charge may be multiplied to five times the original if the complaint is found to be completely unfounded. Besides the processing charge, the company will be obliged to reimburse the direct expenses incurred by the Supervisory Commission for the clarifications in the case.

Separate payments will be charged for the preliminary inspections.

VII OTHER STIPULATIONS

113 § Publicity. The decisions and opinions of the Supervisory Commission and Inspection Boards on issues concerning subsequent supervision are public information. The part of the marketing and other materials concerning the examined individual marketing arguments or other measures is public information. Preliminary inspection decisions are not public.

The private parties not committed to the PIF Code will be sent the decision upon separate request following the price list separately adopted by the PIF Board.

114 § Correction of an error in the substance matter or in the procedure. The Inspection Board or the Supervisory Commission can, at the request of the party concerned, withdraw its erroneous decision and take a new decision in the case if

- the decision by the Inspection Board or Supervisory Commission is based on a clearly faulty or incomplete report; or
- on an obviously incorrect application of the Code; or
- a procedural fault has been committed during the decision-making process.

The decision can be corrected either for or against the interested party. Correcting the decision against the interested party, calls for the consent of the interested party to submit the decision for correction. However, the consent of the interested party is not necessary if the error is evident and it has been caused by the interested party's own action.

115 § Correction of typos. The Chairperson and Secretary of the Inspection Board or Supervisory Commission must correct an evident miscalculation or typo or other similar clear mistake in the decision taken by these instances.

However, the mistake must not be corrected if such correction would lead to an unreasonable result from the interested party's point of view, and the mistake is not due to the interested party's own action.

116 § Initiation and processing of correction issues. The Inspection Board or Supervisory Commission will process the correction issues on their own initiative or at the request of the interested party. The initiative of correction must be taken within 30 days of the decision. The correction request must be made within 30 days from the date in which the interested party was served written notice of the decision.

The correction of a mistake in a substance matter or procedure calls for new processing and decision in the case. A typo will be corrected by replacing the decision document containing the mistake by a corrected version of the same. The interested party must be reserved an opportunity to be heard before the typo is corrected.

117 § Complementary stipulations concerning the correction procedure. While discussing the corrections of substance-matter mistakes or typos, the Inspection Board or Supervisory Commission can ban execution until further notice.

If an appeal against a decision by the Inspection Board, to be corrected, has been lodged with the Supervisory Commission, the Inspection Board must inform the Supervisory Commission about the correction, supplying the corrected decision to the latter. The processing of a correction issue does not influence the period of appeal against the decision by the Inspection Board.

118 § Confidentiality commitment. The PIF Board must request that the Chairpersons, Members and Secretaries of the Supervisory Commission and Inspection Boards commit to secrecy regarding the documents related to the case at hand. The documents or their copies must not be given to parties other than those participating in the handling or to the interested parties without the consent of the party object of the document in question. Moreover, the Members or Secretaries of the Supervisory Commission and Inspection Boards must not disclose – apart from the decision or opinion issued – anything of the matters that have come up during the discussion of the case.

119 § Management of the monitoring system finances. The finances of the Supervisory Commission constitute a part of the PIF financial management. The expenses incurred for the operation of the Supervisory Commission will be covered primarily by the funds accumulated from processing and preliminary inspection charges, sanction payments and contractual penalties. PIF will cover the eventual deficit in the Commission's accounts, and is entitled to receive the surplus, if any.

The outside experts heard by the Supervisory Commission and the Inspection Boards will receive a reasonable compensation for the work performed. The expenses incurred for the hearing of experts or for

other reports may also be imposed on the companies involved.

The Supervisory Commission will issue an annual report on its operations on the PIF website.

120 § Giving notice. The notice of withdrawal from the agreement on the compliance with the PIF Code of Ethics must be given in writing to Pharma Industry Finland. The period of notice is six months. The notice does not prevent the processing of violations that have taken place before the end of the period of notice, in line with the system under this Code of Ethics.

121 § Entry into force. This PIF Code will enter into force on 1 January 2014. The former PIF Code, which entered into force on 1 January 2013, will be repealed as each company commits to the new PIF Code, no later than 30 June 2014.

122 § Transitional provisions. The violations taking place before 1 January 2014, with eventual

sanctions, will be examined in line with the PIF Code of 1 January 2013 but otherwise the procedure will follow the provisions of the new PIF Code.

The stipulations related to the term and re-election of the Members of the Supervisory Commission and the Inspection Boards will be applied to the Members in office at the moment of the entry into force of the present PIF Code as from 1 January 2014.

The approved broadcasting period of a spot, adopted by the Inspection Board I before 1 January 2014 in preliminary inspection, will continue unaltered after the entry into force of the new version of the PIF Code.

The prohibition concerning gifts (Article 32) will enter into force on 1 July 2014.

123 § Pharmaceutical companies agree to abide by the resolutions taken in accordance with the present Code. No claims for damages can be addressed to the Supervisory Commission or Pharma Industry Finland PIF for the sanctions or other losses incurred for sanctions imposed under the Code.

VIII CODE FOR THE DISCLOSURE OF TRANSFERS OF VALUE

124 § Information obligation and scope of application. In line with Articles 125-130 of the present PIF Code, the company must document and publish the economic benefits targeted at healthcare organisations or professions (persons entitled to prescribe or dispense medicines) who have their principal place of business, work address or registered domicile in Europe.

Economic benefit refers to all direct or indirect transfers of economic value either in cash, in benefits in kind or other forms of benefit.

The information obligation does not relate to economic benefits:

- not included in the categories under Article 125;
- constituting part of the usual sales and purchasing operations between the pharmaceutical company and healthcare professional or organisation.

125 § Individual disclosure. As a main rule, the economic liaisons are published by specifying the

name of the recipient party (organisation or professional). The values of the economic benefits received by an individual recipient are published for each reporting period by classifying them, as far as possible, into the categories hereunder.

The economic benefits received by an individual recipient can be published by annual aggregate categories, provided that the individual sums in euro can be presented at request to the recipient and/or the authorities.

1.Sums allocated to healthcare organisations:

- Donations and grants** allocated to institutions, organisations or associations or societies with the mission of supporting healthcare and/or whose membership is constituted by healthcare professionals and/or healthcare providers.
- Contributions to the costs of events.** Contribution to the costs of events through healthcare organisations or third parties, including sponsorship to healthcare professionals in the form of their participation costs, such as:

- registration fees;
 - agreements with healthcare organisations or third parties named by them on sponsorship provided for the organisation of events;
 - travelling and accommodation costs.
- c) **Service and consultation fees.** Economic benefits derived from or related to the contracts concluded between the companies and institutions, organisations or healthcare professional associations,
- on the basis of which these institutions, organisations or associations provide the pharmaceutical company with any services; or
 - any other type of funding not included in the above categories a) or b).

2. Sums allocated to healthcare professionals

a) Contributions to the costs of events.

- Contributions to the costs of events, such as
- registration fees;
 - travelling and accommodation costs.

b) Service and consultation fees.

Economic benefits derived from or related to the contracts concluded between the companies and healthcare professionals,

- based on which these professionals provide the pharmaceutical company with any services; or
- any other type of funding not included in the above category a).

126 S Aggregate disclosure. If the information related to economic benefits cannot be published on the level of individuals due to legal reasons, the total sums must be published in aggregate form for each category and reporting period.

For each category, the summary must specify:

- the number of recipients of economic benefits as well as each recipient's percentage share of the total sum; and
- the total sum of the economic benefits allocated to the recipients.

127 S Non-repetition of information. If the economic benefits published under Art. 125 or 126 are channelled to the healthcare professional indirectly

through the healthcare organisation, the publication need not be repeated. The publication must take place, as far as possible, under Art. 125 above.

128 S Economic benefits related to research and product development. A summary of the economic benefits related to research and product development during each reporting period must be published as aggregate sums.

129 S Publication methods. The company must provide a brief presentation (memorandum) of the methods used in the publication and identification of each category of economic benefits as per Article 125 above. The memorandum must include:

- a general summary and/or description of particular remarks per country;
- the description of the methods used in the categorisation and identification of the economic benefits;
- a report on the way in which multiannual contracts have been taken into account, as well as on VAT and other fiscal issues;
- questions related to exchange rates;
- the other issues related to the timing, amounts and matching of economic benefits to particular fiscal years, as applicable.

130 S The publication takes place annually and the reporting period is one full calendar year.

The first reporting period is the calendar year 2015. The information must be published within six months from the end of the reporting period. The information must be publicly accessible for at least three years from the publication. The information must be kept for at least five years.

The publication takes place in the Finnish language on the company's webpage, following the template structure given by PIF.

In the publication of economic liaisons, the obligation under Article 45 of the present PIF Code regarding the updated list of sponsored patient organisations must also be taken into consideration.

APPENDIX 1

GOOD MEDICAL REPRESENTATIVE CONDUCT Guidelines by Pharma Industry Finland PIF and the Association of Finnish Local and Regional Authorities

The pharmaceutical companies and healthcare units should respect the following principles of good medical representative conduct in the respective events:

1. The medical sales representative must possess the necessary basic knowledge in order to be able to provide as complete information about the medicinal product as possible. The medical sales representative must have the registered medical sales representative (RLE) or registered self-care medicine representative (ILE) diploma, or otherwise possess the knowledge required for the proper performance of the work.
2. The medical representations must be based on advance agreements on the visit timetable.
3. The healthcare unit must issue clear instructions as to where and how the pharmaceutical companies can book free representation times, also indicating the respective contact persons. The instructions must be based on solutions that are purposeful from the perspective of the unit's operation. The instructions must contain information as to the person and the procedure (by phone, by email) and times of booking the medical representation times. Instructions specific to each unit should be given to the pharmaceutical companies, for example, through Pharma Industry Finland.
The pharmaceutical companies must follow the instructions given by the healthcare unit regarding the booking of the visits in order to avoid unnecessary contacts that might disturb the operation of the unit.
4. The medical representation activities taking place in the health care unit premises must be arranged in the physician's consulting room, the medical staff's common room or other similar premises assigned by the health care unit for presentation purposes, to allow for the presentation to take place in privacy, without disturbing the other activities of the health care unit.
The medical representations can also be arranged in premises other than those of the healthcare unit.
5. Reasonable time must be reserved for the medical representation events, and the parties should, as far as practicable, respect the agreed starting and ending hours. Eventual cancellations of the presentations must be made in good time.
6. Medical presentation must be based on the therapy-approach: the medicines presented must be necessary in view of the work of the physicians participating in the event, considering, e.g., their experience and speciality, the novelty of the medicinal product being presented or the new research data on the medicine. In their work, the medical sales representatives must focus primarily on the medicinal product scheduled for the event in question.
7. The information about the medicine given at the medical representation event must correspond to the latest adopted summary of product characteristics (SPC) and be accurate, correct, reliable as well as sufficiently complete and clear. The material used in the presentation must give a true overall picture of the medical importance of the medicinal product presented. The marketing material must always contain information in line with the adopted summary of product characteristics, indicating the correct and safe use of the medicine. Moreover, the information on the pharmaceutical must contain the legal dispensing conditions, health insurance reimbursement criteria, average medication costs as well as the retail prices of different packages sizes, if possible.

The adverse effects, interactions and counter-indications of the medicine as well as other aspects related to the safe use of the medicinal product must be presented in a sufficiently clear manner.

The research data presented by the medical representative, not included in the summary of product characteristics (SPC), must correspond to or support the information in the SPC.

Any quotes, figures and tables from literature or research reports must correspond to the original. Different research results must not be combined, for example, for purposes of comparisons between different products.

The origins of the information used in the presentation must be indicated accurately, and the sources used must be available to those participating in the event. If reference is made to unpublished research material, it must be provided for the participants if so requested.

8. The hospitality offered at the medical representation events must be reasonable, suitable for the situation and secondary to the scientific and training contents of the medical representation in question. As far as hospitality is concerned, the general instructions related to the accepting of hospitality by officials (see Appendix) as well as the Code for the Marketing of Medicinal Products of Pharma Industry Finland (PIF) must be followed.
9. Free samples of pharmaceuticals can be given only to persons who are authorised to prescribe or dispense them, and as regards prescription-only medicines, only to those who

are entitled to write prescriptions. The sample must correspond to the smallest marketable package size of the product in question. In one year, each recipient can be given one sample package of each strength and pharmaceutical form of each medicinal product. The pharmaceutical sample is dispensed against a written, signed and dated request, accompanied by the product's summary of product characteristics SPC

The use of starter packs in the marketing of medicinal products is prohibited. However, during their presentation visits, the medical sales representatives can provide the health-care unit with the necessary starter packs.

10. The member companies of Pharma Industry Finland (PIF) are committed to following the PIF Code for the Marketing of Medicinal Products. The current guidelines constitute a part of the Code. Responsible for following the respect of the Code, the Supervisory Commission for the Marketing of Medicinal Products and the Inspection Boards subject to it, may impose sanctions defined in the Code on companies breaking the Code.

Physicians are free to decide whether or not they intend to participate in medical representation events at their free time, considering the stipulations of the obligations of civil servants and employees of public corporations. Asking or receiving hospitality or other benefits must not jeopardise the public trust in the authorities, civil servants or employees of public corporations (see Appendix).

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