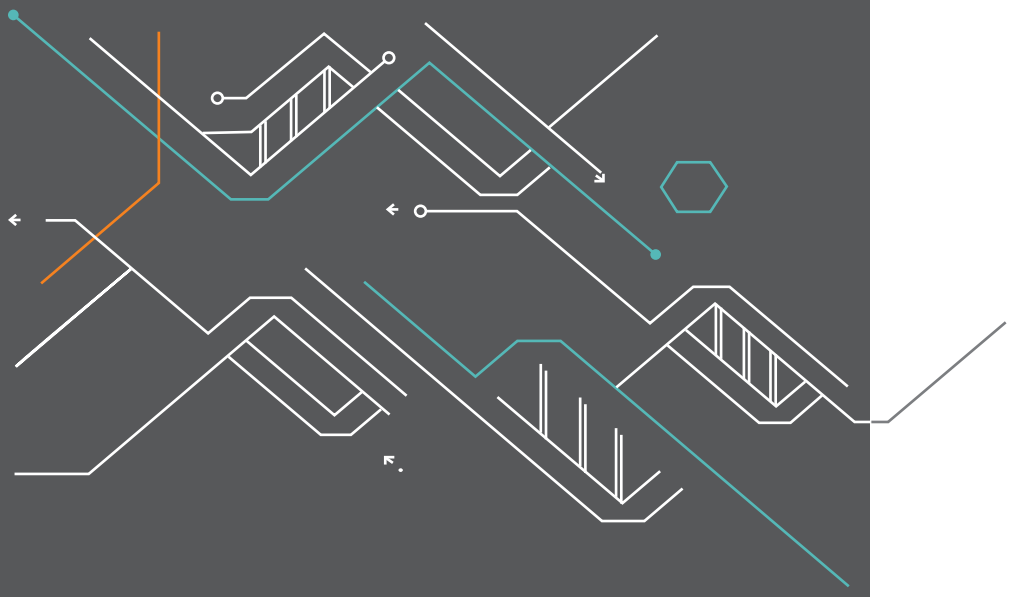

The Pharmaceutical Industry

Code of Good Practices

version of the amendment, 2019

INFARMA
Związek Pracodawców
Innowacyjnych Firm Farmaceutycznych


MEDICAL
Health Care
Doctor
Hospital
Pharmacist
Nurse
Dentist
First Aid
Surgeon
Emergency

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 with regard to the administration of medicinal products, has approved the Code of Good Practice of the Pharmaceutical Industry (hereinafter referred to as the "**Code**").

Summary

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, Healthcare Organisations and Patient Organisations:

non-interventional studies 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:
   1) "**Advertising Audience**" shall refer to a person authorised to issue prescriptions or a person trading in medicinal products;
   2) "**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 study group in which the method of treatment is specified not on the basis of a study protocol, but depends on current practice, while the decision to administer the drug is unambiguously separated from the decision to include the patient in the study;
      c) patients do not receive any additional diagnostic or monitoring procedures, while epidemiological methods are used to analyse the data gathered.
   3) "**Donations**" – donations, grants and other services provided free of charge, including funding and physical benefits;
   4) "**Code**" – this Code of Good Practice of the Pharmaceutical Industry;
   5) "**Penal Code**" – the Penal Code of 6 June 1997 (Journal of Laws of 1997, No. 88, item 553, as amended);
   6) "**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

      – with their registered offices in Europe. Entrepreneurs conducting wholesale or retail trade of medicinal products are not considered Healthcare Organisations;
   7) "**Patient organisation**" shall refer to entities associating patients or carers representing or supporting patients or organisations associating such entities;
   8) "**Pharmaceutical Law**" – the Pharmaceutical Law of 6 September 2001 (Journal of Laws of 2008, No. 45, item 271, as amended);
   9) "**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;

10) "**Healthcare Professional**" 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.

    Persons employed by a Signatory of the Code under employment contracts or civil law contracts, whose main occupation is practising the professions specified in a) or b) above shall also be considered Healthcare Professionals.
11) "**Representative**" shall refer to a senior employee designated by a Signatory of the Code who is responsible for monitoring compliance with the Code by the Signatory of the Code, its employees and associates;
12) "**Court**" shall mean the disciplinary Court operating at the Employers' Association of Innovative Pharmaceutical Companies INFARMA;
13) "**Signatory of the Code**" –
    a) a member of INFARMA,
    b) other entities which have accepted the Code in accordance with Article 60 of the Code;
14) "**Personal Data Protection Act**" – the Personal Data Protection Act of 29 August 1997 (Journal of Laws of 2015, item 2135, as amended);
15) "**Act on the Electronic Provision of Services**" – the Act on the electronic provision of services of 18 July 2002 (Journal of Laws of 2013, item 1422, as amended);
16) "**Act on Combating Unfair Competition**" – the Act on combating unfair competition of 16 April 1993 (Journal of Laws of 2003, No. 153, item 1503, as amended);
17) "**Events**" shall refer to information, promotional, scientific or professional meetings, congresses, symposia and other such events, including inter alia meetings of advisory bodies, visits to research institutions and production sites, meetings of investigators, meetings on planning, training and other issues regarding clinical or non-interventional studies, organised or sponsored by, on behalf of or on contract to a Signatory of the Code;
18) "**INFARMA**" shall mean the Employers' Association of Innovative Pharmaceutical Companies INFARMA.

2. 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;
3. the term "**good customs**" shall be understood as good practices in accordance with the interpretation of this concept under the Act on Combating Unfair Competition.

Article 3
Precedence of the statutory law

1. The provisions of the generally applicable law governing the issues constituting the subject matter of the regulations of this Code shall always take precedence over the provisions of the Code.
2. If the provisions of the generally applicable law provide for more stringent requirements regarding matters constituting the subject matter of the regulations of this Code, the Signatory of the Code undertakes to satisfy these requirements at the same time, as far as possible in compliance with the provisions of the Code. If the provisions of the applicable law provide for less stringent requirements with regard to the matters constituting the subject matter of the regulations of this Code, this shall not rule out the obligation of the Signatories of the Code from applying the provisions of the Code.

3. The provisions of the Code shall supplement the 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 (OJ. L 311, 28.11.2001, p.67), as well as the provisions of the Pharmaceutical Law and the secondary regulations issued on its basis.

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;
c. good practices of cooperation with Healthcare Professionals, Healthcare Organisations and Patient Organisations;
d. good practices regarding transparency of websites, owned, administered or sponsored by the Signatories of the Code.

Article 5
Objective applicability of the Code

1. The provisions of the Code shall apply to the following:
    a. advertising of prescription-only medicinal products, in particular: verbal or written communication, advertisements in magazines, correspondence, measures undertaken by Representatives, measures undertaken using the Internet and other means of electronic communication, application of audiovisual systems, provision of samples and hospitality to Healthcare Professionals;
    b. the provision of materials or items of an educational or information nature, as well as items intended for performing a medical or pharmaceutical practice by Healthcare Professionals;
    c. non-interventional trials and studies using medicinal products authorised for marketing;
    d. 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 being conducted or other relations arising from concluded contracts;
    e. cooperation between Signatories of the Code and Patient Organisations;
    f. websites owned, administered or sponsored by a Signatory of the Code.
2. The provisions of the Code do not apply to the following:
    a. advertising of non-prescription medicinal products;
    b. information contained on packaging and attached to the packaging of medicinal products in compliance with the marketing authorisation;
    c. information related to the business of a Signatory of the Code, including financial data, descriptions of research and development programmes, discussion of strategies for regulatory developments affecting a Signatory of the Code and his products, in particular information for investors and current or potential company employees of a Signatory of the Code provided that they do not simultaneously constitute advertising of a medicinal product;
    d. non-promotional correspondence, the objective of which is to provide answers to a specific question about a specific medicinal product;
    e. informative announcements not directed to the public, relating, in particular, to a change of packaging, adverse reactions warnings, provided that they do not include product claims;
    f. information on human and animal health or diseases, provided that this does not, even indirectly, refer to medicinal products;

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 on which they signed the statement of accession to the Code, the specimen of which is attached as Appendix 1 to the Code and for members INFARMA – on the date on 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 the operations of their employees, Representatives and third parties acting on their behalf with regard to the activities covered by the regulations of the Code, in particular: consultants, entities conducting market research and training, as well as advertising agencies.
2. Signatories of the Code shall make every effort to ensure that the companies from its group, as well as entities which are operating on its behalf or on contract to it with respect to activities covered by the regulations of the Code, respect the provisions of the Code.
3. The personnel of a Signatory of the Code, as well as anyone for whose activities a Signatory of the Code is responsible under this Article, shall be trained on the applicable provisions of the law and provisions of the Code.

CHAPTER II
ADVERTISING AND PROMOTION OF MEDICINAL PRODUCTS

Article 8
Advertising audience

1. Subject to the provisions of the generally 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.
2. Advertising of a medicinal product should be addressed exclusively to such Advertising Audiences where it is reasonable to assume they require such advertising and are interested in it.
3. If advertising of medicinal products is addressed to physicians performing public functions within the meaning of Article 115 § 19 of the Penal Code, in particular: national consultants, province consultants, director of a hospital or head of a hospital ward, 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, must be consistent with the provisions of the Personal Data Protection Act and the Act on the Electronic Provision of Services.
2. Promotional content may only be sent by electronic means of communication at the request of or with the consent of the Advertising Audience.
3. 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 data subject in accordance with the provisions of the Personal Data Protection Act.

Article 10
General principles of advertising and promotion

1. Advertising of a medical product shall be conducted in line with applicable laws and good customs as well as with the observance of high ethical standards.
2. Advertising of a medicinal product is allowed only after obtaining marketing authorisation in the Republic of Poland and shall be conducted in line with the information contained in the Summary of Product Characteristics. The above-mentioned condition shall not limit the right to full information on research and medical progress provided that it does not have the features of an advertisement.
3. Advertising of a medicinal product shall not mislead, in particular through distortion, exaggeration, improper suggestion, omission, ambiguity or in any other way. This especially applies to the medicinal product's properties or method of action.
4. An advertisement of a medicinal product shall present the medicinal product objectively, without exaggeration and shall provide information about its rational use. Claims contained in the advertisement shall not suggest that the medicinal product or its active ingredient have unique properties or quality, if such claims cannot be justified.
5. Advertising of a medicinal product shall be consistent with the Summary of Product Characteristics.
6. Advertising of a medicinal product shall not decrease confidence in the pharmaceutical industry.

7. Advertising activities shall take into account the special nature of medicinal products as well as the professional position of the Advertising Audience.
8. Advertising shall not be offensive to the Advertising Audience and shall not refer to the feelings of the Advertising Audience by inducing fear or taking advantage of superstition.
9. In the case of advertising of medicinal products with different compositions of active ingredients, the simultaneous presentation of such products in an advertisement is acceptable under the condition that the advertisement of the presented products meets the requirements set out in the Code and in the generally applicable provisions of the law.
10. The presentation of medicinal products with the same active ingredient but having different pharmaceutical forms in a single advertisement is acceptable.

Article 11
Obligatory content of advertisement

1. Advertising material shall contain basic information on the medicinal product, in line with the Summary of Product Characteristics and with the applicable provisions of the law.
2. The advertising material must include at least the following data on the advertised medicinal product:
   a. the name of the medicinal product, as well as its commonly used name;
   b. the qualitative and quantitative composition with reference to active ingredients, as well as the excipients in the case of which such information is crucial for proper administration;
   c. the pharmaceutical form;
   d. the therapeutic indication or indications for use; however, it is possible to present the selected therapeutic indications only, under the condition that the remaining information communicated in the advertisement refers to those indications only;
   e. the dosage and administration method;
   f. the contraindications;
   g. special warnings and precautions regarding use;
   h. adverse reactions;
   i. information on the Marketing Authorisation Holder;
   j. the 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 the healthcare services.
3. The information referred to in section 2 of this Article must be presented visibly and legibly.
4. The obligation to include the information referred to in section 2 of this Article does not apply to recall advertising, provided that the recall advertising only contains the name of the medicinal product or the trademark without containing references to therapeutic indications, the pharmaceutical form, the dose, advertising slogans or other advertising content.

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 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 patients' requests for health advice shall be limited to a recommendation to consult a physician.

Article 14
Transparency of websites

1. The content of a website which is owned, administered or sponsored by a Signatory of the Code, shall explicitly indicate:
   a. the name and address (including e-mail) of the Signatory of the Code;
   b. the source or author of the information as well as the date of publication on the website;
   c. the target audience of the website (e.g. Healthcare Professionals, patients and the general public or both groups at the same time);
   d. the objective of the website.
2. For detailed guidelines regarding the content of the websites see Appendix 2 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 medicinal product advertised;
   b. should be based on an up-to-date assessment of the relevant reference materials and clearly indicate those 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 (abstracts) published in indexed scientific magazines (e.g. supplements). Such data shall be communicated consistently with the original materials indicating their source and publication date.

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 taken from specialist publications or scientific magazines shall be communicated consistently with the original, indicating their source as well as the publication date or the date of the most recent revision, and, in particular:

a. the results of trials, scientific news and abstracts shall not be used in a fashion which might evoke an 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 give an inappropriate or erroneous impression regarding their clinical value;
c. the course of the trial referred to in an advertisement should be described in an explicit and unambiguous fashion;

d. a comparison of the effects of various medicinal products or comparison of the 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".
e. this data may be provided on condition that the advertisement of a medicinal product containing them is not in conflict with the Summary of Product Characteristics.

Article 17
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 session or Event 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 the Healthcare Professionals 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 and contains explicit information about the principal of the market research.

Article 18
Quotations in advertisements

1. Quotations, tables and other illustrations obtained from published medical studies, medical or scientific literature to be used in advertisements shall:
   a. be faithfully reproduced, except where their adaptation or modification is required for the advertisement to remain in compliance with the provisions of the Code and it is simultaneously clearly indicated that these materials have been adapted or modified;
   b. precisely specify the source of their origin.
2. Special care must be taken to ensure that the materials contained in the advertisement are not misleading with regard to the nature of the product (e.g. whether it can be administered to children), claims about it or comparisons (e.g. through the use of incomplete or not statistically significant information or an atypical scale).
3. The use of a model of quotation suggested by indexed medical magazines is recommended.
4. Quotations, figures or charts obtained from research papers used for the purpose of comparing medicinal products shall not be misleading or be used to discredit a competitive medicinal product.
5. Quotations from specialist magazines, tables and other illustrations used in advertisements shall not create the erroneous impression that the research or documentation were developed for another, competitive medicinal product, e.g. a generic.

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 the composition, active ingredients, properties, effects of the 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", the expression "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 frequently prescribed" only if there is up-to-date statistical evidence confirming these statements and the conditions specified in Article 17, item c) of the Code have been satisfied;
d. the term "new" may only be used with reference to a medicinal product whose composition includes an active ingredient or a mixture of active ingredients 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 arise as to the terms used;
i. the word "safe" shall not be used unless its usage is appropriately substantiated.

2. An advertisement shall not contain information suggesting that the use of the medicinal product does not have any adverse effects, a risk of poisoning or risk of addiction.

Article 20

The obligation to disclose data substantiating statements used in advertisement

The Marketing Authorisation Holder or his representative shall disclose the documentation constituting the source of the data contained in the advertisement in response to the written request of the Advertising Audience, the Marketing Authorisation Holder or its representative, within 21 days of service of the request to disclose the documentation. In particular, the claims contained in the advertisement regarding the adverse effects should reflect the available scientific data or be justifiable on the basis of clinical experience. Justifications are not required of claims contained in the advertisement regarding items contained in the approved Summary of Product Characteristics.

Article 21

Comparative advertisement

1. Comparative advertisements shall meet the requirements arising from the generally applicable law, including the Act on Combating Unfair Competition.
2. Comparative advertisements shall cumulatively satisfy all of the following conditions:
   a. they must provide the name, pharmaceutical form, as well as dosage of the medicinal products compared;
   b. they cannot be misleading;
   c. they only compare medicinal products with the same properties or in the same indications reliably and in a manner which can be checked on the basis of objective criteria;
   d. the comparison shall refer to specific qualities of the medicinal products compared supported by research results; it should be objective, reliable and verifiable; the ability to check the information included in the comparison needs to be assured through the provision of the source of the information presented, together with the date of the publication or the last update;
   e. the comparison shall refer to one or several significant, characteristic, typical and verifiable qualities, including the price of the medicinal products compared;

f. the comparison of selected qualities of medicinal products shall not be misleading in terms of characteristics of the medicinal products compared, as well as the qualities not included in the comparison; it shall not make the medicinal products, their trademarks, company logos or other distinctive features indistinguishable;
g. they shall not discredit the competitive medicinal product or Marketing Authorisation Holder;
h. they shall not present a medicinal product as an imitation or copy of a product labelled with a registered trademark or another distinguishing mark.
i. the reputation of the trademark, the enterprise's marking or the markings distinguishing the competitor shall not be used dishonestly.

Article 22
Samples

1. It is permissible to provide samples of only new medicinal products.
2. For the purposes of this Article:
   a. a medicinal product shall be considered new:
      – for five years from the first placement of the product onto the market in Poland or
      – if it is covered by a marketing authorisation, which is extended to include a new indication, for five years from the date on which the decision extending the marketing authorisation to include the new indication becomes effective.
   b. a medicinal product shall not be considered new:
      – if it is a different dose or pharmaceutical form or new package size of a previously approved medicinal product unless the scope of indications compared to the previous marketing authorization, has 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, persons authorised to prescribe the specific medicinal product being advertised, in response to a written request made to the Marketing Authorisation Holder or entity operating on contract to it.
7. It is prohibited to distribute samples of medicinal products containing intoxicants or psychotropic substances.
8. It is prohibited to provide more than four samples of the same medicinal product to one person within a calendar year and to provide samples of a given medicinal product after two years from the first time this person made a written request to obtain samples of the given medicinal product. The maximum number of samples of the same medicinal product provided to one person shall not exceed eight samples.
9. The person providing free samples shall keep a register of such samples in line with the provisions of the law.
10. Each Signatory of the Code shall implement an appropriate supervision system and shall be responsible for ensuring that the samples are distributed in line with the provisions of the law and the Code. Samples of the 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
REPRESENTATIVES

Article 23
Obligation regarding training of the Representative

The Representatives of the Signatory of the Code, including the personnel acting for the Signatory of the Code under contracts with third parties and all other persons who pay visits to the Advertising Audience on behalf of the Signatory of the Code at pharmacies, hospitals and other healthcare facilities, in order to promote the medicinal products, must be trained on the provisions of the generally applicable law, as well as the provisions of the Code and must have sufficient medical knowledge to be able to provide accurate and complete information on the medicinal products they are advertising.

Article 24
The Representative's responsibilities

1. Representatives shall fulfil their responsibilities in accordance with the provisions of the law, as well as the principles set out in the Code reliably and ethically.
2. The Representative shall provide the Summary of Product Characteristics for the presented medicinal product or make it available to the Advertising Audience visited.
3. The Representative shall immediately provide the Marketing Authorisation Holder for the given product or its representative in the Republic of Poland with any new information regarding the application of the medicinal products, in particular their adverse effects.
4. The Representative shall make sure that the frequency, dates as well as duration of visits paid to the Advertising Audience in pharmacies, hospitals and other healthcare facilities, as well as the course of such visits are consistent with the applicable laws, do not cause any difficulties in the work of such facilities and take place upon prior arrangement of the time of the meeting.
5. The Representative shall not use any forms of incentive to make an appointment with the Advertising Audience.
6. During a visit or while making an appointment, the Representative shall not mislead the Advertising Audience as to his identity or the identity of the Marketing Authorisation Holder he represents.

CHAPTER IV
PRINCIPLES OF ORGANISING SYMPOSIA, CONGRESSES AND OTHER EVENTS

Article 25
Objectivity of the criteria for selecting participants of Events and prohibition to use incentives

1. The criteria for selecting individuals to be invited to an Event shall be objective and based on substantive factors.
2. The Representative shall not use any forms of incentive with respect to the persons referred to in section 1 to encourage their involvement in the Event.

Article 26
Venues of events

1. Events organised or financed by or on behalf of a Signatory of the Code must be held at a venue which is appropriate for the main purpose of the Event.
2. Events shall not be held at venues considered to be extravagant or famous for the entertainment offered.
3. The Signatories of the Code shall not organise or finance, directly or indirectly, meetings held abroad, unless this is justified by important substantive or organisational reasons, particularly if the majority of invited participants are from outside of the country where the Event is to be held.

Article 27
Hospitality

1. Hospitality offered to participants of Events should not be excessive and shall be directly related to the basic objective of the Event, i.e. it should be limited to covering the following expenses: travel, board and lodging, as well as registration fees related to participation in the Event. When analysing the justification of the level of hospitality offered, conditions should be accepted in which the average participant of the Event would be inclined to accept on his own.
2. The costs referred to in section 1 should only include the costs of the participants of the Event and not their companions or family members, unless the companions are also authorised to issue prescriptions and have been invited to the Event independently on the basis of objective substantive criteria.
3. Hospitality shall not include financing or organising entertainment during the Event (e.g. sports or recreation events). The Signatory of the Code shall not provide or offer Healthcare Professionals any meals (either food or drink), the value of which per person per meal exceeds:
   a. PLN 200 for meals offered in Poland or
   b. the sum specified by the competent local organisation for meals offered outside Poland, or
   c. the equivalent of EUR 100 if no maximum sums are specified locally.

   The aforementioned sums include output tax on goods and services pursuant to Polish law 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

In the case of international Events, all materials or information provided 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 Event is being held.

CHAPTER V
NON-INTERVENTIONAL STUDIES AND OTHER STUDIES

Article 29
Principles of conducting non-interventional studies

1. Non-interventional studies conducted with the use of a medicinal product authorised for marketing shall be conducted in accordance with the appropriate provisions of Polish law and the principles specified in this chapter.
2. Non-interventional studies encompassing the collection of patient data by individual Healthcare Professionals, must satisfy the following requirements:
   a. the study must have a specific scientific objective;
   b. there is a written study protocol;
   c. the medicinal product is used in the study in compliance with the marketing authorisation;
   d. patients are assigned to a particular study group in which the method of treatment is specified not on the basis of a study protocol, but depends on current practice;
   e. the decision to administer the drug is unambiguously separated from the decision to include the patient in the study;
   f. the patient involved in the study/trial shall not be subject to any additional diagnostic or health monitoring procedures;
   g. patients shall express their written consent to their participation in the trial if the trial procedure requires access to source documents on the part of the sponsor's representative;
   h. epidemiological methods are used for analysing the data collected.
   i. the study is conducted with respect for the right of the study participants to the protection of their personal data.

Article 30
Transparency of studies

1. Conducting non-interventional Studies or the trials/studies referred to in Article 36 constituting a form of subliminal advertising and an enticement to recommend, prescribe, purchase or use a given medicinal product is prohibited.
2. Non-interventional Studies or the trials/studies referred to in Article 36 shall not be used for the purpose of exerting an influence on physicians regarding the treatment methods they use.

Article 31
The obligation to conduct trials and studies in line with the protocol

Non-interventional studies shall be conducted in accordance with the trial protocol stipulating the exact number of patients and the observation time.

Article 32
Responsibility of the Medical Department

1. The Medical Department of the Signatory of the Code is responsible for approving and supervising non-interventional studies. Supervision over such trials encompasses (among other things) the verification of all responsibilities related to these trials.

2. An appointed person from the Medical Department shall confirm that he/she has examined the protocol of the non-interventional study and believes that it meets the requirements of the 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
Publication of information on the start of a Non-interventional Study

1. Information on starting a non-interventional Study shall be provided forthwith (no later than on the date on which the first patient is taken under observation) to INFARMA, which shall post it in its website that is only available to the Signatories of the Code.
2. Such information shall include, at least, the following elements:
   a. the name of the Signatory of the Code financing the trial;
   b. the title of the trial;
   c. the objective of the trial;
   d. the planned number of patients, if applicable;
   e. the duration of the trial;
   f. the patient observation time, if applicable;
   g. the planned date of the first visit of the first patient and the date of the last visit of the last patient, if applicable.
3. Access to the information referred to in section 1 should be encoded by the requirement to enter a username assigned by INFARMA to its members and other entities who have joined the Code.
4. Where a non-interventional Study is not communicated in accordance with this Article, on the written request of a Signatory of the Code, the entity responsible for organising the trial shall, provide the following within 21 days:
   a. the information referred to in section 2;
   b. the protocol of the trial;
   c. the patient documentation form (Case Report Form), if applicable;

   a specimen contract with the investigator or the Healthcare Organisation conducting the trial.

Article 35
Concluding a trial/study, results of non-interventional Studies

1. The results of the non-interventional Studies shall be analysed and prepared in the form of a final report for the Medical Department of the Signatory of the Code no later than 12 months from the end of the observation of the last patient and published no later than 24 months from the end of the observation of the last patient.
2. The Signatory of the Code shall send the summary report to all investigators involved in the study and make it available at the request of INFARMA.
3. If the results of the study are important for assessing the relationship of the benefits to the risk of using the product, the summary report shall be provided forthwith to the relevant authority.

The Medical Department of the Signatory of the Code shall keep an archive file of reports referred to in this Article.

Article 36

Conditions for conducting other studies

Conducting trials other than non-interventional Studies is admissible provided that they belong to one of the following categories:

a. epidemiological studies, understood as studies 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 the preparation of an economic assessment of specific therapeutic, preventive and diagnostic procedures as well as procedures modifying physiological functions, including pharmacoeconomic studies;
d. market research should be conducted by independent entities and shall not constitute subliminal advertising. It is admissible not to disclose the principal's name to the respondent, but the branch of industry in which the sponsor operates must be disclosed.

Article 37

Representatives in non-interventional studies

1. Representatives may participate in non-interventional studies only for the purpose of performing administrative functions.
2. The participation of Representatives in studies shall not be related to the advertising of a medicinal product and shall be supervised by the Medical Department (or its equivalent) of the Signatory of the Code which shall provide appropriate training to the Representatives.

CHAPTER VI
PRINCIPLES REGARDING CONTACTS WITH HEALTHCARE PROFESSIONALS

Article 38[1]
Objective of contacts with Healthcare Professionals

The objective of all contacts with Healthcare Professionals should be to increase their knowledge of the medicinal products that are available on the market to the extent permissible by the generally applicable provisions of the law or to improve the quality of care over patients. Similarly, all direct and indirect financial flows, as well as any economic or personal benefits provided to Healthcare Professionals may only serve this purpose and take place in compliance with the generally applicable provisions of the law; in particular, they cannot determine therapeutic decisions made by the Healthcare Professionals.

Article 38
Prohibition of gifts

1. No gift or monetary benefits, in cash or in kind, may be given, offered or promised to Healthcare Professionals.
2. Informational or educational materials or objects may be provided to Healthcare Professionals if they satisfy all of the following conditions:
   a. their value does not exceed the gross amount of PLN 100;
   b. they are directly related to the medical or pharmaceutical practice;
   c. they are directly beneficial to the care of patients;
   d. they do not bear the name or logo of a medicinal product;
   e. they bear the logo of the Signatory of the Code;
   f. they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.
3. Items intended for use in the medical or pharmaceutical practice or objects may be provided to Healthcare Professionals if they satisfy all of the following conditions:
   a. their value does not exceed the gross amount of PLN 100;
   b. their objective is directly the education of Healthcare Professionals and patient care;
   c. they do not reduce the routine costs of running a medical or pharmaceutical practice.
   d. they do not bear the name or logo of a medicinal product;
   e. they bear the logo of the Signatory of the Code; they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.
4. It is admissible to provide pens, notepads, bags or files of negligible value bearing only the company-'s logo, which are used to take notes at meetings with the Healthcare Professionals, the exclusive organiser of which the Signatory of the Code.

Article 39
Donations to the Healthcare Organisations

1. Donations or given to Healthcare Organisations are only allowed if:
   a. they are explicitly intended to support healthcare or research;
   b. they are documented and the documentation is kept by the donor;
   c. they are not incentives to recommend, prescribe, purchase, supply, sell or use specific medicinal products.

2. Donations to individual Healthcare Professionals are prohibited. This does not apply to donations which are admissible by the provisions of the Pharmaceutical Law and the provisions of the Code.

Article 40
Sponsorship of Healthcare Professionals

1. Sponsorship, by a Signatory of the Code, of a given Healthcare Professional's participation in an international Event shall be consistent with the generally applicable provisions of the law and the provisions of the code in force in the country in which the given Healthcare Professional practices his/her profession and not in the country in which the Event takes place.
2. It is prohibited to offer a fee as compensation only for the time devoted by the Healthcare Professionals to participation in the Event.

Article 41
Services rendered by Healthcare Organisations to the Signatories of the Code

Contracts between the Signatories of the Code and Healthcare Organisations under which the said Healthcare Organisations provide any type of service to the Signatories of the Code shall be allowed only if they satisfy all of the following conditions:

a. they apply to activities supporting healthcare 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 or advisers on the provision of services which involve the need to pay remuneration and cover other costs related to the provision of services, e.g. travelling expenses or other reasonable expenses which need to be incurred for the performance of the agreement. In particular, such services may apply to the following: speeches or presiding over Events, involvement in medical or scientific studies/research, clinical trials, training, participation in meetings of advisory bodies or participation in market research.
2. The cooperation referred to in section 1 shall satisfy all of the following conditions:
    a. a written or documented contract is signed before providing the services, stipulating the nature of the services to be provided, as well as the grounds for making payment for the services;
    b. there is a reasonable need for providing such services which has been clearly identified before ordering such services and before making arrangements with potential consultants;
    c. the consultant selection criteria are directly related to the identified need, while the persons responsible for the selection have the knowledge required for assessing whether given Healthcare Professionals meet these criteria;
    d. the number of service providers shall not exceed the reasonable number of persons required for the purpose of satisfying the identified need;
    e. the signatory of the Code shall keep appropriate documentation and shall appropriately use the services provided by the consultants;
    f. the employment of Healthcare Professionals for providing a given service shall not be an inducement to recommend, prescribe, purchase, procure, sell or use the medicinal products;
    g. the fee offered is appropriate to the market value of the services provided.

3. The relevant provisions of Chapter IV shall apply to a Healthcare Professional participating in an Event as a consultant or adviser, particularly in terms of admissible hospitality.
4. It is recommended that contracts with Healthcare Professionals incorporate appropriate provisions obligating the Healthcare Professional to include a declaration stating that he/she has entered into a contract with the Signatory of the Code in all his/her public appearances or written works with regard to matters constituting the subject matter of the contract.
5. Where Signatories of the Code hire professionally active Healthcare Professionals as part-time employees, it is recommended that the contracts contain a clause obligating the hired person to provide information that he/she is employed by the given Signatory of the Code in public appearances or written works regarding the subject matter of the employment. There should be also an obligation to inform other employers and other persons, to whom the employee represents the interests of his/her employer, of the contracted employment in question. Such an obligation exists regardless of the nature of the matters which constitute the subject matter of the employment, namely regardless of whether or not they are related to the advertising of the medicinal product.

It is recommended that contracts concluded by and between Signatories of the Code and Healthcare Professionals contain an obligation of the Healthcare Professional to obtain the consent of his/her employer or the entity to which it continuously provides services to taking up the cooperation specified in the contract, with particular account taken of the need to avoid conflicts of interest.

CHAPTER VII
COOPERATION BETWEEN SIGNATORIES OF THE CODE AND PATIENT ORGANISATIONS

Article 43
General principles

1. The 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. The cooperation shall not apply to the advertising of prescription-only medicinal products.
3. The objectives and 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. The provision of financial and non-financial support, directly or indirectly (e.g. through a third party) to a Patient Organization requires the conclusion of a contract in writing.
2. The contract shall stipulate:
   a. the subject matter of the contract;
   b. the date of conclusion of the contract;
   c. the names of cooperating institutions and a third party, if applicable;
   d. the purpose of the support;
   e. the amount or value of the support;
   f. the responsibilities of the parties;
   g. the terms and conditions of the contract;
   h. a description of the support to be provided;
   i. the obligation of the Patient Organisation to observe the Code when executing 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. The use of a Patient Organisation's logo or materials publicly by the Signatory of the Code requires the written consent of the Patient Organisation.
2. When requesting consent to the public use of the Patient Organisation's logo or materials, the objective and the manner of their use must be explicitly defined.

Article 46
Content of materials

1. The Signatory of the Code shall not influence the content of the materials provided by the Patient Organisation it is sponsoring in a manner which exerts a positive influence on its own business interests.
2. The above-mentioned restriction shall not encompass the right of the Signatory of the Code to correct substantive errors found in the materials of the Patient Organisation.

3. At the request of the Patient Organisation, the Signatory of the Code may work with the Patient Organisation on the preparation of the materials on condition that such an influence of the Signatory of the Code on the materials is honest and balanced from the scientific point of view.

Article 47
Transparency

1. Each Signatory of the Code shall make a list of Patient Organisations, to which it provides financial or non-financial support, publicly available.
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. In the case of non-financial support, the value of which is difficult to estimate, the description shall indicate the benefit provided to the given Patient Organisation.
4. The Signatory of the Code shall obtain from the Patient Organizations a written confirmation of the acceptance of the offered support.
5. The information referred to in sections 1–3 above shall be posted in the website of the Signatory of the Code, and if no such website is available, in the global website of the group of the Signatory of the Code or in the INFARMA website, 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 of the Code 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 the services provided by the given Patient Organisation and the total fee paid to that Patient Organisation in the previous calendar year.
2. Agreements between Signatories of the Code and Patient Organisations for the provision of services by those Patient Organisations shall only be permitted when such services are provided to support healthcare or research.
3. It shall be permissible to engage Patient Organisations as experts or advisers in such services as, for example, participation in meetings of advisory bodies or public appearances. Agreements for consulting services or other services shall satisfy the following criteria:
    a. there is a reasonable need for the provision of the services which has been expressly identified and documented before ordering such services and before entering into the contract;
    b. the service selection criteria are directly related to the identified need, while the persons responsible for the selection have the knowledge required for assessing whether given experts and advisers meet these criteria;
    c. the scope of services does not exceed the scope necessary for satisfying the identified need;
    d. a written agreement, stipulating the nature of the services and the basis for paying the fee for the services, subject to sub-section g, has been concluded before providing the service;
    e. the signatory of the Code keeps the documentation on the services and makes appropriate use of the services purchased;
    f. engaging a Patient Organisation shall not be an inducement to recommend a particular medicinal product;
    g. the fee for the services is adequate and does not exceed the market value of the services provided;
    h. it is recommended that written agreements with Patient Organisations contain a provision by 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 constituting the subject-matter of the agreement or on other issues regarding the 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 about a prescription-only medicinal product to patients. In particular, this will apply to activities related to websites, symposia, lectures, convention materials, as well as other forms of communication.

Article 49

Principles of financing

A Signatory of the Code shall not demand exclusive rights for sponsoring a Patient Organisation or any of its programmes.

Article 50

Events and hospitality

The principles contained in Chapter IV regarding the organization of Events and hospitality also apply to Patient Organisations.

Article 51

Non-financial forms of support

In is recommended that Patient Organisations are sponsored with contributions in kind, e.g. in the form of training or assistance in the implementation of educational programmes.

CHAPTER VIII
DISPUTE SETTLEMENT

Article 52
Disciplinary Court

Any disputes which may arise in connection with the application of this Code which cannot be resolved amicably and any cases of possible infringement of the Code shall be settled by the Court operating at the Employers' Association of Innovative Pharmaceutical Companies INFARMA in accordance with the INFARMA Statutes, as well as the Rules 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 raise the high ethical standards of marketing activities in the pharmaceutical industry.

Article 54
Entities entitled to lodge a complaint

The right to file cases for settlement with the Court is vested in:

a. A Signatory of the Code;
b. other entities – through the INFARMA Management Board.

Article 55
Exclusions from the Court's jurisdiction

1. In cases regarding the infringement of the generally 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 of the Code to immediately stop further breaches and submit a written declaration stating that such breaches will be prevented.
2. Proceedings may continue despite the fact the defaulting party has stopped the breaches 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 degree of harmfulness of the breach as well as the benefits gained by the defaulting party and whether or not the Court has declared a breach of the provisions of the Code by the same entity over the previous 12 months, rule as follows:
   a. a prohibition on the continuation of the challenged actions, in particular, the immediate withdrawal of the advertising materials breaching the provisions of the Code from all mass media;
   b. a reprimand or rebuke;

c. an order to submit a single or repeated statement of particular wording to specified mass media or to specified addressees;
d. a notice to the Main Pharmaceutical Inspector regarding the decision;
e. a notice to the EFPIA (The European Federation of Pharmaceutical Industries and Associations) or IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) regarding the decision that was issued;
f. a notice regarding the decision to affiliated entities of the party breaching the Code;
g. the obligation to publish the decision or its parts in specified mass media once or multiple times;
h. the suspension or expulsion from INFARMA in the case of gross breaches of the Code.

2. The 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 breaches: the name of the company, together with the details of the case;
   b. in the case of a minor breach, the details of the case may be published but without the name of the company. If the Court acknowledges that there was no breach, the wording of the judgement will only be published on the request of the party against which the proceeding.
3. In every case, the Court shall decide on the content of the published information 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 employ or appoint qualified staff responsible for information regarding its medicinal products, as well as approving advertising materials before their distribution.
2. The above-mentioned staff shall include a physician or, if justified, a pharmacist with sufficient knowledge for deciding whether a given promotional material satisfies the requirements stipulated in the Pharmaceutical Law, as well as in this Code.
3. Each Signatory of the Code should appoint at least one senior employee to be responsible for supervision over the compliance with the Code by its employees and associates.

Article 60
Accession to the Code

1. This Code is open for accession to all companies in the pharmaceutical industry as well as organisations associating pharmaceutical companies.
2. Accession to the Code requires the submission of a written statement on accession to the Code according to the specimen attached as Appendix 1 to the Code.
3. The accession document shall be submitted to INFARMA or to the organisation, which is a party to the Code, and of which the acceding pharmaceutical company is a member. If it is not a member of any organisation being a party to the Code or if an organisation is acceding to the Code, the accession document may be submitted to any selected organisation being a party to the Code.
4. An organisation which is a party to the Code shall immediately inform the Management Board of INFARMA of every new party to the Code, as well as the accession date. The Management Board of INFARMA shall inform all Signatories of the Code of this.
5. An organisation being a party to the Code shall keep and update the 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 this Code shall result in the termination of the Code of Marketing Ethics for the Pharmaceutical Industry which was binding on the member of INFARMA to date without the need to submit any additional statements.

Article 61
Termination of the Code

Every Signatory of the Code may terminate the Code with 30 days' notice by submitting a notice of termination to the Management Board of INFARMA.

Article 62
Amendments to the provisions of the Code

1. Amendments to the Code shall be accepted by simple majority of voting Signatories of the Code.
2. Proposals of amendments to the Code may be presented by Signatories of the Code, the Management Board of INFARMA, the management board of another organisation which is a party to the Code or the Court.
3. Proposals of amendments shall be communicated to an organisation being a party to the Code which shall immediately communicate them to all the other Signatories of the Code for approval or rejection.

4. The failure of a Signatory of the Code to communicate its opinion within one month of the date of receipt of the above-mentioned proposal shall be equivalent to the acceptance of the amendment without reservations.
5. INFARMA shall inform all Signatories of the Code about the opinions received, as well as the approval or rejection of amendments no later than within one month of the expiration of the consultation term referred to in section 4.
6. Amendments approved in accordance with this Article shall enter into force on the date specified in the notice referred to in section 5, yet no earlier than 14 days from the date on which the notice is sent.

Appendix 1

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:
_____

Appendix 2

GUIDELINES REGARDING WEBSITES ACCESSIBLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND GENERAL PUBLIC IN THE EUROPEAN UNION

1. **Content of websites owned, administered or sponsored by a Signatory of the Code**.
   a) Information posted 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 Signatory of the Code; (ii) information on health education; (iii) information for Healthcare Professionals; and (iv) non-advertising information for patients and the general public regarding particular medicinal products marketed by the Signatory of the Code to the extent permitted by the Pharmaceutical Law, (v) information on benefits provided to Healthcare Professionals and Healthcare Organisations.
      i) General information about the Signatory of the Code. Websites may contain information in which investors, media or general public might be interested, including 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 the provisions of the Pharmaceutical Law, provided that its objective is not to encourage the recommendation, prescription, purchase, supply, sales or administration of medicinal products.
      ii) Information on health education. Websites may contain non-advertising information devoted to health education, describing characteristics of diseases, preventive measures, as well as tests and treatment methods and other information intended to promote public health. They may refer to medicinal products on condition that the discussion on them is balanced and appropriate. Appropriate information on alternative treatment methods may be presented, including information on surgery, diet, changing one's lifestyle and other interventions not involving the use of any medicinal products. Websites containing information on health education shall always recommend consulting a physician for further information.
      iii) Information for the Advertising Audience. Any advertising information on websites intended for the Advertising Audience shall be consistent with the Code. Such information shall be explicitly identified as information intended for the Advertising Audience, as well as appropriately secured against access by persons not authorised to receive such information.
      iv) Non-advertising information for patients and the general public. Subject to all applicable provisions of the law, websites may contain non-advertising information intended for patients and the general public on products offered by a given Signatory of the Code (including but not limited to information on their indications, adverse 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 Characteristics. The website shall provide full, unedited copies of the current Summary of Product Characteristics, as well as the Patient Information Leaflet for each product presented. These documents should

be provided together with other information on products or related to the discussion via a visible link informing the reader to read them. Additionally, a website may contain a link to complete, unedited copies of any public assessment reports published by the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products or another relevant authority. Trade names should be accompanied by international names. A website may contain links to other websites containing reliable information on medicinal products, including but not limited to websites managed by government authorities, entities conducting medical research, Patient Organisations, etc. A website shall always advise visitors to consult a physician for further information.

2. **Questions sent via e-mail**. A website may invite Healthcare Professionals, patients or the general public to submit questions via e-mail in order to obtain further information on products or other issues (e.g. the provision of feedback regarding the website itself). A Signatory of the Code may reply to such an enquiry in the same manner as it would reply to an enquiry received by regular mail, by telephone or through other means of communication. Information sent to patients or representatives of the 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 physician for further information.
3. **Links to other websites**. A website owned or sponsored by a Signatory of the Code may contain links to websites sponsored by other entities yet the Signatory of the Code should not create links from websites intended for the general public to websites sponsored by the Signatory of the Code which are intended for Healthcare Professionals. Similarly, links to separate websites may be created, including websites sponsored by the Signatory of the Code or other persons. Such links should usually be connected with the home page of the website or be managed in such a way as to make the visitor 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 for posting on their websites has been checked for accuracy and consistency with the Code. This task may be performed by the Medical Department, or other appropriately qualified persons.
5. **Protection of privacy**. A website shall be consistent with the generally applicable provisions of the law, in particular the Personal Data Protection Act and the Act on the Electronic Provision of Services.

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