

**THE PHARMACEUTICAL INDUSTRY  
CODE OF GOOD MARKETING PRACTICES,  
INTERACTIONS WITH HEALTHCARE  
PROFESSIONALS AND PATIENT  
ORGANISATIONS**

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## INTRODUCTION

Employers' Union of Innovative Pharmaceutical Companies INFARMA and its members, being aware of importance of precise communication, reliable and objective information on medicinal products in making rational decisions regarding administration of medicinal products, have approved the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations (hereinafter referred to as the "Code").

### CHAPTER I GENERAL PROVISIONS

#### Article 1

##### Objectives of the Code

The objective of the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations is to create a mechanism of voluntary control of advertising of prescription-only medicinal products as well as support and promotion of the following:

- a. fair competition,
- b. reliable and lawful advertising of medicinal products,
- c. fair and transparent cooperation with healthcare professionals and patient organisations,
- d. non-interventional studies and phase 4 clinical trials in line with highest ethical standards.

#### Article 2

##### Definitions

1. For the purpose of this Code the terms listed below shall bear the following meaning:
  - a. "Signatory of the Code" shall refer to a member company of UoE INFARMA, subsidiaries as well as affiliates of member companies of UoE INFARMA or their subsidiaries, in the event the said companies have agreed to observe provisions of the Code as well as other entities which have signed this Code;
  - b. the terms: "promotion", "advertising", "marketing undertakings" shall be understood as "advertising" as defined by provisions of the Pharmaceutical Law Act (hereinafter referred to as "Pharmaceutical Law") of September 6, 2001 (Dz. U. [Journal of Laws] of 2004, No. 53, item 533 with subsequent amendments);
  - c. the terms: "Marketing Authorisation Holder", "medicinal product", "advertisement of a medicinal product", "Summary of Product Characteristics" as well as "Patient Information Leaflet" shall be understood as defined by provisions of the Pharmaceutical Law;
  - d. the term "good customs" shall be understood in line with the meaning defined in the Act on counteracting unfair competition (hereinafter referred to as the "Act on Counteracting Unfair Competition") of April 16, 1993 (Dz. U. 1993, No. 47, item 211, final text of June 26, 2003, Dz. U. No. 153, item 1503 with subsequent amendments);
  - e. "Medical Sales Representative" shall refer to a person who on behalf of a Marketing Authorisation Holder pays visits to addressees of advertisement in pharmacies, hospitals and other health care facilities in order to promote medicinal products;
  - f. "patient organisation" shall refer to entities associating patients or carers representing or supporting patients or organisations associating such entities.
  - g. "Non-interventional study" shall refer to a study, during which: (a) medicinal products are prescribed in the usual manner, in accordance with the terms of the marketing authorisation; (b) patients are assigned to a particular therapeutic strategy group not on the basis of a study

protocol, but depending on current practice and the prescription of the medicine is clearly separated from the decision to include a patient in the study; (c) patients do not receive any additional diagnostic or monitoring procedures; epidemiological methods are applied for analysis of the collected data.

### **Article 3**

#### **Precedence of the statutory law**

1. Provisions of binding law, regulating issues being the subject of this Code, shall always have precedence over provisions of the Code.
2. In the event of breach of provisions of binding law, within the scope not regulated in this Code, provisions of article 55, section 2 of the Code shall apply.
3. Provisions of this Code shall supplement selected provisions of the 2001/83/EC European Parliament and Council Directive of November 6, 2001 on community code referring to medicinal products administered to humans (allowing for amendments introduced by virtue of Directive 2004 27/EC) as well as the Pharmaceutical Law along with the executive provisions.

### **Article 4**

#### **Scope of the Code**

The Code stipulates the following:

- a. good practices regarding advertising of prescription-only medicinal products,
- b. good practices regarding non-interventional studies as well as phase 4 clinical trials,
- c. good practices of cooperation with healthcare professionals and patient organisations,
- d. good practices regarding transparency of the source of websites.

### **Article 5**

#### **Objective applicability of the Code**

1. Provisions of the Code shall apply to the following:
  - a. advertising or promotion of prescription-only medicinal products, and particularly in the case of: verbal or written communication, advertisements in magazines, direct advertising delivered by mail, measures undertaken by Medical Sales Representatives, measures supported by the Internet and other means of electronic communication, application of audiovisual system, such as films or videos, data storage services etc. as well as offering free samples, gifts and hospitality;
  - b. trials and studies using medicinal products authorised for marketing;
  - c. cooperation between Signatories of the Code and healthcare professionals, including cooperation under trials and studies or other contractual relations (e.g. contracts for consultancy);
  - d. cooperation between Signatories of the Code and patient organisations.
  - e. Websites
2. Provisions of the Code shall not apply to the following:
  - a. advertising or promotion of non-prescription medicinal products;
  - b. labelling of medicinal products and leaflets attached to such products, within the scope regulated by the provisions of binding law;
  - c. non-promotional information about a Code Signatory, including financial data, descriptions of research and developments programs, discussion of strategies for regulatory developments affecting a Code Signatory and his products, in particular - information for investors or current or potential company employees of a Code Signatory;
  - d. correspondence, of non advertising nature, intended to provide answers for particular question about a particular medicinal product;

- e. informative announcements relating in particular to the change of packaging, adverse-reactions warnings, provided that they do not include product claims;
- f. general non-promotional information relating to health or diseases.

#### **Article 6**

##### **Subjective applicability of the Code**

1. Provisions of the Code are binding for its Signatories, who have accessed the Code as of the day they signed accession declaration and as of the day the Code was approved by UoE INFARMA in the case of its members.
2. Other entities may apply provisions of the Code as a set of standards whose voluntary observation ensures consistency with high ethical standards in the case of their operations.

#### **Article 7**

##### **Scope of responsibility of a Signatory of the Code**

1. A Signatory of the Code shall be responsible for operations of its employees, Medical Sales Representatives as well as persons acting on his behalf, including actions covered by the Code the Signatory has commissioned third parties to perform, particularly for hiring sales personnel, employing consultants, conducting market research, personnel training or operations of an advertising agency.
2. Signatories of the Code shall make any efforts in order to ensure that the party not acting on behalf of a Signatory of the Code, but which has been ordered to design, implement or execute actions covered by the Code, observes provisions of the Code.
3. Personnel of a Signatory of the Code as well as personnel employed pursuant to contracts concluded with the Signatory, which is responsible for preparing materials and executing promotion related undertakings, should be trained in applicable legal regulations as well as requirements stipulated in the Code.

### **CHAPTER II**

#### **ADVERTISING AND PROMOTION OF MEDICINAL PRODUCTS**

#### **Article 8**

##### **Addressee of promotion**

1. With the reservation of provisions of binding law, advertising of prescription-only medicinal products may be addressed only to the persons authorised to issue prescriptions or to the persons who commercially purchase or issue medicinal products (hereinafter referred to as "addressee of promotion").
2. Advertising of medicinal products should be addressed exclusively to such persons in the case of which it is reasonable to assume they require such advertising and are interested in it.
3. In the event advertising or promotion of medicinal products is addressed to doctors performing public functions within the meaning of article 115 § 19 of the Penal Code and in particular: function of the national consultant, province consultant, head of a hospital or of a hospital department, it should be of paramount importance to make sure the abovementioned advertising or promotion addressed to these persons does not come into conflict with their positions and thus with the applicable law.

## **Article 9**

### **Protection of personal data of the promotion addressee**

1. Advertising, particularly preparing correspondence and mailing lists used for the purpose of promoting medicinal products shall be consistent with provisions of the Act on protection of personal data of August 29, 1997 (final text Dz. U. [Official Journal] from 2002, No. 101, item 926 with amendments).
2. Sending promotional content regarding medicinal products via fax, e-mail, automatic paging systems, text messages as well as other electronic means of communication is allowed only after obtaining consent of the addressee.
3. Correspondence and mailing lists should be updated regularly.
4. Personal data included in a correspondence or mailing list used for the purpose of advertising medicinal products shall be deleted or modified if requested by the promotion addressee.

## **Article 10**

### **General principles of advertising and promotion**

1. Advertising of a medical product as well as undertakings related to promotion, including trainings for Medical Sales Representatives shall be conducted in line with applicable legal regulations, good customs as well as high ethical standards.
2. Advertising of a medicinal product is allowed only after obtaining marketing authorisation in the Republic of Poland and it shall not exceed approved indications. The abovementioned condition shall not limit the right to full information on research and medical progress.
3. Advertising must be realised in an open manner.
4. Advertising must be precise, presented in a balanced, fair, objective and sufficiently complete fashion in order for the addressee to be able to form his/her own opinion on the therapeutic value of a given medicinal product.
5. Advertising shall not include information which is directly or indirectly misleading, e.g. through suggestion, omission, exaggeration, ambiguity or other distortion of information on the medicinal product, particularly regarding qualities or administration method of the product.
6. Advertising should promote rational application of a medicinal product through objective and free from exaggeration presentation of the product.
7. Advertising should be based on most up-to-date information on the medicinal product as well as assessment of its documentation.
8. Advertising and promotion of a medicinal product shall be consistent with the data included in the Summary of Product Characteristics.
9. Advertising of a medicinal product shall not decrease confidence in the pharmaceutical industry.
10. Advertising related undertakings shall allow for special character of medicinal products as well as professional position of advertising addressees.
11. Advertising shall not be offensive for its addressee and shall not refer to addressee's feelings through disturbing or misleading presentation of lesions, injuries to the human body as well as effects of a medicinal product, through instilling fear or taking advantage of superstition.

## **Article 11**

### **Obligatory content of advertisement**

1. Promotion material shall include basic information on the medicine, in line with the Summary of Product Characteristics and legal requirements, as well as the date (at least the month and the year) the material was prepared or the date the most recent modification of the material was approved.
2. Information on a medicinal product shall be presented prominently and in a legible form.
3. The scope of information included in the advertisement shall include at least the following data on the advertised medicinal product:
  - a. name of the medicinal product as well as its commonly used name,

- b. qualitative and quantitative composition with reference to active substances as well as those excipients in the case of which such information is crucial for proper administration,
- c. pharmaceutical form,
- d. indications for use,
- e. dosage and administration method,
- f. contraindications,
- g. special warnings and precautions regarding application,
- h. adverse reactions,
- i. information on the Marketing Authorisation Holder,
- j. number of the marketing authorisation as well as the name of the issuing authority,
- k. information on the assigned availability category,
- l. information on the official retail price and the maximum surcharge amount to be covered by the patient - in the case of medicinal products included in the reimbursed medicine list.

## **Article 12**

### **Transparency of promotion**

1. Promotional materials published, among others, in magazines directly or indirectly financed or co-financed by a Signatory of the Code, its representative or entity acting pursuant to an order of the Marketing Authorisation Holder, shall not appear to be independent publications.
2. Materials on medicinal products as well as their usage, financed by a Signatory of the Code, shall be explicitly labelled as sponsored, regardless of their nature.
3. Clinical assessments, post-marketing monitoring and analysis programs as well as trials and studies conducted after obtaining marketing authorisation (also those of retrospective nature) shall not be used as concealed promotion. Such assessments, programs, trials and studies must be conducted most of all for the research and education oriented purposes.

## **Article 13**

### **Replies to patients' requests for advice**

Replies to patient's requests for advice regarding health shall be limited to a recommendation to see a doctor or another person authorised to issue prescriptions.

## **Article 14**

### **Transparency of websites**

1. A website, its content and objective, owned or financed by a Signatory of the Code shall explicitly indicate:
  - a. name and address (including e-mail) of the website sponsor;
  - b. reference or author of the information as well as the date of publishing on the website,
  - c. target audience of the website (e.g. healthcare professionals, patients and general public or both at the same time);
  - d. objective of the website.
2. Detailed guidelines regarding content of websites may be found in Annex 1 to the Code.

## **Article 15**

### **Information in advertisement**

1. Information used to advertise a medicinal product:
  - a. shall be precise and objective and sufficiently complete in order for the addressee to be able to form his/her own opinion on the therapeutic value of the advertised medicinal product.

- b. should be based on up-to-date assessment of relevant reference materials and clearly indicate references,
  - c. may be based on scientific evidence presented at congresses or scientific symposia provided that the said evidence has been included in generally available materials, e.g. on websites of a given scientific congress or in summaries published in indexed scientific magazines (e.g. supplements). Such data shall be communicated consistently with original materials; reference shall be indicated as well as their publication date.
2. Information on changes in the Summary of Product Characteristics may be communicated only after the changes have been approved by the relevant authority (except for the information regarding therapy safety, e.g. on adverse reactions or interactions).

## **Article 16**

### **Scientific data in advertisement**

Scientific data, analyses and results derived from specialist publications or scientific magazines shall be communicated consistently with the original, indicating the reference as well as the publication date or the date of the most recent revision, and, in particular:

- a. results of trials, scientific news and abstracts shall not be used in a fashion which might evoke erroneous impression regarding their character, scope, applicability or meaning,
- b. in vitro trials or tests on animals shall not be used in a fashion which might result in inappropriate or erroneous impression regarding their clinical value,
- c. course of the trial referred to in an advertisement should be described in an explicit and unambiguous fashion,
- d. comparison of effects of various medicinal products or comparison of effects of medicinal products and non-pharmacological treatment methods shall be expressed in a fashion which clearly depicts its statistical and clinical value. In the case there is no statistical significance the following information is required: “difference statistically insignificant” or “NS”.

## **Article 17**

### **Quotations in advertisements**

1. Quotations, charts and other illustrations derived from medical magazines or other research papers, to be used in advertisements, shall be accurately reproduced and their reference clearly indicated.
2. It is recommended to use the quotation model suggested by reputable medical magazines.
3. Quotations, figures or charts derived from research papers used for the purpose of comparison of medicinal products shall not be misleading or be used to discredit a competitive medicinal product.
4. Quotations from specialist magazines, charts and other illustration used in advertisements shall not create erroneous impression that research or documentation were developed for another, competitive medicinal product, e.g. a generic.

## **Article 18**

### **Unfair reference to sources**

1. The following elements shall not be used as reference data in medicinal product advertising:
  - a. unpublished data on file of the Marketing Authorisation Holder, unless the data is included in the registration file available on request,
  - b. data which were printed only in materials from a scientific session or meeting financed by a Marketing Authorisation Holder or organised by a scientific society, unless the materials are published in the form fulfilling requirements stipulated in article 15, item 1c of this Code,
  - c. information obtained from advertising addressees during personal communication or obtained through market research conducted by a Marketing Authorisation Holder

or through outsourced market research, unless the data have been published or made available on a generally available website.

## **Article 19**

### **Statements in advertisements**

Any statements regarding a medicinal product included in its advertisement shall be consistent with approved Summary of Product Characteristics and supported by relevant evidence, in particular:

- a. information on composition, active substances, properties, effects of a medicinal product shall be precise, consistent with the information included in the Summary of Product Characteristics and shall not be misleading,
- b. comparative expressions, such as “better than”, “more effective than”, significantly “cheaper than” etc. shall not be used without relevant, up-to-date evidence proving their authenticity,
- c. a medicinal product may be referred to as "most often prescribed" only in the case the statement is based on up-to-date statistical evidence,
- d. the term "new" may be used only with reference to a medicinal product whose composition includes an active substance or a mixture of active substances which has not been registered in the Republic of Poland as a medicinal product before,
- e. the term "new" shall not be used with reference to a medicinal product after 12 months from the day it was authorised for marketing in the Republic of Poland,
- f. the term "new" shall not be used with reference to therapeutic indications of a medicinal product after 12 months from the date of registration of changes in the Summary of Product Characteristics,
- g. the term "new" shall not be used with reference to a medicinal product in a new form or dose after 12 months from the day it was authorised for marketing in the new form or dose,
- h. data on safety of application of a medicinal product, e.g. contraindications, precautions as well as adverse reactions, shall be clearly described so that no doubts as to the used terms arise,
- i. “safe” or “efficacious” shall not be used unless their usage is appropriately substantiated.

## **Article 20**

### **The obligation to disclose data substantiating statements used in advertisements**

Marketing Authorisation Holder or its representative who has used certain data in an advertisement for the purpose of substantiating an advertisement statement shall disclose the documentation or its part being the source of the said data at written request of the advertisement addressee, Marketing Authorisation Holder or its representative, within 21 days from serving the request for disclosing the said documentation.

## **Article 21**

### **Comparative advertisement**

1. Comparative advertisements shall meet requirements resulting from the provisions of binding law, including regulations on unfair competition.
2. Comparative advertisements shall meet cumulatively all of the following requirements:
  - a. provide name, pharmaceutical form as well as dosage of compared medicinal products,
  - b. description of the comparison, restrictions related to the comparison as well as the data used in the comparison shall be presented in a fashion excluding the possibility of misleading the addressee,
  - c. the comparison may be used only in the case of medicinal products of analogous qualities or medicinal products of identical indications,

- d. the comparison shall refer to specific qualities of compared medicinal products supported by research results,
- e. the comparison shall refer to one or several significant, typical and verifiable qualities, including price of the compared medicinal products,
- f. the comparison shall be objective, reliable and verifiable; information included in the comparison shall be verifiable and thus reference should be made to the source of presented information as well as the date of publication or the most recent revision,
- g. comparison of selected qualities of medicinal products shall not be misleading in terms of characteristics of compared medicinal products as well as the qualities not covered by the comparison; it shall not make the compared products, their trademarks, company logos or other distinctive features indistinguishable,
- h. it shall not discredit the competitive medicinal product or any Marketing Authorisation Holder,
- i. it shall not present a medicinal product as an imitation or copy of a product labelled with a registered trademark.

## **Article 22**

### **Samples**

1. Signatory of the Code shall implement a system ensuring supervision over and responsibility for the distribution of samples at its representatives' disposal; the person directly responsible for distribution of free samples shall maintain a relevant register.
2. Samples of medicinal products may be distributed only to persons authorised to issue prescriptions who have sent a written request for to obtain such free samples to a Medical Sales Representative or sales representative.
3. It shall be prohibited to distribute free samples of medicinal products containing intoxicants or psychotropic substances.
4. Each free sample of a medicinal product shall be prominently labelled with the following information: "Free sample - not for sale". Summary of Product Characteristics should be attached to each sample.
5. A single free sample shall not exceed the smallest packaging of a medicinal product, authorised for marketing in the Republic of Poland.
6. One person shall not receive more than five samples of a given medicine within one calendar year.

## **CHAPTER III**

### **MEDICAL SALES REPRESENTATIVES**

## **Article 23**

### **The obligation regarding Medical Sales Representative trainings**

Medical Sales Representative as well as other person who on behalf of a Signatory of the Code pay visits to advertising addressees in pharmacies, hospitals and other health care facilities in order to promote medicinal products shall be trained in applicable legal regulations as well as provisions of the Code and shall have sufficient medical knowledge in order to provide accurate and reliable information on promoted medicinal products.

## **Article 24**

### **Responsibilities of a Medical Sales Representative**

1. Medical Sales Representatives shall fulfil their responsibilities in line with applicable legal regulations as well as principles included in the Code.

2. A Medical Sales Representative shall provide the visited persons with the Summary of Products Characteristics for the presented medicinal product or make such SPC available to them.
3. A Medical Sales Representative shall immediately provide the Holder of Marketing Authorisation for the given product or its representative in the Republic of Poland with any new information regarding application of medicinal products as well as adverse reactions of the products.
4. A Medical Sales Representative shall make sure the frequency, dates as well as duration of visits paid to advertising addressees in pharmacies, hospitals and other health care facilities as well as the course of these visits are consistent with the principles applicable at these facilities and do not cause any difficulties in terms of their operation.
5. A Medical Sales Representative shall not use any financial incentives in order to make an appointment with an advertising addressee.
6. During a visit or while making an appointment a Medical Sales Representative shall not mislead the advertising addressee with regard to his identity or identity of the Marketing Authorisation Holder he represents.

## **CHAPTER IV**

### **PRINCIPLES OF ORGANISING SYMPOSIA, CONGRESSES AND OTHER MEETINGS**

#### **Article 25**

##### **Objectivity criteria for selection of meetings participants**

Selection criteria applicable when choosing persons to be invited to a congress or a symposium shall be objective and based on substantive factors.

#### **Article 26**

##### **Venues of meetings**

1. Promotion, scientific or professional meetings, congresses, conferences, symposia as well as other similar events, including meetings of advisory bodies, visits in research institutes, manufacturing plants, meetings of researchers, devoted to planning, training and other issues related to clinical or non-interventional studies (hereinafter referred to as "meetings") organised or financed by or on behalf of a Signatory of the Code must be held at a venue appropriate for the main purpose of the meeting.
2. Meetings shall not be held at venues thought extravagant or known for offered entertainment.
3. Signatories shall not organise or finance, directly or indirectly, meetings held abroad, unless it is substantiated with significant economic, substantive or organisational reasons, particularly in the case a majority of invited participants comes from outside of the country where the meeting is to be held.

#### **Article 27**

##### **Hospitality**

1. Hospitality offered to participants of Meetings should not be excessive and shall be directly related to the basic objective of the Meeting, that is should be limited to covering the following expenses: travel, board and lodging as well as registration fees related to participation in the meeting.
2. The costs referred to in item 1 should include only costs covered by participants of the Meeting and not their companions or relatives.
3. Hospitality shall not include financing or organising entertainment during the meeting (e.g. sport or recreation events).

## **Article 28**

### **Promotion of medicinal products outside the Republic of Poland**

In the case of international congresses, all transferred materials or information should inform the participants of the differences in registration terms and conditions of a given medicinal product between the Republic of Poland and the country where the meeting is held (if any).

## **CHAPTER V**

### **NON-INTERVENTIONAL STUDIES, PHASE 4 CLINICAL TRIALS AND OTHER STUDIES**

## **Article 29**

### **Principles of conducting trials and studies**

1. Clinical trials conducted with the use of a medicinal product authorised for marketing (hereinafter referred to as "phase 4 clinical trials") shall be conducted in line with Good Clinical Practice as well as relevant legal regulations applicable in the Republic of Poland.
2. Non-interventional studies should have a specified scientific objective.
3. Non-interventional studies shall meet the following requirements:
  - a. the medicinal product is used in the trial in line the Summary of Product Characteristics,
  - b. applied therapy is consistent with the accepted medical practice,
  - c. selection and application of the medicinal product is independent of the decision to include a patient to the study/ trial,
  - d. the patient included to the study/trial shall not be subject to any additional diagnostic or health monitoring procedures,
  - e. patients shall express their consent in writing for participation in the trial in the case the trial procedure requires access to source documents on the part of the sponsor representative,
  - f. epidemiological methods shall be used for the purpose of analysing collected data.

## **Article 30**

### **Transparency of trials and studies**

1. Conducting non-interventional studies or trials/studies referred to in article 36 shall be prohibited in the event they represent a form of concealed advertising aiming at increasing the number of issued prescriptions.
2. Conducting non-interventional studies shall not be used for the purpose of exerting influence on doctors with reference to treatment methods used by them.
3. Non-interventional studies shall not be used to compare medicinal products.

## **Article 31**

### **The obligation to conduct trials and studies in line with the protocol**

1. Non-interventional studies shall be conducted in line with the trial protocol stipulating the number of patients and the observation time. Extending a trial in the same facilities or starting a new trial with the same scientific objective shall not be allowed unless it results from decisions made by appropriate authorities or provisions of binding law.
2. It is recommended to submit the trial protocol to the appropriate ethical committee.

## **Article 32**

### **Responsibilities of the Medical Department**

1. Signatory's Medical Department shall be responsible for approval and supervision over non-interventional studies and phase 4 clinical trials. Supervision over such trials shall cover (among others) revision of all responsibilities related to trials, particularly with reference to any responsibilities of Medical Sales Representatives.
2. Appointed person from the Medical Department shall confirm that he/she has examined the protocol of the non-interventional study and that the said protocol meets requirements of the applicable Code.

## **Article 33**

### **The obligation to conclude a contract for financing a trial/study**

1. It is necessary to conclude a written contract with the Code Signatory financing a trial and professionals of health care or institutes where the trial is to be conducted; the contract shall stipulate the nature of services to be rendered as well as the remuneration to be paid for conducting the trial.
2. Remuneration shall be adequate to time and workload related to the research and shall reflect standards applicable on the Polish market.

## **Article 34**

### **Publishing information about a trial/study start-up**

1. Information on starting a non-interventional study or a trial referred to in article 36 shall be published immediately through the website of the appropriate Association associating Marketing Authorisation Holders.
2. The abovementioned information shall include, at least, the following elements:
  - a. name of the Code Signatory financing the trial,
  - b. title of the trial,
  - c. objective of the trial,
  - d. planned number of patients, if applicable,
  - e. duration of the trial,
  - f. patient observation time, if applicable,
  - g. date of the first visit of the first patient as well as the date of the last visit of the last patient, if applicable.
3. Access to the information referred to in item 1 should be coded, that is should require entering one's login assigned by the appropriate Association to its members and other entities who have signed the Code.
4. In the event a non-interventional study or a trial referred to in article 36 is not communicated in line with this article, the entity responsible for organising the trial, at a written request of a Signatory of the Code or its representative, shall be obliged to provide, within 21 days, the following:
  - a. information referred to in item 2,
  - b. protocol of the trial,
  - c. sample of the a patient documentation (Case Report Form), if applicable,
  - d. sample of the contract concluded with the researcher or the organisation conducting the trial.

## **Article 35**

### **Concluding a trial/study, results**

1. Results of phase 4 trials as well as non-interventional studies shall be analysed and prepared in form of a final report not later than 12 months from the end of the observation of the last

patient and published or presented at a medical symposium not later than 24 months from the end of the observation of the last patient.

2. Signatory of the Code should communicate the summary report to all researchers involved in the research project as well as make it available at INFARMA request.
3. In the event trial results are significant for assessment of the product, the summary report shall be communicated immediately to the relevant authority.
4. Medical Department of a Signatory of the Code shall maintain an archive file of reports referred to in this article.

#### **Article 36**

##### **Conditions for conducting other studies**

1. Conducting trials other than non-interventional studies of phase 4 clinical trials is allowed provided they belong to one of the following categories:
  - a. epidemiological trials understood as trials based on collecting population data,
  - b. registers understood as collecting data on therapeutic, preventive and diagnostic procedures or procedures modifying physiological functions, including data on pharmacotherapy,
  - c. health economics studies understood as collecting data enabling preparing economic assessment of specific therapeutic, preventive and diagnostic procedures as well as procedures modifying physiological functions, including pharmacoeconomics studies.
2. Market research shall be conducted by independent entities and shall not be a form of concealed advertising. It is allowed not to disclose the customer name to the respondent, but it is necessary to indicate the branch of industry the sponsor operates in.

#### **Article 37**

##### **Medical Sales Representatives and trials/studies**

1. Medical Sales Representatives may participate in trials referred to in this chapter only for the purpose of performing administrative functions.
2. Such participation shall not be related to advertising of a medicinal product and shall be supervised by the Medical Department (or its equivalent) of the Signatory of the Code which is to ensure their appropriate training.
3. It is recommended that Medical Sales Representatives should not participate in non-interventional studies.

### **CHAPTER VI**

#### **PRINCIPLES REGARDING CONTACTS WITH HEALTHCARE PROFESSIONALS**

#### **Article 38**

##### **Gifts**

1. It is prohibited to advertise medicinal products through giving, offering or promising material benefits, gifts, prizes or trips.
2. The abovementioned prohibition shall not refer to giving or accepting items for the gross value up to PLN 100 related to medical or pharmaceutical practice and labelled with a logo of a Code Signatory or a medicinal product.

#### **Article 39**

##### **Contributions to the Health Care**

1. Contributions or other benefits donated to institutions, organisations or associations associating healthcare professionals, rendering medical services or conducting research related to health care are allowed only in the following cases:
  - a. they are donated to the explicitly defined objective to support health care or research,

- b. they are documented and the documentation is maintained by the donator,
  - c. they are not incentives to recommend, prescribe, purchase, supply, sell or use particular medicinal products.
2. Donations to individual healthcare professionals shall be prohibited.
3. It is recommended for a Signatory of the Code to make the information on the abovementioned contributions, grants or other benefits donated for the benefit of health care institutions widely available.

#### **Article 40**

##### **Sponsorship of healthcare professionals**

1. Sponsorship, by a Signatory of the Code, of participation by an individual healthcare professional in an international meeting shall be consistent with provisions of binding law as well as provisions of this Code.
2. It is prohibited to offer a payment as a compensation only for the time devoted by healthcare professionals for participation in the meetings.

### **CHAPTER VII**

#### **PRINCIPLES REGARDING CONTACTS WITH HEALTHCARE PROFESSIONALS**

#### **Article 41**

##### **Services rendered by health care centres to the Signatories**

Contracts between the Code Signatories and institutions, organisations or associations of healthcare professionals pursuant to which the said institutions, organisations or associations rendering any services to the benefit of the Code Signatories shall be allowed only in the event the said contracts meet the following requirements:

- a. they pertain to supporting health care or scientific progress;
- b. they are not incentives to recommend, prescribe, purchase, supply, sell or use particular medicinal products.

#### **Article 42**

##### **Employing consultants**

1. It shall be allowed to employ healthcare professionals as consultants, advisors or speakers in the case of services the rendering of which is related to the necessity to pay remuneration and cover other costs related to rendering services, e.g. travel costs or other reasonable expenses necessary for the purpose of rendering the service. In particular such services may pertain to the following: speeches or presiding over meetings, involvement in medical or scientific studies/research, clinical trials, training, participation in meetings of advisory bodies or participation in market research.
2. Cooperation referred to in item 1 shall meet cumulatively all of the following requirements:
  - a. a written contract has been signed stipulating the nature of the services which are to be rendered as well as the basis for payment of remuneration for the services prior to rendering the services;
  - b. there is a reasonable need for rendering such services, which has been clearly indicated prior to ordering such services and prior to making arrangements with potential consultants;
  - c. consultant selection criteria are directly related to the indicated need and persons responsible for the selection have the knowledge necessary for assessing whether particular healthcare professionals meet requirements defined by the said criteria;

- d. the number of service providers shall not exceed the reasonable number of persons necessary for the purpose of satisfying the indicated need;
  - e. the customer shall maintain appropriate documentation and use the services rendered by the consultants in an appropriate manner;
  - f. employment of healthcare professionals for the purpose of rendering a particular service shall not be aimed at increasing sales of a medicinal product;
  - g. offered remuneration is adequate to the market value or rendered services.
3. Relevant provisions of Chapter IV shall apply in the case of a healthcare professional participating in a meeting referred to in item 1 of the Code as a consultant or an advisor, particularly in terms of allowed hospitality.
  4. It is recommended to include in contracts with consultants appropriate provisions regarding consultant's obligation to include a declaration stating that he/she is acting on behalf of a given Code Signatory, in all his/her presentations, written texts or other forms of the contract realisation.
  5. It is also recommended for the Code Signatories hiring healthcare professionals, who are active professionally, as part time employees, to include a clause in employment contracts, obliging them to inform other employees and other persons before whom they represent interests of their employers, that these persons have an employment contract concluded with the given Code Signatory.

## **CHAPTER VIII COOPERATION BETWEEN THE CODE SIGNATORIES AND PATIENT ORGANISATIONS**

### **Article 43**

#### **General principles**

1. Cooperation between patient organisations and the pharmaceutical industry should be based on mutual respect and should ensure independency of patient organisations in terms of their undertakings; opinions expressed by and decisions made by each partner shall be equivalently important.
2. Cooperation shall not pertain to advertising prescription-only medicinal products.
3. Objectives and the scope of the cooperation shall be transparent and precisely defined.
4. Support provided by the pharmaceutical industry shall be explicitly documented.

### **Article 44**

#### **Contracts in writing**

1. Providing financial support or support in kind, directly or indirectly (e.g. through an agency) for the benefit of a patient organization shall require concluding a contract in writing.
2. The contract shall stipulate:
  - a. subject of the contract;
  - b. contract signing date;
  - c. names of the cooperating institutions as well as the name of the third party, if any;
  - d. the objective of the support;
  - e. the amount of the support;
  - f. responsibilities of the parties;
  - g. term of the contract;
  - h. description of the support to be provided;
  - i. the provision obliging the patient organisation to observe provisions of the Code within the scope of execution of the contract;

- j. the obligation of providing an evidence of using the support in the manner stipulated in the contract.

#### **Article 45**

##### **Use of patient organisation logo and materials**

1. Use of patient organisation logo or materials publicly by the Signatory requires a written statement signed by the said organisation.
2. The statement shall explicitly define the objective as well as the manner of using the organisation logo or materials.

#### **Article 46**

##### **Content of materials**

1. Signatory of the Code shall not influence the content of the materials provided by the financed patient organisation.
2. The abovementioned restriction shall not refer to correcting substantive errors found in such materials.

#### **Article 47**

##### **Transparency**

1. Each Marketing Authorisation Holder shall make publicly available the lists of patient organisations for the benefit of which it provides financial support or support in kind.
2. The list should include a brief description of the nature of the provided support.
3. Provided information should be updated at least once a year.
4. The Marketing Authorisation Holder shall obtain confirmation of acceptance of the offered support.

#### **Article 48**

##### **Promotion prohibition**

Signatory of the Code shall not use a patient organisation as a tool for the purpose of communicating advertising pertaining to a prescription-only medicinal product to patients; this shall particularly refer to undertakings related to websites, symposia, lectures, convention materials as well as other forms of communication.

#### **Article 49**

##### **Principles of financing**

Signatory of the Code shall not require exclusive rights for sponsorship of a patient organisation or any of its programs.

#### **Article 50**

##### **Meetings and hospitality**

Principles stipulated in Chapter IV regarding meetings and hospitality shall also apply with regard to patient organisations.

#### **Article 51**

##### **Contributions in kind**

It is recommended to support patient organisations with contributions in kind, e.g. trainings, assistance related to educational programs.

## **CHAPTER IX DISPUTE SETTLEMENT**

### **Article 52 Disciplinary Court**

Any disputes which may arise with relation to this Code, in the event parties fail to solve the disputes amicably or the cases of possible violation of the Code, shall be settled by the Disciplinary Court (hereinafter referred to as the "Court") operating at Związek Pracodawców Innowacyjnych Firm Farmaceutycznych INFARMA, pursuant to Articles of Association of INFARMA as well as the Court policy.

### **Article 53 Primary objective of the Court**

The primary objective of the Court is not to issue decisions regarding a party's fault but settling a dispute to the benefit of the whole pharmaceutical industry in order to improve its high ethical standards.

### **Article 54 Entities entitled to lodge a complaint**

Signatories of the Code, INFARMA members as well as other entities – through INFARMA Management Board – shall be entitled to refer a case to the Court for settlement.

### **Article 55 Exclusions from the Court jurisdiction**

1. Cases regarding which proceedings have been commenced before state administration authorities or courts of law shall be excluded from the Court jurisdiction.
2. In cases pertaining to violations of provisions of binding law as well as the Code provisions, the Court shall issue decisions pertaining only to violations of the Code provisions.

### **Article 56 Demand to stop further breach**

1. The allegedly aggrieved Signatory of the Code may request the Signatory responsible for breaching the Code provisions to immediately stop further breach and submit a written declaration stating that such breaching will be prevented.
2. Proceedings may be continued despite the fact the party in default has stopped breaching before the end of the proceedings.

### **Article 57 Sanctions**

In the event breaching of the Code provisions is revealed the Court, allowing for the type and harmfulness of the breach as well as benefits gained by the party in default and whether or not the Court has declared breaching of the Code provisions within the previous 12 months, may rule as follows:

- a. ban on continuing sued actions, particularly immediate withdrawal from all mass media of the advertising breaching provisions of the Code,
  - b. reprimand or rebuke,
  - c. order to submit to the indicated media or to the indicated addressees single or repeated statement of particular wording,
  - d. notice to the Main Pharmaceutical Inspectorate regarding the decision,
  - e. Notice to the EFPIA (*The European Federation of Pharmaceutical Industries and Associations*) or IFPMA (*International Federation of Pharmaceutical Manufacturers and Associations*) regarding the issued decision;
  - f. notice regarding the decision to the equity related companies (hereinafter referred to as the "Headquarters") of the party responsible for breaching provisions of the Code,
  - g. obligation to single or repeated publication of the decision or its parts in indicated mass media.
2. Sanctions may be imposed cumulatively.

#### **Article 58**

##### **Publication of the Court decisions**

1. Information on the final decision of the Court shall be published in UoE INFARMA Bulletin.
2. Such information shall include particularly the following:
  - a. in the case of serious or repeated breach: name of the company along with details of the case;
  - b. in the case of minor breach or in the event no breach was found: details of the case may be published but the name of the company may not.
3. In each case content of the published information shall be decided by the Court.

#### **CHAPTER X**

##### **EXECUTIVE PROVISIONS**

#### **Article 59**

##### **Observing provisions of the Code**

1. Each Signatory of the Code shall keep a signed copy of the Code in its records.
2. Signatory of the Code shall employ or appoint trained personnel responsible for information regarding its medicinal products as well as approving promotion materials prior to distribution.
3. The abovementioned personnel shall include a doctor or, if necessary, a pharmacist with sufficient knowledge for deciding whether a given promotional material meets requirements stipulated in the Pharmaceutical Law as well as this Code.
4. Signatory of the Code should appoint at least one senior employee to be responsible for supervision over observing provisions of the Code on the part of the Marketing Authorisation Holder, its employees as well as partners (hereinafter referred to as the "Representative").
5. Written information on the name and position of the person referred to in item 4 shall be communicated to UoE INFARMA within 30 days of the day this Code has come into force. Within identical period of time, the Signatory shall inform about each change with reference to the abovementioned person.
6. The Representative shall verify the final version of the promotional material and confirm it is consistent with the requirements of the Code as well as relevant legal regulations pertaining to advertising, that it is in line with the Summary of Product Characteristics and presents facts pertaining to the medicinal product in a fair and precise manner.
7. A representative should:
  - a. ensure consistency of undertakings of the Marketing Authorisation Holder with provisions of the Code regarding advertising of medicinal products,
  - b. verify whether Medical Sales Representatives employed by the Marketing Authorisation Holder have been appropriately trained and whether they fulfil their responsibilities in line with provisions of the Code,
  - c. At Court request UoE INFARMA shall provide him with access to any information and advertisements of medicinal products published by the Signatory,
  - d. ensure final and binding decisions of the UoE INFARMA Court are immediately and fully implemented by the entity responsible for advertising related undertakings.

#### **Article 60**

##### **Accession to the Code**

1. This Code is open for accession for to all representatives of the pharmaceutical industry as well as social organisations associating pharmaceutical companies.
2. Accession to the Code requires a written statement on accession to the Code, consistent with the sample constituting Appendix 2 to this Code.
3. Accession document shall be submitted to INFARMA or to the social organisation being a party to the Code in the event the accessing pharmaceutical company is a member of that organisation.

In the event an accessing pharmaceutical company is not a member of any organisation being a party to the Code or in the event a social organisation is accessing the Code, the abovementioned accession document may be submitted in any social organisation being a party to the Code.

4. An organisation being a party to the Code shall immediately inform all the other organisations being parties to the Code of any new party which has accessed the Code as well as of the accession date.
5. An organisation being a party to the Code shall maintain and update a register of all entities which have accessed the Code as well as make the register available also via its website.
6. Accession to the Code shall result in denouncing the Code of Marketing Ethics for the Pharmaceutical Industry currently binding for the member of UoE INFARMA without the necessity to submit any additional statements.

#### **Article 61**

##### **Termination of the Code**

Each party may terminate the Code with 30-day long notice by informing the following:

- a. the social organisation which accepted the accession declaration – in the case of companies,
- b. all the other organisations being parties to the Code - in the case of social organisations.

#### **Article 62**

##### **Amending provisions of the Code**

1. Amendments of the Code shall be accepted by simple majority of voting Signatories.
2. Proposals of amendments and supplements of the Code may be presented by Signatories or the Court.
3. Proposals shall be communicated to the organisation being a party to the Code which shall immediately communicate them to all the other Signatories for approval or rejection.
4. In the event a Signatory fails to communicate its opinion within one month from the date of receiving the abovementioned proposal, it shall be equivalent to accepting the proposal or the supplement without any objections.
5. UoE INFARMA shall inform all Signatories of received opinions as well as approval or rejection of amendments or supplements not later than within one month from the expiration of the consultation date referred to in item 4.
6. Amendments and supplements approved in line with this article shall come into force on the date agreed by the Signatories and stipulated in the notice referred to in item 5, yet not sooner than 14 days from sending the notice.

## Appendix 1

### **GUIDELINES REGARDING WEBSITES ACCESSIBLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND GENERAL PUBLIC OF THE EUROPEAN UNION**

#### **1. Content of the websites owned or financed by a Signatory of the Code.**

(a) Information available on a website shall be updated regularly and shall be presented in a legible manner for each page and/or element, depending on the structure, with the date of the most recent update of the content.

(b) Examples of information which may be published via a website: (i) general information about the Code Signatory; (ii) information on health education; (iii) information for healthcare professionals and (iv) non-promotional information for patients and general public regarding particular medicinal products marketed by the Code Signatory within the scope allowed in line with provisions of the Pharmaceutical Law.

- i. General information about the Code Signatory. Websites may contain information that investors, media or general public might be interested in, that is financial standing data, descriptions of research and development programs, regulatory issues influencing the Code Signatory and his products, information for potential employees etc. Content of the abovementioned information shall not be regulated by these guidelines or provisions of the Act on advertising medicinal products.
- ii. Information on health education. Websites may include non-advertising information devoted to health education describing characteristics of diseases, preventive measures as well as tests and treatment methods and other information aiming at promoting public health. Appropriate information on alternative treatment method may be presented, including information on surgeries, diet, changing one's lifestyle and other interventions not involving the use of any medicinal products, if applicable. Websites containing information on health education shall always recommend consulting a doctor in order to obtain further information.
- iii. Information for healthcare professionals. Any non-promotional information available on websites and intended for healthcare professionals shall be consistent with provisions of the Code. Such information shall be explicitly identified as information intended for healthcare professionals as well as appropriately secured against accessing by persons unauthorised for receiving such information.
- iv. Non-advertising information for patients and general public. With reservation of any applicable legal regulations, websites may contain non-advertising information intended for patients and general public on products offered by a given Code Signatory (among others information on their indications, side effects, interactions with other medicinal products, appropriate usage, clinical trial reports etc.), provided such information is balanced, precise and consistent with the approved Summary of Product Characteristics. For each presented product the website shall provide full, unchanged copies of current Summary of Product Characteristics as well as the Patient Information Leaflet. The said documents should be provided along with the other information pertaining to products or connected with the discussion via an evident link advising the reader to get familiar with them. Additionally, a web site may include a link to complete, unchanged copies of any public assessment reports announced by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products or another relevant state authority. Trade names should be accompanied by international non-proprietary names. A website may include links to other websites containing reliable information on medicinal products, among others to websites managed by government

authorities, organisations conducting medical research, patient organisations etc. A website shall always inform visitors to consult a healthcare professional in order to obtain further information.

**2. Questions sent via e-mail.** A website may invite healthcare professionals, patients or general public to submit question via e-mail in order to obtain further information on the company products or other issues (e.g. send feedback regarding the website). The Code Signatory may reply to such information in the same manner as it would reply to a question delivered by regular mail, telephone or other means of communication. Information sent to patients or general public should not cover topics related to personal health related issues. In the event personal medical information is revealed, it needs to be kept confidential. When appropriate, replies should recommend consulting a healthcare professional in order to obtain further information.

**3. Links to other websites.** A website owned or financed by a Code Signatory may include links to websites financed by other entities yet Code Signatories should not create links between websites intended for the general public and websites financed by the Code Signatory and intended for healthcare professionals. Similarly, links to separate websites may be created, among others to websites financed by the Code Signatory or other entities. Such links should transfer the user to the homepage of the website or be managed in such a manner as to make the user aware of the type of website he is viewing.

**4. Information assessment.** Code Signatories should make sure scientific and medical information prepared by them with the intention of publishing on their websites has been verified in terms of accuracy and consistency with the Code. Medical Department may be responsible for this function or it may be assigned to other appropriately trained persons.

**5. Privacy protection.** A website shall be consistent with legal regulations as well as applicable codes of conduct pertaining to privacy protection, safety and confidentiality of personal data.

Appendix 2

**DECLARATION OF ACCESSION TO THE PHARMACEUTICAL INDUSTRY CODE  
OF GOOD MARKETING PRACTICES IN COOPERATION WITH HEALTH CARE  
AUTHORITIES AND PATIENT ORGANISATIONS**

I, the undersigned \_\_\_\_\_, (*name of the person or persons authorised to represent the member of UoE INFARMA accessing the Code*), acting on behalf of \_\_\_\_\_ (*name of the represented member of UoE INFARMA*), registered in \_\_\_\_\_ (*name of the register*), at \_\_\_\_\_ (*registration number*), having read and understood the Pharmaceutical Industry Code of Good Marketing Practices in Cooperation with Health Care Authorities and Patient Organisations (hereinafter referred to as the "Code"), acting pursuant to article 60.2 of the Code hereby submit this declaration of accession to the Code pursuant to the principles stipulated therein.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Position, name of the member of UoE INFARMA: \_\_\_\_\_