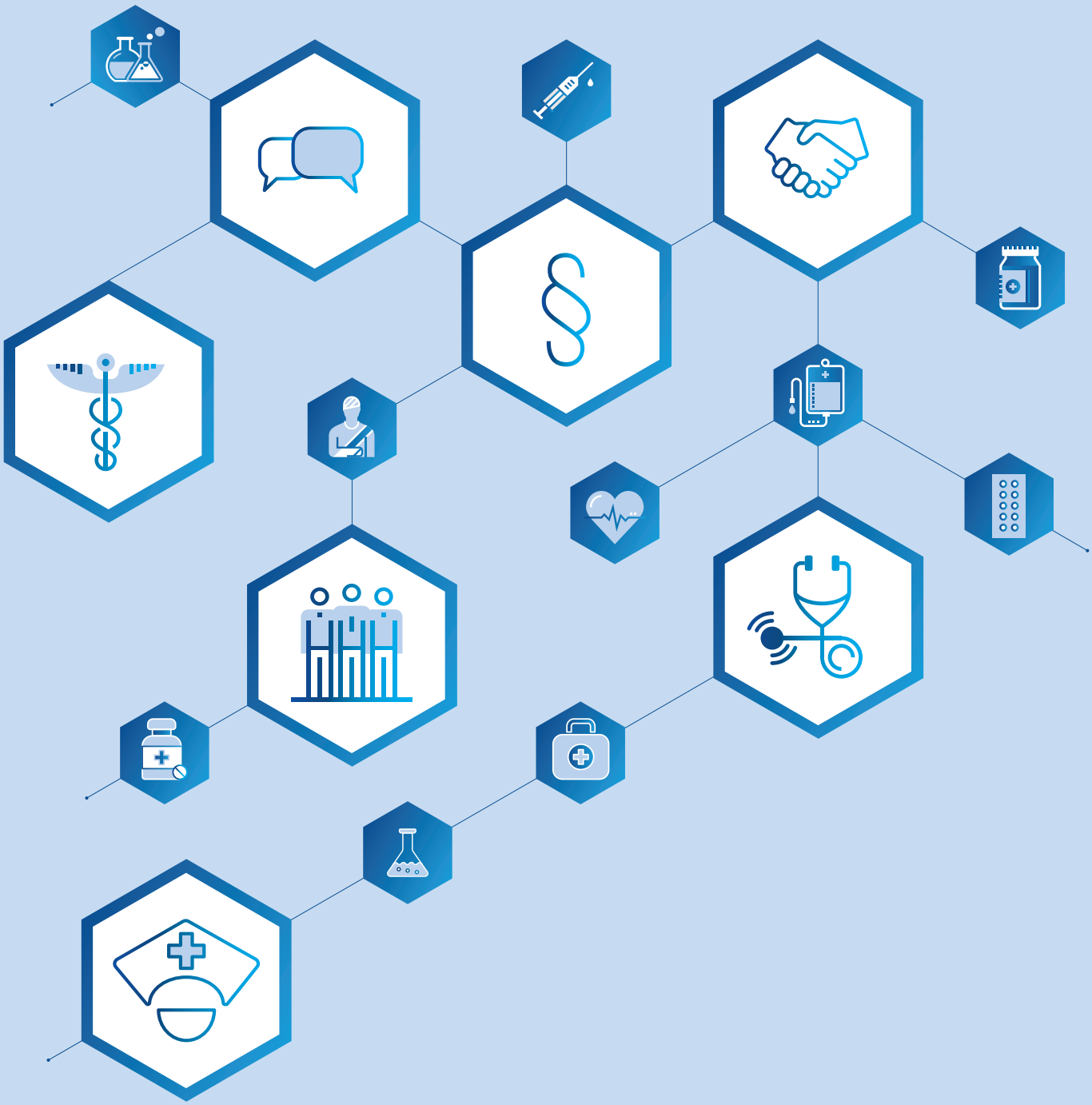
INFARMA
Związek Pracodawców
Innowacyjnych Firm Farmaceutycznych



INFARMA
CODE OF GOOD PRACTICE

Version of the Code of Good Practices
valid from 1 January 2021 (first edition)

The Employers' Union of Innovative Pharmaceutical Companies INFARMA represents 25 leading pharmaceutical companies engaged in research and development as well as the production of innovative medicines.

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The **PATIENT** always comes first
We engage with all our partners with **RESPECT**
We proceed with **INTEGRITY**
We cultivate **TRANSPARENCY**

PREAMBLE

We, the Signatories of this Code, cooperate with health care professionals, health care organisations, patient organisations, and their representatives, with competent authorities, and with society at large in the interests of health and wellbeing. We are fully cognisant of the fact that ensuring utmost standards of operation is one of the critical elements upon which trust in the pharmaceutical industry is based, and we are aware of our immense responsibility.

In light of the above, we declare the following to be our shared values:

- *Most importantly, THE PATIENT ALWAYS COMES FIRST. We strive to ensure that all our actions are to the patients' benefit. Our primary contribution to society at large is comprised in development and production of high-quality medicinal products and propagating their correct, rational use.*
- *We proceed with INTEGRITY in all our actions, cooperating with our partners in a responsible manner and always striving for substantive correctness, legal compliance, and overall balance in our communications. We own up to our decisions, our conduct, and our contacts and accept responsibility for them, and we encourage others to observe the same high ethical standard.*
- *We approach all our partners with RESPECT. We are committed to dealing with all our partners in the spirit of openness, responding to their needs in a constructive way and, at the same time, learning from them. We value the input and independent decisions contributed by our partners acting in reliance on sound evidence and in the best interests of patients. We are receptive to public opinion and are willing to duly adjust our courses of action. We abide by the requirements concerning protection of health data.*
- *We cultivate TRANSPARENCY. We are open about our work and our interactions, and we encourage our partners to do likewise.*

The above are not empty slogans, but actual values which we uphold and which we expect to inform all our work in all its aspects. In this spirit, it is our shared belief that definition of specific frameworks and principles of action may be conducive to furthering this goal. Accordingly, we have chosen to formulate and adopt this INFARMA Code of Good Practice drawn up by the Employers' Union of Innovative Pharmaceutical Companies INFARMA in accordance with guidelines by the European Federation of Pharmaceutical Industries and Associations (EFPIA). It is our belief that due observance and popularisation of the basic principles and specific rules laid down herein can ensure operation of the pharmaceutical industry not only in accordance with the letter of the law, but also with the spirit of the highest ethical norms.

CHAPTER 1. GENERAL PROVISIONS

Article 1. Objectives of the Code

This Code has the objective of defining, in accordance with the highest ethical standards, of rules governing:

1.1. Promotion of Medicinal Products,

1.2. Interactions between Signatories of the Code and Healthcare Professionals, Healthcare Organisations, and Patient Organisations,

1.3. Provision to the general public of information concerning Transfers of Value to the benefit of Healthcare Professionals, Healthcare Organisations, and Patient Organisations.

Article 2. Definitions

As used in this Code, the following capitalised terms shall have the meaning set out below:

2.1. **"Non-Interventional Study / NIS"** – is a study where:

- **a.** Medicinal Product(s) is (are) prescribed in accordance with the terms of the marketing authorization,
- **b.** assignment of the patient to a group covered by a particular therapeutic strategy is not decided by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study,
- **c.** no additional diagnostic or monitoring procedures are applied to the patient and epidemiological methods are used for the analysis of collected data;

2.2. **"Recipient"** – means any HCP or HCO or PO whose primary practice or place of incorporation is in Europe and who receives Transfers of Value as discussed in Art. 2.30 below;

2.3. **"Personal Health Data"** – means any and all information related to physical and/or mental health or to the inherited or acquired genetic characteristics of an identified or identifiable natural person, including the provision of health care services, which reveals information about this person's physiology or health status;

2.4. **"Donations and Grants"** – means funds, benefits in kind or services given for the purpose of supporting health care, scientific research or education without reciprocal obligation of the Recipient;

2.5. **"Medical Education"** – includes educational measures related to human health and diseases and specific non-promotional educational measures related to Medicinal Products;

2.6. **"EFPIA"** – means the European Federation of Pharmaceutical Industries and Associations;

2.7. **"INFARMA"** – means the INFARMA Employers' Union of Innovative Pharmaceutical Companies;

2.8. **"Code"** – means this INFARMA Code of Good Practice;

2.9. **"Criminal Code"** – means the legislative Act of 6 June 1997 – the Polish Criminal Code (consolidated text: Dz.U. 2019 item 1950 as amended);

2.10. **"Location"** – means the geographic place where the Event is organized (e.g. the city, town);

2.11. **"Informational or Educational Material"** – means inexpensive materials (of a value not exceeding PLN 100 gross) directly relevant to the practice of medicine or pharmacy and directly beneficial to patient care;

2.12. **"Venue"** – means the facility where the Event is organized (e.g. the hotel, the congress centre);

2.13. **"Reporting Period"** – means the period, coinciding with the calendar year, for which information concerning ToVs is provided in accordance with this Code;

2.14. **"Healthcare Organisation / HCO"** – means any legal person/entity:

a. that is a health care, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or scientific society (except for POs) and/or

b. through which one or more HCPs provide services,

– whose business address, place of incorporation or primary place of operation is in Europe. For these purposes, HCOs shall not include business enterprises dealing in Medicinal Products on a wholesale or retail basis;

2.15. **"Patient Organisation / PO"** – means a non-for-profit legal person/entity (including an umbrella organisation to which it belongs) assembling patients and/or caregivers that represents and/or supports the needs of patients and whose business address, place of incorporation or primary place of operation is in Europe;

2.16. **"Third Party"** – means a legal person/entity or individual that represents a Signatory of the Code or interacts with other persons or entities on behalf of a Signatory of the Code or relating to a Medicinal Product, such as distributors, wholesalers, consultants, organisations conducting clinical, non-clinical and/or non-interventional studies on a contract basis, professional congress organisers, sales agents, market research companies, advertising agencies, providers of services related to Events, public relations firms;

2.17. **"Signatory of the Code Personnel"** – means personnel employed by a Signatory of the Code or retained by way of contract with Third Parties who are concerned with any matter covered by this Code;

2.18. **"Contribution to Costs related to Events"** – means covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual HCP or PO Representative at an Event organised or prepared by a Signatory of the Code and/or a Third Party;

2.19. **"Pharmaceutical Law"** – means the legislative Act of 6 September 2001 – the Polish Pharmaceutical Law (consolidated text: Dz.U. 2020 item 944, as amended);

2.20. **"Medicinal Product"** – shall have the meaning specified in the Pharmaceutical Law, subject to the reservation that, as used in this Code, the term Medicinal Product shall apply only to prescription-only products used in human medicine and shall mean any substance or combination of substances presented as having properties for treating or preventing disease in human beings and/or used in or administered to human beings for diagnostic purposes or with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic effect;

2.21. **"Medical Sample"** – shall have the meaning specified in the Pharmaceutical Law and means a sample of a Medicinal Product provided free of charge to persons qualified to prescribe so that they can familiarize themselves with a new Medicinal Product and acquire experience;

2.22. **"Items of Medical Utility"** – means inexpensive materials (of a value not exceeding PLN 100 gross) aimed directly at education of HCPs so as to enhance provision of medical services and patient care and which do not offset routine operating costs of the medical or pharmaceutical practice;

2.23. **"Medical Representative"** – mean personnel employed by a Signatory of the Code or retained pursuant to a contract with a Third Party who interacts with HCPs and HCOs in connection with Promotion of Medicinal Products;

2.24. **"Patient Organisation / PO Representative"** – means a person who is mandated to represent and/or express the collective views of a PO on a specific issue or disease area;

2.25. **"Healthcare Professional / HCP"** – means any natural person:

a. who is a physician, dentist, pharmacist, physician assistant (senior physician assistant), nurse, midwife, medical laboratory scientist, paramedic, or pharmaceutical technician or

b. a person other than specified in a. above who, in the course of his/her professional activities, is qualified to prescribe, purchase, supply, recommend or administer a Medicinal Product,

– whose main place of practice is within Europe.

For purposes of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may purchase, supply (wholesalers excluded), or administer Medicinal Products, if these persons participate in the process of purchasing, supplying or administering Medicinal Products and (ii) any person retained by a Signatory of the Code pursuant to an employment contract or another civil law relationship whose primary function comprises practicing the professions specified in a. and b. above;

2.26. **"Promotion"** – includes any activity undertaken, organised or sponsored by a Signatory of the Code, or with its authority, which constitutes inducement to recommend, prescribe, purchase, supply, sell, or administer or consume Medicinal Product(s);

2.27. **"Court"** – means the disciplinary court affiliated with the Employers' Union of Innovative Pharmaceutical Companies INFARMA;

2.28. **"Sponsorship"** – means support provided by or on behalf of a Signatory of the Code, insofar as permitted by law, as a contribution towards the costs of specific activity (including an Event) performed, organised, and/or prepared by a HCO, a PO or a Third Party;

2.29. **Signatory of the Code"** – means the following entities::

a. members of INFARMA,

b. other entities who have acceded to this Code;

2.30. **"Transfers of Value / ToVs"** – means direct and indirect ToVs, whether in cash, in kind or otherwise, made by Signatories of the Code in direct or indirect connection with Medicinal Products. Direct ToVs are those made directly by a Signatory of the Code directly for the benefit of a Recipient. Indirect ToVs are those made on behalf of a Signatory of the Code for the benefit of a Recipient, including made through a Third Party, where the identity of the Recipient is known to the Signatory of the Code or can be readily ascertained by him;

2.31. **"Research and Development Transfers of Value / ToVs"** – means Transfers of Value to HCPs or HCOs related to the planning or execution of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice), (ii) clinical trials (as defined in Regulation No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC) or (iii) prospective NIS that involve the collection of patient data by HCPs;

2.32. **"Territory of Europe"** – means countries in which relevant codes of practice (analogous to this Code) have been implemented by a local EFPIA member organisation;

2.33. **"Events"** – means professional, promotional, scientific, and/or educational meetings, congresses, conferences, symposia, and other, similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a Signatory of the Code;

2.34. **"Host Country Principle"** – means the rule stipulating primacy of the nominal threshold value of meals (food and beverage) defined in the country in which a given Event is being held

in accordance with the applicable code implemented in that country by an EFPIA member organisation.

Article 3. Precedence of statutory law

3.1. 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.

3.2. Where 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 in a manner complying, as far as possible, 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 exempt the Signatories of the Code from their duty of applying the provisions of the Code.

3.3. 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, as amended), of the Pharmaceutical Law, and of applicable laws.

Article 4. Objective applicability of the Code

4.1. The provisions of this Code shall apply to:

- **a.** Promotion of Medicinal Products, in particular oral and written communications, journal and direct mail advertising, the activities of Medical Representatives, use of digital channels such as websites and social media, use of audio-visual systems such as films, video recordings, data storage services etc., provision of Informational or Educational Materials and Items of Medical Utility, hospitality in relation to Events and Medical Samples,
- **b.** interactions between Signatories of the Code and HCPs, HCOs and POs,
- **c.** disclosure of ToV made by Signatories of the Code,
- **d.** communications using digital channels.

4.2. The Code does not apply to the following:

- **a.** labelling of Medicinal Products packaging and accompanying package leaflets within the scope regulated by laws of absolute application,
- **b.** correspondence accompanied by material of a non-promotional nature needed to answer a specific question about a particular Medicinal Product,
- **c.** announcements of an informational character not addressed to the general public concerning, in particular, packaging changes, adverse-reaction warnings, trade catalogues and price lists, provided they include no product claims as to the properties of Medicinal Products,
- **d.** advertising or promotion of over-the-counter medicinal products,
- **e.** information about a Signatory of the Code setting out financial data, descriptions of research and development programmes, or discussions of the general directions of regulatory measures potentially impacting on a Signatory of the Code and his products, in particular information addressed to investors and to present and/or potential employees of a Signatory of the Code, provided that any such information does not simultaneously constitute Promotion of Medicinal Products.

Article 5. Subjective applicability of the Code

5.1. The provisions of the Code are binding on INFARMA members as of the date of its coming into force in accordance with Art. 45.1 below. For other Signatories of the Code, the provisions of the Code shall be binding as of the day on which they submit to INFARMA an accession declaration in accordance with Art. 41 below – not earlier, however, than as of coming into force of the Code.

5.2. Other entities may apply the provisions of the Code as a set of standards, the voluntary respect of which ensures compliance of their operations with high ethical standards.

Article 6. Territorial application of the Code and of other Codes

6.1. 6.1. This Code shall apply to all Signatories of the Code whose registered seats are in Poland.

6.2. Without prejudice to Art. 6.1 above, in the event of embarking on Promotion or establishment of contacts in another country, the provisions of any code implemented by an EFPIA member organisation in that country should be taken into account.

6.3. As regards international Events in which a HCP's participation is sponsored by a Signatory of the Code (in accordance with Art. 20 below), covering of the costs shall be regulated by the code implemented by an EFPIA member organisation in the country in which such HCP practices, with due heed for the Host Country Principle.

6.4. In the event that more than one code implemented by an EFPIA member organisation applies and there arises a conflict or discrepancy between their respective provisions, the most rigorous regulations shall be applied, subject to the reservation that, as regards the value of meals provided (as discussed in Art. 17.6 below), the Host Country Principle shall apply.

Article 7. Scope of responsibility of Signatories of the Code

7.1. Signatories of the Code are responsible for ensuring that their actions comply with this Code and, where applicable, with any other applicable codes implemented by EFPIA member organisations.

7.2. Signatories of the Code shall make every effort to ensure that entities operating on its behalf or on contract to it with respect to activities covered by this Code respect the provisions of the Code.

7.3. Signatories of the Code are responsible for ensuring that entities from their respective corporate groups:

- **a.** provide the Signatory of the Code with relevant information (in particular as regards provision of information concerning ToVs) and/or consult measures taken by them,
- **b.** abide by the provisions of this Code.

7.4. Signatories of the Code shall be responsible for actions of their employees and contracted parties with respect to actions falling within the ambit of this Code, including any actions contracted to Third Parties, actions of external sales personnel, consultants, market research and/or training entities, and advertising and/or marketing agencies.

CHAPTER II. PROMOTION OF MEDICINAL PRODUCTS

Article 8. Marketing authorisation

8.1. A Medicinal Product must not be promoted prior to the grant of the marketing authorization or outside of its approved indications.

8.2. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant Medicinal Product.

8.3. The provisions of Arts. 8.1 and 8.2 above shall not be taken as restricting or impeding the right to full information concerning scientific and medical progress, provided that such information does not bear the traits of Promotion.

Article 9. Information provided

9.1. Any and all information included in Promotion must be presented in a clear and legible manner.

9.2. Promotional material must include basic information about the Medicinal Product, in particular as specified in Art. 9.3 below, in accordance with the summary of product characteristics of the given Medicinal Product, and the date of elaboration – or, as the case may be, of the most recent update – of this information must be specified.

9.3. The promotional material must include, at the very least, the following information concerning the Medicinal Product promoted:

- **a.** the name of the Medicinal Product as well as its common name,
- **b.** the qualitative and quantitative composition of the Medicinal Product, taking into account the active substances as well as such auxiliary substances as have material bearing on correct use of the Medicinal Product,
- **c.** the pharmaceutical form,
- **d.** therapeutic indication(s) for use, subject to the reservation that promotional materials may specify only selected therapeutic indications for use under the condition that the promotional material as a whole refers only to those selected indications,
- **e.** dosage, means of administration,
- **f.** contra-indications,
- **g.** special warnings and safety measures concerning use,
- **h.** side effects/adverse effects,
- **i.** identification of the marketing authorisation holder,
- **j.** marketing authorisation number, identification of the authority which had issued the marketing authorisation,
- **k.** assigned supply classification ,
- **l.** where required (for Medicinal Products included in the reimbursement scheme) – information about the retail price, and the co-payment incumbent on the patient.

9.4. A promotional material constituting a reminder of a full material published previously may, apart from specifying the name of the Medicinal Product as well as its common name, contain only the trademark, without elaborating on the therapeutic indications, pharmaceutical form, dosage, promotional slogans or other promotional content (in such an event, the detailed regulations set out in Arts. 9.2 and 9.3 above shall not apply).

Article 10. Promotion and its contents

10.1. Promotion of Medicinal Products may be addressed only to persons qualified to issue prescriptions and/or dealing in Medicinal Products.

10.2. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the addressee to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. It must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue suggestion, ambiguity, excessive emphasis, omission or in any other way.

10.3. Any claims included in Promotion must be justified. In particular, claims concerning side effects/adverse effects included in Promotion must be borne out and confirmed in available evidence and/or in clinical practice. At the substantiated request of a Signatory of the Code and/or an addressee of the promotion, documentation confirming the soundness of claims included in Promotion shall be presented promptly, and not later than within 21 days following receipt of such a request, subject to the reservation that this requirement shall not apply to information included in the marketing authorisation and in the summary of product characteristics of the Medicinal Product.

10.4. The Promotion should present the Medicinal Product objectively, without exaggeration, and provide information about its rational use. Claims included in the Promotion may not suggest that the Medicinal Product and/or the active substance contained therein have any special properties or quality unless such claims can be substantiated.

10.5. In the case of Promotions of Medicinal Products containing different active substances, simultaneous presentation of such various formulations within a single Promotion is acceptable as long as the Promotion of each and every specific Medicinal Product complies with this Code and with applicable laws.

10.6. Simultaneous presentation within a single Promotion of Medicinal Products containing the same active substance, but in different pharmaceutical forms is permitted.

10.7. Any comparative Promotion must comply with applicable laws, including the legislative Act of 16 April 1993 regarding counteraction of unfair competition (consolidated text: Dz. U. 2019, item 1010, as amended). A comparative Promotion must jointly fulfil, among others, the following requirements:

- **a.** the name, pharmaceutical form, and dosage of the Medicinal Products being compared must be provided,
- **b.** the Promotion may not be misleading,
- **c.** the Promotion must present an honest, objectively verifiable comparison only of Medicinal Products with analogous properties and/or the same indications,
- **d.** any comparison should refer only to specific, study-tested properties of the Medicinal Products being compared, should be honest, objective, and verifiable; the possibility of checking the information included in the comparison should be guaranteed by citing the source of the information along with the date of its publication or most recent update,
- **e.** any comparison should refer to one, or a few, material, characteristic, typical, and verifiable traits – this may include the price of the Medicinal Products being compared,
- **f.** comparison of the selected traits of Medicinal Products should not be misleading as to the properties of the products being compared or to their traits not covered by the comparison, and it may not cause mistakes in differentiation between specific Medicinal Products, trademarks, company names / logos and/or other distinguishing marks,

g. a comparison may not discredit a competing Medicinal Product or marketing authorisation holder,

h. a comparison may not present a Medicinal Product as an imitation or copy of a product bearing a protected trademark or another distinguishing mark,

i. a comparison may not unfairly exploit the renown of a competitor's trademark, company name / logo and/or other distinguishing marks.

10.8. Particular care must be taken to ensure that data included in Promotion does not mislead about the nature of a Medicinal Product (for example, whether it is appropriate for use in children) or lead to erroneous conclusions (for example by using incomplete or statistically irrelevant information or unusual scales).

10.9. Comparative expressions such as "better than", "more effective than", "cheaper than" and similar expressions may not be used without appropriate, up-to-date and current evidence confirming their veracity.

10.10. A Medicinal Product may be described as "most often prescribed" only when there exists up-to-date, current statistical evidence confirming such statements and when, at the same time, the conditions specified in Art. 11.2.c of this Code are met.

10.11. The expression "new":

a. may be used only in reference to a Medicinal Product whose composition includes an active substance, or a combination of active substances, which had not previously been registered in Poland as a Medicinal Product,

b. may not be used in reference to a Medicinal Product after the elapse of 12 months from introduction of that Medicinal Product to the market in Poland,

c. may not be used in reference to the therapeutic indications of a Medicinal Product after the elapse of 12 months from registration of changes to its summary of product characteristics,

d. may not be used in reference to a new form or dosage of a Medicinal Product after the elapse of 12 months from introduction of the Medicinal Product in that form or dosage to the market.

10.12. Information concerning safety of a Medicinal Product's use, e.g. contra-indications, safety measures, and side effects, should be presented clearly, in a manner which leaves no doubt as to the language used.

10.13. The expression "safe" may not be used in reference to a Medicinal Product without due justification.

10.14. Promotion may not include claims to the effect that imbibing / consumption / use of a Medicinal Product does not entail any side effects, risk of poisoning, or risk of addiction.

Article 11. Quotes, references to source data

11.1. It shall be allowed to cite data from medical / scientific literature, published studies, and scientific evidence presented in the course of scientific congresses or symposia as long as such evidence has been set out in materials available to the general public, e.g. on the website of the given scientific congress or in summaries (abstracts) published in indexed medical periodicals (e.g. supplements). Scientific data, analyses, and study results drawn from professional literature and/or scientific journals should be presented true to the original. In each and every instance, the exact source and the date of publication and most recent update must be given. Moreover, the following conditions should be observed:

a. study results, scientific news, and abstracts may not be used in a manner which may cause misapprehension as to their character, scope, application, or significance,

b. studies performed in vitro and studies performed on animals may not be used in a manner which may cause misapprehension as to their clinical value,

c. the timeline of a study cited in a Promotion should be described clearly, with no room for doubt,

d. any comparison of the operation / effect of different Medicinal Products and/or comparison of the operation / effect of Medicinal Products and of non-pharmacological treatment methods must be expressed in a manner which clearly presents its statistical and clinical value. In cases where no statistical significance arises, the information "difference statistically insignificant" or "NS" should be given.

11.2. Promotion of a Medicinal Product may not use the following as source data:

a. unpublished data of the marketing authorisation holder (data on file), unless such data constitutes part of the registration dossier which is available on request;

b. data which had appeared in print only in the materials accompanying a session or Event sponsored by a Signatory of the Code or organised by a scientific society, unless such materials are publicly available, e.g. on the website of the given scientific congress or in summaries (abstracts) published in indexed medical journals (e.g. supplements);

c. information obtained as a result of market studies conducted by a Signatory of the Code or by another entity, unless such data has been published and includes clear information about the entity commissioning the market study.

11.3. Any data cited (including visuals such as graphs, illustrations, photographs, and tables) should be faithfully reproduced true to their originals, unless adaptation and/or modification thereof is required in order to comply with this Code – in which case the fact that specific elements have been adapted and/or modified must be clearly noted.

11.4. The citation model proposed by indexed medical periodicals is recommended as a template.

11.5. Quotes, numerical data and/or graphs from scientific works used in comparison of Medicinal Products may not be misleading and may not discredit a competing Medicinal Product.

11.6. Quotes from professional literature, tables, and other illustrative materials used in Promotion may not create the misapprehension that the studies or documentation had been produced for another, competing Medicinal Product, e.g. a generic product.

Article 12. Admissibility of Promotion

12.1. Signatories of the Code must always maintain high ethical standards, observe good custom, and pursue Promotion of Medicinal Products in accordance with applicable laws. In particular, Promotion:

a. must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry,

b. must take into account the special character of Medicinal Products and the professional position of its addressees,

c. must not violate good custom.

Article 13. Dissemination of Promotions

13.1. Promotion of a Medicinal Product may be directed only at such addressees (persons qualified to issue prescriptions or dealing in Medicinal Products) with respect to whom there arises the reasonable assumption that they need it or are interested in it.

13.2. Personal data included on a correspondence list or mailing list used for the purpose of Promotion must be processed in accordance with applicable laws.

13.3. Promotion relying on faxes, e-mails, automated calling systems, text messages and other digital channels may be pursued only with due observance of laws regulating such communications.

13.4. Where Promotion of Medicinal Products is addressed to holders of public office within the meaning of Art. 115 § 19 of the Criminal Code, in particular to national public consultants, regional public consultants, hospital directors, and/or head physicians, especial care should be taken to ensure that promotional actions directed at such persons do not conflict with their public office, thus violating applicable laws.

Article 14. Transparency of Promotion

14.1. Promotion must not be disguised. Promotional activity must be pursued in an open, transparent manner.

14.2. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies (including those that are retrospective in nature) must not be disguised Promotion. Such assessments, programmes and studies must be conducted with an exclusive scientific or educational purpose.

14.3. Where a Signatory of the Code, whether directly or indirectly, pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble or mimic independent editorial matter.

14.4. Material relating to Medicinal Products and their uses, whether promotional in nature or not, which is sponsored by a Signatory of the Code must clearly indicate that it has been sponsored by that Signatory of the Code.

14.5. Detailed principles concerning use of digital communications channels are defined in Appendix 3 to this Code.

Article 15. Promotion at international Events

15.1. Unless local laws provide otherwise, information provided to participants of international Events and/or presented at exhibition stands may refer to Medicinal Products not registered in the country in which the Event is taking place and/or to Medicinal Products subject to different registration conditions. Under such circumstances, the following conditions must, respectively, be met:

a. any and all materials provided should contain information about the countries in which the Medicinal Product has been registered as well as clearly indicating that the Medicinal Product has not been registered locally,

b. any and all materials provided should make note of the differences in conditions for registration of the given Medicinal Product.

Article 16. Replies to requests for advice

16.1. Patients and/or members of the general public approaching a Signatory of the Code with requests for advice on health matters should be encouraged to consult with a HCP.

Article 17. Events and hospitality

17.1. Any and all Events (organised and/or sponsored by or on behalf of a Signatory of the Code for HCPs, HCOs, and POs) must be held in Locations and Venues conducive to the main purpose of the Event, avoiding those that are generally seen as "renowned" for their entertainment facilities or as "extravagant".

17.2. INFARMA auxiliary criteria for classification of Locations and Venues as compliant with Art. 17.1 above are laid down in the INFARMA procedures for Events certification.

17.3. A Signatory of the Code may not organise or sponsor an Event to be held outside Poland unless organisation of the Event abroad is justified by organisational or substantive considerations such as:

- **a.** the fact that most of the invitees are from outside Poland, or
- **b.** availability of resources or specialised expertise in the given Location.

17.4. Hospitality by Signatories of the Code may not be excessive – the INFARMA auxiliary criteria concerning classification of hospitality at Venues define the INFARMA procedures for Events certification. Moreover, hospitality must be strictly connected to the main purpose of the Event, and must comply with the applicable Code as provided for in Art. 6 above. As a general rule, the hospitality offered may not depart beyond the standard that the average participant of that Event would be willing to budget on his/her own.

17.5. Hospitality offered to Event participants should be reduced to covering the cost of travel, meals, accommodation, and registration fees associated with participation in the substantive part of the Event.

17.6. Signatories of the Code may not provide or offer to HCPs, to HCO Personnel, or to PO Representatives any meals (food and beverage) the value of which, per person and per meal, exceeds the limits defined in accordance with the Host Country Principle, i.e.:

- **a.** PLN 200 – for meals offered in Poland, or
- **b.** The amount defined by the relevant local EFPIA member organisation – for meals offered outside Poland, or
- **c.** The equivalent of EUR 100 – for meals offered outside Poland where there is no monetary threshold defined by a relevant local EFPIA member organisation.

17.7. The amounts specified in Art. 17.6 above include VAT in accordance with Polish law or the analogous value-added tax / goods and services tax applicable in accordance with the laws of the host country.

17.8. Hospitality may be extended only to entitled Event participants, and not to persons accompanying them or to their family members. Travel, meal, accommodation, and registration fees entailed in participation in the Event of an accompanying person may be covered on the same terms only in exceptional cases associated with health reasons (e.g. disability or injury).

17.9. Hospitality may not include sponsoring or organisation of entertainment (e.g. sports events or recreation).

Article 18. Prohibition of gifts

18.1. Gifts of a personal nature (e.g. tickets for sports events or entertainment, presents marking milestones or occasions) may not be given, whether directly or indirectly, to HCPs, HCO Personnel, or to PO Personnel. Giving or offering of cash, cash equivalents, and of personal benefits is likewise prohibited. For purposes of this Code, personal benefits shall be taken as any and all performances of a non-professional nature resulting in personal benefit / utility to the Recipient.

18.2. A gift of a promotional character is an object given for promotional purposes (other than the materials specified in Chapter II of this Code). In the context of Promotion of Medicinal Products, presenting or offering such objects to HCPs, to HCO staff, or to PO Representatives is prohibited.

18.3. Ballpoint pens, notebooks, tote bags and/or folders of insignificant value inscribed with company logos may be provided for note-taking in the course of meetings organised exclusively by a Signatory of the Code.

Article 19. Donations and grants to HCOs and POs

19.1. Donations and Grants (in cash or in kind or otherwise) to HCOs and/or POs are only allowed if:

- **a.** they are made for the clearly defined purpose of supporting health care, research or education,
- **b.** they are documented and kept on record by the donor/grantor,
- **c.** they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

19.2. As qualified by the Pharmaceutical Law and by this Code, Donations and Grants to individuals are not permitted. The rules governing Contribution to Costs related to Events for HCPs are defined in Art. 20 of this Code.

Article 20. Contribution to costs related to events and Sponsorship

20.1. Signatories of the Code shall apply objective, substantive criteria in selecting HCPs and PO Representatives and contributing to costs of their participation in Events. It is prohibited to offer payments to HCPs and PO Representatives solely as recompense for time expended to attend an Event.

20.2. Public use of an HCO or PO´s logo and/or proprietary material by a Signatory of the Code requires written permission from that organisation. In seeking such permission, the way the logo and/or proprietary material will be used and the specific purpose must be clearly stated.

20.3. Signatories of the Code must ensure that the fact of Sponsorship of a HCO or PO is clearly defined and established and that it is openly disclosed from the very outset.

Article 21. Diverse financing sources

21.1. No Signatory of the Code may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes.

21.2. Signatories of the Code welcome broad funding and sponsorship of POs and HCOs from multiple sources.

Article 22. Service provision to Signatories of the Code

22.1. Execution of contracts between Signatories of the Code and HCPs, HCOs, POs and/or PO Representatives pursuant to which the Signatories of the Code shall benefit from any services (not covered by other provisions of this Code) shall be permitted only where such services:

- **a.** are provided for the purpose of supporting health care, research or education, and

b. do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

22.2. It is permitted to contract HCPs or PO Representatives for the provision of services whose performance entails payment of fees and covering other attendant costs (e.g. travel costs). Such contracting may concern provision of services as experts / advisors / consultants, services such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research. The arrangements that cover such services must fulfil all the following criteria:

a. a contract is executed in written or document form in advance of commencement of the services which specifies the scope of the services to be provided and, subject to item g. below, the payment for those services or the basis for calculating such payment,

b. there exists a legitimate need for the services which has been clearly identified and documented prior to commissioning such services and execution of the contract,

c. t he criteria for selecting service providers are directly related to the identified need and the persons responsible for selecting them have the expertise necessary to evaluate whether the particular individual meets those criteria,

d. the number of service providers retained and the extent of the service are not greater than reasonably necessary to achieve the identified need,

e. the Signatory of the Code maintains documentation concerning the contract and duly makes use of the services provided,

f. the retaining of the given person to provide the relevant service may not be an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular Medicinal Product,

g. the remuneration for the services is commensurate and reflects the fair market value of the services. In this regard, pretended contracts executed for the sole purpose of contriving a basis for payments to HCPs or PO Representatives are prohibited.

22.3. Without prejudice to the objective applicability of this Code as defined in Art. 4 above, Signatories of the Code are urged:

a. to include in the contracts discussed in this Art. 22 provisions regarding the obligation of the service providers to declare that they are consultants to the Signatory of the Code whenever they write or speak in public about a matter that is the object of the contract or any other matter relating to that Signatory of the Code,

b. that, whensoever they employ on a part-time basis HCPs who are still practising their profession, they obligate such persons to declare their employment arrangements with the Signatory of the Code whenever they write or speak in public about a matter that is the object of their retaining or any other matter relating to that Signatory of the Code and, irrespectively of the above, to notify this fact to their employers and to other entities vis a vis such person represents the interests of his/her employer.

22.4. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Art. 22, provided that the HCP, HCO Personnel member or PO Representative is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration for participation in research complies with market terms.

22.5. The provisions of Art. 17 regulating hospitality shall apply respectively to HCPs, HCO staff members, and PO Representatives participating in an Event (international or otherwise) in the capacity of advisor/ expert.

Article 23. Interactions with HCPs

23.1. Any and all interactions with HCPs should have the goal of expanding their knowledge about therapeutic areas, illnesses / conditions, diagnostic technology, and Medicinal Products available in the market, insofar as permitted under laws of general application, and of improving patient care. Accordingly, any and all cash flows, whether direct or indirect, and any other ToVs provided to HCPs must be subordinated exclusively to this goal and must proceed in accordance with applicable laws; in particular, any and all cash flows and/or other ToVs may not predicate therapeutic decisions made by the HCPs.

Article 24. Medical Education

24.1. Medical Education is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve health and patient outcome.

24.2. Signatories of the Code may engage in different types of Medical Education but such activities must not constitute Promotion.

24.3. When supporting independent Medical Education or organizing Medical Education activities independently or in collaboration with Third Parties, Signatories of the Code must ensure that their participation and role is apparent from the outset. When organising Medical Education activities in which Signatories of the Code have input in the substantive content, they are responsible for what is communicated during the activities. Such content must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions.

Article 25. Informational or Educational Materials and Items of Medical Utility

25.1. Informational or Educational Materials may be provided to persons qualified to issue prescriptions and/or dealing in Medicinal Products provided that the following conditions are jointly fulfilled:

- **a.** their value does not exceed PLN 100 gross,
- **b.** they are directly relevant to the practice of medicine or pharmacy,
- **c.** they are directly beneficial to the care of patients.

25.2. Items of Medical Utility may be provided to persons qualified to issue prescriptions and/or dealing in Medicinal Products provided that the following conditions are jointly fulfilled:

- **a.** their value does not exceed PLN 100 gross,
- **b.** they are directly beneficial to these persons' education and to the care of patients,
- **c.** they do not reduce the routine operating costs of persons to whom they are presented.

25.3. The nature of Informational or Educational Materials and Items of Medical Utility considered may not constitute a circumvention of the prohibition on gifts defined under Article 18 of this Code. The provision of such materials or items must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

25.4. Informational or Educational Materials and Items of Medical Utility should include the Signatory of the Code name, but must not be product branded, unless the Medicinal Product's name is essential for the correct use of the material or item.

Article 26. Non-Interventional Studies

26.1. Non-Interventional Studies sponsored by a Signatory of the Code must be conducted with a primarily scientific purpose and must not be disguised Promotion.

26.2. Non-Interventional Studies which involve gathering of patient data by HCPs must fulfil all the following conditions:

- **a.** there must be a study protocol strictly defining the number of patients and the time of observation,
- **b.** the study protocol should be submitted to an appropriate bioethics commission,
- **c.** the study protocol must be approved by the Signatory of the Code's Medical Department supervising the study as described in Art. 28.2,
- **d.** the study results must be analysed, by, or on behalf of, the Signatory of the Code commissioning the study, and the final report must be made available to the Medical Department of the Signatory of the Code within 12 months from the end of observation of the final patient. The Medical Department shall be obligated to ensure archivisation,
- **e.** the results of a Non-Interventional Study must be published within 24 months following the end of observation of the last patient,
- **f.** the summary report must be sent to all HCPs who participated in the study, and also made available at the request of INFARMA. Where the results of the study are relevant to assessing the benefits-to-risk ratio of the given Medicinal Product, the summary report must be promptly presented to the competent authority,
- **g.** Medical Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Signatory of the Code's Medical Department who will also ensure that the Medical Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

26.3. It is recommended that Signatories of the Code observe Art. 26.2 also with respect to other types of studies, including epidemiological studies, registers, and other retrospective studies. In each and every instance, such studies shall be subject to Art. 22.1 above.

26.4. Detailed terms regulating conduct of Non-Interventional Studies and other studies are set out in Appendix 2 to this Code.

Article 27. Medical Samples

27.1. Provision of Medical Samples shall be governed by the following rules:

- **a.** the general rule is that Medical Samples may not be presented. Medical Samples may be presented on an exception-only basis,
- **b.** Medical Samples are presented for the purpose of affording recipients the opportunity to become familiar with the Medicinal Product and to gain experience,
- **c.** Medical Samples must not be given for the purpose of inducing to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products. Medical Samples may not be presented for the sole purpose of ensuring patient treatment,
- **d.** the number of Medical Samples of any one Medicinal Product which may be delivered shall be restricted. No given person may receive more than four Medical Samples of any one Medicinal Product within a single calendar year, or receive Medical Samples of the given

Medicinal Product beyond the elapse of two years from that person's first request for Medical Samples of that Medicinal Product (the "4 x 2 principle"),

e. Medical Samples of only new Medicinal Products may be provided. For purposes of this Art. 27.1:

i. a Medicinal Product shall be deemed "new":
within five years following its first introduction to the Polish market, or
for a Medicinal Product whose original marketing authorisation has been expanded to include new indications, within five years following the coming into force of the decision thus expanding the marketing authorisation;

ii. a new strength / dosage or pack size of the existing Medicinal Product shall not be deemed a "new" Medicinal Product unless the indications have been expanded in comparison to the previous marketing authorisation,

f. Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product. Written requests must be signed and dated by those who ask for the Medical Samples,

g. Medical Samples of Medicinal Products containing psychotropic and narcotic substances may not be given,

h. Each Medical Sample must be no larger than the smallest pack of that particular Medicinal Product approved for the Polish market,

i. Each Medical Sample must be marked "free medical sample – not for sale",

j. Each Medical Sample must be accompanied by a summary of product characteristics.

27.2. The Signatories of the Code shall implement an appropriate system for control and tracking of Medical Samples issued to Medical Representatives and provided to qualified persons. This system ought to provide for unequivocal definition of the Medical Samples quantities provided in accordance with Art. 27.1 above.

Article 28. Signatory of the Code Personnel

28.1. Signatory of the Code Personnel should be trained and should be familiar with the requirements binding in accordance with this Code and with applicable laws.

28.2. Each Signatory of the Code must establish a service (e.g. Medical Department) having appropriate scientific knowledge in charge of information about its Medicinal Products, approval of promotional material, and approval and supervision of NIS. Signatories of the Code are free to decide how best to establish such service(s) (i.e. whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and internal organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist:

a. disposing of the knowledge necessary to ascertain that the given promotional material is in accordance with the law and with this Code,

b. responsible oversight of any NIS (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities entrusted to Medical Representatives).

28.3. All promotional material must be approved for compliance with this Code, with applicable laws, and with the summary of product characteristics; such approval shall also ensure fair and truthful presentation of the facts about the Medicinal Product.

28.4. Every Non-Interventional Study protocol must be approved for compliance with this Code and with applicable laws.

28.5. Each Signatory of the Code must appoint at least one senior employee responsible for supervising compliance with this Code by the given Signatory of the Code and its subsidiaries.

28.6. Each Signatory of the Code must ensure that its Medical Representatives are familiar with the relevant requirements of this Code and with applicable laws and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Medicinal Products they present. Moreover:

- **a.** Medical Representatives must comply with all relevant requirements of this Code and with applicable laws, and Signatories of the Code are responsible for ensuring such compliance by their sales staff,
- **b.** Medical Representatives must approach their duties responsibly and ethically,
- **c.** during each visit, and subject to applicable laws, Medical Representatives must give the persons visited, or ensure that they are given, a summary of the product characteristics for each Medicinal Product they present,
- **d.** Medical Representatives must forthwith transmit to the relevant employees of the Signatory of the Code any information they receive in relation to the use of their company's Medicinal Products, particularly reports of side effects,
- **e.** Medical Representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other health care facilities, and likewise the manner and conduct of such visits, do not impede operations of such facilities, and that their times are arranged in advance,
- **f.** Medical Representatives must not use any inducement to gain an interview. In an interview, or when seeking an appointment for an interview, Medical Representatives must not mislead as to their identity or that of the Signatory of the Code they represent.

CHAPTER V. SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

Article 29. Interactions with POs

29.1. ignatories of the Code must comply with the following principles in interactions with POs:

a. independence of POs, in terms of their judgement and activities, must be assured,
b. interactions between POs and Signatories of the Code must be based on mutual respect, with the views and decisions of each partner having equal value,
c. interactions between POs and Signatories of the Code may not concern Promotion of Medicinal Products,
d. the objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Signatories of the Code must always be clearly acknowledged.

29.2. Promotion of Medicinal Products may not be addressed to the general public (including POs).

29.3. Provision of financial or non-financial support to a PO, whether directly or indirectly (e.g. through an advertising agency), shall require execution of a contract in written or document form specifying:

a. the object of the contract,
b. the date of execution,
c. the identities / names of any cooperating institutions or Third Parties, where applicable,
d. the amount / value of the support and its designated / earmarked purpose (e.g. a grant for general purposes, a grant towards a specific Event or publication, etc.). Moreover, the contract should, depending on the circumstances, set out a description of the non-financial support, whether indirect (e.g. time of a public relations agency and the character of its involvement) or direct,
e. the duties of the parties,
f. the contract's duration,
g. undertaking by the PO to observe the Code in performance of the contract, also as regards identifying and indicating the Signatory of the Code as the entity supporting the given project,
h. the duty to present confirmation / proof that the support made available has been used in accordance with the contract.

29.4. Signatories of the Code must not influence the text of PO material they sponsor in a manner favourable to their own commercial interests. This does not preclude Signatories of the Code from correcting substantive errors in PO material. In addition, at the request of POs, Signatories of the Code may cooperate in the preparation of material, always subject to the reservation that such cooperation must be fair and balanced from a scientific perspective.

29.5. Signatories of the Code encourage supporting POs with the use of non-pecuniary benefits, e.g. in the form of training or assistance with educational programmes.

29.6 Signatories of the Code support the sourcing of funding by POs from varied sources.

ROZDZIAŁ VI. DISCLOSURE OF ToVs MADE BY SIGNATORIES OF THE CODE

Article 30. Timing of information provision

30.1. Publication of information in accordance with this Chapter VI must be effectuated by each Signatory of the Code within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless:

- **a.** shorter period is required under applicable laws and/or
- **b.** the legal basis for processing of data (which may include, depending on circumstances, e.g. a justified interest, a legal duty, or consent of the Recipient) has ceased to apply.

30.2. Publication of information about ToVs extended to Recipients in the previous year shall be effectuated between 20 June and 30 June of every calendar year.

Article 31. Provision of information about ToVs to HCPs and HCOs

31.1. **[Introduction]** This Art. 31 defines duties with respect to provision of information about ToVs to HCPs and HCOs, whether directly or indirectly. When deciding how a ToV must be disclosed, Signatories of the Code should, wherever possible, identify and provide at the individual HCP (rather than HCO) level, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws.

31.2. **[Precedence of applicable laws]** In the event of any discrepancy between this Art. 31 and general laws applying to the given Signatory of the Code, with the latter preventing compliance with this Art. 31, the given Signatory of the Code shall proceed in accordance with such laws of absolute application, and the resulting lack of compliance with this Code shall not be regarded as a violation.

31.3. **[Duty to provide information about ToVs]**

- **a.** **General rule.** Subject to the terms of this Art. 31, each Signatory of the Code must document and publish (as specified in Art. 31.5) information about ToVs it makes, directly or indirectly, to or for the benefit of a Recipient.
- **b.** **Exemption from the duty to provide information.** The following ToV categories shall not be covered by the duty to provide information discussed in Art. 31.3.a above:
  - **i.** ToVs solely relating to medicinal products sold on an over-the-counter basis,
  - **ii.** ToVs not specified in Art. 31.5 below, e.g. Items of Medical Utility (as regulated by Art. 25), meals (as regulated by Art. 17, and in particular by Art. 17.6), and Medical Samples (as regulated by Art. 27) and/or
  - **iii.** are part of ordinary course of purchases and sales of Medicinal Products by and between a Signatory of the Code and a HCP (such as a pharmacist) or a HCO, including inter alia rebates, discounts and other commercial facilitations.

31.4. [Procedure for information disclosure]

- **a.** **Annual Disclosure Cycle.** Disclosures. Information disclosure must be made on an annual basis and each Reporting Period must cover a full calendar year.
- **b.** **The form.** As qualified by Art. 31.4.c below, in the interests of consistency and cohesion, information shall be disclosed using the structure set out in the Form constituting Appendix 4 to this Code.
- **c.** **Means of information disclosure.** Information shall be made available via the following channels, always subject to the reservation that unlimited public access to the provided information is ensured:

i. on the website of the given Signatory of the Code, with due heed for the requirements arising from applicability of a relevant local code of a relevant EFPIA member organisation (Art. 31.4.d below) and/or

ii. on the central internet platform for information provision operated by INFARMA or by a relevant body, where INFARMA and/or a relevant body have provided for such a possibility.

d. **Applicable national code.** Provision of information must proceed in accordance with the relevant local code of a relevant EFPIA member organisation of the country where the Recipient has its professional address. Accordingly:

i. if the Recipient has its professional address in Poland, disclosure shall proceed in accordance with this Code, also in the case of ToVs from foreign affiliates of the Signatory of the Code, and the Signatory of the Code shall ensure that such affiliates provide any and all necessary information to it,

ii. if the Recipient has its professional address outside Poland, the Signatory of the Code shall ensure that disclosure is made in accordance with the local code of a relevant EFPIA member organisation. Towards this end, Signatory of the Code shall forward data for disclosure to the relevant affiliate of such Signatory of the Code; if, meanwhile, the Signatory of the Code does not have an affiliate in the given country which might provide the information, that Signatory of the Code shall be obligated to effectuate disclosure in accordance with this Code.

e. **Language of disclosure.** As qualified by Art. 31.4.d above, information about ToVs shall be disclosed in Polish. Signatories of the Code are encouraged to, additionally, also provide information in English.

f. **Documentation and retention of records.** Each Signatory of the Code must document all ToVs required to be published pursuant to Art. 31.3 above and maintain the relevant records for a minimum of 5 years after the end of the relevant Reporting Period, unless another period is required under applicable laws.

g. **Currency.** As qualified by Art. 31.4.d above, ToV values shall be specified in Polish złotys (PLN).

31.5. [Individual and aggregate provision]

a. **Individual provision.** Except as expressly provided by this Art. 31, information about ToVs shall be provided on an individual basis. Thus, the Signatory of the Code must provide, on an individual basis for each clearly identifiable Recipient, information about the amounts attributable to ToVs to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Information about ToVs provided to the given Recipient must be presented on a category-by-category basis. ToVs may be valuated as total amounts within the specific category provided that itemised details of individual ToVs within the given category must be made available by the Signatory of the Code at any request of the relevant Recipient and/or the competent authorities.

ToVs shall be ascribed to the following categories:

i. ToVs to HCOs:

1. **Donations and Grants.** Donations and Grants to HCOs that support health care, including Donations and Grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide health care (detailed provisions concerning Donations and Grants are set out in Art. 19 of this Code).
2. **Contribution to costs related to Events.** Contributions to costs related to Events effectuated through HCOs and/or Third Parties, including financing of HCP participation in Events (where such transfers cannot be ascribed to individual HCPs) shall include inter alia:
   – Registration fees,

- Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event, and
- Travel and/or accommodation (detailed provisions concerning Events and hospitality are set out in Art. 17 of this Code).

3. **Fees for Service and Consultancy.** ToVs resulting from contracts between Signatories of the Code and HCOs under which such HCOs provide any type of services to a Signatory of the Code or any other type of funding not covered in the previous categories. Information about fees and ToVs relating to expenses agreed in writing shall be provided as separate amounts.

ii. For ToVs to HCPs:

1. **Contribution to costs related to Events.** Contribution to costs related to Events, such as:
   - Registration fees, and
   - Travel and/or accommodation (detailed provisions concerning Events and hospitality are set out in Art. 17 of this Code).
2. **Fees for services and consultancy.** ToVs resulting from contracts between Signatories of the Code and HCPs under which such HCPs provide any type of services to a Signatory of the Code or any other type of funding not covered in the previous categories. Information about fees and ToVs relating to expenses agreed in writing shall be provided as separate amounts.

b. **Collective disclosure.** In cases where, in light of applicable laws, information about ToVs cannot be disclosed individually for the individual categories specified above as received by the Recipient, the Signatory of the Code shall disclose, on a collective basis, information about amounts corresponding to the aggregate ToVs to such Recipients within the given Reporting Period. For every ToV category, such collective disclosure ought to specify:

i. the number of Recipients concerned expressed as an absolute value and as a percentage of all Recipients obtaining ToVs from the given Signatory of the Code within the given Reporting Period, and

ii. the aggregate monetary amount of ToVs provided to such Recipients.

c. **Data protection.**

i. For Recipients who are natural persons, the Signatory of the Code shall be obligated to ensure that provision of information proceeds without detriment to the Recipient's rights as regards protection of his/her personal data. In particular, where required by applicable laws, the Signatory of the Code shall take the necessary measures to obtain due consent of the Recipient,

ii. the Signatory of the Code shall ensure exercise of the Recipient's rights arising from applicable personal data protection laws, including the right to object and to revoke consent for data processing.

31.6. **[Non duplication]** Where a ToV is obtained by a specific Healthcare professional through a Healthcare organisation, that ToV shall be disclosed only once. . To the extent possible, such disclosure should be made on an individual HCP (with details of the HCP specified).

31.7. **[Research and Development ToV]** Information about Research and Development ToVs in each Reporting Period must be provided on an aggregate basis. Costs related to Events that are related to research and development activities can be included in the aggregate amount under the "Research and Development Transfers of Value" category. Detailed rules concerning provision of information in connection with Non-Interventional Studies are set out in Appendix 2 to this Code.

31.8. **[Methodology]** Each Signatory of the Code must publish a note summarising the methodology used

by it for purposes of disclosing information and classifying ToVs to the specific category. Such note, apart from a general summary and overview of the key principles, should describe the ToV ascription methodologies applied and, as necessary, the principles adopted for multi-year contracts, tax aspects (including VAT), and other issues related to the ascription of the ToVs to the given Reporting Period and defining ToV amounts.

Article 32. Provision of information about support and agreements with POs

32.1. Every Signatory of the Code shall publish a list of POs to which he provides financial or non-financial support, whether directly or indirectly, and with which he has executed relevant contracts.

32.2. In the context of the provision of information referred to in Art. 32.1 above, the Signatory of the Code should publish the name of the PO and information about the nature of the support provided and/or services rendered. The data ought to be formulated in a manner which ensures safeguarding of confidential information but, at the same time, enables the average reader to understand the nature of the support provided and/or services rendered. Moreover, the following elements ought to be accounted for:

- **a.** For support (financial or non-financial):
  - **i.** the value of financial support and of invoiced costs,
  - **ii.** for non-financial support the value of which is difficult to quantify, a description of the characteristics of the ToV obtained by the PO.
- **b.** For contracted services: the total amount paid to the given PO in the given Reporting Period.

33.3. The information referred to above should be provided on an annual basis, with every Reporting Period covering a full calendar year. Publication shall be on the website of the Signatory of the Code (at national or European level).

32.4. Every Signatory of the Code shall publicise information about the methodology adopted in drawing up the list and the terms for defining the type and value of support provided.

CHAPTER VII. VIOLATIONS, DISPUTES

Article 33. The Court

33.1. Any disputes which may arise in connection with application of this Code or cases of violation of the provisions hereof shall be settled by the Court affiliated with 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.

33.2. With respect to matters or cases involving violation of generally applicable laws and of this Code, the Court shall consider only potential violations of this Code.

Article 34. Initiation of proceedings

34.1. Proceedings shall be initiated on the basis of a complaint lodged by:

- **a.** Signatory of the Code,
- **b.** the INFARMA Board,
- **c.** another party.

34.2. A complaint may be lodged with INFARMA directly or through EFPIA.

34.3. INFARMA shall confirm receipt of the complaint and proceed.

Article 35. Procedural principles

35.1. The overarching objective of the Court shall be comprised not in ruling on the culpability of a party, but in resolving a dispute coming before it for the general good and in ensuring high ethical standards.

35.2. Proceedings before the Court shall be impartial, whatever the identity or origin of the parties.

35.3. The Court shall sit in two instances.

35.4. The panel ruling on any given case may not include a representative of a Signatory of the Code whom the case concerns or whose impartiality in the given case may be reasonably questioned on other grounds.

35.5. The language of the Court's proceedings shall be Polish. Where justified by circumstances, the presiding member of the panel may decide to hold some of the proceedings in a foreign language.

35.6. The detailed procedure is set out in the Rules of Procedure of the Court.

Article 36. The Court's ruling

36.1. If it is not established in the course of proceedings that the Code had been violated, the complaint shall be dismissed.

36.2. If a violation is established, the Court shall order the Signatory of the Code to cease and desist the proscribed actions and to submit, within a specified deadline, a written undertaking to prevent such violations in the future. Irrespectively of the above, the Court may apply the sanctions discussed in Art. 39 of this Code.

Article 37. Appeal

37.1. The verdict of the Court at first instance may be appealed. The verdict of the Court at first instance shall become final and definitive of none of the parties brings an appeal within the deadline specified in Art. 37.2 below.

37.2. An appeal may be brought within 14 days following service of the verdict of the Court at first instance along with its reasoning.

37.3. In the course of appeal proceedings, the case shall be considered by a panel whose members did not take part in formulation of the appealed verdict.

37.4. The Court at second instance shall conduct its own assessment of the evidence assembled in the case.

37.5. The verdict of the Court at second instance shall be final and definitive.

Article 38. Call to desist in violations

38.1. An entity with respect to whom a potential violation of this Code has occurred may approach the Signatory of the Code perpetrating the violation with a call to desist in the violations forthwith and to present a written undertaking to prevent such violations in the future.

38.2. Proceedings may continue even though a party has desisted in its violations prior to such proceedings' conclusion.

Article 39. Sanctions

39.1. If a violation of this Code is established, the Court, taking into account the type and gravity of the breach, the benefits accrued to the violating party in connection with the violation, and any other findings of violations with respect to the same Party made by the Court over the past 12 months, may:

- **a.** caution or censure the Signatory of the Code,
- **b.** order the making of a specified statement, on a one-time or multiple basis, in a specific public medium or to specified addressees,
- **c.** notify the Chief Pharmaceutical Inspectorate of the verdict,
- d. notify EFPIA and or IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) of the verdict,
- e. notify any equity affiliated of the party who had violated the Code of the verdict,
- f. order the verdict's publication in whole or in part, on a one-time or multiple basis, in a specific public medium,
- g. impose a financial penalty in accordance with the Rules of Procedure of the Court, with the proceeds from such penalty earmarked towards educational projects and/or ethics propagation projects pursued within INFARMA,
- h. in the event of gross violation of the Code, exclude the violating party from INFARMA.

39.2. The Court may also apply a combination of the sanctions specified above. Performance of / submission to the sanctions shall proceed in accordance with the deadlines and means specified in the verdict.

Article 40. Publication of Court verdicts

40.1. Information about every final and definitive verdict of the Court shall be published in the INFARMA newsletter, subject to the following rules:

- **a.** a. in the case of grave or recurring violations, the published details shall always name the violating Signatory of the Code and specify the details of the case,
- **b.** in the case of minor violations, or if no violation has been established, published details may omit the name of the Signatory of the Code,
- **c.** in the case of precedent-setting matters and matters of especial international interest (whether or not a violation is found to have occurred), without prejudice to items a. and b. above, an English-language summary of the case may be published.

40.2. The details and text of the information to be published shall be decided upon by the Court on a case-by-case basis in its judgment.

40.3. Publication of verdicts shall proceed with due heed for personal data protection.

CHAPTER VIII. FINAL PROVISIONS

Article 41. Accession to the Code

41.1. This Code is open for accession to all enterprises in the pharmaceutical industry.
41.2. Accession to the Code requires the submission to INFARMA of a written statement on accession to the Code according to the specimen attached as Appendix 1 to the Code.
41.3. INFARMA shall inform all Signatories of the Code of the fact of accession of a new entity to the Code.

Article 42. Technical provisions

42.1. INFARMA shall post the current, up-to-date text of the Code on its website.
42.2. INFARMA shall keep on file statements of accession to the Code, maintain a list of Signatories of the Code, and post it on its website.
42.3. The Management Board of INFARMA may accept guidelines and clarifications concerning application of this Code; such guidelines and clarifications shall be auxiliary in character.

Article 43. Withdrawal

43.1. Any Signatory of the Code may withdraw and terminate its application subject to a 30-day period of notice by serving a statement to that effect on the Management Board of INFARMA.

Article 44. Amendments of the Code

44.1. Amendments to the Code shall be accepted by simple majority of voting Signatories of the Code.
44.2. Proposals of amendments to the Code may be presented by Signatories of the Code, the Management Board of INFARMA, or by the Court.
44.3. Proposals of amendments shall be promptly communicated to all Signatories of the Code for approval or rejection. 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.
44.4. 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 deadline specified in Art. 44.3 above.
44.5. Amendments approved in accordance with this Art. 44 shall enter into force on the date specified in the notice referred to in Art. 44.4, but not earlier than 45 days from the date on which the notice is sent.

Article 45. Coming into force, interim regulations

45.1. This Code shall come into force as of 1 January 2021.
45.2. As of its coming into force, this Code shall supplant and replace:
- **a.** the Transparency Code of the INFARMA Employers' Union of Innovative Pharmaceutical Companies,

b. the Code of Good Practice of the Pharmaceutical Industry of the Employers' Union of Innovative Pharmaceutical Companies INFARMA.

45.3. The first Reporting Period within the meaning of this Code shall be the year 2021. As regards reports submitted for previous years, the Transparency Code of the INFARMA Employers' Union of Innovative Pharmaceutical Companies shall have application.

Appendix 1
Statement re accession to the Code

STATEMENT re ACCESSION
TO THE INFARMA CODE OF GOOD PRACTICE

The undersigned, ...

.....,
(given name(s) and surname(s) of person(s) authorised to represent the entity acceding to the Code)

acting on behalf of:

Entity name	
Register in which the entity is entered	
Register entry number	

having perused the **INFARMA Code of Good Practice ("the Code")**, hereby declare(s) accession to the Code in accordance with its Art. 41.2.

We agree to submit any and all disputes arising in connection with application of the Code and/or violations of the Code to settlement by the Court affiliated with the Employers' Union of Innovative Pharmaceutical Companies INFARMA, in accordance with the Statute of INFARMA, with the Code as well as the Rules of Procedure of the Court.

.....
Date:

.....
Signature:

.....
Position:

Please enclose with this statement a document confirming authority to execute it (e.g. a National Court Register extract)

Appendix 2
Detailed rules re NIS and other studies

DETAILED RULES re CONDUCT OF NON-INTERVENTIONAL STUDIES AND OTHER STUDIES

I. Provision of information about ToVs in connection with NIS

Information concerning Transfers of Value in connection with Non-Interventional Studies shall be provided as follows:

1. ToVs associated with research and development activity (e.g. ToVs associated with a non-interventional prospective study) > aggregate disclosure
2. ToVs not encompassed by the definition of ToVs associated with research and development activity (e.g. ToVs associated with a non-interventional retrospective study) > individual disclosure.

NB: The following criteria may be helpful in differentiating between prospective and retrospective studies:

Prospective NIS	Retrospective NIS
Prospective cohort studies in which the decision to administer the Medicinal Product is clearly independent from the inclusion of the patient in the study. A retrospective study to which a prospective element is subsequently introduced. Long-term extended studies with patient follow up beyond trial protocol specified time for observation and active collection of additional data.	Review of data bases and/or documentation. Retrospective review of documentation subsequent to all material events – e.g. clinical-control studies (case control study), cross sectional studies, and cohort studies of exclusively retrospective character. Studies in which the prescriber later becomes an investigator, but prescribing has already occurred - e.g. retrospective data collection from individual medical records at the site of the investigator.

II. Detailed rules re conduct of Non-Interventional Studies

As a supplement to Art. 26 of the Code, the following rules applicable to NIS are hereby implemented:

1. **Patient consent, protection of patient data**
   - **a.** In the event that the study requires access of a sponsor representative to source documents, patients must give their written consent for participation in the study.
   - **b.** Studies shall be conducted with due respect for the right to personal data protection of the study participants.
2. **Transparency of study actions**
   - **a.** NIS and/or studies specified in III below which constitute concealed Promotion and an inducement to recommend, prescribe, purchase and/or use a given Medicinal Product are prohibited.
   - **b.** NIS and/or studies specified in III below may not be an instrument for influencing HCPs with respect to their choice of treatment methods.

3. **Execution of the contract**
   A written contract must be executed between the Signatory of the Code sponsoring the study and HCPs and/or HCOs at which the study will be conducted, specifying the character of services to be provided and the remuneration for the study, subject to the reservation that the remuneration should be commensurate to the time and labour expended on the study and reflect customary Polish market practice.
4. **Publication of information re study commencement**
   a. Information about the commencement of a NIS shall be promptly (not later than the day on which observation of the first patient commences) communicated to INFARMA which, in turn, shall post the information on its intranet (available to Signatories of the Code only).
   b. Such information should specify, at the very least:
      i. the name of the Signatory of the Code sponsoring the study,
      ii. the study title,
      iii. the study objective,
      iv. the planned number of patients, where applicable,
      v. duration of the study,
      vi. duration of patient observation, where applicable,
      vii. the dates of the first visit of the first patient and the last visit of the last patient, where applicable.
   c. Access to the information referred to in item a. should be restricted, requiring a login assigned by INFARMA to its members and to other entities acceding to the Code.
   d. Where a NIS has not been disclosed in accordance with this item 4, the organiser of such study must, at the written request of a Signatory of the Code, present, within 21 days following submission of such request:
      i. the information referred to in item b.,
      ii. the study protocol,
      iii. the patient documentation (CRF) template, where applicable,
      iv. the template contract with the investigator or HCO conducting the study.

III. Other studies

Conduct of studies other than NIS is permitted provided that such studies belong to one of the following categories:

1. epidemiological studies (in the sense of gathering population data),
2. registers (in the sense of gathering data on therapeutic, preventative, and diagnostic procedures or procedures modifying physiological functions, including pharmacotherapy methods),
3. health care economics studies (in the sense of gathering data enabling economic assessment of specific therapeutic, preventative, and diagnostic procedures or procedures modifying physiological functions, including pharmaco economic studies),
4. market studies / market research, which may not constitute crypto Promotion. Not disclosing the identity of the entity sponsoring the study to respondents is permitted, but it is necessary to specify the industry in which the sponsor operates.

Appendix 3
Guidelines re Digital Channels

These guidelines are intended as a supplement to the provisions of the INFARMA Code of Good Practice that apply to all types of communication, including via digital channels.

Signatories of the Code shall apply these guidelines taking into account their particular needs and requirements. Without prejudice to the foregoing, Signatories of the Code are encouraged to adopt additional measures which extend further than the express provisions of this document.

This Appendix 3 sets out guidelines concerning the most commonly used digital channels and what to be aware of when communicating to and with the public and/or HCPs.

1. PRINCIPLES APPLICABLE TO ALL TYPES OF COMMUNICATION

Compliance with laws, regulations and codes of practice

A digital channel is only a platform for communicating. Accordingly, laws and regulations applicable to other platforms and media also apply to digital media. The content, target group and use of the platform are relevant factors to determine applicable rules, not the medium as such. Therefore, the provisions of the Directive 2001/83/EC related to the Medicinal Products' advertising and of the INFARMA Code of Good Practice apply to digital communication. Moreover, Promotion using digital channels must also comply with applicable data protection regulations.

Responsibility

Signatories of the Code are responsible for any and all material disseminated via any digital channel that is initiated, branded and/or sponsored by Signatories of the Code (or by any Third Party acting on their behalf), including promotion of Medicinal Products.

A Signatory of the Code owning the social media page or site is responsible for the content posted thereon. For instance, any mention of a Medicinal Product is likely to be considered promotion of that Medicinal Product and, as such, be prohibited. Another example might be the use of generally accessible social media to alert HCPs about the publication of a study on a Medicinal Product – such an announcement may also be deemed to constitute promotion of the given Medicinal Product and, accordingly, may not be addressed to the public at large.

Signatories of the Code may also have responsibilities when interacting on digital channels owned by other companies or organisations.

Signatories of the Code are also responsible for information disseminated by their staff who do so via their private social media channel in situations where a) the given individual may reasonably be perceived as representing a Signatory of the Code, or b) if the given individual posts content on their private profile / site on instructions, with permission, or with assistance from the Signatory of the Code. Signatories of the Code should have internal guidelines in place on how its staff should behave on digital channels, including their own private profile / site activities.

For digital channels owned by Signatories of the Code, processes should be established to monitor, moderate and/or delete any inappropriate content in a timely manner to the extent permitted by the data

protection regulations and applicable laws and codes of ethics. Signatories of the Code may also find it necessary to institute similar processes when using digital channels owned by other companies or organisations.

Pharmacovigilance

Signatories of the Code should consider developing specific guidance for digital channels from the pharmacovigilance perspective, and likewise consulting their pharmacovigilance experts on specific projects in order to duly meet all their pharmacovigilance responsibilities, including the obligation to monitor, record and report any adverse effects that are discussed about their Medicinal Products.

Transparency

Art. 14.4 of the INFARMA Code of Good Practice requires Signatories of the Code to clearly indicate when they have sponsored a communication or materials concerning Medicinal Products. Whenever a Signatory of the Code or an individual or entity acting on behalf of a Signatory of the Code provides information on a digital channel, involvement of the Signatory of the Code should be clearly stated (including but not limited to highlighting the relevant content and stating that the Signatory of the Code has covered some or all of the costs).

Irrespectively of the above, transfers of value to HCPs, HCOs and POs are subject to mandatory disclosure in accordance with Chapter VI of the INFARMA Code of Good Practice.

When possible, the target audience of the channel should be clearly identified (e.g. HCPs and the public, or a combination thereof).

2. HOW TO IDENTIFY PERMITTED INFORMATION FOR THE DIFFERENT DIGITAL CHANNELS

It is important that the Signatory of the Code differentiates what content is appropriate for the different digital channels and the respective audiences. All laws and regulations in this regard must be complied with in the same way as for other media.

Information made available via a digital channel should be regularly updated and should clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.

The following questions may be useful to assess risks associated with digital communication and appropriateness of digital channel content, access, set-up and maintenance:

What is the objective of the communication (promote, inform, exchange)?

What content will be made available on the digital channel?

- *Is the content related to Medicinal Products?*
- *Is the content promotional or non-promotional?*
- *Is the content related to disease awareness?*
- *Is the content related to healthcare information e.g. in connection with diagnosis, treatment education, or dietary support?*

- *Is the role of the Signatory of the Code in providing/developing the content clear?*

Who is the intended audience? The general public, HCPs or both?

- *Is verification of the audience required?*
- *If yes, how?*

What is the channel standard set-up / configuration?

- *Is the digital channel open to audience reaction such as sharing, commenting, or exchanging?*
- *How is the information cascaded across the digital channels?*
- *Is the digital channel an open platform available to the general public, or is it for a closed audience only?*
- *Are there limitations in content size (as in the case of e.g. Twitter)?*
- *Are there any community guidelines / house rules applicable (as in the case of e.g. Facebook or YouTube)?*
- *How is the information about the platform / channel audience / visitors processed?*

How is the content reviewed, approved and maintained, including by the Signatory of the Code itself?

3. GUIDANCE FOR SIGNATORIES OF THE CODE FOR VARIOUS DIGITAL CHANNELS

Set out below is a short description of the general use of different types of digital channels. When deciding which digital channel to use and how to develop it, the general principles set out above should be taken into account.
The content published by a Signatory of the Code on any digital channel must be appropriate and aligned with relevant regulations, laws and codes, including the INFARMA Code of Good Practice.

Websites

Websites are classified as a channel that reaches the public, unless verification (e.g. with a login and password) is required to access the website. Some websites may include forums where the public can exchange information or discuss topics.

Since many website visits are a result of using a search engine, keyword optimization has become an important tool. Signatories of the Code can use appropriate search optimization to ensure that their websites are displayed high on the list of search results for relevant key words. At the same time, however, Signatories of the Code need to ensure that any use of keyword optimization is appropriate for the intended audience. For example, optimized search through use of key words directed at websites with therapy-oriented information for the public would, by its very nature, be different from that for websites aimed at HCPs which can only be accessed by authorized individuals.

Signatories of the Code may sponsor website material to be produced by a Third Party, provided that the role of the Signatory of the Code is clearly stated. If the Signatory of the Code i) is initiating the material, or the general concept for it; ii) is influencing the substantive content of the material in any way; or iii) is selecting or directly paying the authors, then the Signatory of the Code is very likely to be deemed responsible for the contents of the website. If the reverse is true, and there is a strictly arm's length

arrangement with the Signatory of the Code just providing a grant, then there is the possibility that the Signatory of the Code may not be deemed responsible.

Signatories of the Code should be confident about the choice of linked websites and that these do not promote Medicinal Products to the public. If a Signatory of the Code includes website addresses in an advertisement of a Medicinal Product to HCPs, the core principles apply to ensure the content of those websites is appropriate.

Social media

In general, social media (websites or applications on which people can interact in social networks e.g. Facebook, Twitter, Snapchat, LinkedIn, YouTube, Instagram) are digital channels that are considered to be aimed at the public, and are used to reach or interact with the public. That said, a social media platform can also be a closed channel for a targeted audience where verification of the audience is required before providing access.

Blogs

The difference between a text on a website and on a blog is that a blog is usually owned and updated by an individual or a group of individuals posting on the blog regularly.

A blog can be owned and run by a Signatory of the Code, or a Signatory of the Code may engage (either through sponsorship or consultancy fees) the owner (e.g. a "social influencers") to write on a blog. In both cases, the blog should clearly state the involvement (substantive and/or financial) of the Signatory of the Code.

Given that, by its very nature, a blog is for contributors to freely and spontaneously express their personal views on a subject, Signatories of the Code should not sponsor such blogs if they were intended, or could reasonably be expected, to promote Medicinal Products.

Podcasts

A Signatory of the Code can record and post its own podcasts, which should follow the same rules as for websites.

A podcast can be downloaded from any podcast distributor. Core principles apply, of ensuring the recipient is well defined and targeted and that content is appropriate. A podcast promoting Medicinal Products, for instance, should only be addressed to HCPs.

Applications (Apps)

An application, usually referred to as an "app", is to be downloaded on an electronic device (e.g. smartphone, computer or tablet).

A Signatory of the Code can develop apps for the use of external stakeholders (e.g. HCPs, HCOs, patients, payers), provided that they follow the same rules as for websites. Also, they should consider potential

regulatory requirements if the app fulfils the requirements for a medical device. Core principles apply, including ensuring the audience is well defined and targeted.

An app can also be developed to improve compliance with a treatment method. If an app targets a specific group (e.g. HCPs, patients, caregivers), it is important that only this group is offered access to the app content.

Webinars

A webinar is an on-line event (e.g. a lecture, presentation or other event) conducted via the internet, and it can be either performed as a live streaming event or as an on-demand service.

A Signatory of the Code can be the direct organiser of a webinar and/or use a Third Party facilitator to run the event, although the Signatory of the Code shall remain responsible for these webinars, including the content and ensuring that the audience is well d efined and targeted. Similar arrangements apply to Third Party webinars sponsored by Signatory of the Code.

Webinars can be used for communication with external stakeholders (e.g. HCPs, HCOs, patients, payers), provided that they follow the same rules as apply for websites.

Direct channels

The distinction is observed between “one-to-one” and “one-to-many” channels, which are targeting selected recipients. These are most commonly private, not visible to non-selected recipients; they could be replies on social media channels to an individual.

Signatories of the Code should, whensoever required, ensure they have the consent of the recipients to be in contact with them, and the recipients should be able to stop receiving messages (unsubscribe) easily. Appropriateness of the frequency of contact should be borne in mind.

Discussion forums

If a Signatory of the Code facilitates a discussion forum on a Third Party platform or hosts a forum on its own platform, the Signatory of the Code must be confident that they can moderate the site so that the content complies with relevant regulations, laws and principles including the INFARMA Code of Good Practice. The intended audience should be identified so that relevant requirements are complied with. If discussion forums are used for market research, Signatories of the Code should ensure these are compliant with relevant legal and ethical guidelines.

Appendix 4
Template form

Date of report publication: _____

	Given name and surname / name of entity	Seat / place of business	Country	Business address	Unique country identifier[1] (optional)	Donation and grants to HCO	Covering of Events costs			Service and advisory fees		Total (optional)
							Sponsor agreements with HCO or 3rd parties designated by HCO to organise Event	Registration fees	Travel and accommodation costs	Fees	Ancillary expenses, incl. travel and accommodation	
HCPs	*Individual disclosure - separate item for every HCP (ToVs made in the given Reporting Period shall be added together; itemised summary may be presented only at the request of the entitled entity)*											
	Other – information which could not be disclosed individually											
	Value of ToVs to Recipients											
	No. of Recipients in collective summary											
	% of Recipients included in the collective summary vs. total number of Recipients – by category											

HCOs	*Individual disclosure – separate item for every HCP (ToVs made in the given Reporting Period shall be added together; itemised summary may be presented only at the request of the entitled entity)*											
	Other – information which could not be disclosed individually											
	Value of ToVs to Recipients											
	No. of Recipients in collective summary											
	% of Recipients included in the collective summary vs. total number of Recipients - by category											

Research and development activity (collective summary)	
Amount	

* Tax ID number (NIP) for HCOs and medical license number fo HCPs

SIGNATORIES OF CODE

AbbVie Polska Sp. z o.o.
www.abbvie.pl

Allergan Polska Sp. z o.o.
www.abbvie.pl

Almirall Sp. z o.o.
www.almirall.pl

Amgen Biotechnologia Sp. z o.o.
www.amgen.pl

Angelini Pharma Polska Sp. z o.o.
www.angelini.pl

Astellas Pharma Sp. z o.o.
www.astellas.com

AstraZeneca Pharma Poland Sp. z o.o.
www.astrazeneca.pl

Bayer Sp. z o.o.
www.bayer.com.pl

Biogen Poland Sp. z o.o.
www.biogen-poland.pl

Boehringer Ingelheim Sp. z o.o.
www.boehringer-ingelheim.pl

Bristol-Myers Squibb Polska Sp. z o.o.
www.bms.com/pl

Chiesi Poland Sp. z o.o.
www.chiesi.pl

Eli Lilly Polska Sp. z o.o.
www.lilly.pl

GSK COMMERCIAL Sp. z o.o.
www.pl.gsk.com

IPSEN POLAND Sp. z o.o.
www.ipsen.com/poland/

Janssen-Cilag Polska Sp. z o.o.
www.janssen.com/poland/

Leo Pharma Sp. z o.o.
www.leo-pharma.pl

Lundbeck Poland Sp. z o.o.
www.lundbeck.com/pl

Merck Sp. z o.o.
www.merckgroup.com/pl

MSD Polska Sp. z o.o.
www.msd.pl

Novartis Poland Sp. z o.o.
www.novartis.pl

Novo Nordisk Pharma Sp. z o.o.
www.novonordisk.pl

Pfizer Polska Sp. z o.o.
www.pfizer.com.pl

Roche Polska Sp. z o.o.
www.roche.pl

Sanofi-Aventis Sp. z o.o.
www.sanofi.pl

Servier Polska Sp. z o.o.
www.servier.pl

Takeda Pharma sp. z o.o.
www.takeda.com/pl-pl

UCB Pharma Sp. z o.o.
www.ucb.pl

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