

Code of Ethics



PHARMA INDUSTRY FINLAND (PIF)
2008

CONTENTS

I	Introduction	3
II	Code for the marketing of medicinal products	4
III	Code for the good medical sales representation practices	12
IV	Code for the co-operation between the pharmaceutical industry and patient organisations	14
V	Code for health awareness information and other information on health and diseases targeted at consumers	15
VI	Monitoring of the compliance with the codes, preliminary inspection, sanctions and other stipulations	18

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I INTRODUCTION

Correct information on pharmaceuticals promotes their correct use. The purpose of marketing activities, sales promotion and advertising is to provide healthcare professionals with updated information on medicines for the prevention, alleviation and cure of diseases. As a result, there is less need for more expensive medical treatments, people are able to maintain their ability to work or restore it more quickly, and as medicines help to maintain better health, the overall healthcare expenditure is smaller. The marketing of non-prescription medicines to consumers provides them with information about the available treatment options in cases where the treatment of the illness does not call for medical attention, directing the consumers towards the correct and safe use of medicines.

The objective of the voluntary guidance is to increase the reliability of the marketing of medicines and to promote the information value of the marketing message vis-à-vis the consumers and healthcare professionals, thus contributing to an appropriate use of medicines. The research, development and production of medicinal products meet the highest quality standards. The same objective also applies to the marketing of medicinal products.

The pharmaceutical industry performs research on medicines, introducing them to the market for the pharmacy professionals as well as physicians, dentists and veterinarians to dispense, prescribe or use for the treatment of the patients. The healthcare professionals also play a core role in the collecting of the pharmaceutical research and other information. In order to guarantee pharmaceutical development and proper use of medicines, the co-operation between the pharmaceutical industry and the healthcare professionals is of vital importance. The co-operation must take place in the framework of unambiguous and transparent guidelines.

Representing the medicine users and their close ones, the patient organisations play a significant role.

The co-operation between patient organisations and pharmaceutical companies is necessary but it must be transparent by nature, conducted in the framework of clear guidelines so that the autonomy of both parties is safeguarded.

The consumers and patients have an increasing need to obtain information on various diseases. The pharmaceutical industry can also provide such information, having substantial information on various diseases as well as on their prevention, diagnosis and treatment. The information disseminated by the pharmaceutical companies is complementary to that given by, among others, the healthcare professionals and the Authorities, and it has to meet the high ethical requirements related to the quality and objectivity of the information.

The legislator and the medicines control authorities regulate and monitor some of the themes covered by the present Code of Ethics. The voluntary ethical control by the pharmaceutical industry is complementary to their work.

The present Code of Ethics incorporates the following guidelines and instructions regarding pharmaceutical marketing and other information distributed by the pharmaceutical companies, as well as the co-operation between the pharmaceutical industry and its various stakeholder groups.

- Code for the Marketing of Medicinal Products
- Code for the Good Medical Sales Representation Practices
- Code for the co-operation between the pharmaceutical industry and patient organisations
- Code for health awareness information and other information on health and diseases targeted at consumers

Moreover, the Code of Ethics also includes a section on the monitoring of the compliance of the above codes, on preliminary inspection operations, on the sanctions following from non-compliance as well as on certain other stipulations.

The Code of Ethics sets forth generally accepted operative principles which the pharmaceutical companies shall comply with in their operations. In particular, the purpose of the Code of Ethics is to ensure that the healthcare professionals and consumers receive correct information on the medicines and their use and that the co-operation between the pharmaceutical industry and its co-operation partners is transparent, respecting the autonomy of both parties.

Distributing information on medicines is the responsibility and social obligation of any pharmaceutical company. Without it, the information about new medications would spread slowly which would be a disadvantage, especially for patients awaiting treatment. The pharmaceutical companies play a central role in the production and distribution of information on medicines.

The principles behind the Code for the Marketing of Medicinal Products are based on legislation relating to medicinal products, marketing, consumer protection and competition, 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 the 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 and of the Council concerning unfair business-to-consumer commercial practices in the internal market; 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.

The Code for the Good Medical Sales Representation Practices is a recommendation jointly issued by Pharma Industry Finland and Association of Finnish Local and Regional Authorities. In preparing the above document, the recommendation for quality criteria for sales promotion of medicines issued by National Agency for Medicines in 2007 was also taken into consideration.

The instructions regarding the co-operation between the pharmaceutical industry and patient organisations have been prepared in line with the corresponding EFPIA Code of practice from 2007, in particular.

II CODE FOR THE MARKETING OF MEDICINAL PRODUCTS

SCOPE OF APPLICATION

1 § *Relationship to other regulations.* In the marketing of medicinal products, the companies must comply not only with legislation and guidance given by the Authorities but also with this Code. In their international marketing operations, the pharmaceutical companies must meet, at a minimum, the requirements imposed by the EFPIA and IFPMA Codes.

The present Code must also be followed in marketing targeted to Finns abroad or in international conferences. In these cases, the marketing operations must also be in line with the rules and regulations issued by the local Authorities.

The Supervisory Committee for the Marketing of Medicinal Products and the Inspection Boards only apply the present Code.

2 § *Definitions.* The term 'pharmaceutical company' refers to an enterprise engaged in the marketing or importation of medicines, to a holder of a marketing authorisation or to other business enterprise involved in marketing of medicinal products.

'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 free samples of medicinal products.

'Healthcare professionals' refers to persons who in their work prescribe, handle, distribute or in practice administer medicines to patients or who otherwise need medicine-related information in their work.

'Consumers' refers to all persons other than the healthcare professionals.

3 § *Scope of application.* The Code applies to all forms of marketing utilised by the pharmaceutical companies in their marketing operations, from person-to-person marketing to the operations taking place through the media. As appropriate, the Code also applies to the marketing of veterinary medicines.

The following does not fall within the scope of application of the Code

- a) products other than those meeting the definition of medicines set forth in the Medicines Act (395/1987);
- b) the summary of product characteristics, the package leaflets and labelling;

- c) the replies to specific questions about the medicine and the non-commercial material eventually related to the reply;
- d) informative notices regarding, for example, changes in packaging or warnings about adverse effects;
- e) product and price lists which do not contain any claims related to the medicinal product;
- f) general statements related to health and diseases if the direct objective of such statements is not the promotion of the sales of a medicine;
- g) scientific material published by the pharmaceutical 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 pharmaceutical companies; and
- j) distribution of free starter packs to a healthcare unit by the personnel of a pharmaceutical company.

GENERAL PRINCIPLES

4 S *Responsibility for compliance with the Code.* The pharmaceutical company is always responsible for the compliance of its marketing with this Code. The pharmaceutical company is also responsible for the marketing if it has assigned its marketing operations to a third party.

5 S *Precondition related to the marketing authorisation.* It is not permissible to market medicines other than those with valid marketing authorisations.

6 S *Nature of marketing.* Pharmaceutical marketing and the information on the medicine given in marketing contexts must be matter-of-fact, presenting the various effects of the medicine in a comprehensive manner, thus conducive to a 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 hidden, and the marketing must be designed so that the recipient easily recognises it as pharmaceutical marketing.

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

Minor deviations from the summary of product characteristics are acceptable in case of serious diseases, if there is clear proof that the treatment according to the latest knowledge is superior to earlier treatments. Such marketing must, however, highlight the valid summary of product characteristics.

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, origin, 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 maintain 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 on the medicine given in marketing contexts must be reliable, and it must not contain such verbal or visual presentations or other effects as 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.

7 S *Reminder advertisements.* If the only purpose of a medicine advertisement is to be a reminder of the name of the medicine, the advertisement may contain only the name or trade name of the medicine, the name of its active substance and the trademark of the medicine, as well as the name of the holder of the marketing authorisation, the marketer, importer or manufacturer and its company logo. The name of the medicine refers to its trade name, accompanied by the strength and pharmaceutical form.

8 S *Good practices of the marketing of medicinal products.* The marketing of medicinal products must comply with good practices in a way that inspires trust and respect. Insulting or tasteless expression are not allowed, and the marketing must not contain such verbal or visual presentations as may denigrate or offend any professional group, patient group, product or pharmaceutical company or cast a suspicion on them. 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.

The marketing of medicinal products must promote the good public image of the pharmaceutical industry. Such marketing must not jeopardise the public's trust in the impartiality of prescribing or dispensing of medicines.

9 § Comparisons. The comparisons between different medicines, active substances, 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 substances 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 are particularly underlined as far as comparisons are concerned.

In the marketing of non-prescription medicines to consumers, special attention must be paid to the limitation under Article 13, Paragraph 1 b) of the present Code.

10 § 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-interventional studies under Article 37 hereunder.

The scientific service unit must employ at least one physician or pharmacist with a Master's or Bachelor's Degree, with adequate conversance and experience, responsible for the approval of the company's marketing measures before their publication, including events, advertisement gifts and market studies. This person must ensure that the final form of the marketing measure complies with the present Code and the legislation on pharmaceuticals marketing. Moreover, he or she must control the implementation of the non-intervention studies under Article 37, ensuring that the study plan complies with the present Code and the applicable legislation.

Any company staff member involved in the marketing of medicinal products or non-intervention studies must be fully aware of the rules contained in the present Code.

INSTRUCTIONS FOR GOOD CONSUMER MARKETING PRACTICE

11 § 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.

According to this Code, it is not prohibited to target information on prescription-only medicines at consumers if such information only contains information that is equal to the details included in the summary of product characteristics or the package leaflet.

According to this Code, it is neither prohibited to target impartial and matter-of-fact information at consumers on the characteristics of diseases or issues related to their prevention, diagnosis and treatment. Such health information can also refer to prescription-only medicines if the information is of impartial and matter-of-fact nature, covering all alternative medicines on the market. In such cases, sufficient information on non-medicinal forms of treatment must also be given.

In questions related to personal health, the consumers must be advised to turn to their 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.

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

- a) name of the medicine and the active substance if the medicine in question only contains one active substance;
- 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 safe use of the medicine;
- d) explicit advice to read the package leaflet or the user instructions contained in the package;
- e) name of the marketing authorisation holder, 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.

As an exception to the above, reminder advertisements referred to under Article 7 above are permitted.

13 § 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;
- d) is targeted at children;
- e) suggests that the medicinal product is a nutritive product, cosmetic product 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; or
- j) contains a reference to the medicine having a marketing authorisation.

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

- emphasise the presence or lack of such ingredients in the product as have no material pharmacological or health-promotional significance;
- exaggerate or over-dramatise symptoms or their alleviation;
- give a misleading or one-sided picture of the efficacy of the product; or
- strongly divert the consumer's attention from the subject matter of the advertisement.

14 § Use of study results and the use of sources. The study results and their 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. Reference to the source material must be made so that the source can be identified without difficulty.

15 § 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.

16 § 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.

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

Sponsorship comprises any operations the purpose of which is to support one or several persons, company or event, or part thereof, financially or otherwise, in such person's or party's scientific, artistic, sport-related or other pursuit and which entail rights conferred to the sponsor to promote its own business operations by using the sponsored person or party.

When sponsoring TV or radio broadcasts, the sponsorship element must be clearly and understandably separate 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 instructions contained in the present Code.

18 § Co-operation with patient organisations. Pharmaceutical companies can collaborate with patient organisations. Such co-operation must be transparent and in line with the stipulations of this Code, and in international co-operation, also with the stipulations of the applicable EFPIA Code. Moreover, the co-operation must comply with the Code for the co-operation between the pharmaceutical industry and patient organisations issued by Pharma Industry Finland.

19 § Forbidden measures in consumer marketing. Pharmaceutical marketing to consumers must not involve competitions with prizes.

If the consumer buying a non-prescription medicine will receive another commodity or other benefit (the so-called giveaway) at the same price, such an offer must not entice the consumer to purchase or use the medicine unnecessarily, and it must not endanger the appropriate dissemination of the information on the correct and safe use of medicines to consumers.

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

INSTRUCTIONS FOR GOOD PRACTICE IN MARKETING TARGETED AT HEALTHCARE PROFESSIONALS

20 § *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.

21 § *Targeting of pharmaceutical marketing measures.* Non-prescription medicines can be marketed to all healthcare professionals. The marketing of prescription-only medicines must be targeted at such persons authorised to prescribe or supply medicines as can reasonably be expected to need the information on the medicine in question. As regards the prescription-only medicines, the other groups of healthcare professionals can only be subject to guidance and training related to the correct and safe use of the medicine.

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

22 § *Contents of information on a medicine.* All information on a medicine must contain, at least, the information which is consistent with the most recent adopted summary of product characteristics of the product and which is essential for the physician to be able to prescribe the medicine. The information on a medicine will contain the legal conditions of supply as well as health insurance reimbursement criteria, average medication costs as well as the retail prices of different package sizes, if possible.

As an exception to the above, reminder advertisements referred to under Article 7 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 clearly shows 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 clarifying notice specifying 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.

23 § *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.

24 § *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.

25 § *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, it is permissible to include in the material for the marketing of medicinal products articles which have been accepted for publication in a scientific journal, as well as the results of trials or studies submitted to the regulatory Authorities in association with marketing authorisation applications.

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

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

The unpublished study results must meet the same quality criteria applied to published results. The use of unpublished study results is subject to the

consent of the responsible investigator. If the pharmaceutical marketing refers to unpublished study results, additional information on the contents must be given upon request.

The reference to study results must be associated with explicit information on the trial arrangements (e.g., *in vivo*, *in vitro*, animal testing).

26 § 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 25 of the Code for detailed instructions.

27 § Information liability. If the clinical use of the medicine reveals new important aspects, information thereof must be given in an appropriate manner.

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

28 § Medical sales representatives. In order to ensure the distribution of correct information, the pharmaceutical company must ensure that a person giving verbal information in the context of medicinal product marketing meets, or he/she will be trained, no later than within one year from the start of medical sales representative work, to meet at least the level of a registered medical sales representative (RLE) or registered medical sales representative of self-care medicines (ILE). Verbal information must meet the criteria imposed in the Code on any information and it must be based on written documents.

Moreover, the specific Code for the Good Medical Sales Representation Practices must be followed in medical sales representation events taking place in the public healthcare units. The guidance in question must also be followed, as applicable, in the sales representation events taking place in pharmacies and in

the framework of private healthcare, targeted at persons entitled to prescribe or supply medicines.

During their visits, the medical sales representatives must provide their clients with the summary of product characteristics of each medicine presented as well as the respective price and reimbursement data, or make the information available to them through other means.

All the significant information given to the medical sales representatives in relation to the clinical use of the medicine they are presenting, and especially to the possible adverse effects of the same, must be forwarded by them to the scientific service unit referred to under Article 10 above.

At the request of the Secretary of the Inspection Board or the Supervisory Commission, the company must provide these bodies with the presentation material used by the medical sales representative.

29 § Events organised or sponsored by the pharmaceutical industry. The emphasis of the events must be related to pharmaceutical information or research or other medical education so that most of the time spent by the participants involves a scientific programme or training. The participants must always be provided with a written programme of the event.

When the company organises or sponsors an event, this must always be made clear.

Pharmaceutical companies can participate in the expenses of further or complementary training only if the company is provided with sufficient conditions to actively distribute information.

Such events must be organised in a place that is appropriate in view of the demands of scientific or training programme implementation. The events must not be organised in venues that are renowned for their entertainment facilities or are extravagant. 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 target group of the events must be constituted by healthcare professionals, and the expenses incurred for the events must be materially related to the scientific programme or training.

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

30 § Hospitality. In events or sessions organised or sponsored by the pharmaceutical industry, the usual local norms of hospitality will be followed. The hospitality can extend only to the registration costs related to a scientific or training event, as well as to the travelling, accommodation and meal expenses. Hospitality must be reasonable, matched to the circumstances and secondary in view of the purpose of the event, and it must not be extended to parties other than the 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 daytime scientific or training programmes of which the pharmaceutical companies have sponsored, if

- a) there is more than one company sponsoring the scientific or training programme;
- b) the sponsorship allocated to the organisation of the scientific or training programme is justified in extent;
- c) the hospitality related to the evening programme is reasonable and suitable in view of the situation, and the eventual entertainment element is secondary;
- d) the eventual participation fee charged for the evening programme is the same for each participant;
- e) no single company is the designated sponsor of the evening programme; and
- f) no medicines are marketed during the evening programme.

The healthcare professionals must not be offered or paid a compensation merely for their use of time to participate in an event arranged or sponsored by a 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 beyond the expenses a typical guest of the event would be prepared to cover themselves, should they pay for their own expenses.

31 § Incentives, advertising gifts and other support measures. The distribution and offer of advertising gifts related to the marketing of medicinal products must be reasonable. The advertising gifts must have minor economic significance for the recipient, and they must have a bearing on their professional operation.

Healthcare professionals must not be offered or otherwise provided with direct or disguised economic incentives or inducements.

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

32 § Market research. Market research can be used to obtain information, e.g., about medicinal behaviour, use of medicines and treatment practices, with the objective of promoting the correct use of medicines and patient safety. In organising market research, special attention must be paid to the protection of the privacy of the patients and those who are the objects of the research. The questions must respect the objectiveness principle. Market research must not have an impact on the treatment of individual patients.

Market research must be of limited scope, such as one-off telephone interviews or questionnaires sent by mail, email or the Internet, and the opinion of the healthcare professionals must not be asked repeatedly, considering the frequency of the contacts in general and the contacts related to a specific research project in particular.

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

33 § Competitions. The competitions organised for marketing purposes must be associated with the company or the product. The prizes must be of reasonable economic value and associated with the professional activities of the participants.

34 § Free samples of medicines. Free samples of medicines can be given only to persons who are authorised to prescribe or supply them, who factually prescribe or supply the medicinal product in question, and therefore benefit from the opportunity to familiarise themselves with the product in question. A free sample of medicine refers to the smallest marketed package size of the medicinal product, given for free to the recipients to allow them to familiarise themselves with the product. Each recipient can be given only one free sample of each medicinal product, strength and pharmaceutical form in one calendar year.

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 supply limitation, such 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 in 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.

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. On 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 to institutes, organisations or associations, the members of which are constituted by healthcare professionals or which provide healthcare or are engaged in research and which do not otherwise fall within the scope of application of the present Code, are permissible only if their purpose is to support healthcare or research and the donor or the party giving the grant documents the respective information, keeping records of them. 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 giving grants to individual healthcare professionals is not permitted, with the exception of grants for investigator-initiated clinical trials with an appropriate study protocol, which have been approved by the regulatory Authorities and ethics committee and which otherwise comply with the requirements set in the legislation for clinical trials.

The pharmaceutical companies are encouraged to publish the information on the donations, grants and benefits in kind in line with the present Article.

36 § *Use of consultants.* The use of healthcare professionals as a group or as individual consultants or advisers is admissible. For example, they can act as speakers or chairpersons in meetings or training events, participate in medical or scientific studies or clinical trials or participate in the meetings of advisory committees or participants of market research in cases where compensation is paid for their participation or their travelling costs are reimbursed.

The arrangements related to such consultant or other services must meet the following criteria:

- a) Before the services start, a written contract is made with the person in question or the company owned by the person, specifying

the nature of the services offered and the criteria for the fee payable for them in line with Paragraph g) hereunder;

- b) The service need must be identified clearly before the request for the services and the signing of the eventual contracts made with the consultants;
- c) The selection criteria of the consultants are directly related to the identified service needs, and the persons responsible for the selection of the consultants have sufficient expertise to evaluate whether the healthcare professionals in question meet such criteria;
- d) The number of the healthcare professionals retained for the job must not exceed the reasonable number required to meet the service need;
- e) The pharmaceutical company constituting a party to the contract keeps records of the services provided by the consultants;
- f) The use of healthcare professionals as service providers does not constitute an incentive to recommend, prescribe, purchase, supply, 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 consultant arrangements must not be used as a pretext for the compensations paid to healthcare professionals.

In their written consultant contracts, the pharmaceutical companies must include a term whereby the consultant is liable to disclose his or her consultation relationship to the company whenever he or she writes or speaks in public about the issue constituting the object of the contract 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 his/her employment relationship with the company whenever he/she writes or speaks in public about the issue constituting the object of this employment relationship or otherwise related to the company. The stipulations under this Paragraph also apply to written or oral presentations other than the marketing or sales promotion of medicines.

This stipulation does not apply to the market research referred to under Article 32.

If a healthcare professional participates as a consultant in an event, the stipulations under Article 29 and 30 regarding the events arranged and sponsored by the pharmaceutical industry and the respective hospitality also apply.

37 § Non-interventional studies on medicines with a marketing authorisation. Non-interventional 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 not determined in advance in the study protocol but is based on the normal treatment practice. The decision on the prescription of a medicine is independent of the inclusion of the patient in the study. No additional diagnostic or other monitoring procedures are applied to the patients. Epidemiological methods are used for the analysis of the information collected.

Prospective non-interventional studies, whereby individual healthcare professionals collect patient data, are permitted under the following conditions:

- a) The study is made for a scientific purpose;
- b) The study is accompanied with a written study protocol and with written contracts between the healthcare professionals or the units at which the study will take place and the company financing the study. The contracts 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 fair market price of such services;
- d) Whenever possible, the study protocol is approved by an ethics committee;
- e) The Personal Data Act is followed in connection with the study;
- f) The study does not constitute an incentive for the recommendation, prescription, purchase, supply, selling or administration of a particular medicinal product;
- g) The company's scientific service unit has approved the study protocol, monitoring the progress of the study;
- h) 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 for the Marketing of Medicinal Products. 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

sent immediately to the competent Authorities;

- i) 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.

III CODE FOR THE GOOD MEDICAL SALES REPRESENTATION PRACTICES

38 § Medical sales representations. 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 physicians. Their objective is to disseminate information on the medicinal product presented, in order to promote the sales of the product in question. At its best, medical sales representation provides the actively practicing physicians and pharmacists with updated state-of-the-art 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.

39 § Purpose of the Code. The purpose of the present Code is to provide instructions for the healthcare units using medicines and the pharmaceutical companies marketing them, regarding the medical representation taking place during the physicians' working hours. However, the ultimate decision on the implementation of medical sales representation events is taken by the management of the healthcare unit in question.

40 § 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.

41 § Medical sales representation related to prescription-only medicines. Medical sales representation events to promote the sales of prescription-only medicines can be targeted only at persons entitled to

prescribe or dispense such medicines. However, the principles of this Code must also be followed, as applicable, in situations in which the representatives of pharmaceutical companies instruct and train nurses in the correct and safe use of the medicine.

42 § *Good medical sales representation practices.* The pharmaceutical companies and healthcare units should respect the following principles of good medical sales representation practices in the respective events:

- a) 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 medical sales representative of self-care medicines (ILE) diploma, or otherwise possess the knowledge required for the proper performance of the work.
- b) The medical sales representations must be based on advance agreements on the visit timetable.
- c) The healthcare unit compiles clear instructions regarding the procedure for the pharmaceutical companies to book medical sales representation visits, also indicating respective contact persons. The instructions are based on solutions that are purposeful from the perspective of the unit's operation. The instructions contain information as to the person and the procedure (by phone, by email) and times of booking the medical sales representation visits. 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.
- d) 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.

- e) Reasonable time must be reserved for the medical sales representations, and the parties should, as far as practicable, respect the agreed starting and ending hours. Eventual cancellations of the visits must be made in good time.
- f) Medical sales representation 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 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.
- g) The information about the medicine given at the medical sales representation event must correspond to the latest adopted summary of product characteristics 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.

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 medicinal product must contain the legal dispensing conditions, health insurance reimbursement criteria, average medication costs as well as the retail prices of different package sizes, if possible.

The adverse effects, interactions and contraindications 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 study results presented by the medical sales representative, not included in the summary of product characteristics, must correspond to or support the information in the summary of product characteristics.

Any quotes, figures and tables from literature or research reports must correspond to the original. Different study 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.

- h) The hospitality offered at the medical sales representation events must be reasonable, suitable for the situation and secondary to the scientific and training contents of the medical sales representation in question. As far as hospitality is concerned, the general instructions related to the accepting of hospitality by officials as well as the Code for the Marketing of Medicinal Products of Pharma Industry Finland must be followed.
- i) Free samples of pharmaceuticals can be given only to persons who are authorised to prescribe or supply them, and as regards prescription-only medicines, only to those who are entitled to write prescriptions. The sample must correspond to the smallest marketed 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 free sample is delivered against a written, signed and dated request, accompanied by the product's summary of product characteristics.
- j) 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 healthcare unit with the necessary starter packs.
- k) The member companies of Pharma Industry Finland are committed to following the Code for the Marketing of Medicinal Products, a part of which the current Code constitutes. 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.

43 § *Presentation events during the physicians' free time.* Physicians are free to decide whether or not they intend to participate in medical sales representation events at their free time. When organising such events, the stipulations of the obligations of civil servants and employees of public corporations must be taken into consideration. Hospitality or other benefits that are offered must not jeopardise the public trust in the Authorities, civil servants or employees of public corporations.

44 § *Responsibility for compliance with the Code.* In addition to the activities of its own staff, the pharmaceutical company is also responsible for the activities of assisting parties, such as the subcontractors providing medical sales representation services.

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

45 § *Patient organisations.* The term 'patient organisations' refers to organisations of public utility, including their local and regional associations and central organisations, constituted around a certain illness, disease or injury or a group thereof, with the majority of the members being patients or their close ones taking care of them. The patient organisations represent or promote the interests of the patients or their close ones.

46 § *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.

47 § *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.

48 § *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.

49 § *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.

50 § *List of the sponsored organisations.* The pharmaceutical company must publish an annual list of the sponsored patient organisations. The list must be accompanied by a brief description of the nature of

the sponsorship. The information published must be readily accessible to those looking for such data.

51 § Transparency. The pharmaceutical company must ensure that its sponsorship to the patient organisation is public by nature, and that such support is clearly disclosed, as applicable, on the occasion of the sponsored activities.

52 § Principle of multiple sponsorship. A pharmaceutical company cannot be the only founding member of a patient organisation or require that it should act as the sole funder of a patient organisation or a significant form of its activities.

53 § Events. An event sponsored or organised by a pharmaceutical company must be held in a place that is appropriate from the point of view of the materialisation of the main purpose of the event. The events must not be organised in venues that are renowned for their entertainment facilities or are extravagant. The event can be organised abroad if the majority of the participants come from countries other than Finland or if the purpose or theme of the event calls for resources or expertise justifying the organisation abroad.

54 § Hospitality. The hospitality offered at events sponsored or organised by a pharmaceutical company must be of a reasonable level, secondary to the main purpose of the event. The hospitality can extend only to the registration costs related to the event, as well as to the travelling, accommodation and meal expenses.

55 § Responsibility for compliance with the Code. The pharmaceutical company is responsible for the compliance with the Code when co-operating with the patient organisation. The pharmaceutical company is responsible for the compliance with the Code also when using the assistance of third parties.

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

HEALTH AWARENESS INFORMATION

56 § Objectives and nature of health awareness information. The aim of health awareness information is to encourage the consumers to maintain a good state of health both personally and among

those close to them, to help them identify diseases, their symptoms and risks and to guide them in the search for further information for health promotion 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.

57 § 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 dramatised. Health awareness information must not entice the consumers to unjustified use medicines or to seek unnecessary treatment.

58 § 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.

59 § 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 information must in no way direct the choice between different therapy options.

Health awareness information may also include information about the prescription medicines used

for the treatment of diseases. 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 by 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 devices usable for the medicinal products of one single pharmaceutical company only can also qualify as disguised marketing.

60 § 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 study results, such data must always come from articles in scientific publications. References to sources must be given in an appropriate manner.

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

The information given together with the study results must be impartial 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.

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

62 § 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.

63 § 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.

64 § Competitions. 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 must be taken into account.

65 § Visual image of health awareness information. The visual image (including illustrations or colours) of health awareness information must not be the same as the image used in the marketing of the prescription-only medicine used for the treatment 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.

66 § 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).

67 § Health awareness campaigns. If health awareness information is channelled through several media, or the material is composed of various elements, for

example 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.

68 § *Special stipulations concerning Internet sites.* If the Internet site containing health awareness material includes links, the following principles must be followed:

- 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 home page 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 or package leaflet of one medicine, there must also be links to the summaries of product characteristics or package leaflets of all medicinal products used for the treatment of the disease in question; and
- f) 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.

All Internet sites targeted at Finns, with the address formulated as "www.disease.fi" (such as www.migraine.fi), must always meet the criteria 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.

69 § *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, including any operations of an assisting third party. For example, no articles written by healthcare professionals or their interviews or patient narratives must advertise any particular therapy option.

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

PATIENT INSTRUCTIONS DISTRIBUTED AS SUPPORT MATERIAL WITH THERAPIES PRESCRIBED BY PHYSICIANS

70 § *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. 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 71–73 are respected.

71 § *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.

72 § *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.

73 § *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 the treatment prescribed for them, and are not generally distributable to all patients.

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

THE SUPERVISORY COMMISSION FOR THE MARKETING OF MEDICINAL PRODUCTS AND THE INSPECTION BOARDS

74 § Competence. The Supervisory Commission for the Marketing of Medicinal Products, hereinafter "the Supervisory Commission" as well as two Inspection Boards subject to it, are charged with the task of monitoring and directing the matter-of-factness and compliance with the respective Codes of pharmaceutical marketing, medical sales representation activities, co-operation between the pharmaceutical companies and patient organisations as well as the health awareness information and other information on health and diseases.

At the request of Pharma Industry Finland, the Supervisory Commission can also issue opinions on marketing or on individual marketing measures on the basis of the EFPIA or IFPMA Codes, in force at each given time.

The Supervisory Commission issues the opinions to outside parties.

75 § Inspection Boards. The Supervisory Commission acts as an umbrella for two Inspection Boards: Inspection Board I, involved in pharmaceutical marketing targeted at consumers, the co-operation between pharmaceutical companies and patient organisations as well as health awareness information and the distribution of other information on health and diseases, and Inspection Board II, which focuses on pharmaceutical marketing to healthcare professionals and the operations of medical sales representatives.

Joint rules covering the procedure at the Supervisory Commission and Inspection Boards

76 § General rules on the initiation of cases. The cases examined by the Inspection Boards are initiated through the board's own control initiatives, 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.

If a case has already been initiated and is being examined by the Authorities, the Supervisory Com-

mission or Inspection Boards cannot issue a decision until such proceedings have been finalised. After a final and legally valid decision by the Authorities has been issued, the case can be decided in the manner referred to under Article 74, Paragraph 1, considering the dimensions of the decision by the Authorities as well as the eventual sanctions imposed.

Any disputes between pharmaceutical companies should be resolved primarily between the interested companies. The companies can only agree to end an incorrect action, not to approve of an action contrary to the Code. In situations referred to in Article 107, Paragraphs 4 and 5 of the present Code of Ethics, or in cases of marketing of non-prescription medicines to consumers, the dispute needs not be solved between the companies in question before submitting the case to the Inspection Board.

When a company contacts another pharmaceutical company to solve a dispute, it must specify the points in the marketing or other measure which it requests to be deleted or changed, as well as the rules in the present Code which underpin its request. The contact must be taken in the language used in the marketing or other measure in question. The eventual reply given as a result of the contact must also be compiled in the language used in the marketing or other measure in question.

Should the companies not be able to find a solution in the case within seven working days from the first verifiable contact, the dispute can be submitted to the Inspection Board. The dispute must be submitted to the Inspection Board within 30 days from the first verifiable contact, on pain of the case otherwise lapsing. Before filing the complaint, the other company must be notified, in a verifiable manner, about the case being submitted to the Inspection Board, unless the situation at hand is one referred to in Article 107, Paragraph 4 or 5 of the present Code of Ethics, or if the case relates to the marketing of non-prescription medicines to consumers.

A complaint to the Inspection Board or appeal to the Supervisory Commission must be made in writing, and signed by a person/s who is/are authorised to sign for the business name of the company. The complaint or appeal must be written, except for the attachments, in the language used in the marketing measure in question. The complaint or appeal must be clear and sufficiently specified, containing all relevant information related to the complaint or appeal. If the complaint or appeal is ambiguous or incomplete, the applicant must be asked to complete the complaint or appeal at the preparatory phase, within five days of the date in which the notice of the request was served.

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

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

The Inspection Boards can take up the case on their own initiative under circumstances described in Articles 90 and 91 of the present Code.

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

77 § *Limitation period.* Any violation against the present Code must be submitted to the complaint system described in the Code within one year of the violation.

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

79 § *Minutes and decisions.* Minutes will be kept of the meetings, recording the meeting participants, agenda, decisions and relevant motivations in matters other than those related to the compliance with the present Code of Ethics, disagreeing opinions as well as a list of documents attached to the Minutes.

As regards issues related to the compliance with the present Code of Ethics, a separate decision will be written on each issue, including the complaint made, the marketing measure examined or its written description, replies, opinions obtained, motivations, names of those participating in the decision-making, as well as any disagreeing opinions.

The Minutes and the decisions will be signed by the Chairperson of the Supervisory Commission or Inspection Board (or if the Chairperson is impeded, the Vice Chairperson) and the Secretary. The decisions will be sent to the parties involved by mail.

No appeal can be lodged against the decisions of the Supervisory Commission.

80 § *Disqualification.* As concerns the disqualification of the Chairmen 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. Persons employed by a pharmaceutical company must not participate in the examination of a case if they or their employers could draw special benefits from the decision.

If the Supervisory Commission returns an issue to the examination of the Inspection Board, the Members of the Board that had earlier participated in the discussion of this case in subsequent supervision must refrain from examining it again, if the case can still be solved respecting the quorum criteria.

The Supervisory Commission can examine the request to correct its own decision in the same composition that made the original decision.

81 § *Confidentiality commitment.* The Board of Directors of Pharma Industry Finland must request from the Chairmen, Members and Secretaries of the Supervisory Commission and the Inspection Boards a commitment of confidentiality regarding the documents involved in the examination of a case, and the documents or copies thereof must not be given to anyone other than those participating in the discussion of the case or the parties to the case, without the consent of the party to whom the document refers. Moreover, the Members or Secretaries of the Supervisory Commission and Inspection Board must not disclose – apart from the decision or opinion issued – anything of the matters that have come up during the discussion of the case.

82 § *Complementing the Supervisory Commission or the Inspection Boards.* If a Member resigns from the Supervisory Commission or Inspection Board in the middle of the term, or is otherwise permanently impeded from fulfilling his/her responsibilities, the appointing party, Pharma Industry Finland, will nominate a new Member to act as a substitute until the end of the term.

83 § *Financial administration.* The Secretary of the Supervisory Commission is in charge of its finances and administration. The Secretary has the sole right to make all decisions related to the finances of the Commission.

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. Pharma Industry Finland will cover the eventual deficit in the Commission's accounts, and is entitled to receive the surplus, if any.

The Supervisory Commission constitutes a unit which is financially independent of Pharma Industry Finland. Constituting a part of Pharma Industry Finland's overall budget, the Supervisory Commission will present its own budget for the following calendar year for Pharma Industry Finland's approval. The operating result of the Supervisory Commission will be recorded and specified under Pharma Industry Finland's Income Statement.

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 clarifications may also be imposed on the companies involved.

The Supervisory Commission will issue an annual report on its operation. The annual report will be sent to the major stakeholders of the Supervisory Commission for their information.

Supervisory Commission

84 § *Composition of the Supervisory Commission.* The Supervisory Commission is constituted by its Chairperson, five Members and Secretary.

The Board of Pharma Industry Finland appoints the Supervisory Commission, nominating its Chairperson, Vice Chairperson, four ordinary Members and their personal substitutes. Moreover, the Board of Pharma Industry Finland also appoints five persons employed by pharmaceutical companies, among whom one person, with no impediments, will be separately chosen to join the examination of the case at hand at any given time.

The substitute of the Member employed by a pharmaceutical company is the Director General of Pharma Industry Finland.

Pharma Industry Finland also appoints the Secretary of the Commission, and the substitute of the Secretary.

The term of the Chairperson and Members of the Commission is three calendar years so that every year two Members, with substitutes, will resign in turn. The Chairperson, Vice Chairperson, Member or substitute can be re-elected for the maximum of three subsequent terms.

85 § *Secretary of the Supervisory Commission.* The Secretary of the Supervisory Commission acts as the presenting official, keeps the Minutes of the Commission meetings and administers the Commission's finances. The Secretary has no vote in decision-making. If the Secretary is disqualified or impeded from examining a case, the respective functions – includ-

ing the financial administration – will be covered by the Secretary's substitute.

86 § *Supervisory Commission meetings and quorum.* The Supervisory Commission will be convened by the Chairperson, or if he is impeded, by the Vice Chairperson.

The Secretary of the Supervisory Commission will propose to the pharmaceutical companies which are parties to the case, a non-biased person employed by a pharmaceutical company to be adopted as a Member to discuss the case. If the pharmaceutical company, party to the case, is opposed to the proposal of the Secretary, a substitute Member will be convened.

The summons to the meeting must be sent to the Members no later than seven days prior to the meeting. A Member recognising his 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 Vice Chairperson and at least two Members or the substitute Members are present.

The decisions of the Supervisory Commission will be taken by simple majority. In case of an even vote, the Chairperson will cast the deciding vote.

87 § *Main responsibilities of the Supervisory Commission.* The Supervisory Commission shall

- a) examine the appeals against the decisions made by the Inspection Boards as well as the issues submitted by the Boards under Article 107, Paragraphs 4 or 5 of the present Code;
- b) if necessary, discuss and issue opinions on questions which are related to pharmaceutical marketing, good medical sales representation practices, co-operation between pharmaceutical companies and patient organisations as well as health awareness information and the distribution of other information on health and diseases, in principle, or which set guidance for the work of the Inspection Boards.

88 § *Hearing.* Before issuing its opinion, the Supervisory Commission shall hear the parties, the rights of which are involved in the case and which have not yet had the opportunity to express their views in this context, and, at the discretion of the Secretary of the Supervisory Commission, the Inspection Board involved. The hearing can take place by letter, fax or email.

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 exceed 14 days, save for exceptional reasons. Failure to give a reply does not constitute an obstacle to the examination of the case by the Supervisory Commission. The reply must be written, except for the attachments, in the language used in the marketing measure in question.

The replies given will be sent to the other parties for their information.

89 § Scope of the examination. The Supervisory Commission will make the decisions on the appeals and on the issues submitted by the Inspection Boards on the basis of the material provided by the parties or the Inspection Board, and is not liable to acquire any further information on the case at hand. At its discretion, the Supervisory Commission can also examine the marketing or other measure beyond the scope defined in the appeal, as far as the case concerns issues taken up by the Inspection Board on its own initiative.

Inspection Boards

90 § Competence of Inspection Board I. Inspection Board I controls 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 can take up a marketing or other measure of a pharmaceutical company under examination on its own initiative or on the basis of a complaint.

91 § Competence of Inspection Board II. Inspection Board II controls the marketing targeted at health-care professionals as well as medical sales representative activities, and, on request, resolves marketing-related disputes. In matters of principle, Inspection Board II can initiate proceedings under the present Code on its own initiative.

92 § Composition of the Inspection Boards. Inspection Board I has five Members or their personal substitutes and the Secretary, as well as a veterinary medicine expert member or a personal substitute who will only participate in the discussion of cases which are related to the marketing of veterinary medicines. Inspection Board II has four Members or their personal substitutes and the Secretary, as well as a veterinary medicine expert member or a personal substitute who will only participate in the discus-

sion of cases which are related to the marketing of veterinary medicines. The Board of Pharma Industry Finland will appoint the Members of the Inspection Boards. Both Inspection Boards elect the Chairperson and Vice Chairperson for the term among their ordinary Members. Pharma Industry Finland will appoint the Secretaries of the Inspection Boards.

The term of the Members of Inspection Board I is three calendar years so that every year two Members, with substitutes, will resign in turn. The term of the Members of Inspection Board II is four calendar years so that every year one Member, with substitute, will resign in turn and every four years the veterinary medicine expert member, with substitute, will resign. The Member or substitute can be re-elected for the maximum of three subsequent terms.

93 § Meetings. The Inspection Board is convened by the Chairperson as is necessary. A written complaint must be taken up without delay.

94 § Hearing. Before issuing a request to abstain from incorrect marketing or other measures or imposing a sanction payment, the Inspection Board must reserve the parties the opportunity to be heard.

The Inspection Board must ask a reply to a written complaint from the parties, the rights of which are involved in the case and which have not yet had the opportunity to express their views in this context. The reply can be requested by letter, fax or email. The reply must be given within a short timeframe determined by the Inspection Board or its Secretary. The deadline must not be shorter than seven days or exceed 14 days, save for exceptional reasons. Failure to give a reply does not constitute an obstacle to the examination of the case by the Inspection Board. The reply must be written, except for the attachments, in the language used in the marketing or other measure in question.

If the reply contains such new facts as have a bearing on the decision, the Inspection Board or its Secretary must request an opinion – to be given within a short period of time either in written or spoken form – from the party which had made the original complaint. The deadline must not exceed seven days, save for exceptional reasons.

95 § Scope of the examination. In resolving a case related to the marketing targeted at consumers, the co-operation between the pharmaceutical industry and patient organisations, or the health awareness information and other information on health and diseases targeted at consumers, Inspection Board I must examine the marketing measure as a whole, and form its opinion of the

compliance of the marketing with the present Code.

In resolving a case related to the marketing targeted at healthcare professionals or medical sales representative activities, Inspection Board II must examine the marketing measure or the medical sales representation activity to the extent complained against. At its discretion, Inspection Board II may also examine a marketing measure more thoroughly than was requested in the complaint. In matters of principle, in which Inspection Board II initiates proceedings under the present Code on its own initiative, it can examine the marketing measure to the extent it finds appropriate.

The Inspection Boards will make the decisions on the complaints on the basis of the material provided by the parties, and they are not liable to acquire any further information on the cases at hand.

96 § Principles and the interpretation of the Code. The Inspection Board can request the Commission's opinion on the principles to follow in the case at hand as well as on the correct interpretation of the present Code of Ethics. After receiving the opinion, the Inspection Board must make the decision in the case without delay.

97 § Decision-making. The Inspection Board constitutes a quorum when the Chairperson or Vice Chairperson plus two Members or substitute Members are present.

The decisions of the Inspection Board will be taken by simple majority. In case of an even vote, the Chairperson will cast the deciding vote.

However, the Chairperson and Secretary of the Inspection Board may decide on the lapsing of the case under Article 76, Paragraph 6 after the expiry of the 30-days deadline.

98 § Temporary request to abstain from incorrect activity. If a material mistake is identified in the marketing or other activities of the pharmaceutical company, the Chairperson and Secretary of the Inspection Board may together issue a temporary request to abstain from the 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 or other incorrect activity 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.

99 § Appeal. Appeal against the decision taken by the Inspection Board or by the Chairperson and Sec-

retary under Article 97 Paragraph 3 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.

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.

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. The Chairperson and the Secretary of the Supervisory Commission can together order, upon the request of the party involved and for particular reasons, that the decision of the Inspection Board must not be enforced until the Supervisory Commission has made a decision in the case (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.

PRELIMINARY INSPECTION

100 § Preliminary inspection. A pharmaceutical company can request from Inspection Board I a preliminary inspection of the marketing or other measure targeted at the 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 will include the summary of product characteristics, package leaflet, and if necessary, also the package itself. 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.

101 § Exceptional order related to preliminary inspection of spots. An exception to the rule of voluntary action under Article 100, Paragraph 1, radio and TV spots of medicines must be submitted to preliminary inspection. The pharmaceutical company is liable to organise the preliminary inspection referred to hereunder.

If the radio or TV spot covered by the obligatory preliminary inspection rule refers to an Internet site, the Internet site in question is not covered by the preliminary inspection obligation.

102 § *Broadcasting of TV and radio spots.* The liability to comply with the preliminary inspection decision lies with the pharmaceutical company which is conducting the marketing operations.

103 § *Procedure in the preliminary inspection of radio and TV spots.* During preliminary inspection of radio and TV spots, the Inspection Board can

- a) approve the planned spot without changes; or
- b) fail the planned spot.

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

If the Inspection Board is presented with a version other than the final spot, the opinion expressed by the Board in relation to a non-finalised spot will not constitute the Board's final opinion on the completed spot. However, the Inspection Board is tied to its opinions related to the compliance of the spot manuscript with the present Code.

The Inspection Board will provide the applicant with a separate motivated decision on the preliminary inspection of the spot, marking the date of the decision. Notice of the decision must be served to the applicant immediately.

A spot that has undergone the preliminary inspection and approval procedure at the Inspection Board can be broadcasted for the maximum of three years from the date of the respective approval.

104 § *Procedure in other preliminary inspections.* As concern marketing and other measures, other than radio or TV spots, the preliminary inspection may focus on the question whether the measure in question complies with the present Code of Ethics and whether it would be prohibited in subsequent supervision. If only a part of a larger marketing or other measure is submitted for preliminary inspection, the preliminary inspection decision does not signify the final approval of the measure as a whole but it only constitutes an opinion related to the aspects that have come up in that context. The preliminary inspection decision must specify the reasons for which the measure does not comply with the present 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 this Code, the Inspection Board can examine the case in terms of normal subsequent supervision.

105 § *Preliminary inspection charge.* The Supervisory Commission will impose a preliminary inspection charge on the applicant, the amount of which will be decided by the Board of Pharma Industry Finland annually when adopting the budget for the Supervisory Commission.

SANCTIONS

106 § *Sanctions.* The Inspection Board or Supervisory Commission can decide to give an admonition to the pharmaceutical company for future reference, or request the interested company to abstain from incorrect marketing or other activities contrary to the present Code ("request to abstain from incorrect activity"), decide on the processing charge, the compensation payable for unfounded complaint and the sanction payment as well as order the company to correct its incorrect activity. Moreover, the Supervisory Commission can impose a contractual penalty.

A sanction can be imposed due to the violation of the present Code, even though the pharmaceutical company in violation thereof would already have given up such measures.

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

107 § *Decisions related to marketing and other actions contrary to the present Code.* If the marketing or other measure is found to be contrary to the present Code, the pharmaceutical company in question can be issued an admonition for future reference, or the said company can be requested to abstain from the incorrect activity (request to abstain from incorrect activity).

The admonition for future reference can be given when the violation of the Code is of minor importance. The admonition for future reference must be associated with a reasonable deadline by which time the advertisement or other material must be revised. In this case, the pharmaceutical company can, within the set timeframe, complete an agreed campaign or finish the printed materials.

The request to abstain from incorrect activity can be given when the violation of the Code is not of minor importance. In this case, the pharmaceutical company must abstain from its incorrect activity immediately once it has been served oral or written notice of the request to abstain. Moreover, the eventual material must be immediately withdrawn from the market.

If the company violates an admonition for future reference, continues operations which do not comply with the Code despite the request to abstain, violates the decision made during the preliminary inspection of radio or television advertisements, circumvents the system referred to in the Code, violates a contract made amicably with another pharmaceutical company in relation to the discontinuation of incorrect activity, or neglects to correct its incorrect activity as ordered by the Inspection Board or the Supervisory Commission, the Inspection Board must submit the case to the Supervisory Commission. If the case has already been initiated at the Supervisory Commission, the latter will directly examine the case which could be submitted to it.

If the company continues its incorrect activity despite the temporary request to abstain from it, the Inspection Board must submit the case to the Supervisory Commission. In this case, the violation against the temporary request to abstain is equal to the violation of the actual request to abstain from incorrect activity.

108 § Processing charge. The Supervisory Commission or Inspection Board can impose on the company that has caused the proceedings a charge per each handling necessary in the case. 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. If the activity focused on is found to violate against the present Code, no charge can be imposed on the company that has made the complaint. However, the processing charge may also be imposed on the complainant company if the complaint has been unfounded or the complainant company has requested that the case be dismissed.

The amount of the processing charge will be decided annually as Pharma Industry Finland adopts the budget for the Supervisory Commission. The purpose of the processing charge is to cover the expenses incurred for the processing, which must be taken into account when the amount is being determined. 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. Preliminary inspections are subject to separate charges determined on the occasion of the adoption of the budget.

109 § Compensation payable for unfounded complaint. Upon the request of the interested party, the

Inspection Board or the Supervisory Commission can, at their discretion, impose a € 5,000 compensation payment on the company behind a completely unfounded complaint, made merely for the purpose of harming the competitor, payable to the company suffering from the complaint to cover the costs incurred for the reply to the unfounded complaint.

110 § Sanction payment. At their discretion, the Inspection Board or the Supervisory Commission can impose a sanction payment ranging from the minimum of € 1,000 to the maximum of € 50,000 on a company that has violated against the present Code of Ethics. The sanction payment must be proportional to the quality and extent of the violation as well as to the eventual benefits gained by the company through such violation. The sanction payment associated with a request of abstaining from incorrect activity must be bigger than the one on an admonition for future reference. If the case is about the marketing of veterinary medicines, this constitutes a factor diminishing the sanction payment.

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

111 § Correction of incorrect measures. The Inspection Board or Supervisory Commission can order that an incorrect marketing or other measure be corrected using the same method as the one used for distributing the incorrect information, if such correction can be deemed possible. The Inspection Board or Supervisory Commission can also issue this order on their own initiative. The order must specify the aspects which must, at least, be contained in the correction as well as the timeframe in which the correction must be made. In considering the correction 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 vis-à-vis the present Code of Ethics shown by such incorrect operation.

112 § Contractual penalty and other sanctions. If the company neglects an admonition, request or temporary request to abstain from incorrect activity and continues to operate in a way that does not comply with the present Code, violates the decision made during the preliminary inspection of radio or television advertisements, circumvents the system referred to in the Code, violates a contract made amicably with another pharmaceutical company in relation to the discontinuation of incorrect activity, or neglects to correct its incorrect measures as ordered by the Inspection Board or by the 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 and maximum of € 200,000 on the company that has violated the Code.

When determining the amount of the contractual penalty, the Supervisory Commission must consider the extent of the incorrect measures, the media used, the eventual negligence vis-à-vis the Code shown by such incorrect activity, as well as any other relevant issues. If the incorrect marketing takes place on television, this constitutes a particular factor increasing the amount of the contractual penalty.

113 § Conciliation. The sanction can be conciliated if, determined under the present Code, it would lead to an unreasonable situation. When assessing the unreasonableness of the sanction, the following aspects must be taken into consideration: the entire contents of the measure under examination; the status of the party; the circumstances during the measure and thereafter; the eventual benefit gained by the party through the measures; and other relevant aspects.

OTHER STIPULATIONS

114 § Publicity. The decisions and opinions of the Supervisory Committee and Inspection Boards on issues concerning subsequent supervision are public information. Preliminary inspection decisions are not public.

Correction of mistakes in decisions

115 § Correction of an error in the substance matter or in the procedure. If the decision of the Inspection Board or Supervisory Commission is based on clearly erroneous or incomplete information or on evidently wrong interpretation of the Code, or if a procedural error has taken place in the decision-making process, the Inspection Board or Supervisory Commission can, at the request of the interested party, cancel the erroneous decision and take up the case for further examination.

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.

116 § 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.

117 § Initiation and processing of correction issues. The Inspection Board or Supervisory Board will process the correction issues on their own initiative or at the request of the interested party. The initiative concerning the correction must be made 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 the opportunity to be heard before the correction of the typo, unless it is unnecessary.

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

If a complaint 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.

Special provisions

119 § Notice. The notice of withdrawal from the agreement on the compliance with the present 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.

120 § Entry into force. This Code of Ethics will enter into force on 1 July 2008. The Code for the Market-

ing of Medicinal Products, in force since 1 February 2007, will be repealed as the companies commit themselves to the new Code, however no later than 31 December 2008.

121 § Transitional provisions. Any violations that take place before 1 July 2008 and the respective sanctions will be examined under the Code for the Marketing of Medicinal Products, in force since 1 February 2007, while the rules and regulations of the new version of the Code will be applied for the procedure.

The Members of the Supervisory Commission and Inspection Boards will continue as bodies under the new Code until the end of their term determined earlier. However, the composition of Inspection Board I must be complemented in line with the present Code as from 1 July 2008.

The stipulations under Articles 84 and 92 of the present Code, 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 Code as from 1 January 2010.

The approved broadcasting period of a spot, adopted by the Inspection Board I before 1 July 2008 in preliminary inspection, will continue unaltered after the entry into force of the new version of the Code.

The stipulations under Article 37 on the non-interventional studies will be applied only to the new studies launched after the entry into force of the present Code.

The pharmaceutical companies must publish the list of sponsored patient organisations, referred to in Article 50, no later than 31 March 2009. The published list must cover the sponsorship in 2008.

122 § Pharmaceutical companies agree to abide by the resolutions taken in accordance with the present Code. It is not possible to seek compensation from the Supervisory Commission or Pharma Industry Finland for the damages resulting from the sanctions imposed under the present Code or from other decision entailed by the Code.

Admonition for future reference	106, 107, 110 and 112	Disguised advertising	11
Agreement on sponsorship	47	Disputes between companies	76
Appeal	99	Donations	35
Business entertaining	3	Enforcement ban	99 and 118
Business gifts	31	Entry into force	120
Celebrity	16 and 62	Events	29–30 and 53
Children	13, 15 and 63	Exploitation of celebrity	16 and 62
Circumventing the system	107 and 112	Free medicine samples	34 and 42
Commercial nature	6	Giveaways	19
Company logo	7 and 17	Good medical sales representation practices	42
Company name	69	Good pharmaceutical marketing practice	8
Comparisons	9	Grants	35
Compensation for unfounded complaint	109	Health awareness information	3, 11 and 56–69
Competitions	19, 33 and 64	Healthcare professionals	2
Complaint	76, 90, 91, 93 and 108	Hearing of experts	78
Conciliation	113	Hospitality	30 and 54
Confidentiality commitment	45	Inappropriate expression	13
Consumer	2	Incentives	31
Contents of information	12, 22 and 59	Information in international events	22
Contractual penalty	106 and 112	Information liability	27
Correction of an erroneous decision	115–118	Information on company operations	3
Correction of incorrect measures	111	Informative notifications	3
Dating of marketing material	24	Inspection Board	
Disease awareness campaign	56–69	– appeal	99

– competence	75 and 90–91	Scope of application	1–3
– completing	82	Sources of information	14, 26 and 60
– composition	92	Special groups	15 and 63
– decision	79	Sponsorship	17
– decision-making	97	Study results	6, 9, 14, 24, 25 and 60
– disqualification	80	Summary of product characteristics	3, 6, 11, 22, 28 and 100
– hearing	94	Supervisory Commission	
– initiation of a case	76	– competence	74
– meetings	93	– completing	82
– Minutes	79	– composition	84
– reply	94	– decisions	79 and 88
– scope of the examination	95	– disqualification	80
Internet sites in health awareness communications	68	– finances	83
Labelling	3	– hearing	88
Legislation	1	– initiation of a case	76
Limitation period	77	– meetings	86
List of recipients of sponsorship	50	– Minutes	79
Market research	32	– quorum	86
Marketing abroad	1, 22, 29 and 30	– reply	88
Marketing	1–3	– responsibilities	87
Medical sales representation	28 and 38–44	– scope of the examination	89
Medical sales representative	28	– Secretary	85
Medicines marketed to consumers	11	Targeting of pharmaceutical marketing measures	11 and 21
Minimum information	12 and 22	Temporary request to abstain from incorrect activity	98, 107 and 112
Misleading information	6, 13, 14 and 60	Tests	61
Nature of information	6, 23 and 56	Transitional provisions	121
Nature of marketing	6	Transparency	51
Non-intervention study	37	TV spot	100–104, 107 and 112
Novelty	6	Unpublished studies	25
Objective of information	20 and 56	Updatedness	6 and 22
Orders by the Authorities	1	Use of consultants	36
Package leaflets	3, 11, 12 and 100	Use of prestige or celebrity	16 and 62
Patient instructions	70–72	Vaccination campaign	11
Patient organisations	18 and 45–55	Veterinary medicines	3, 12 and 110
Pharmaceutical company	2	Visual image	65
Precondition related to marketing authorisation	5		
Preliminary inspection	100–105, 107, 112 and 114		
Presenting therapy options	9		
Prizes	19 and 33		
Processing charge	106 and 108		
Product and price lists	3		
Prohibited information	13		
Prohibition of marketing of prescription-only medicines	11, 46 and 58		
Publicity	114		
Radio spot	101–104, 107 and 112		
Reference to further information	66		
Reminder advertisements	7, 12 and 22		
Request to abstain from incorrect activity	98, 106, 107, 110 and 112		
Responsibility for compliance	4, 44 and 55		
Sanction payment	106 and 110		
Sanctions	70–71 and 75–77		
Scientific material	3		
Scientific service unit	10		

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