Pharma Industry Finland – Code of Ethics
QUESTIONS AND ANSWERS 1/2

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Pharma Industry Finland – Code of Ethics: Questions and Answers

This document is a tool to assist those who apply the Pharma Industry Finland's Code of Ethics (hereinafter: PIF Code of Ethics or PIF Code) in practice. The purpose of the interpretations contained here is to facilitate the work of the companies committed to the PIF Code on the one hand and, on the other hand, to support the supervisory system in its tasks.

I SCOPE OF APPLICATION AND DEFINITIONS

1 § RELATIONSHIP TO OTHER REGULATIONS

Are there any special provisions and regulations related to direct email marketing?

In accordance with the Act on the Protection of Privacy in Electronic Communications, the provisions of the Act (Sections 26, 27 and 29) must be taken into consideration in email marketing or organisation of competitions associated with marketing elements, if the marketing is targeted at natural persons or corporations. The provisions apply to the client's advance consent for the use of their contact data in direct marketing. If electronic-form direct marketing is sent without the recipient's advance consent, such marketing is traditionally deemed improper under the Consumer Protection Act.

In accordance with the Act on the Protection of Privacy in Electronic Communications, the service provider or the seller of the product must give the client the opportunity to prohibit, easily and at no separate charge, the use of their contact information in the direct marketing of the product.

Client communications aimed at the client relationship management, with no marketing involved, do not qualify as direct marketing. Examples of such communications may include the transmission of research outcomes over the email, provided that it does not include any marketing elements (such as the product logo).

The same provisions also apply to the direct marketing implemented with the help of SMS, voice or multimedia messages.

See also Article 4.

4 § SCOPE OF APPLICATION

Who is bound by the Code?

The PIF Code of Ethics is based on the agreement between Pharma Industry Finland PIF and the pharmaceutical companies on the compliance with the PIF Code. The PIF Code is binding to the member companies of Pharma Industry Finland as well as to the non-member companies committed to complying with the PIF Code in their own operations.

The companies committed to the PIF Code must comply with it in their Finland-based operations covered by the scope of application of the PIF Code. Moreover, the companies must follow the PIF Code in any functions abroad if such operations and activities are targeted at Finland-based healthcare professionals.

Faced with activities under the scope of application of the PIF Code, the pharmaceutical company is not only responsible for the action of its own personnel but also for those of the third parties used for these operations (see also what is said under §5).

Does the PIF Code also apply to marketing and other measures in the Internet and the social media?

Yes, it does. The PIF Code applies to all activities of the committed companies, irrespective of the venue of such actions and operations. The PIF Code focuses on the contents of the measure, not to the platform used. Therefore, they apply to all activities implemented in the electronic media, covered by the PIF Code.

What is 'information focusing primarily on the operations of the company'?

Information focusing primarily on the operations of the company includes, among other issues:

- stock exchange releases or other press releases based on the statutory information liability of the pharmaceutical companies;
- press releases on new marketing authorisations;
- Annual Reports of the company;
- information on the company and its products targeted at job candidates, such as advertisements for vacancies;

- communications aimed at increasing the public awareness of the company operations, such as research focuses or on-going research projects.

What is 'a vaccination campaign approved by competent Authorities' in view of the fact that it is permissible to inform the general public about such campaigns?

Vaccine information based on product names will always require the examination by the Authorities. The information material must be sent to Fimea for assessment before it is published. This type of information must be underpinned by public health grounds, and it must not contain any marketing elements.

Are press releases and press conferences always covered by the scope of application of the PIF Code?

Under §3 of the PIF Code, pharmaceutical marketing comprises any information, order acquisition or incentive measures, with the purpose of promoting the prescription, supplying, purchase or use of medicines.

Not all press releases drafted or press conferences organised by pharmaceutical companies automatically qualify as pharmaceutical marketing as referred to in the PIF Code. For example, an information release containing objective and neutral facts about the outcome of a scientific research on a medicine, with no intention of promoting the sales of the product in question, may fall out of the scope of application of the PIF Code.

An appropriate and well-drafted press release focusing on the new research outcome related to a medicinal product is seen as pharmaceutical information if it contains no marketing elements. If the press release or conference includes some marketing elements, the release or conference falls within the context of marketing materials. In a press release drafted or press conference organised by a pharmaceutical company, a healthcare professional, patient or other third party cannot say anything else about the medicinal product except what is permissible on the basis of the PIF Code. The pharmaceutical company is also responsible for the compliance with the PIF Code by any other parties assisting the company in these contexts.

The mere mentioning of the name of the medicinal product in the pharmaceutical company's press release or press conference does not turn the release or the conference into marketing. Therefore, the name of the medicinal product can be mentioned if the event or the press release otherwise complies with the PIF Code. However, the name must be mentioned in a neutral manner and it must not contain any features distinguishing it as marketing.

For example, the following can be identified as marketing elements:

- emphasising the good properties of the product;
- extending the interpretations about the significance of the study outcome;
- creating an image of the superiority of the company's own medicine;
- inducing the audience to purchase the medicine or using other marketing allegations; or
- highlighting unessential aspects related to pharmaceutical research.

A single image or allegation can also constitute a marketing element.

What should be considered in the consumer communications on pharmaceutical research results?

Neutral information to the consumers about the results of scientific research is permissible. As such, it is not deemed to be marketing of the medicines. The highlights of the research can be published in the form presented in the research itself. Aspects related to the effect or safety of the medicine must not be exaggerated on the basis of the research.

If the medicine has a Finnish marketing authorisation for the indication in question, the Finnish trade name of the medicine can be mentioned in the information, together with the active ingredient, provided the trade name of the medicine is also quoted in the original study. The trade name of a product with no marketing authorisation must not be mentioned. If the press release provides further information on the medicines involved in the study, the additional information must be equitable, covering all products studied and not only the company's own medicine.

When reporting on the research outcome, the information must be limited to the results of the study and not deviate from them. Moreover, the headings of the press release must correspond to the factual results of the study. Special attention must be paid to presenting all major outcomes of the study in an equitable manner. The results must not be presented selectively, shedding positive light on the company. It is not permissible to highlight the positive results of the company's own product only, failing to mention the results that are negative for the company's product or that do not show any difference between the products compared in the study.

The results related to the end-point of the study must always be reported. In its press release, the company cannot concentrate on the positive issues related to its own product, secondary to the end-point. No speculative assessment on the significance of the results must be given. This also applies to situations in which, for example, an investigator, the company's medical director or other management comments on the research outcomes.

A press release can be deemed to constitute marketing if it directly encourages the consumers to buy the product. Presenting price or reimbursement status data can also qualify as marketing.

If the information contains an extensive discussion of the disease in question, it can qualify as health awareness information. In such cases, all available therapy options must be presented in an equitable manner.

Consumer marketing of prescription-only medicines is prohibited.

Is it allowable to provide journalists with information on research outcomes, based on a study abstract?

Yes, it is if the medium of the journalist in question is targeted at those entitled to prescribe or dispense the medicine, and

- the information strictly focuses on the data contained in the abstract;
- the press release clearly indicates that the data is based on an abstract;
- the press release clearly indicates that the final research outcomes have not yet been published; and
- the press release does not contain any marketing elements.

Please see the answers to the previous questions.

In which cases does the PIF Code prohibit the marketing of a product without a marketing authorisation to healthcare professionals?

The information on a product without a marketing authorisation constitutes prohibited advance marketing to healthcare professionals if, for example,

- the press release uses the trade name when reporting on the results of a scientific study while the outcome of the research, for example the article, only mentions the name of the active ingredient;
- the press release does not concentrate, in a neutral manner, on the results shown by the study but also discusses evaluations extending beyond the study or exaggerates the significance of the results. The comments of investigators or other experts are permitted if they are in line with the study outcomes.
- the press release also contains company information, other than neutral data (for example, the research focus areas can be mentioned).

Is it permissible for the pharmaceutical company to publish the information on the marketing authorisation, adopted wholesale price or reimbursement status issued by the Authorities for the company's medicine?

Yes, it is, if the communication does not go beyond the public information on the case at hand, provided by the Authorities. The press release can be deemed of marketing nature if it contains details other than the information published by the Authorities.

What qualifies as scientific material published by the pharmaceutical industry, not directly geared to promote the sales of a medicine?

For example, the forwarding of published study results in unaltered form.

Is it permissible to mention the products with special permits in the product or price lists?

Yes it is, because the product catalogues or price lists are not covered by the scope of application of the PIF Code. However, the product and price lists must not contain any statements on the medicinal products.

What does business entertainment mean?

A business entertainment event must not contain any elements that can be deemed as pharmaceutical marketing. The PIF Code does not regulate any business entertainment or other events with no medicine marketing involved.

Only events organised by the executives of the company can qualify as business entertainment. However, the fact that a company executive attends an event does not, as such, turn the event into business entertainment. A further requirement is that the business entertainment event must not involve any elements interpretable as medicine marketing.

The events organised by medical sales representatives, product managers or other members of the daily sales staff for their clients, entitled to prescribe or dispense medicines, are not business entertainment events. The events organised by these persons must always focus mainly on the scientific or training programme.

If a member of the company executives invites 60 physicians to see an ice-hockey match, and the company's sales and/or marketing staff is also present, the event does not qualify as business entertainment. However, the company's 50th anniversary party, with the company's marketing staff present, would qualify as business entertainment, as would an event or meeting organised by the management for the representatives of one or several stakeholders, to discuss, for example, about the general issues related to the pharmaceutical sector.

Congress trips paid by the companies, involving the marketing of the company's medicinal products, will constitute marketing as a whole. The clients cannot be organised any programme related to leisure or other activities during these trips, for example, by offering them tickets to sports or cultural events or taking them to sightseeing tours.

According to the opinion issued by the Finnish Tax Administration (12 December 2003) at the request of Pharma Industry Finland, a business entertainment event is often a closed event, with the advance invitations extended to a limited group of people.

5 § RESPONSIBILITY FOR COMPLIANCE

How can the pharmaceutical company ensure that the service provider used for its marketing is aware of the PIF Code?

In the light of the PIF Code, the pharmaceutical company is also responsible for the service providers used. The competence of the service provider can be guaranteed, for example, through sufficient training and information.

When does the pharmaceutical company respond for the presentations or opinions of a third party (such as celebrities, patients or physicians)

concerning the company's prescription-only medicines?

The pharmaceutical company must show particular care and ensure that the PIF Code is also complied with in the collaboration with the parties not committed to the PIF Code (third parties). This applies to situations of collaboration with parties such as celebrities, expert physicians or patients.

For example, the pharmaceutical company must ensure that measures targeted at consumers do not include the marketing of prescription-only medicines through third parties.

The pharmaceutical company must, for instance, verify the compliance of papers or interview-based articles by experts or patients before they are presented or published. Moreover, the company must oblige the expert to disclose their ties to the company or product in question (see §15 on the disclosure of ties and relationships).

Can the company invite consumers to forward the marketing message to their friends?

'Tell your friend' marketing of medicines is prohibited because the consumer cannot become responsible for another person's state of health.

II GENERAL PRINCIPLES

6 § PRECONDITION RELATED TO MARKETING AUTHORISATIONS

Is it prohibited to organise a training event for physicians on a therapy area where the organising company cannot yet offer a medicinal product with a valid marketing authorisation?

The advance marketing of a product is prohibited. A training event can be organised if it does not involve a specific message of a product with no marketing authorisation yet granted, using its future trade name that is potentially already known. However, the generic name of the medicine can be used in the event, reporting objectively on the published study results.

The event reporting objectively on research outcomes cannot be immediately followed by a medical sales representation event focusing on a medicinal product involved in the study, even if the product in question had a marketing authorisation for another indication. Dissemination of scientific information in close connection with medical sales representation activities can in such cases be deemed as prohibited advance marketing of the medicinal product for an indication where the product does not have a marketing authorisation.

If a physician participating, for example, in an international training event has learned the name of a product that has not yet a Finnish marketing authorisation but will be called with that name in Finland, the company can inform the physician about the issue if directly asked about it. Active marketing of the product is, however, prohibited.

7 § NATURE OF MARKETING

Is it permissible to market a medicine for just one of its many indications?

Yes, it is. In marketing, the use of the product can be limited to only one of its several approved indications. However, it is prohibited to shorten the description of the medicine's indications under the SPC in a manner to give a more extensive picture than is factually the case.

Examples:
According to the SPC of the analgesic X, the indications are temporary conditions of pain and fever, muscular and joint pain, headache, rheumatic pain, menstrual pain and toothache. In the marketing of the medicine, it is possible to highlight only one indication, such as the menstrual pain.

Under the SPC, the indication of emulsion cream Y is the local treatment of muscular or joint pain caused by sprains, strains, sports traumas and overstrain. In this case, the medicine cannot be marketed for muscular and joint pain only because this would suggest that the medicine would be suitable for a use that is more extensive than that in the SPC, such as the treatment of rheumatism.

The information on a medicine must be updated. How old material can still be used?

The marketing material of a pharmaceutical company must be in line with the most recent knowledge, and any information given in marketing contexts, including price data, must always be updated. Obsolete information must not be used. Any individual piece of information given in marketing is evaluated separately to establish whether it is obsolete or not. Likewise, the evaluation depends on the factual possibilities to update the material, considering, for example, the printing and publishing timetables of magazines or event programmes.

The marketing material must always correspond to the SPC of the medicine, valid at each given time. The marketing material must be updated according to any adopted revision of the SPC.

If trials have proven the efficacy of the medicine in an indication not included in the product's adopted SPC, can the medicine be marketed for this new indication?

No, it cannot. All information given on a medicine in marketing contexts must be based on the most recent adopted SPC. The new indication must be included in the medicine's SPC before it is marketed.

The professionals entitled to prescribe or dispense medicines can be informed about the new study results but the study material must not be closely associated with the marketing material, for example, in the same letter, PowerPoint slides or binder with the marketing material. Therefore, it is prohibited to distribute any such material in a medical sales representation event as is not included in the SPC.

A medicine must not be marketed as a novelty after one year of its introduction to the market. What does 'introduction to the market' mean?

Introduction to the market refers to the day in which the medicine, with a marketing authorisation, becomes available at the pharmaceutical wholesalers, in other words, the date of notification of introduction to the market made to Fimea. The granting of the marketing authorisation alone does not mark the beginning of the one-year term.

What does it mean to say that the recipients must be able to familiarise themselves with the information in the advertisement without difficulty? For example, are there provisions concerning the size or positioning of the text?

The information on a medicine must be given so clearly that it can be consulted without difficulty. There is no particular provision about the size of the text but the font size must be large enough so that a person with a normal eye sight can easily read it, and the text must be clearly distinguishable from the background. The text in the TV spots must be visible long enough to allow for the spectators to read it. The positioning of the text is not regulated, on the condition that it is easy to read. In radio and TV spots, the speaker must give the information so slowly and clearly as to allow for the listener to understand it.

If the printed advertisement of a medicine is divided into many pages of a paper or magazine, each part of the advertisement must make reference to the page where the basic information on the medicine can be found.

8 § REMINDER ADVERTISEMENTS

What are the different alternatives permitted in reminder advertising?

Reminder advertisements can include no more than the following elements:

1. the medicine's trade name (such as Pill) or its name (such as Pill 200 mg tablet); and
2. the name of the active ingredient (such as ibuprofen); and
3. the trademark (logo) of the medicine; and
4. the name of the pharmaceutical company (such as Pharmaceutical Company Ltd); and
5. logo of the pharmaceutical company.

One or several of the elements can be left out as desired. Potential reminder advertisements can therefore include the following: "Pill", "Pill 200 mg tablet", "Pill ibuprofen", "Pill, Pharmaceutical Company Ltd", "Pill 200 mg tablet, Pharmaceutical Company Ltd", "Pill ibuprofen, Pharmaceutical Company Ltd", or "Pill 200 mg tablet, ibuprofen, Pharmaceutical Company Ltd". There are dozens of different permissible options. What is essential is that the reminder advertisement must not contain more than the five elements listed above. However, it is not obligatory to use all elements.

Can a reminder advertisement contain the logo or logo paper of a medicinal product?

Reminder advertisements can include the logo of a medicinal product. The logo paper of a medicinal product is considered as reminder advertising.

Can visual materials be used in reminder advertising?

Reminder advertising can include freely chosen colours but the colours must not constitute an image. Moreover, the font used in reminder advertising can be freely chosen, and the font type used in other marketing material or packaging can also be used in reminder marketing. With the exception of the colour and logo, the trademark of the medicinal product and the logo of the company, the reminder advertisement must not contain any other visual material, such as an image of the package.

Can the name of the medicine be used as a domain name?

Domain names are regarded as reminder advertisements of medicines. The names of self-care medicines can be used as domain names. The use of the names of prescription-only medicines as domain names is permitted only if the domain name is not used in the marketing material targeted at consumers. In addition, the Fimea requires that the Internet pages with marketing for prescription-only medicines are protected with passwords to prevent the access of consumers to such pages. For this question, please refer to the more detailed instructions under §26.

11 § SCIENTIFIC SERVICE UNIT

What are the criteria applicable to a scientific service unit?

The scientific service unit must have full insight in the products of the company. It needs to have the sufficient expertise

to be responsible for the information on the products and the correctness of such information, as well as to reply to any queries about the products. The service unit must be able to answer the inquiries received in the language in which the medicine in question has been marketed in Finland. The scientific service unit must also be fully aware of the contents of the PIF Code, being responsible for the compliance of the distributed information with the PIF Code.

The scientific service unit must include at least one physician, a pharmacist with Bachelor's or Master's Degree, or, alternatively, a dentist or a veterinarian in the case of dental or veterinary medicines. However, this person need not have a direct employment relationship with the company but it is sufficient that they are available to the company when necessary. The services of this person can thus also be purchased from an outside service provider.

12 § EVENTS ORGANISED AND SPONSORED BY THE PHARMACEUTICAL INDUSTRY

What does 'main part of the time spent by the participants in the event' mean?

The main part is half of the time reserved for the event. In all events, half of the time available, excluding the travelling days, must be used for the scientific or training programme. No entertainment events must be organised.

Can the company sponsor the physician's participation in a congress, paying for the trip, if the physician asks for an earlier departure date or later return date in order to spend time off at the destination beyond the time required by the congress?

No, it cannot. The departure and return trips must be booked according to the congress participation requirements. The pharmaceutical company must not sponsor the physician's free time at the congress destination by paying the tickets, not even if the physician pays for the extra accommodation for the days spent at the congress destination. Paying for the free-time trips (even if combined with a business trip) can be interpreted as an offer of a bribe.

What does it mean that the companies can pay expenses if they are in the position to engage in active information operations?

It means that the companies must not sponsor or arrange events where they do not have any factual possibility to distribute information on their medicines (unless the programme of the event otherwise envisages the distribution of pharmaceutical information which is important from the company's point of view). Events with no practical opportunity to actively inform the participants include dissertation parties and those of medical societies, pharmacist societies or circles.

How does the PIF Code influence the events organised by the pharmaceutical company in collaboration with a specialist or other medical societies?

The PIF Code applies to both the events organised by the company and to those sponsored by them through exhibition or advertisement payments. Therefore, the pharmaceutical companies can only sponsor events

- with the main focus on pharmaceutical information or research;
- targeted at healthcare professionals only;
- with the associated hospitality limited to reasonable travelling, accommodation and meal expenses; and
- otherwise complying with the PIF Code.

However, Article 13, Paragraph 2 of the PIF Code contains an exception to the hospitality rule related to the participation of representatives of pharmaceutical companies in the evening programmes organised in association with medicine events, training sessions of specialist societies and corresponding scientific or training events, the day-time scientific or training programmes of which the pharmaceutical companies have sponsored. Even though the evening programme includes hospitality that is not in line with Article 13, Paragraph 1 of the PIF Code (such as minor entertainment) or the event is targeted, besides the healthcare professionals, also to their spouses who are not healthcare professionals, the participation in the event is possible if all the criteria under Article 13, Paragraph 2 are met at the same time.

A scientific or training event (such as medicine days of the annual meeting of a specialist society) organised by a medical society with the sponsorship of one or several pharmaceutical companies, and the associated evening event organised or sponsored by one or several pharmaceutical companies, is considered to constitute one single event for the purpose of interpretation of the PIF Code. For all aspects, the event must meet the conditions set for pharmaceutical marketing. Such an evening programme does not constitute business entertainment if the company in charge of the organisation or sponsoring the evening markets its products in other parts of the event programme, such as the exhibition.

The PIF Code only applies to events organised or sponsored by pharmaceutical companies. Events organised by the specialist societies or similar, completely without the sponsorship of the pharmaceutical companies, do not fall within the scope of the PIF Code.

Does the event always have to have a written programme?

It is characteristic of a training event is that there is an advance written programme available. However, a written programme is not required for a brief medical sales representation at the physician's place of work or pharmacy.

Can the event be organised abroad?

The company needs valid scientific or training grounds to organise an event abroad.

Valid scientific or training grounds for organising the event abroad can be at hand

- if the majority of the event attendants are not Finns (for example, an international conference); or
- if there is such scientific or training programme available abroad as requires the event to be organised there and the corresponding event cannot be organised in Finland.

Financial grounds alone do not justify the organisation of the event abroad.

Can a scientific or training event be organised in conjunction with a cruise?

If the participants of a scientific or training event organised on board a cruise ship cannot disembark in a foreign country, even if the ship sailed outside the Finnish territorial waters, the event does not qualify as one organised abroad. In this case, the event can be organised in conjunction with the cruise although the criteria set for an event organised abroad are not met. If the cruise envisages a change to disembark in a foreign country, the above criteria related to valid scientific or training grounds must be met.

In connection with cruises, the companies must always consider

- the provisions under §12 Paragraph 5, first sentence, of the PIF Code according to which the cruise ship must have the appropriate facilities and equipment for the organisation of a scientific or training event;
- as well as the other provisions in the PIF Code related to scientific or training events and the associated hospitality.

When is a venue appropriate in view or the implementation of the scientific or training programme and when would it be renowned for its entertainment offer or luxury?

The venue will be appropriate from the point of view of the implementation of the scientific or training programme when the place has been chosen based on the availability of lecturers, smooth meeting arrangements as well as good accommodation possibilities and traffic connections. The potential for leisure activities cannot be the first priority in choosing the venue. Moreover, the events must not be organised in connection with golf or tennis tournaments, motor races or high-profile sports events or games.

The events organised for the healthcare professionals of a specific geographic area (for example, Central Finland) must be organised in that area. If the event participants come from various parts of Finland, the choice of the event venue must be based on criteria that are material for the implementation of the scientific or training programme.

The question whether the venue is renowned for its entertainment offer or luxury will be evaluated on a case-by-case basis. For example, restaurants with a Michelin star, snow and ice hotels as well as destinations designed for golfing or other purely holiday-related purposes are such venues renowned for their entertainment offer or luxury as are not the proper venues for the meetings.

However, organising the events in congress hotels at skiing resorts or spas is not excluded as a premise. Special attention must be paid to the place being appropriate for the implementation of the scientific or training programme, suitable for organising such events.

Is it permissible for persons other than those entitled to prescribe or dispense medicines to participate in events focusing on prescription-only events?

The marketing of prescription-only medicines can only be targeted at those entitled to prescribe or dispense the medicines, or physicians, dentists, veterinarians, senior or staff pharmacists. Marketing can also be targeted at the nurses, opticians and dental hygienists with the limited prescription rights and only to the extent to the medicines they are entitled to prescribe. The so-called 'avec registration fee' payable by the accompanying person does not entitle that person to attend the event if he or she does not belong to the permitted target group.

In a closed pharmaceutical sales representation event organised by the healthcare unit, it is permissible to distribute information related to prescription-only medicines to the HCPs entitled to prescribe or dispense medicine, also in the presence of other members of the care team. Pharmaceutical information must not be targeted at HCPs other than those entitled to prescribe or dispense the medicine.

Can the invitation to an event be extended to an individual physician?

The invitations to the physicians employed in public healthcare regarding events organised during working hours must be sent through the respective unit, not directly to individual physicians. When addressing the invitations, please consider the joint recommendation by Pharma Industry Finland and the Association of Finnish Local and Regional Authorities regarding the expenses of the further training of physicians, paid by the pharmaceutical industry.

Is it permissible to refer to clinical practice guidelines in the context of the information disseminated in patient organisation events sponsored by the pharmaceutical industry?

The clinical practice guidelines are intended mainly for the use of the physician planning the treatment of individual patients. If reference to clinical practice guidelines is made in the information distributed in the patient organisation events, the reference must be neutral so that the information would not suggest the choice of a particular prescription-only medicine or therapy option.

What kind of events the pharmaceutical company can sponsor the patient organisation representatives to attend?

The pharmaceutical company can sponsor the participation of the representatives in, for example, an international congress arranged by the patient organisation's umbrella organisation or a meeting of international cooperation body. The participation of patient organisation representative in events of mainly social nature cannot be sponsored. A visit to the production plants of a company is a marketing event by nature, and thus they must not be sponsored.

14 § MARKET RESEARCH

In a market survey or opinion poll, is it possible to ask questions about medicinal products with no granted marketing authorisation or specific indication or similar?

No. All aspects of a market survey must be based on an adopted marketing authorisation of the product in question. Therefore, it is not possible to ask in a market survey whether the physician uses a particular medicine outside the adopted indication. Moreover, it is not possible to ask consumers for comment on potential packaging alternatives for a product with no granted marketing authorisation.

When is the compensation for the participation in a survey of minor economic value?

As a premise, compensations not exceeding 35 euro can be deemed of minor economic value. For a justified reason, related, for example, to the scope of the study or the ample time spent by the participant, the compensation can be increased to the maximum of 100 euro.

What does it mean that the opinion of the healthcare professionals should not be repeatedly asked?

The contacts taken by the same pharmaceutical company to a particular physician must not be so frequent as to disturb the physician. This applies both to the contacts regarding one study and the studies on one medicine.

Do the provisions of the PIF Code also apply to situations in which the market research is ordered from a subcontractor?

Yes, they do. According to the PIF Code, the pharmaceutical company is also responsible for the operations of the subcontractor which must comply with the PIF Code.

15 § USE OF EXPERTS

Are personnel services purchased by the pharmaceutical company from an agency providing temp services regarded as specialist services referred to in the PIF Code?

No, they are not. The provisions of the PIF Code regarding the use of specialists are not applicable to the purchase of temp worker services for the pharmaceutical company.

What are the items to be included in the contracts made with the specialist?

The written contract should include, at least, the following:

- the service constituting the object of the contract made with the healthcare professional;
- the period and, if necessary, the place of the service;
- the criteria for paying the compensation and its value in terms of money;
- if necessary, a clause regarding the right of possession or use of the materials or similar results generated during the service.

Should the contract be compiled on any services purchased by the pharmaceutical company, such as one lecture given at an event?

Yes, it should. The contract requirement applies to all situations where the pharmaceutical company pays a specialist a compensation for the services rendered.

In which form should the experts report their linkages?

According to the PIF Code, the expert must always tell about the linkages whenever speaking or writing in public about the issue constituting the object of the contract or another issue related to the company. The need to report on the links and contacts must be evaluated on a case-by-case basis because giving an individual lecture in an event organised by the pharmaceutical company or the participation in a clinical trial create a different type of linkage to the company. For example, the expert who has played an essential role in the medicine development work, must always report on this linkage.

III CODE FOR MARKETING OF MEDICINAL PRODUCTS

1. Code for the good marketing practice – consumers

17 § PHARMACEUTICALS MARKETED TO CONSUMERS

Is it permissible to target a campaign at consumers, only inviting them to turn to a doctor if certain symptoms appear?

Yes, it is, if the campaign does not make any reference to a particular prescription-only medicine, if there are several therapy options to treat the symptoms in question and if the other conditions under Articles 48–61 of the PIF Code are fulfilled. In this case, the campaign is not considered to be pharmaceutical marketing but it is deemed to constitute general information about health and diseases, or the so-called health awareness information. Disguised advertising of medicines is prohibited.

Can health awareness campaigns use the same visual elements used in the marketing of prescription-only medicines targeted at healthcare professionals?

The disease awareness consumer campaigns must not use the same colours and pictures or otherwise similar visual image as is used in the marketing of the prescription-only medicines for the treatment of the disease in question, targeted at healthcare professionals.

Is it permissible to tell the consumers that they will receive the Kela reimbursement on the medicine if they ask the physician to write a prescription?

No, it is not permissible. This would qualify as marketing of prescription-only medicines to consumers because the entitlement to reimbursements calls for a prescription. Consumer marketing of prescription-only medicines is prohibited.

18 § MINIMUM INFORMATION IN AN ADVERTISEMENT FOR A MEDICINE

Under Article 18 of the PIF Code, the advertisement for a medicine must include information on the indication of the medicine. If the product has several indications, can the advertisement include only some of them?

Yes, it can. The marketing can limit the use of the product to only one of its approved indications. However, it is prohibited to shorten the description of the medicine's indications under the SPC in a manner to give a more extensive picture than is factually the case.

Please also refer to the examples under §7.

What is the 'necessary information for the correct and safe use of the medicine as well as any special precautions of use, interactions and adverse effects significant for the medicine safety', referred to in §18 Paragraph 1 c) of the PIF Code?

The advertisement must contain the information needed by the patient or consumer in the purchase situation to deduct whether the product in question is suitable for them. What is, in practice, meant here is whether the product is suited for pregnant or breast-feeding mothers or certain age groups or not. Likewise, if the use of the product entails time-related limitations (for example, the products must not be used for longer than 14 days without the physician's recommendation), such limitations must be mentioned. If the use of the product entails the risk of overdose, the advertisement must contain a special warning highlighting the importance of the dosage instructions. However, TV spots need not list the potential allergens or lactose in the medicine, nor give detailed dosage instructions.

Do web banners have to include the minimum information required of a pharmaceutical advertisement?

Web banners are examined as part of a larger whole. The minimum information required of an advertisement can be presented at a site directly clickable from the web banner.

23 § SPONSORSHIP

Can the product name or logo of a medicine be used in sponsorship activities related to consumer marketing?

In consumer marketing, sponsorship based on the medicine product name or logo is prohibited. Only the company's business name or logo can be used.

24 § PROHIBITED METHODS IN CONSUMER MARKETING

Can a medicine be given as a giveaway with another medicine?

No, it cannot. Under the Medicines Act, the retail price of a medicine must always be that quoted in the pharmaceutical tariff.

What are the stipulations of the consumer protection legislation concerning giveaways, and do they also apply to medicines?

In using giveaways, the respective provisions of the Consumer Protection Act (Chapter 2, Sections 1 and 4) as well as the instructions issued by the consumer protection Authorities

must be taken into consideration. They apply to the use of giveaways in all consumer marketing, thus also in pharmaceutical marketing. Under these provisions and stipulations, the marketing must clearly indicate the contents and value of the offer, as well as the separate prices of the goods or services, unless the price of the giveaway is less than 10 euro. Moreover, the terms and conditions of the offer must be indicated, such as its duration and any quantitative or other limitations. The giveaway must not constitute the main message of the advertisement, and it must not be called free or a gift because the consumer must always buy the main product (here the medicine) to get the giveaway.

A company planning the use of giveaway should read the instructions at the Consumer Agency (Kuluttajavirasto) Internet site (www.kuluttajavirasto.fi > Yritykselle> Markkinointi ja mainonta > kylkiäiset ja lisäedut), with more detailed instructions to follow in order to meet the above requirements.

2. Code for good marketing practice – healthcare professionals

26 § TARGETING OF PHARMACEUTICAL MARKETING MEASURES

Can prescription-only medicines be marketed to medical students with a Bachelor in medicine or to pharmacy students?

Prescription-only medicines can be marketed to medical students after their 4th year of study, i.e., when they have the Bachelor's degree in medicine, at which point they can work as a physician and prescribe medicines.

Medicines can be marketed to pharmacy students once they have completed their studies for their pharmacist degree.

Moreover, the students of medicine and pharmacy can participate in pharmaceutical marketing events where the majority of the other participants are persons authorised to prescribe or supply medicines. Therefore, the student magazines, calendars, address directories, leisure overalls or similar objects must not contain marketing of prescription-only medicines, and events focusing on prescription-only medicines must not be organised for students who have not yet completed the studies specified above.

Corporate image marketing targeted at students is permitted.

Can prescription-only medicine marketing be targeted at all nurses?

No. Prescription-only medicines can be marketed solely to the nurses who are entitled to prescribe them. Moreover, the marketing to these nurses must concern merely the prescription-only medicines they are entitled to prescribe. The marketing of prescription-only medicines to other nurses is prohibited.

For example, the marketing of prescription-only medicines is prohibited in magazines and other materials targeted at all nurses. In such materials, it is prohibited to make advertising allegations, incite the nurses to use prescription-only medicines and to distribute promotional gifts. The company must also ensure that in events open to all nurses, the marketing is targeted only at nurses who are entitled to write prescriptions.

Which kind of information on the correct and safe use of medicines can be given to nurses?

According to the PIF Code, it is permissible to provide the nurses and other healthcare professionals with information on the correct and safe use of the medicine if they need such information to assist the patients in the correct use of the product.

The material promoting the correct and safe use of the medicine includes the summary of product characteristics (SPC) and the package leaflet as well as the patient instructions intended to be handed out to them. Such information can be distributed to all healthcare professionals without being deemed as marketing of prescription-only medicines.

The events promoting the correct and safe use of a medicine can include, for example,

- patient training related to the administration of the medicine (such as the correct use of the dosage device);
- teaching of injection techniques etc.;
- aspects related to the correct and safe use of the medicine or, for instance, to life habits which the nurse should tell the patient before the beginning of the medication}

In these occasions, the prescription-only medicine must not be marketed to the nurses in any way. It is thus also prohibited to use the name of the prescription-only medicine in a 'brand-like' manner. Materials (such as stands, roll-ups) cannot be the same as those used for the marketing of prescription-only medicines to physicians.

In the events targeted at nurses, the Arts. 12 and 13 of the PIF Code on events and hospitality apply.

Does the PIF Code also apply to the marketing targeted at the healthcare professionals employed at the private sector?

Yes, it does. The PIF Code applies to the marketing targeted at any healthcare professionals, irrespective of whether they work in the public or the private sector.

Is it obligatory to protect the Internet marketing of prescription-only medicines through passwords?

The Internet sites targeted directly at consumers must not contain any marketing related to prescription-only medicines. Moreover, Section 91 b of the Medicines Act stipulates that

the electronic marketing of prescription-only medicines must be carried out in protected form to prevent it from reaching third parties. In practice, Fimea requires that the Internet sites containing marketing of prescription-only medicines be protected with a password which could be, for example, the physician's health insurance number.

27 § CONTENTS OF INFORMATION ON A MEDICINE

What is the information essential for the physician to be able to prescribe the medicine as referred to here?

The information consistent with the SPC, essential for the physician to be able to prescribe the medicine, normally covers the following:

- indications (which can be limited but not extended)
- dosage and way of administration
- contra-indications
- warnings and precautions related to the use
- interactions
- information related to pregnancy and breastfeeding
- information on the effect on driving or use of machines (if any)
- adverse effects
- conditions (prescription, eventual restrictions)

The warnings and precautions related to use, interactions and adverse effects can be expressed at a general level. However, if the adverse effects or similar are rare but severe, they must normally also be mentioned. The accuracy and detail of the information is, however, estimated on a case-by-case basis. This is dependent on factors such as the age or complexity of the medicine as well as the target group of the marketing (for example, the general knowledge of the adverse effects of antineoplastics among oncologists).

Does the marketing targeted at physicians through email messages always have to contain the information essential for prescription purposes?

Yes, it does. The PIF Code applies to all marketing measures, including the marketing through electronic media. The marketing material sent by email must contain the information essential for the physician to be able to prescribe the medicine, as per §27 of the PIF Code.

Client communications sent by email, with the objective keeping contacts to maintain client relationships, do not qualify as marketing if they do not contain any marketing elements. Therefore, a particular research article or the reply to a physician's specific question can be sent by email, but the message must not contain any marketing elements. Please refer to §4 regarding the information on study results.

Is it permitted to market products or indications with no Finnish marketing authorisation to the participants of an international event organised in Finland?

According to the Medicines Act, it is only permissible to market products with a valid marketing authorisation. However, in the case of international events with the majority of the participants coming from countries other than Finland, the practice has been flexible as regards the presentation of such medicinal products or indications as have a valid marketing authorisation in countries of the participants coming from outside Finland.

The marketing of the products or indications with no Finnish marketing authorisation must not be targeted to Finnish participants, in particular: for example, there must be no marketing material in the Finnish language on products or indications with no Finnish marketing authorisation.

29 § RESULTS OF CLINICAL TRIALS

If an article has been approved for publication, can it be used in the marketing material?

Yes, it can. However, the company must here demonstrate that the material has been approved for publication. Moreover, the company must provide the article approved for publication to anyone asking for it.

Can the study results submitted to the regulatory authorities as a support material for the marketing authorisation application be used as the source of pharmaceutical marketing materials?

Yes, it can, if the company provides the research results supplied to the Authorities to any party asking for them.

Can new study results be used in the marketing materials, although the information in these results is not yet included in the SPC?

The new information given in marketing contexts must be coherent with the adopted SPC of the medicine. New information deviating from the SPC cannot constitute the main marketing message, and the product cannot be recommended for a use that is contrary to the valid SPC, e.g., for an indication with not valid marketing authorisation.

Can different study results be combined in one figure in the marketing material?

The results of different studies, combined in one table or graph, must not be presented in a misleading way. Combining the data is possible only if the graphs or tables of published meta analyses are being quoted.

Can a company invite physicians to prescribe medical practice guidelines regarding a medicine which is not yet in the market but which has been

the object of a study published in a high-quality medical journal?

No, it cannot, since it is not permissible to market medicines other than those with valid marketing authorisations. A medicine cannot be marketed on the basis of medical practice guidelines until it has a valid marketing authorisation. Once the marketing authorisation has been issued, the medical practice guidelines used in the marketing of the medicine must be in line with the information contained in the adopted SPC.

If the medical practice guidelines have been compiled at the assignment of a pharmaceutical company, the role of the company must be clearly indicated in the guidelines in question.

30 § SOURCES OF INFORMATION IN THE MARKETING OF MEDICINAL PRODUCTS

Can the marketing of a generic medicine refer to a study made on the original innovative medicine without any mention to that effect?

Yes, it can, if the studies have been made on the active ingredient and if the reference to the studies is made by using the name of the active ingredient.

Is it permissible to eliminate elements of an original table or graph included in a study referred to?

Any graph or table must be reproduced accurately as concerns its contents. If, for particular reasons, the elements of the original graph or table are eliminated, this must be clearly and visibly justified in the caption, and the reader must be provided with the opportunity to see the original publication.

Any quotations from the material used as the reference material must be presented in a sufficiently complete form so that the contents of the quotations are not in conflict with the complete material used as the source material, such as the abstract or results of a published study.

Can patient cases be used in the marketing targeted at healthcare professionals?

As a premise, the use of patient cases in the pharmaceutical marketing targeted at healthcare professionals in permitted. However, it is important to remember that the information on the medicine must not be misleading (for example, different from the SPC) or it must not give an incorrect idea of the therapeutic value of the medicinal product. Patient cases in which the effects and characteristics of the medicine are presented in a more positive light than would in practice be the case in a group of similar patients on average, are misleading. Likewise, it would be misleading to present a very exceptional patient case as an example. The use of patient cases must be limited to cases of typical patients, unless there is special reason to do otherwise.

32 § INCENTIVES, GIFTS, PROMOTIONAL GIFTS AND OTHER SUPPORT MEASURES TO HEALTHCARE PROFESSIONALS (HCP)

What constitutes gifts and what is corporate image marketing?

It is forbidden to give gifts to HCPs. In addition to objects given for keeping, other benefits with monetary value as well as free rights of use of various commodities are also gifts. This also corresponds to the interpretation by the tax Authorities.

General **corporate image marketing** is permitted. A gift given to a *HCP* does not turn into permissible corporate image marketing just by printing the pharmaceutical company's logo on the object. Corporate image marketing can continue in other forms, for example, by purchasing a sponsor slot for the company logo in an ice-hockey team jersey (as long as it is not a team made of HCPs) or a patient organisation magazine.

Is it possible to distribute pens (or other promotional gifts) to HCPs?

1. It is always forbidden to give pens (and other promotional gifts) advertising **prescription-only medicines**.

In training events organised by the companies it is, however, acceptable to provide the participants with paper and pen to take notes. However, the logo of a prescription-only medicine must never be used. It is forbidden to distribute promotional gifts related to self-care medicines in events where prescription-only medicines are marketed.

2. In the marketing of self-care medicines, it is possible to give out promotional gifts (such as a pen) with **the logo of the self-care product**. However, the distribution of pens must not offset routines business practices of the clinic pharmacy or corresponding party. It is not permissible to provide them with office supplies. However, a single pen or a notepad given to an individual qualifies as a promotional gift and is therefore permissible. The promotional gifts must always be inexpensive and related to the recipient's professional activities.

- **What is the meaning of an "inexpensive" promotional gift?**
  An indication can be constituted by tax audits where a reasonably-priced promotional gift is deemed to be one with the maximum value of 35 euro (retail price including VAT). Moreover, the gift must be related to the recipient's work. The value of the gift is always assessed from the recipient's perspective (the price the recipient would have to pay when purchasing the corresponding item) and not on the basis of the price paid by the company offering the gift.

- **When is the promotional gift directly relevant to the practice of medicine or pharmacy?**
  Gifts that are directly relevant to the practice of the HCPs could be objects that the recipients factually need in their work, with the primary use relevant to that person's profession, and not to their leisure time. It is prohibited to give promotional gifts that are not relevant to the recipient's professional activities. It is always prohibited to give alcohol as a present.

Giving pens/notepads to HCPs in various occasions:
(please, see the table below)

	WITH COMPANY LOGO	WITH THE LOGO OF A SELF-CARE MEDICINE	WITH THE LOGO OF A PRESCRIPTION-ONLY MEDICINE
Training event (subject: self-care medicines)	OK	OK	NO
Training event (subject: prescription-only medicines)	OK in events hosted by the company	NO	NO
Congress bag	NO	OK in self-care medicine congress	NO
Exhibition stand	NO	OK at self-care medicine stand	NO
Meeting/pharmaceutical sales representation	NO	OK in meeting on self-care medicines	NO

In a pen with the company logo, it is possible to mention a particular therapy area (such as *company x, diabetes*). It is also possible to give a pen with the company logo or self-care medicine logo to *consumers*.

Is it possible to give presents to HCPs on their birthdays, on Christmas or similar?

No, it is not permissible, since giving presents is prohibited.

Is it allowed to organise competitions or a lottery for HCPs?

No. All types of competitions and lotteries are seen as present-giving and are therefore forbidden.

Can the pharmacy discounts, rebates on purchases or similar constitute prohibited incentives under the PIF Code?

According to the Medicines Act, the pharmacies can be given discounts only by changing the official wholesale price. An exception to this are the medicinal products sold in stores other than the pharmacies.

Such changes must be communicated equitably to all pharmacies. This provides all pharmacies with the same opportunity to procure the medicine at a unified wholesale price, constituting the basis of the medicine's retail price and, at the same time, the pharmacy sales margin.

Incentives prohibited by the PIF Code include, for example,

- the allocation of rebates to individual pharmacies;
- tie-in sales of medicines and the so-called freely sold products, cosmetics, nutrition additives, equipment and other non-medical products so that the rebates on non-medical products are tied to the purchase of a certain quantity of the medicine;
- paying overprice for advertising space, for example in the pharmacy information leaflet or outside advertising, for display or advertising space in the pharmacy window or premises (shelf, cashier counter, TV screens, stands, etc.),

for training operations, medical sales representation or the space used for them, or for shelf space;
- other similar measures.

Likewise, the discounts, credits or unreasonable compensation in view of the services rendered, given to companies managed by the pharmacists but legally separated from the pharmacies, can be seen to violate the PIF Code. Such arrangements constitute financial incentives or inducements given to individual pharmacists in breach of Art. 32 Paragraph 2 of the PIF Code.

Since the PIF Code only applies to pharmaceutical marketing, the sales of the non-regulated products, cosmetics etc. by the pharmaceutical company to the pharmacy, without any financial link to the pharmaceutical sales, are not covered by the PIF Code.

33 § INFORMATIVE AND EDUCATIONAL MATERIAL AND ITEMS OF MEDICAL UTILITY

What is informative or educational material?

This category includes the materials produced for patients or HCPs to support the education and training focusing on a disease or its care. The material must not generate personal benefit to the HCP receiving it. Such materials may include, for example, educational brochures on diseases, patient self-assessment and tracking tools as well as leaflets that can be given to patients to promote their adherence to medicine regimens, healthy lifestyle choises or to the availability of patient assistance programmes.

Commercially available professional literature, subscriptions to journals as well as rights to use online databases are regarded to constitute gifts and are therefore prohibited.

A further condition for the distribution of informative and educational material is that it must be inexpensive, materially related to the professional activities of the recipient and directly useful in their patient work.

Informative and educational material could include:
- Lecture slides, summaries and presentation materials
- Published studies (printed/on a memory stick)
- Off-prints of published studies
- Off-prints of Current Care Guidelines
- Patient instructions and guidelines (see as from Art. 62)
- Anatomy chart/poster
- Treatment tracking tools

Can the informative and educational material include a product or company logo?

The informative and educational material must not include marketing elements such as product logos. Company logos can be used. As an exception to this rule, the patient instructions may include one product logo on the front cover page.

What is "inexpensive" informative or educational material?

The price must be normal and reasonable for materials of this kind. The value is always assessed from the recipient's perspective (the price the recipient would have to pay when purchasing the corresponding material) and not on the basis of the price paid by the company offering it. For informative and educational materials, the maximum value is 45 euro.

When is the material relevant to the recipient's professional activities?

Materials relevant to the professional activities of the HCPs could be objects that the recipients factually need in their profession, with the primary use relevant to that person's profession. Giving materials that do not relate to the professional activities means giving a prohibited gift.

What does it mean that the materials must not constitute an incentive for the recommendation, prescription, purchase, supply, sales or administration of a particular medicinal product?

The main purpose of providing the recipient with informative and educational materials must not be marketing, and therefore the material must not contain marketing elements such as product logos. Company logos can be used. The purpose of the informative and educational material is to provide the recipient with professional added value relevant to their profession.

Is it permissible to give a memory stick containing informative and educational materials?

Giving a memory stick (or other corresponding data storage media, such DVDs) is permissible, as long as they are of minor economic value and contain informative and educational materials that are materially connected to the recipient's professional activities and can be directly utilised in patient care. The purpose of giving such storage media must be the transfer of the information in question.

Does this regulation also cover educational materials online?

Yes, they do. The materials distributed or downloadable in the web must meet the same criteria as any other material. The rights to use commercially available online databases or the right to read a journal in the web qualify as gifts and are therefore prohibited. However, it is permissible to give an individual article or study.

Do the limitations of distribution of informative and educational materials also cover materials given to HCP organisations or associations?

Yes, they do. The rules are generally applicable irrespective of whether the materials are given to individuals or organisations.

What are items of medical utility?

Such items support the care of patients. These items include asthma pipes (without the active ingredient) and devices with the purpose of teaching the patient to use a dosage device, such as injection pens. These items must not generate personal benefits to the HCP, nor must they offset routine business practices of the recipient.

Items of medical utility may include:

- Demo dosage devices for a particular product (such as asthma pipes, insulin pens)
- Supplies that are used for training the correct use of the product (such as injection pads)
- Storage devices that are crucial for the transportation or storage of a product
- Supplies that essentially promote the correct and safe use of a particular product (for example, a special support to complement the pharmacotherapy of a joint).

Can items of medical utility carry the product or company logo?

Items of medical utility must not contain marketing elements, such as product logos. An exception to this are the demo dosing devices and aids intended to be used with a particular product, provided that:

- their correct and safe use calls for identifying of the medicinal product
- the use of the product logo is necessary so that the dosing device is not used with a wrong product
- the product logo does not include any slogans and particular attention is paid to the limitations related to reminder marketing.

The use of company logos in items of medical utility is permitted.

Is it allowed to supply items of medical utility that are to be given to the patient or to be used in their education?

It is permissible to give items of medical utility provided that they are directly relevant to the recipient's professional activities or patient care, and that they are inexpensive and do not offset any routine business practices of the recipient. The supplies can be used to instruct or teach the patients. The supplies can only be given in connection to a particular medication to patients who will benefit from it.

What kind of costs are seen as routine business costs?

Such expenses include routine costs, such as rent and administrative costs, office supplies or items needed in patient work (disposable gloves, tissues, stethoscope, blood pressure gauge etc.).

Is there a list of objects that constitute gifts and are therefore prohibited?

No. It is prohibited to give any sort of gifts and supplies to offset routine business practices of the recipient unless they qualify as educational or informative material or meet the criteria imposed on items of medical utility.

Is it necessary to report the distributed informative and educational materials and items of medical utility in line with the disclosure obligation under Articles 124–130 of the PIF Code?

No. These materials and items are not covered by the disclosure obligation.

34 § MEDICAL SAMPLES

What is a medicine sample?

The term 'medicine sample' refers to the smallest package size of the medicinal product, supplied on request and with no charge by the pharmaceutical plant or pharmaceutical wholesaler for the purpose of the recipients familiarising themselves with the pharmaceutical product. The outer package of the medicine sample must have the text "Ilmainen lääkenäyte – ei myytäväksi / Gratis läkemedelsprov – inte till salu" (Free medicine sample – not for sale) or other text of similar contents.

Does each medicine sample have to be accompanied by the SPC?

Yes, it does.

What is the way for the company to ensure that a physician, for example visiting a congress exhibition and asking for a medicine sample, has not already received the sample of that medicine during the year in question?

When taking the physician's signature for receipt of the sample, it is advisable to give a written reminder telling that the free medicine sample can be given only once a year per each medicinal product, strength and pharmaceutical form. However, before handing out the free sample, the pharmaceutical company must always verify whether the physician in question has already received the same medicine sample during the calendar year. The company is responsible for distributing medicine samples in line with the PIF Code.

How long can the medicine samples be distributed?

Samples of the medicine can be distributed during the two years following its introduction to the market or the adoption of its reimbursable status. This applies to both the innovative original medicines and the generics. Only self-care medicines are excluded from this regulation.

The company can decide whether the distribution of the samples starts from the introduction to the market or the reimbursable price decision. However, the total time is maximum 2 years.

A six-month transitional period is applied to the Article on the free samples of medicines (see §122 of the PIF Code). During

the transitional period, the medicine samples can be distributed under the Code of Ethics that entered into force in 2008.

If the samples have already been distributed for two years before the entry into force of Arts. 34 and 122 of the new PIF Code, it is no longer permissible to distribute them.

Samples of the medicinal product have been distributed for two years. Can they be distributed anew if, for instance, a new indication for the product is approved?

No. If there is no other change than the new indication, the repeated distribution of the samples of the product is not allowed. Moreover, a mere new pharmaceutical form or strength does not entitle the company to start distributing the samples again.

The repeated distribution of samples of the medicine for the maximum of two years is only allowed if the medicinal product is granted

- a new indication and new pharmaceutical form
- a new indication and a new strength
- a new indication, new pharmaceutical form and new strength.

35 § DONATIONS AND GRANTS FOR THE SUPPORT OF HEALTHCARE OR RESEARCH

Can the pharmaceutical company donate money to a foundation which distributes personal grants to individual healthcare professionals?

Yes, it can, if the donation is made to an autonomous foundation which decides on the distribution of the grants independent of the pharmaceutical company, choosing the recipients of the grants among a wide number of applicants.

Can the pharmaceutical company make a donation, for example, to support nature conservation or youth sports activities?

Yes, it can. The limitations under Article 32 of the PIF Code only apply to situations in which the recipients of the grant or donation are healthcare professionals or their institutes, organisations or associations.

Can the pharmaceutical company donate money to a hospital for the purpose of paying for a portrait painting to honour an anniversary of a physician?

No, it cannot. Even if the donation were made to an institution and not to an individual healthcare professional, this type of donation cannot be interpreted as support provided to healthcare operations or research as referred to in §32 of the PIF Code.

Can the pharmaceutical company donate money to a clinic in order to sponsor a scientific seminar celebrating the anniversary of the clinic or a physician working there?

Yes, it can. In this case, the donation is made to the institution and not to an individual person and it supports healthcare in line with the criteria expressed in the PIF Code.

In what form should the pharmaceutical company publish the information regarding the grants, donations and other support given to healthcare/medical associations and societies?

The pharmaceutical companies must publish the support given to patient organisations and to healthcare and medical associations and societies. Based on this rule, the support to other organisations such as those in limited liability company form, is excluded from the publication obligation.

It is not possible to draw a detailed list of the type of collaboration with the patient organisation or associations and societies that would qualify as sponsorship. There are innumerable ways to provide support. One way to analyse the situation is to think whether the company would have purchased the same service from the market. Would the price have been the same as the one paid to the patient organisation or the healthcare and medical association? If the reply is negative, this is support that must be published.

The company must list the patient organisations or associations and societies sponsored. The support given to patient organisations must be published, also giving the amount in euro. It is recommended that the sums of the donations, grants and other support provided to healthcare/medicine associations and societies are also disclosed. For the rest, it is sufficient that the list includes a brief description of the support given.

The list must be updated. In practice, this means that it must be updated on a quarterly basis. It is not indispensable for the company to publish the list, for example, on its Internet site but it is sufficient that it gives the data to the party asking for the information without undue delay.

36 § NON-INTERVENTION STUDIES ON MEDICINES WITH A MARKETING AUTHORISATION

What is the difference between an intervention study and a non-intervention study?

Any time the effects or properties of a medicine studied intervene with research subject's integrity, the company is faced with an interventional study. Fimea must be provided with advance information on the study which must also obtain a positive opinion from the ethics committee. Respective provisions are contained in the Medicines Act, the Medical Research Act as well as in the Regulation issued by Fimea regarding clinical trials.

According to the Regulation by the Fimea, non-intervention studies, not requiring notification, fulfil the following criteria:

- What is taking place is the usual treatment of patients, no different from normal clinical practice;
- The integrity of the patient is not intervened with through means resulting from the study.
- No extra diagnostic or other follow-up methods are applied to the research subjects but the information is gathered during the data generated in normal treatment.
- The medicines are prescribed as usual, in line with the established therapy practice.
- The decision to prescribe the medicine is fully independent on the decision to include the patient in the study.
- The study plan does not provide an advance order regarding the patient's particular treatment scheme or medicine choice.
- Epidemiological methods are used for the analysis of the information.

Why is the approval of the ethics committee not an absolute requirement for every study plan?

According to the Medical Research Act, the ethical committees must examine intervention studies only. The examination of non-intervention studies by the ethics committees is voluntary, or can be based on an internal decision by a hospital district or similar. There is no statutory obligation for the ethics committee to issue opinions on non-intervention studies.

What is the reasonable time to analyse the results and supply the summary to the scientific service unit?

Three months would be a reasonable time.

What is the reasonable time to keep the summaries of the studies in the company files?

A reasonable time would be at least one year from the end of the study and the sending of the summary of the results to those participating in the study.

3. Code for good pharmaceutical representation practice

40 § GOOD MEDICAL SALES REPRESENTATIVE CONDUCT

What should be the procedure if the management or senior medical officer of the clinic or unit permits, or directly invites, to continue to use the cafeteria for medical sales representation purposes?

According to the Code, it is up to the clinic or unit to decide how the presentations should be arranged in the future. The units should inform the pharmaceutical companies about the arrangements either directly or through PIF. The representatives of the companies must follow the instructions given by the management or the senior medical officer. Pharma Industry Finland and the Finnish Medical Association recommend to organise a brief information session on the local modes of operation to the pharmaceutical companies involved in these activities.

What should be the procedure if an individual physician insists on meeting in the cafeteria although the unit instructions prohibit it?

These requests should not be accepted. Arranging the presentations in the cafeteria are possible only if it is in line with the instructions given by the unit, its management or senior medical officer.

Would the visit qualify as a spontaneous visit if the physician has asked to phone or knock on the door on a certain day but no agreement has been made on the exact hour?

No, it would not, because an agreement has been made with the physician on a certain day and possibly also on a certain timeframe during which the medical sales representative checks whether the physician is free.

Can the visit be booked, for example, by phoning the physician 5 minutes before the visit from the car or from outside the healthcare station or hospital?

Yes, it can, if the booking of the presentation times by directly phoning the physician in question at that time is permitted under the instructions given by the unit, its management or senior medical officer. If the instructions call for another way to book for the visit, such instructions must be followed. If it is a company that has not signed the commitment to follow the PIF Code, any matter related to this company must be submitted directly to Fimea.

Who in the clinic or unit can give the permission to meet the physicians in the cafeteria?

The management of the clinic or unit, or the senior medical officer issue the instructions regarding the presentations.

Can the medical sales representatives pay the cafeteria for the physician's coffee and pastry in advance so that the physician can go and pick them up after the presentation?

No, they cannot.

What should be the procedure if a medical sales representative of the competitor acts contrary to the Code, for example, by arranging the presentation in the cafeteria contrary to the instructions of the clinic in question?

If this is a permanent mode of operation, it would be advisable for the person observing such behaviour to inform his or her own superior who will decide on the further measures to take. The company can make a complaint to Inspection Board II, if the company acting contrary to the Code is not willing to stop the incorrect procedure or is not stopping it despite the promises to that effect.

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

42 § AGREEMENT ON SUPPORT PROVIDED

Can the pharmaceutical company sponsor events arranged by a patient organisation?

Yes, it can. For example, the pharmaceutical company can pay for the reasonable costs incurred for the event, or assist in the respective practical arrangements. Corporate image marketing is permissible but non-prescription medicines must not be marketed in such events. This must be taken into consideration also if outside lecturers are used, such as physicians or patients. The pharmaceutical company is also responsible for the presentation of the physician or patient complying with the PIF Code.

43 § PATIENT ORGANISATION'S LOGO AND OTHER MATERIALS

Can the pharmaceutical company post on its own homepage a link with logo leading to the patient organisation's site?

This is possible only upon an express agreement with the patient organisation.

44 § MATERIALS PUBLISHED BY THE PATIENT ORGANISATION

Can the pharmaceutical company collaborate with the patient organisation in compiling patient guidebooks?

Yes, it can. In compiling patient guidebooks, attention must be paid to the instructions regarding health awarenessinformation and other information on health and diseases targeted at consumers. The patient guidebooks compiled with the support of the company must not contain consumer marketing of prescription-only medicines. Therefore, the pharmaceutical company cannot sponsor a patient guidebook in which, for example, a patient with a particular condition tells the name of the prescription-only medicine taken. This also applies to other materials supported by the pharmaceutical company in collaboration with the patient organisation.

Is it permissible to distribute only the SPCs or package leaflets of the company's own medicines in an event focusing on a certain disease and targeted at consumers or patients, arranged in collaboration with a patient organisation?

No, it is not permissible. In these events, all therapy options must be presented neutrally, and therefore highlighting only certain therapy options, for example, by distributing their SPCs is not permitted. Moreover, these events must be arranged in line with the instructions related to health awareness information and other information on health and diseases targeted at consumers.

Can the representative of a patient organisation bring marketing material regarding an individual prescription-only medicine to a patient organisation meeting sponsored by the pharmaceutical company?

No, it is not permissible. The events organised in collaboration with the patient organisations are targeted mainly at consumers, and it is prohibited to market prescription-only medicines to them. The pharmaceutical company is always responsible for the compliance of its marketing with the PIF Code, even when sponsoring the events of the patient organisations. The programme and other arrangements of the events must in all respects comply with the principles included in the PIF Code regarding the equitableness and matter-of-factness of the information. Therefore, the pharmaceutical company cannot sponsor an event where, for example, the representatives of the patient organisation exhibit marketing materials related to the use of one individual prescription-only medicine or other materials normally needed by healthcare professionals when guiding the patients towards the correct and safe use of the medicine in question.

Events organised by the patient organisations completely without the sponsorship of the pharmaceutical companies do not fall within the scope of the PIF Code.

45 § LIST OF THE SPONSORED ORGANISATIONS

In what form should the pharmaceutical company publish the support provided to the patient organisation?

See what is said under §35.

Can a pharmaceutical company provide financial support to a patient organisation, without specifying the object of the support?

Yes, it can but the pharmaceutical companies and patient organisations should equally make a written agreement on such forms of collaboration, specifying the related rights and obligations of the parties involved.

When is the other support provided by the pharmaceutical company so significant that a written agreement is in place?

In cases where the annual calculatory value of the support exceeds 2,500 euro.

Moreover, the agreement should clearly state that all parties are fully aware of the fact that the information on the support provided is public.

47 § PRINCIPLE OF MULTIPLE SPONSORSHIP

When is the form of activity of the patient organisation so important that one pharmaceutical company should not seek to act as the sole financer?

In cases where the economic value of the activity in question exceeds 10,000 euro.

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

62 § PATIENT INSTRUCTIONS

Can a nurse also give the patient instructions to the patient?

When the medicinal product in question has been prescribed for the patient, the respective patient instructions can be given either by the physician or a nurse.

Can the patient instructions carry the product logo?

The product logo is a marketing element (reminder marketing) which cannot be used in the patient instructions. However, to ensure patient safety, it is permissible to include one product logo on the front cover of the instructions. The logo must not contain any marketing assertions, slogans or statements. The product logo can also be visible in an eventual picture of the medicinal product package printed in the instructions.

Can patient instructions produced in line with the risk management plan adopted by Fimea be used as such?

No, they cannot. In addition to the Fimea approval, the instructions must meet all requirements contained in the PIF Code.

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

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

What does the expression "verifiable contact" in §77 Paragraph 2 mean?

If necessary, the complainant must be able to show that it has factually contacted the other company to solve the dispute. The proof provided by the complainant could be a registered letter or email message.

§77 Paragraph 1 sets a 30-day deadline for bringing the issue to the Inspection Board. Does this apply to each separate publication of the advertisement?

The deadline refers to each separate marketing measure of a pharmaceutical company, constituting the reason why the other company has contacted the competitor. For example, the advertisements with identical contents published in different papers in different times constitute different marketing measures. The fact that the 30-day deadline of an advertisement published earlier has expired does not prevent the Inspection Board from taking up a new complaint concerning an advertisement published later if the 30-day deadline regarding the first contact between the companies has been respected in the case of the latter advertisement. Incorrect marketing cannot thus continue incessantly without the supervisory bodies intervening, even if the deadline applicable to a separate published advertisement had already expired.

Is the complaint regarding continued incorrect marketing made to the Supervisory Commission or to an Inspection Board?

The complaint against incorrect marketing continuing despite the decision by the Inspection Board must be lodged with the Inspection Board whose decision has been violated. Likewise, the case regarding the breach of an understanding between companies to end an incorrect marketing measure must be submitted to the Inspection Board competent for these matters. If the Inspection Board finds that it is a case of continued incorrect marketing contrary to the decision of the Inspection Board or the agreement between the companies, the Board in question will submit the case to the Supervisory Commission.

A complaint concerning continued incorrect marketing contrary to the decision of the Supervisory Commission must be submitted directly to the Commission.

88 AND 95 § HEARING

What should be the contents of a reply given in conjunction of a hearing?

The company involved must always submit the necessary proofs to support the allegations in its reply.

For example:

- evidence of the allegedly incorrect measure being in line with the PIF Code; or
- if the complaint refers to continued incorrect measures, evidence of the fact that such incorrect measures did no longer continue after the admonition or the request to abstain from incorrect marketing, issued by the Inspection Board, or after the agreement between the companies to abstain from incorrect measures.

The Supervisory Commission or the Inspection Boards subject to it will make the decision 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.

89 § SCOPE OF THE EXAMINATION

What are the matters of principle in which Inspection Board II can initiate proceedings under the PIF Code on its own initiative?

Such matters of principle can include claims contrary to the PIF Code or other marketing measures which jeopardise patient safety or the public image of the sector or which provide one pharmaceutical company with an unreasonable competitive edge over other companies.

5. Preliminary inspection of measures targeted at consumers

98 § PRELIMINARY INSPECTION

What materials should be submitted to Inspection Board I in connection with preliminary inspections?

The following materials, among others:

- A sufficiently detailed manuscript of the TV and radio spots so that the Inspection Board can easily have a clear view of the intended final version based on the manuscript. The final broadcast version can also be submitted for preliminary inspection, without a manuscript approved in advance.
- The most recent adopted SPC of the medicine;
- The most recent adopted package leaflet of the medicine;
- Studies and statistics referred to in the advertisement.

6. Sanctions

104–112 § DECISIONS RELATED TO MARKETING AND OTHER ACTIONS CONTRARY TO THE PIF CODE

When does the company have to end the marketing found to be incorrect by the Inspection Board or Supervisory Commission?

If the company has been issued an admonition, the incorrect marketing measure must not be continued or repeated after the deadline indicated in the decision.

The company must abstain from incorrect marketing immediately when served notice, with orally or in writing, of the request to abstain from the marketing. In the advertising in the printed media, this does not necessarily mean the timeframe indicated in the terms and conditions of advertisement of the publication in question, but it is normally possible to implement the changes more rapidly. The company must investigate possibilities to change the advertisements at a more rapid rate.

108 § CORRECTION OF INCORRECT ACTIVITIES

When can the rectification of an incorrect marketing or other measure be an option?

The Inspection Boards and the Supervisory Commission can order rectification of the incorrect activities when they find such rectification necessary. This could be the case in situations when the incorrectness have or may lead to jeopardising patient safety, and the publication of the rectification is necessary for medicine safety reasons. Patient safety can be jeopardised, for example, when the marketing presents the indications of the medicine contrary to the SPC. The companies can also agree on the rectification in their mutual negotiations.

VII OTHER STIPULATIONS

113 § PUBLICITY

In which way are the decisions of the control bodies made public?

The subsequent control decisions of the Supervisory Commission and the Inspection Boards, as well as the summaries thereof, are currently published in the Pharma Industry Finland extranet. The summarised decisions are also published every year in the Annual Report of the Supervisory Commission.

The decisions will be sent to private parties other than those committed to the PIF Code, at request in line with a separate price list.

The decisions related to preliminary inspections are confidential, since they contain business secrets, and they are not given to parties other than the company in question and its representatives.

120 § GIVING NOTICE

Can the pharmaceutical company withdraw from the PIF Code but still continue as a PIF member?

Pharma Industry Finland requires that all of its member companies are committed to the compliance with the PIF Code valid at each given moment.

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