THE PHARMACEUTICAL INDUSTRY CODE OF GOOD PRACTICES

INTRODUCTION

The Employers' Union of Innovative Pharmaceutical Companies INFARMA and its members, being aware of the importance of communication of reliable and objective information on medicinal products for making rational decisions regarding administration of medicinal products, has approved the Pharmaceutical Industry Code of Good Practices (hereinafter referred to as the "**Code**").

CHAPTER I
GENERAL PROVISIONS

Article 1
Objectives of the Code

The objective of this Code 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 the highest ethical standards.

Article 2
Definitions

1. For the purpose of this Code the terms listed below shall have the following meaning:
   a. "Signatory of the Code" shall refer to a member company of INFARMA, subsidiaries as well as affiliates of member companies of INFARMA or their subsidiaries, where the said companies have agreed to observe the provisions of the Code as well as other entities which have signed this Code,
   b. the terms: "promotion", "advertising", "marketing activities" shall be understood as "advertising" as defined by the provisions of the Pharmaceutical Law Act (hereinafter referred to as "Pharmaceutical Law") of 6 September 2001 (Dz. U. [Journal of Laws] of 2008, No 45, item 271),
   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 the provisions of the Pharmaceutical Law, where "medicinal product" shall only be understood as a medicinal product for human use;
   d. the term "good customs" shall be understood in line with the meaning defined in the Suppression of Unfair Competition Act (hereinafter referred to as the "Suppression of Unfair Competition Act") of 16 April 1993 (Dz. U. of 2003, No 153, item 1503, as amended);
   e. "Medical Sales Representative" shall refer to any person who on behalf of a Marketing Authorisation Holder pays visits to the advertising audience in order to promote medicinal products;
   f. "patient organisations" 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 used 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;

h. "healthcare professionals" shall refer to any natural person:

(a) who is a physician, dentist, pharmacist, physician assistant (senior physician assistant), nurse, obstetrician, medical laboratory scientists, paramedic or pharmacy technician; or

(b) other than the persons listed under (a) above who due to their profession is entitled to prescribe, purchase, supply, recommend or administer medicinal products.

i. "healthcare organisation" shall refer to any entity:

(a) which is a healthcare centre, medical organisation or scientific organisation operating in the area of health or medicine, irrespective of its organisational or legal form, such as a hospital, clinic, foundation, university, other teaching institution or scientific society (except for patient organisations) or

(b) through which one or more Healthcare professionals provide services.

Article 3
Precedence of the statutory law

1. The applicable provisions of law governing the issues contemplated by this Code shall always have precedence over the provisions of the Code.
2. In the event of an infringement of the applicable law, within the scope not regulated in this Code, the provisions of Article 55(2) of the Code apply.
3. The provisions of this Code shall supplement selected provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended) as well as the Pharmaceutical Law along with the implementing provisions.

Article 4
Scope of the Code

The Code stipulates the following:

a. good practices regarding advertising of prescription-only medicinal products for human use,
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. The provisions of the Code shall apply to the following:

a. advertising or promotion of prescription-only medicinal products, in particular: verbal or written communication, advertisements in magazines, direct advertising delivered by mail, measures undertaken by Medical Sales Representatives, measures undertaken using Internet and other means of electronic communication, application of audiovisual systems, 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 on one side and healthcare professionals and healthcare organisations on the other side, including cooperation under trials and studies or other contractual relations (e.g. contracts for consultancy services);
d. cooperation between Signatories of the Code and patient organisations;
e. websites.

2. The provisions of the Code do 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 applicable law;
   c. non-promotional information about a Code Signatory, including financial data, descriptions of research and development programmes, discussion of strategies for regulatory developments affecting a Code Signatory and his products, in particular information for investors and current or potential company employees of a Code Signatory;
   d. non-promotional correspondence intended to provide answers to a specific question about a specific 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. The provisions of the Code are binding on the Signatories of the Code who have acceded to the Code as of the date at which they signed accession declaration, and on members of the Employers' Union of Innovative Pharmaceutical Companies INFARMA as of the date at which the Code was approved by INFARMA.
2. Other entities may apply the provisions of the Code as a set of standards the voluntary respect of which ensures compliance with high ethical standards of operations.

Article 7
Scope of responsibility of a Signatory of the Code

1. Signatories of the Code are responsible for operations of their employees, Medical Sales Representatives as well as persons acting on their behalf, including actions covered by the Code the Signatory has delegated to third parties, in particular for hiring sales personnel, employing consultants, conducting market research, personnel training or actions of advertising agencies.
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 who has been ordered to design, implement or carry out the actions covered by the Code, observes the provisions of the Code.
3. Personnel of a Signatory of the Code as well as personnel employed under contracts concluded with the Signatory of the Code which is responsible for preparing materials and undertaking

promotional activities 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
Advertising audience

1. Subject to the applicable law, advertising of prescription-only medicinal products may only be addressed to the persons authorised to issue prescriptions or to the persons who trade in medicinal products ("advertising audience").
2. Advertising of medicinal products should be addressed exclusively to such persons where it is reasonable to assume they require such advertising and are interested in it.
3. If advertising or promotion of medicinal products is addressed to physicians performing public functions within the meaning of Article 115 § 19 of the Penal Code, 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 above-mentioned 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 advertising audience

1. Advertising, in particular preparing correspondence and mailing lists used for the purpose of promoting medicinal products shall be consistent with with the provisions of the Personal Data Protection Act of 29 August 1997 (Dz. U. of 2002, No 101, item 926, as amended).
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 only allowed after obtaining the consent of the recipient.
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 upon request of the person concerned.

Article 10
General principles of advertising and promotion

1. Advertising of a medical product as well as promotional activities, including training for Medical Sales Representatives, shall be conducted in line with applicable laws, 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 the approved indications. The above-mentioned condition shall not limit the right to full information on research and medical progress.
3. Advertising activities must be carried out in an open manner.

4. Advertisement must be precise, presented in a balanced, fair, objective and sufficiently complete fashion in order for the audience to be able to form their own opinion on the therapeutic value of a given medicinal product.
5. Advertisement shall not include any 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 unexaggerated presentation of the product.
7. Advertising should be based on the 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 communicated in the wording consistent with the Summary of Product Characteristics.
9. Advertising of a medicinal product shall not decrease confidence in the pharmaceutical industry.
10. Advertising activities shall take into account the special nature of medicinal products as well as professional position of the audience.
11. Advertising shall not be offensive for the audience and shall not refer to feelings by inducing fear or taking advantage of superstition.
12. As for advertising of medicinal products with different composition of active substances, simultaneous presentation of such products in an advertisement shall be acceptable under the condition that the advertisement of each of the presented products meets the requirements set out in the Code and in the provisions of law.
13. Subject to Section 12, presentation of medicinal products with the same active substance but having different pharmaceutical forms in a single advertisement shall be acceptable.

Article 11
Obligatory content of advertisement

1. Promotional material shall include basic information on the drug, in the wording in line with the Summary of Product Characteristics and with the applicable provisions of law, and, should there be no Summary of Product Characteristics available, in line with the documentation approved in the process of granting the marketing authorisation, containing the relevant information. It shall also include the date (at least the month and the year) at which the material was prepared or the date at which the most recent modification of the material was approved.
2. Information on a medicinal product shall be presented in a visible and 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. therapeutic indication or indications for use; however, it shall be possible to present the selected therapeutic indications only, under the condition that the remaining information communicated in the advertisement shall refer to those indications only,
    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. in the case of medicinal products included in the reimbursed drug list — information on the retail price and the surcharge amount to be covered by the beneficiary of healthcare services.

Article 12
Transparency of promotion

1. Promotional materials published, among others, in magazines directly or indirectly financed or cofinanced by a Signatory of the Code, its representative or an entity acting pursuant to an order of the Marketing Authorisation Holder, shall not appear to be independent publications.
2. Materials concerning medicinal products as well as their usage, financed by a Signatory of the Code, shall be explicitly labelled as sponsored, regardless of whether they represent advertisement or not.
3. Clinical assessments, post-marketing monitoring and analysis programmes 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, programmes, 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. For detailed guidelines regarding content of websites see 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 advertising audience to be able to form their 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. Where there is no statistical significance, the following information is required: "difference statistically insignificant" or "SI".

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 the requirements stipulated in Article 15(1)(c) of this Code;
   c. information obtained from advertising audience 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 advertisement

1. 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 only be used 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.
2. Should there be no Summary of Product Characteristics available, information defined under Section 1 shall be provided in line with the documentation approved in the process of granting the marketing authorisation, containing the relevant information.

Article 20
The obligation to disclose data substantiating statements used in advertisement

Marketing Authorisation Holder or his 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 of service of the request for disclosing the said documentation.

Article 21
Comparative advertisement

1. Comparative advertisements shall meet the requirements resulting from the applicable provisions of law, including the Suppression of Unfair Competition Act.
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 advertising audience,
c. the comparison may only be used 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. It shall be permitted to provide samples of only new medicinal products.
2. For the purpose of this Article:
   a. a new medicinal product shall be the product:
      - which is covered by the first marketing authorisation; or
      - which is covered by the marketing authorisation extended to include a new indication.

   b. a new medicinal product shall not be:
      - a new package size; or
      - a product with the same quality content of active ingredients as the previously registered product, but of a different dose or pharmaceutical form provided that the scope of indications as compared to the previously registered medicinal product, has not been extended.

3. A single sample shall not exceed the smallest packaging of a medicinal product, authorised for marketing in the Republic of Poland.
4. Each sample of a medicinal product shall be prominently labelled with the following information: "Free sample – not for sale." The Summary of Product Characteristics should be attached to each sample.
5. The labelling, Patient Information Leaflets and Summaries of Product Characteristics of medicinal products distributed as samples shall be in Polish.
6. Samples of medicinal products may only be distributed to persons authorised to issue prescriptions in response to a written request made to a medical representative or sales representative.
7. It shall be prohibited to distribute samples of medicinal products containing intoxicants or psychotropic substances.

8. It shall be prohibited to provide to one person more than four samples of the same medicinal product within twelve months and to provide samples of a given medicinal product after twenty-four months from the first time this person has made a written request to obtain samples of this medicinal product.
9. The person distributing free samples shall maintain a register of such samples in line with the law in force.
10. Each Signatory of the Code shall implement a supervision system and shall be responsible for ensuring that the samples are distributed in line with the applicable law and the Code. Samples of a medicinal product shall be provided to persons authorised to issue prescriptions solely in order to make it possible for these persons to familiarise themselves with the medicinal product and acquire experience in using that product.

CHAPTER III
MEDICAL SALES REPRESENTATIVES

Article 23
The obligation regarding Medical Sales Representative training

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

Article 24
Responsibilities of a Medical Sales Representative

1. Medical Sales Representatives shall fulfil their responsibilities in line with applicable laws as well as the principles set out in the Code.
2. A Medical Sales Representative shall provide the visited individuals 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 effects of the products.
4. A Medical Sales Representative shall make sure that the frequency, dates as well as duration of visits paid to advertising audience in pharmacies, hospitals and other health care facilities as well as the course of such visits are consistent with the applicable laws, do not cause any difficulties in terms of operation of such facilities and take place upon prior arrangements regarding the date of the meeting.
5. A Medical Sales Representative shall not use any financial incentives in order to make an appointment with the advertising audience.
6. During a visit or while making an appointment, a Medical Sales Representative shall not mislead the advertising audience with regard to his identity or the 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 meeting participants

The criteria for selection of individuals 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 institutions, 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 considered to be extravagant or known for offered entertainment.
3. Signatories of the Code 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, i.e. 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 under Section 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. sports or recreation events).
4. The Signatory of the Code will not ensure or offer to healthcare professionals any meals (neither food nor drinks) whose value calculated per person/meal exceeds during a single meeting:
   a. PLN 200 for meals offered in Poland,
   b. the sum specified by the competent local organization for meals offered outside Poland, or
   c. equivalent of EUR 100 if no maximum sums are specified locally.

   The aforementioned sums include payable tax on goods and services pursuant to the Polish laws or value added tax or other similar tax charged pursuant to the laws of other countries.

Article 28
Promotion of medicinal products outside the Republic of Poland

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

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 the applicable laws of 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. the 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 involved in the study/trial shall not be subject to any additional diagnostic or health monitoring procedures;
   e. patients shall express their written consent to the participation in the trial if 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 where 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 regard to treatment methods they use.
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 exact 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 from the applicable law.
2. It is recommended to submit the trial protocol to the appropriate ethics committee.

Article 32
Responsibility of the Medical Department

1. Signatory's Medical Department shall be responsible for the approval and supervision over non-interventional studies and phase 4 clinical trials. Supervision over such trials shall cover (among other things) revision of all responsibilities related to trials, in particular with respect to any responsibilities of Medical Sales Representatives.
2. An 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 between the Code Signatory financing a trial and healthcare professionals or healthcare organisations 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 the time and workload associated with the research and shall reflect the standards adopted in 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 of Marketing Authorisation Holders.
2. Such information shall include, at least, the following elements:
   a. name of the 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 Section 1 should be coded, i.e. should require entering a login assigned by the appropriate Association to its members and other entities who have signed the Code.
4. Where 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 shall, upon a written request of a Signatory of the Code or its representative, provide, within 21 days, the following:
   a. information referred to in Section 2,
   b. protocol of the trial,
   c. patient documentation form (Case Report Form), if applicable,
   d. a template of a contract to be concluded with the healthcare 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 the 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. The Signatory of the Code should communicate the summary report to all researchers involved in the research project as well as make it available upon request of INFARMA.
3. If trial results are relevant for the assessment of the product, the summary report shall be communicated immediately to the relevant authority. The Medical Department of the 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 or phase 4 clinical trials is allowed provided that 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.
   d. Market research should 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 connected with 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 appropriate training of Medical Sales Representatives. It is recommended that Medical Sales Representatives should not participate in non-interventional studies.

CHAPTER VI
PRINCIPLES REGARDING CONTACTS WITH HEALTHCARE PROFESSIONALS

Article 38
Prohibition of gifts

1. No gift or pecuniary advantage, in cash or benefit in kind, may be supplied, offered or promised to a healthcare professional.
2. The transmission to healthcare professionals of informational or educational materials or objects is permitted provided they meet all of the following conditions:

a. their value does not exceed the gross amount of PLN 100;
b. they are directly relevant to the medical or pharmaceutical practice;
c. they are directly beneficial to the care of patients;
d. they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

3. The transmission to healthcare professionals of items of medical utility is permitted provided that they meet all of the following conditions:
   a. their value does not exceed the gross amount of PLN 100;
   b. they are aimed directly at the education of healthcare professionals and patient care;
   c. they do not minimize the costs of conducting the business activity of the recipient.

Article 39
Donations to the Health Care

1. Donations or other benefits given to healthcare organisations associating healthcare professionals or rendering medical services or conducting research relating to health care are only allowed if:
   a. they are explicitly aimed at supporting 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 specific medicinal products.
2. Donations to individual healthcare professionals are prohibited.
3. It is recommended for a Signatory of the Code to make the information on the above-mentioned donations, grants or other benefits given for the benefit of healthcare organisations publicly 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 the applicable law and the provisions of this Code.
2. It is prohibited to offer a payment as a compensation only for the time devoted by healthcare professionals to participation in the meetings.

Article 41
Services rendered by healthcare organisations to the Signatories

Contracts between the Signatories of the Code and healthcare organisations under which the said organisations render any services to the benefit of the Signatories of the Code shall be allowed only if the said contracts meet all of 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 specific medicinal products.

Article 42
Employing consultants

1. Healthcare professionals may be employed as consultants, advisors or speakers for the provision of services which involve the necessity to pay remuneration and cover other costs associated with the provision of services, e.g. travel costs or other reasonable expenses necessary for the provision of services. 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 Section 1 shall meet all of the following requirements:
   a. a written contract has been signed stipulating the nature of the services 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 identified prior to ordering such services and prior to making arrangements with potential consultants; the consultant selection criteria are directly linked to the identified need, and the persons responsible for the selection have the knowledge necessary for assessing whether particular healthcare professionals meet requirements defined by the said criteria;
   c. the number of service providers shall not exceed the reasonable number of persons necessary for the purpose of satisfying the identified need;
   d. the customer shall maintain appropriate documentation and use the services rendered by the consultants in an appropriate manner; employment of healthcare professionals for the purpose of rendering a particular service shall not be aimed at increasing sales of any medicinal product;
   e. offered remuneration is adequate to the market value or rendered services.
3. Relevant provisions of Chapter IV shall apply to a healthcare professional participating in a meeting referred to in Section 1 of this article as a consultant or advisor, particularly in terms of allowed hospitality.
4. It is recommended to incorporate in contracts with consultants appropriate provisions regarding the consultant's obligation to include a declaration stating that he/she is acting on behalf of a given Signatory of the Code in all his/her presentations, written texts and other forms of contract performance.
5. It is also recommended that where Signatories of the Code hire professionally active healthcare professionals as part-time employees the employment contracts should contain a clause obliging the employee to inform other employers and other persons before whom the employee represents the interests of his/her employer that the employee concluded an employment contract with a given Signatory of the Code.

CHAPTER VII
COOPERATION BETWEEN SIGNATORIES OF THE CODE 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 independence of patient organisations in terms of their activities; opinions expressed by and decisions made by each partner shall be equally 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 the conclusion of a contract in writing.
2. The contract shall stipulate:
   a. the subject-matter of the contract,
   b. the date of signing the contract,
   c. names of the cooperating institutions as well as the name of the third party, if any,
   d. the purpose 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 obligation of the patient organisation to observe the provisions of the Code when performing the contract,
   j. the obligation to provide evidence confirming that the support was used in accordance with 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 above-mentioned restriction shall not refer to correcting substantive errors found in such materials.

Article 47
Transparency

1. Each Signatory of the Code shall make publicly available a list of patient organisations to which it provides financial support or substantial support in kind or other non-financial support.
2. The list referred to in Section 1 above shall include a brief description of the nature of the support provided and its value.
3. As for substantial non-financial support the value of which is difficult to estimate, the description shall indicate the benefit provided to a given patient organisation.
4. The Signatory of the Code shall obtain a written confirmation of the acceptance of the offered support.

5. The information referred to in Sections 1–3 above shall be published on the Signatory's website, and if no such website is available, on the global website of the Signatory's capital group or on the website of INFARMA, and shall be updated at least once a year.

Article 47a
Provisions of services for the Signatory of the Code

1. If the Signatory of the Code uses the services of a patient organisation, the provisions of Article 47 apply accordingly. Each Signatory of the Code shall publish a list of patient organisations whose paid services are used by this Signatory. The following information shall be published: information on the nature of services provided by a given patient organisation and the total remuneration paid to that organisation in the reporting period.
2. Agreements between Signatories of the Code and patient organisations for the provisions of services by those patient organisations shall be permitted only when such services are provided to support health care or research.
3. It shall be permitted to engage patient organisations as experts or advisors for the purpose of such services as for example participation in meetings of advisory bodies or public speeches. Agreements for consulting services or other services shall meet the following criteria:
   a. there is a reasonable need for such services which has been expressly identified and documented prior to ordering such services and prior to making the relevant arrangements;
   b. the service selection criteria are directly linked to the identified need, and the persons responsible for the selection of services have the necessary knowledge for assessing whether particular experts and advisors meet those criteria;
   c. the scope of services does not exceed the scope necessary for the purpose of satisfying the identified need;
   d. a written agreement, stipulating the nature of services and the basis for payment of remuneration for the services, subject to Sub-section g, has been made before the provisions of services;
   e. the customer maintains documentation regarding the services and uses the services in an appropriate manner;
   f. engaging a patient organisation shall not be an inducement to recommend a particular medicinal product;
   g. the remuneration for services is adequate and does not exceed the market value of the services provided;
   h. it is recommended that written agreements with patient organisations include a provision under which they are obliged to disclose the fact that they provide paid services to a Signatory of the Code each time they take a position in public on the matter contemplated by the agreement or on other issues concerning a Signatory of the Code.

Article 48
Promotion prohibition

Signatories of the Code shall not use any patient organisation as a tool for communicating advertising messages pertaining to a prescription-only medicinal product to patients; this shall in particular apply to activities relating to websites, symposia, lectures, convention materials as well as other forms of communication.

Article 49
Principles of financing

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

Article 50
Meetings and hospitality

The principles stipulated in Chapter IV regarding meetings and hospitality also apply to patient organisations.

Article 51
Contributions in kind

In is recommended to support patient organisations with contributions in kind, e.g. in the form of training, assistance in the implementation of educational programmes.

CHAPTER VIII
DISPUTE SETTLEMENT

Article 52
Disciplinary Court

Any disputes which may arise in connection with this Code which cannot be solved amicably and any cases of possible infringement of the Code shall be settled by the Disciplinary Court ("Court") operating at the Employers' Union of Innovative Pharmaceutical Companies INFARMA in accordance with the Statute of INFARMA as well as the Rules of Procedure of the Court.

Article 53
Primary objective of the Court

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

Article 54
Entities entitled to lodge a complaint

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

Article 55
Exclusions from the Court jurisdiction

1. Cases in 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 the infringement of the applicable law as well as the provisions of the Code, the Court shall issue decisions pertaining only to the infringement of the provisions of the Code.

Article 56
Demand to stop further breach

1. The allegedly aggrieved Signatory of the Code may request the defaulting Signatory 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 defaulting party has stopped breaching before the end of the proceedings.

Article 57
Sanctions

1. If any breach of the Code provisions is found, the Court may, considering the type and harmfulness of the breach as well as benefits gained by the defaulting party and whether or not the Court has declared breaching of the Code provisions within the previous 12 months, 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 s 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 affiliated undertakings (hereinafter referred to as the "Headquarters") of the party responsible for breaching the 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 the INFARMA Bulletin.
2. Such information shall include in particular:
   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, the content of the published information shall be decided by the Court in the conclusion of the decision.

CHAPTER IX
IMPLEMENTING PROVISIONS

Article 59
Compliance with the provisions of the Code

1. Each Signatory of the Code shall keep a signed copy of the Code in its records.
2. Each 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 above-mentioned personnel shall include a physician or, if necessary, a pharmacist with sufficient knowledge for deciding whether a given promotional material meets the requirements stipulated in the Pharmaceutical Law as well as in this Code.
4. Each Signatory of the Code should appoint at least one senior employee to be responsible for supervision over the compliance with 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 Section 4 shall be communicated to INFARMA within 30 days of the date at which this Code came into force. Within the same period of time, the Signatory shall report any changes in this regard.
6. The Representative shall verify the final version of the promotional material and confirm its compliance with the requirements of the Code and relevant laws pertaining to advertising, and 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 the compliance of activities of the Marketing Authorisation Holder with the 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 under the Code;
   c. upon request of the Court of INFARMA, shall provide the Court with access to any information and advertisements of medicinal products published by the Signatory;
   d. ensure that the final and binding decisions of the INFARMA Court are immediately and fully implemented by the entity carrying out advertising activities.

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 in the form set out in Appendix 2 to this Code.
3. Accession document shall be submitted to INFARMA or to the social organisation being a party to the Code where the acceding pharmaceutical company is a member of that organisation. if an acceding pharmaceutical company is not a member of any organisation being a party to the Code or if a social organisation is acceding to the Code, the above-mentioned accession document may be submitted to 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 acceded to the Code as well as of the accession date.
5. An organisation being a party to the Code shall maintain and update a list of all entities which have acceded to the Code as well as make the list available, including via its own website.

6. Accession to the Code shall result in the termination of the Code of Marketing Ethics for the Pharmaceutical Industry currently binding upon the member of INFARMA without the necessity to submit any additional statements.

Article 61
Termination of the Code

Each party may terminate the Code with a 30 days' notice by notifying:

a. in relation to businesses, the social organisation which accepted the accession declaration;
b. in relation to social organisations, all the other organisations being parties to the Code.

Article 62
Amendments to the provisions of the Code

1. Amendments to the Code shall be accepted by simple majority of voting Signatories.
2. Proposals of amendments to and supplements of the Code may be submitted 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. A Signatory's failure to communicate its opinion within one month from the date of receiving the above-mentioned proposal shall be equivalent to the acceptance of the amendment or supplement without any objections.
5. 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 Section 4.
6. Amendments and supplements approved in line with this article shall enter into force on the date agreed by the Signatories and stipulated in the notice referred to in Section 5, yet not sooner than 14 days from the date of dispatch of the notice.

Appendix 1

GUIDELINES REGARDING WEBSITES ACCESSIBLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND GENERAL PUBLIC IN 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 to the extent permitted by the Pharmaceutical Law.

   i. General information about the Signatory of the Code. Websites may contain information that investors, media or general public might be interested in, i.e. financial data, descriptions of research and development programmes, regulatory issues affecting the Signatory of the Code and its products, information for potential employees, etc. The content of the above-mentioned information shall not be subject to these guidelines or provisions of the Act on Advertising Medicinal Products.

   ii. Information on health education. Websites may include non-advertising information relating 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 the Code. Such information shall be explicitly identified as information intended for healthcare professionals as well as appropriately secured against access by persons unauthorised to receive such information.

   iv. Non-advertising information for patients and general public. Subject to any applicable laws, websites may contain non-advertising information intended for patients and general public on products offered by a given Signatory of the Code (including but not limited to information on their indications, side effects, interactions with other medicinal products, appropriate usage, clinical trial reports, etc.), provided that such information is balanced, precise and consistent with the approved Summary of Product Characteristic. 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 website 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 national authority. Trade names should be accompanied by international nonproprietary names. A website may include links to other websites containing reliable information on medicinal products, including but not limited 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). A Signatory of the Code 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. If any 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 Signatory of the Code may include links to websites financed by other entities yet the Signatory of the Code should not create links between websites intended for general public and websites financed by the Signatory of the Code which are intended for healthcare professionals. Similarly, links to separate websites may be created, including to websites financed by the Signatory of the Code or other entities. Such links should redirect 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.** Signatories of the Code should make sure that scientific and medical information prepared by them with the intention of publishing it on their websites has been verified in terms of accuracy and consistency with the Code. This may be the task of the Medical Department, or other appropriately trained persons.

5. **Protection of privacy.** A website shall be consistent with the law and 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 PRACTICES

I, the undersigned _____ ,
(*name of the person(s) authorised to represent the member of INFARMA acceding to the Code)*, acting on behalf of _____
(name of the represented member of INFARMA), registered
in _____(name of the register*)* under
_____*(registration number*), having read and understood the Pharmaceutical Industry Code of Good Practices ("Code"), acting pursuant to Article 60(2) of the Code, hereby submit
this declaration of accession to the Code in accordance with the principles set out therein.

Date: _____

Signature: _____

Position, name of the member of INFARMA/acceding entity:
_____