

Code of deontology

Modified by the General Assembly
of 13 May 2020

pharma.be

ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

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Preamble

The Preamble to the code is the aspirational basis for the ethical concepts that Member Companies believe in.

pharma.be ethical principles

pharma.be Member Companies invest in medical and biopharmaceutical research and commit to develop innovative solutions for unmet medical needs. They commit to offer their medicines in accordance with all local and international applicable rules and regulations within a global ethical framework.

The first priorities are the health and well-being of patients and the quality of healthcare provision.

The pharma.be Member Companies endorse the following ethical principles:

- 1.** Member Companies aspire to provide medicines that conform to the highest standards of quality, safety and efficacy as determined by regulatory authorities.
- 2.** Member Companies aspire to provide accurate, balanced and scientifically valid data on medicines to their stakeholders.
- 3.** Member Companies aspire that the information in promotional materials support a fair balance of risks and benefits of their medicines and their proper use. Promotion is ethical, accurate, balanced and must not be misleading.
- 4.** Member Companies strive to demonstrate openness and transparency in their relationships with stakeholders and Healthcare Professionals in line with applicable legislation. Member Companies' interactions with stakeholders are ethical, appropriate and professional. As described in applicable legislation, nothing is offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
- 5.** All clinical trials and scientific research sponsored or supported by Member Companies are conducted with the sole intent to develop knowledge that will benefit patients and advance science and medicine. Member Companies are committed to the transparency of industry sponsored clinical trials in patients.

IFPMA Ethos

Member Companies endorse the Ethos of IFPMA. This Ethos underpins the rules of the present code and provides a framework to behave with integrity no matter how testing the circumstances. It serves to instill a culture of ethics and integrity needed to guide Member Companies business behaviours and interactions with the healthcare community.

Our Ethos

Building a culture of trust



Trust

Act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients and other stakeholders.

<https://www.ifpma.org/subtopics/ifpma-ethos/#:~:text=IFPMA%20Ethos&text=The%20Ethos%20is%20the%20foundation,with%20ever%20changing%20society's%20expectations.>

Care

Protect the safety of those who use our products – from the conduct of clinical trials and throughout the product lifecycle.

Innovation

Improve global health through innovative products and services, upholding the highest ethical, scientific, and medical standards.

Quality

Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

Fairness

Support and respect fair trade practices and open competition.

Integrity

Foster a culture in our respective organisations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

Accountability

Be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.

Honesty

Ensure truthful and balanced communication with governmental authorities, Healthcare Professionals, patients and other stakeholders.

Speaking up

Foster a culture in our respective organisations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

Transparency

Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.

Respect

Respect all people and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.

Privacy

Respect privacy rights and appropriately manage and protect personal information.

Education

Support the advancement of the scientific and medical education for the ultimate benefit of patients.

Definitions

Applicable Codes:

- (a) the present code; and
- (b) in the case of the promotion or interaction does not take place in Belgium, the national code that applies in the country where the promotion or interaction takes place.

In case of an event that does not take place in Belgium for which a Member Company sponsors the attendance of a HCP/PO's Representative, if any funding is provided to such HCP/PO's Representative, such funding is subject to the rules of the National Code where such HCP/PO's Representative carries out his/her profession or has its main location, as opposed to those in which the international event takes place.

When, on the basis of the previous paragraphs, several national codes of deontology apply, the most constraining provision shall apply in the event of contradiction between the applicable provisions.

Healthcare Organisation (HCO): any association or organization active in health, medical or scientific care, whatever its legal or organisational form, as well as any legal entity through which one or more Healthcare Professionals provide services, except for POs within the scope of the definition hereunder.

Healthcare Professional (HCP): any natural person practicing medical, dental, pharmaceutical or nursing art who, in the course of his professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicines or medical devices.

For the purpose of Chapter 1 "Promotion of prescription-only medicines to HCPs", HCPs mean any natural person qualified to prescribe or supply a medicinal product.

Member Company: as defined in the pharma.be bylaws, means legal persons who are active in Belgium in the field of medicinal products for human use or goods or services related to the use of medicinal products for human use, from research to production up to and including marketing, whose purpose is to place the above-mentioned products on the market themselves or via third parties, and who have been admitted as members of pharma.be by the pharma.be General Assembly.

Patient Organisation (PO): any not-for-profit organisation (including the umbrella organisation to which it belongs), whether or not it has legal personality, mainly composed of patients and/or (non-professional) caregivers and that serves and/or supports the needs of patients and/or (non-professional) caregivers.

Patient Organisation's Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.

Applicability of the code

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to the pharmaceutical industry such as pharmaceutical, competition, intellectual property and data protection laws, as well as anti-bribery and anti-corruption legislation), Member Companies have agreed to comply with additional standards in the present self-regulatory code.

The present code applies to promotion and interactions that are undertaken, sponsored or organised by or on behalf of, or with, a Member Company.

The present code applies without prejudice of and supplements all legal and regulatory provisions on the subject of promoting and providing information on medicinal product for human use as well as those related to interactions with Healthcare Professionals and organizations, and patient organizations, which must be respected under all circumstances.

The deontological bodies of pharma.be are competent to deal with any offence committed by a Member Company with regard to aforementioned promotion, provision of information and interaction.

The present code also supplements the provisions of the EFPIA code of Practice, of the IFPMA code of Practice and of the code of Ethics of the non-profit association Mdeon. In case of contradiction between the codes, the most constraining provision shall always apply, to the extent compatible with the legislation in force.

Scope of the code

The present code concerns medicinal products for human consumption, as defined by Article 1 of the law of 25 March 1964 on medicines. Failing express indication to the contrary, the provisions of the code apply to all medicinal products, whether subject to prescription or not, and whether reimbursable or not. Medicinal products for veterinary use are governed by their own set of rules.

When it is stated that a rule is only applicable to medicines subject to prescription, Member Companies are strongly encouraged to also respect this rule in regard to their other products.

The present code applies to all means implemented with a view to promoting or providing information on medicinal products, to the interactions between Member Companies and Healthcare Professionals, Healthcare Organisations and Patient Organisations. It covers more specifically:

- promotion of prescription-only medicines to HCPs (whether oral, written or by any other method of promotion);
- interactions between Member Companies and HCPs, HCOs and POs;
- and disclosure of transfers of values from Member Companies to HCPs, HCOs and POs.

Member Companies are responsible for the obligations imposed under any relevant Applicable Code even if they commission a third party to design, implement or engage in activities covered by the Applicable Code on their behalf.

In addition, Member Companies must take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Applicable Code(s) but that do not act on behalf of the Member Company (e.g. joint ventures, licensees) comply with Applicable Codes.

Chapter 1.

Promotion of prescription- only medicines to HCPs



Section 1. Promotion in general

The promotion of prescription-only medicines to HCPs is subject to Belgian legislation and in particular to conditions laid down in article 9 of the law of 25 March 1964 on Medicines and in the Royal Decree of 7 April 1995 on information and advertising of medicinal products for human use.

The following requirements apply in addition to these texts.

ARTICLE 1. Acceptability of promotion

Member Companies must maintain high ethical standards at all times.

Promotion must:

- A.** never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry;
- B.** be of a nature which recognises the special nature of Medicinal products and the professional standing of the intended audience; and
- C.** not be likely to cause offence.

ARTICLE 2. Promotion and its substantiation

- A.** Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from HCPs. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.
- B.** Attention must be paid to ensure that the visual material such as graphs, illustrations, photographs or tables is not used to misleading effect, either in regard to the nature of a medicinal product (for example, whether or not it is suitable for children) or any claim or comparison (for example, by using incomplete information or information of no statistical significance or uncustomary scales).
- C.** Whenever published studies are mentioned in the promotional material, clear references shall be given.
- D.** The terms "safe" and "without danger" or any other term expressing a similar concept may not be used unless clearly defined. The word "new" must not be used to describe any medicinal product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.
- E.** It must not be stated that a medicinal product has no side effects, toxic hazards or risk of addiction or dependency.

ARTICLE 3. Use of quotations in promotion

Citations shall not be invoked in a tendentious manner out of context and shall remain true to the spirit of their author.

ARTICLE 4. Distribution of promotion

It will be presented objectively and according to good practice, avoiding the use of misleading pictures or exaggerated descriptions. It must be presented in a way that does not conceal its real purpose.

Information or promotion relating to medicinal products may only be aimed at those HCPs whose need for, or interest in, the particular information can reasonably be assumed.

The use of digital communications for promotion is only allowed with valid consent and/or at the request of the recipient.

ARTICLE 5. Transparency of promotion

Promotional material for medicinal products must always be identifiable as such.

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 a primarily scientific or educational purpose.

Where a Member Company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter

Material relating to medicinal products and their uses, whether promotional in nature or not, which is sponsored by a Member Company must clearly indicate that it has been sponsored by that Member Company.

ARTICLE 6. Personal medical matters

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult a HCP.

ARTICLE 7. Responsibility of the Member Company

Member Company must appoint at least one senior employee who must be responsible for supervising the Member Company and its subsidiaries to ensure that the standards of the Applicable code(s) are met.

Section 2. Member company staff

ARTICLE 8. Medical representatives

Member Companies exercise control over and assume responsibility for the actions of their personnel. This responsibility continues to apply even if the medical representatives fail to respect the instructions they are given.

They shall ensure that medical representatives, including personnel to which there is recourse on the basis of an agreement with third parties, and all the other company representatives who are in contact with Healthcare Professionals in the framework of the promotion of medicinal products, are familiar with the pertinent provisions of the Applicable code(s), as well as with the applicable legal provisions and regulations.

The holder of the marketing authorisation checks that the medical representatives employed by its company have received adequate training and respect the obligations incumbent upon them.

The obligations of the medical representatives are the following:

- A.** medical representatives must comply with all relevant requirements of the Applicable code(s), and all applicable laws and regulations, and Member Companies are responsible for ensuring their compliance.
- B.** medical representatives must approach their duties responsibly and ethically.
- C.** medical representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.
- D.** medical representatives must not use any inducement or subterfuge to gain an interview.
- E.** in an interview, or when seeking an appointment for an interview, medical representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Member Company they represent.

ARTICLE 9. Scientific service

In addition to the conditions laid down in article 13, §1 of Royal Decree of 7 April 1995 on information and advertising of medicinal products for human use the scientific service organized by the Member Company should include a medical doctor or a pharmacist.

The scientific service is responsible for the approval and the supervision of non-interventional studies which are carried out by or with the support of the holder of the authorisation (cfr. Section 7 of Chapter 2).

ARTICLE 10. Responsible for the information and promotion

The Responsible for the information and promotion as referred to in art. 13 of Royal Decree of 7 April 1995 on information and advertising of medicinal product for human use must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of any Applicable Codes, laws and regulations.

Chapter 2.

Interactions with HCPs and HCOs



Section 1. Ban on Gifts

ARTICLE 11.

With regard to prescription-only medicines, the offer, granting or promise of any gift to a Healthcare Professional or a Healthcare Organisation's member, either directly or indirectly, is prohibited, even when it is of negligible value and concerns the exercising of the medical profession, dental profession or pharmaceutical profession, and in particular:

- gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts);
- cash, cash equivalents or personal services. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the recipient;
- promotional aid or gadget. For these purposes, a promotional aid is a non-monetary item given for a promotional purpose.

Section 2. Informational or educational materials and items of medical utility

ARTICLE 12.

- A.** Member Companies may only provide Healthcare Professionals and members of Healthcare Organisations with informational or educational material when this material is:
- I. of limited value;
 - II. directly relevant to the practice of medicine or pharmacy; and
 - III. directly beneficial to the care of patients.
- B.** Items of medical utility may only be provided for Healthcare Professionals and members of Healthcare Organisations when these items are:
- I. intended directly for the training of Healthcare Professionals and the care of patients;
 - II. of limited value; and
 - III. not part of the basic material or basic equipment which every Healthcare Professional needs for his or her routine practice.
- C.** The term "of limited value" as mentioned above under points A and B is defined in the relevant guidelines.

- D.** Informational or educational materials and items of medical utility can include the Member Company name, but must not be product branded, unless the medicinal product's name is essential for the correct use of the material or item by the patient.
- E.** The nature of informational or educational material and items of medical utility considered may not constitute a circumvention of the prohibition on gifts defined under article 11. Under no circumstances may this material be provided with the intention of encouraging the recommending, prescribing, purchasing or selling, supplying or administering of a medicinal product.

Section 3. Scientific events and hospitality

The sponsoring and the organisation of scientific meetings by or on behalf of Member Companies are subject to Belgian legislation and in particular to conditions laid down in article 10 of the law of 25 March 1964 on Medicines and in Mdeon's code of Ethics and in its related guidelines.

ARTICLE 13.

The invitation of Healthcare Professionals to and the defrayment of the costs of participating in a scientific event which takes place during several consecutive calendar days, as well as the related hospitality, are subject to an advance visa procedure. In which case, Member Companies are obliged to obtain the visa from the Visas Bureau of the non-profit association Mdeon.

In addition to those rules, Member Companies must comply with the following.

- A.** Scientific events that are directly or indirectly supported or organised by Member Companies and that are attended by Healthcare Professionals shall take place within a framework of quality. When a scientific event does not take place in Belgium, it must also, in accordance with the definition of "Applicable code(s)" of the present code, comply with the criteria laid down by the code of deontology that applies in the country where the event takes place.
- B.** The hospitality made available will always be limited to that which the Healthcare Professionals who benefit from it would reasonably be prepared to pay themselves.
- C.** The public use of an HCO logo and/or proprietary material by a Member Company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.
- D.** Member Companies must ensure that their sponsorship to HCOs is always clearly acknowledged and apparent from the outset.

Section 4. Contracted Services

The conclusion of contracts with Healthcare Professionals for the provision of legitimate services of a scientific nature is subject to Belgian legislation and in particular to conditions laid down in article 10 of the law of 25 March 1964 on Medicines.

ARTICLE 14.

Notwithstanding the legal provisions, contracts between Member Companies and institutions, organisations or associations of Healthcare Professionals by the terms of which such institutions, organisations or associations provide services to companies, are only allowed if such services:

- A. support healthcare or research,
- B. do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products.

ARTICLE 15.

- A. Notwithstanding the legal provisions, a Member Company may contract one or more Healthcare Professionals as consultants for services such as speaking at or chairing scientific meetings, involvement in medical/scientific studies, clinical trials or training courses, participation in advisory board meetings or participation in market research, where such participation involves remuneration and/or hospitality.
- B. The arrangements made in this respect, if relevant to this subject, must satisfy the following conditions:
 - I. a legitimate need for the services is clearly identified and documented before retaining the Healthcare Professionals and making arrangements in this respect;
 - II. the criteria for selecting consultants are directly related to the identified legitimate need as referred to in clause I. and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the contacted Healthcare Professionals meet those criteria;
 - III. the number of Healthcare Professionals retained and the extent of the services is not greater than the number reasonably necessary to achieve the identified need;
 - IV. a written contract must be drawn up before the commencement of the services which specifies the nature of the services to be provided by the Healthcare Professionals as well as the basis for payment for their services notwithstanding what is cited in clause VII. hereafter;

- V. the Member Company maintains records concerning the services provided and makes appropriate use of them;
- VI. the engagement of the Healthcare Professionals to provide the services is not an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products and
- VII. the remuneration for the services is reasonable and reflects the usual market value of the services provided.

- C. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation.
- D. For the purposes of transparency, Member Companies are strongly encouraged to include in the written contract as mentioned above in paragraph B, IV, a provision regarding the obligation of the Healthcare Professional in question to declare that he/she is fulfilling a consultancy or advisory mission for the Member Company whenever he/she speaks in public or publishes on matters that are the subject of the agreement or any other issue relating to that company.

Similarly, Member Companies that employ Healthcare Professionals on a part-time basis who are still practising their profession are strongly encouraged to impose on such persons the obligation to declare their employment arrangement with the company whenever they speak in public or publish on matters that are the subject of their employment arrangement or any other issue relating to that company.

- E. Limited market research, such as one-off phone interviews or surveys by post, e-mail or internet are excluded from the scope of this section provided that the Healthcare Professionals or HCO's member concerned are 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 is minimal.
- F. When a Healthcare Professional attends a scientific event in the capacity of consultant, the Section 4 of Chapter 2 of the present code apply.

Section 5. Provision of means

ARTICLE 16. Member Companies funding

No Member Company may require that it be the sole funder or sponsor of an HCO or any of its programmes. Member Companies welcome broad funding and sponsorship of HCOs from multiple sources.

ARTICLE 17. Subsidies and sponsoring

- A.** Notwithstanding the applicable legal provisions, Member Companies are free to make financial resources or other means of functioning available to third parties.

For the purposes of this Article, "financial means or other operating means" are taken to mean: subsidies, sponsoring, provision of services for humanitarian purposes.

Means made available to institutions, organisations or associations that are made up of Healthcare Professionals and/or that provide healthcare or conduct research, are only allowed if they are made available for the purpose of supporting healthcare or research and if they do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products.

Under no circumstances may the means referred to in the previous paragraph be provided to individual Healthcare Professionals.

If means are made available in the context of continuing medical training (CMT), the primary goal of the meetings is to strengthen medical knowledge.

- B.** The Member Company making means available to third parties shall ensure that this is laid down in writing and takes all useful measures to ensure it is informed of the destination and use of the means made available.

If the means made available are for activities linked to information and promotion concerning the medicinal products, the Member Companies themselves shall remain responsible for ensuring that the third parties comply with the rules laid down in the code.

If these activities relate to scientific events which takes place during several consecutive calendar days, as referred to in Section 3 of Chapter 2 of the present code, the Member Companies that made the aforementioned means available are subject to the advance visa procedure as referred to under that Article.

When a Member Company contributes to the content of training activities or programmes (CMT) the materials supplied must be honest, balanced and objective and included in such a way that they enable various theories and recognised views to be expressed. The content must consist of medical, scientific or other information that can contribute to improving patient care.

ARTICLE 18. Grants and Donations

Making available financial means or other operating means, as grant or donation, to institutions, organisations or associations that are made up of Healthcare Professionals and/or that provide healthcare or conduct research, with the exception

of means made available for the purpose of scientific research in the sense of art. 42, §1, al 3 of the Act of 18 December 2016 on diverse dispositions concerning health ("Sunshine Act"), is only allowed under the following conditions:

- A.** Under no circumstances may such means be provided to individual Healthcare Professionals, be it either directly or indirectly;
- B.** Such means can in no way constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products;
- C.** Requests for such means should be unsolicited, meaning that the need for such means is expressed by the Healthcare Organisation;
 - Requests in response to scientific awards, for which the submitted projects are reviewed by an independent and competent medical or scientific panel, are exempted from this condition;
- D.** The means may not impair the independence, the integrity and the credibility of the beneficiary;
- E.** It is only allowed to make such means available for the purpose of supporting healthcare, scientific research or education;
- F.** Such means can only finance activities that are not funded or not funded fully via normal channels;
- G.** The beneficiary of such means cannot be, either directly or indirectly, a group practice (i.e. a group of Healthcare Professionals organised under a same practice, with shared earnings and logistics) or other for-profit organisation;
- H.** Such means can only be granted for projects that are specific, well-defined, and well framed, budgeted and documented;
- I.** The provision of means can not require obligations on behalf of the beneficiary, except for a reference to the company and/or reporting by the beneficiary;
- J.** The Member Company making means available shall ensure that this is laid down in writing and takes all useful measures to ensure it is informed of the destination and the use of the means made available. It also ensures that it has an appropriate non-commercially driven internal review and approval process, including adequate documentation, overseen by an appropriate signing authority.

Section 6. Medical education

ARTICLE 19.

Medical education is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome. Member Companies can be engaged in different types of Medical education but

such activities must have an exclusive scientific character as referred to in the Belgian legislation.

When funding independent medical education or organizing medical education activities directly or in collaboration with third parties, Member Companies must ensure that their participation and role is clearly acknowledged and apparent from the outset.

When organizing medical education activities in which Member Companies have input in the 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.

Section 7. Non interventional studies

Non-interventional studies are subject to the conditions laid down in the law of 7 May 2004 on experiments on the human person. In addition to those conditions, the following applies.

ARTICLE 20.

Non-interventional studies (NIS) shall be conducted within a quality framework.

A non-interventional study is understood to mean a study in which the medicinal products are prescribed in the usual manner, in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current medical practice and the decision to prescribe the medicinal product is clearly separated from the decision to include a patient in the study. The patient in question must not be subject to additional diagnostic or monitoring procedures and epidemiological methods shall be used for the analysis of collected data.

ARTICLE 21.

Non-interventional studies must be conducted with a primarily scientific purpose and must not be disguised promotion.

ARTICLE 22.

Non-interventional studies that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study must comply with all of the following criteria:

- A.** a written scientific protocol shall provide a detailed description of the purpose sought and methodology implemented; the aforementioned purpose and methodology shall always be coherent with one another;

- B.** the scientific protocol must be approved in advance by the Member Company's scientific service as referred to under article 9 of the present code and this service has to supervise the conduct of the study;
- C.** a written contract shall provide a detailed description of the services expected from the investigators as well as of the amount and the procedures for remunerating the investigators;
- D.** the remuneration is commensurate with the services requested and reflects the fair market value thereof;
- E.** the future use of the data collected shall be stated clearly in the protocol;
- F.** the study results must be analysed and reports thereof must be submitted within a reasonable period of time to the Member Company's scientific service which shall maintain these reports for a reasonable period of time;
- G.** the Member Company must send the study results to all Healthcare Professionals who participated in the study; if the study shows results that are important for the assessment of the benefit-risk ratio of the studied medicinal product(s), these results should be immediately forwarded to the competent authority;
- H.** medical sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's scientific service that will also ensure that the medical sale representative are adequately trained. Such involvement must not be linked to the promotion of any medicinal product;
- I.** When required by the legislation and/or required by the ethics committee, the study plan must be submitted to the ethics committee for review.

The scientific service as referred to in article 9 of the code will be responsible for the approval and the supervision of any NIS (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by medical sales representatives). Such person must certify that he or she has examined the protocol relating to the NIS and that in his or her belief it is in accordance with the requirements of any relevant codes, laws and regulations.

Section 8. Samples

The delivery of free medicinal product samples by Member Companies is regulated by the Belgian legislation and, in particular, by art. 12 of the law of 25 March 1694 on Medicine and in the Royal Decree of 11 January 1993 establishing the conditions under which the delivery of medicinal products for human use as samples can be performed.

Chapter 3. Interactions with POs



Section 1. General principles

ARTICLE 23.

In their interactions with POs, Member Companies undertake to comply with the following principles:

- A.** The independence of POs, in terms of their political judgement, policies and activities, must be assured.
- B.** All interactions between POs and Member Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
- C.** Member Companies must not request, nor shall POs undertake, the promotion of a particular prescription-only medicine.
- D.** The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Member Companies must always be clearly acknowledged.

ARTICLE 24.

When Member Companies provide financial support, significant indirect support and/or significant non-financial support to POs, they must have in place a written agreement that includes as a minimum:

- A.** the amount of the funding or, in case of indirect or non-financial support, a precise description of the support,
- B.** the purpose of the funding, such as the allocation of an "unrestricted grant", support for a particular meeting or publication, etc. and
- C.** the code(s) of deontology applicable to the support as describe in the Section "Definitions" of the present code.

Each Member Company shall have an internal approval process in place for these agreements.

ARTICLE 25.

No Member Company may require that it be the sole funder or sponsor of a PO or any of its programmes. Member Companies welcome broad funding and sponsorship of POs from multiple sources.

ARTICLE 26.

Notwithstanding the application of legal provisions and regulations, a Member Company is only allowed to publicly use a Patient Organisation's logo or proprietary

material with the written permission from that organisation. In this permission the purpose and the way the logo or proprietary material will be used must be clearly stated.

ARTICLE 27.

Member Companies must not influence the text of PO's material they sponsor in a manner favourable to their own commercial interests. This does not preclude Member Companies from correcting factual inaccuracies. In addition, at the request of POs, Member Companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

Section 2. Ban on gifts

ARTICLE 28.

The offer, granting or promise of any gift to a PO's Representative is prohibited, and in particular:

- gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts);
- cash, cash equivalents or personal services. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient;
- promotional aid or gadget. For these purposes, a promotional aid is a non-monetary item given for a promotional purpose (e.g. mugs, memory sticks, diaries, calendars, thermometers, ...).

Section 3. Events and hospitality

ARTICLE 29.

- A.** Member Companies may financially support events that are organised by Patient Organisations provided that the main purpose of the event is of a professional, educative and scientific nature or in some other way supports the mission of the Patient Organisation.

Under no circumstances shall the offer of hospitality include sponsoring or organising entertainment events (e.g. sporting or leisure activities).

- B.** Events for patients that are sponsored or organised by or on behalf of a Member Company will always be held in venues that are appropriate and conducive for the main purpose of the event. Locations that are known for entertainment or that are extravagant must be avoided.

- C.** Hospitality that is extended by the Member Companies to Patient Organisations and their representatives must always be appropriate and otherwise comply with the provision of any Applicable code(s).
- D.** The hospitality that is offered in connection with an event shall be limited to the organisation, travel, meals, accommodation and genuine registration fees.
- E.** Hospitality may only be offered to participants in the event. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.
- F.** All forms of hospitality offered to Patient Organisations and their representatives must be "reasonable" in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.
- G.** A Member Company may not organise or sponsor events that take place outside Belgium unless:
 - I.** most of the invitees are from outside Belgium and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country, or
 - II.** given the relevant expertise or infrastructure at the location of the event, it makes greater logistical sense to hold the event in another country.
- H.** Member Companies must comply with criteria governing the selection and support of PO's Representatives to attend events as provided in, or in connection with, any Applicable code(s).
- I.** No payment must be offered to compensate merely for the time spent by the PO's Representative in attending events
- J.** Member Companies must ensure that their sponsorship to POs is always acknowledged and apparent from the outset

Section 4. Contracted services

ARTICLE 30.

Contracts between Member Companies and Patient Organisations or their representatives in which the latter undertake to perform particular services for the former are only allowed if these services

- A.** are provided to support health care, research or education; and
- B.** do not constitute an inducement to recommend, purchase or use specific medicinal products.

ARTICLE 31.

- A.** Member Companies may contract one or more Patient Organisations or their representatives as consultants for services such as speaking at or chairing scientific meetings or general consultancy activities where such contract involves remuneration and/or hospitality.
- B.** Contracts in which these genuine consultancy or other services are regulated must, insofar as they are relevant, comply with the following conditions:
 - I.** prior to the start of the services a written contract must be drawn up in which the nature of the services to be provided is specified and, subject to clause VII. below, the basis for the remuneration for these services;
 - II.** a legitimate need for the services has been clearly identified and documented before the services are requested and before entering into the agreement;
 - III.** the criteria for selecting the consultants are directly linked to the identified need mentioned in clause II. and the people who are responsible for selecting the consultant possess the necessary expertise to evaluate whether the particular consultant satisfies the criteria;
 - IV.** the number of consultants retained and the scope of the service are not greater than that which is reasonably necessary to realise the identified need;
 - V.** the Member Company keeps a report of the services provided and makes appropriate use of it;
 - VI.** the engagement of the consultant to provide the relevant service is not an inducement to recommend and/or purchase or use a particular medicinal product;
 - VII.** the remuneration for the services is reasonable and reflects the fair market value of the services provided. Consultancy contracts made may not be used as justification for remunerating Patient Organisations or their members.

ARTICLE 32.

In their written contracts with consultants, Member Companies are strongly encouraged to put a clause regarding the obligation of the consultant to declare that they are consultant to the company whenever they write or speak about in public about a matter that forms the subject of the contract or about any other matter in connection with the company.

ARTICLE 33.

Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this section, provided that the Patient Organisation or their members are 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 is minimal.

ARTICLE 34.

If a Patient Organisation's representative attends an event (an international event or otherwise) in a consultant capacity, the relevant provisions of Section 3, Chapter 2 must apply.

Section 5. Grants and donations**ARTICLE 35. Grants and donations**

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

- A.** they are made for the purpose of supporting healthcare, research or education;
- B.** they are documented and kept on record by the donor/grantor; and
- C.** they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicinal products.

Donations and Grants to individuals are not permitted.

Section 6. Transparency**ARTICLE 36. Transparency**

Notwithstanding the legal provisions and regulations, in particular those relating to the advertising of medicines, each Member Company will ensure that its sponsorship is always clearly acknowledged and apparent from the outset.

Chapter 4.

Transparency

In order to comply with its obligation to transpose the EFPIA Disclosure Code, adopted on 24 June 2013, pharma.be incorporates into this code the obligation to publish transfers of value as it results from the Law of 18 December 2016 containing various provisions relating to health, Title 3, Chapter 1 (Sunshine Act) and the Royal Decree of 14 June 2017 implementing the Sunshine Act.



Chapter 5.

Supervision - Measures upon non-compliance with the code



Section 1. Generalities

ARTICLE 37.

To ensure compliance with the code and that its rules are properly applied, a number of bodies have been established, including:

- A.** Secretariat;
- B.** A supervisory body: the Bureau for Control on Written Communication, hereinafter referred to as the "BCWC";
- C.** Two disciplinary bodies:
 - I.** the Committee for Deontology and Ethics in the Pharmaceutical Industry, hereinafter referred to as the "DEP Committee"; and
 - II.** the Chamber of Appeal.

ARTICLE 38.

- A.** The Secretariat is tasked with general management duties and overseeing the organisation and administration of the deontological scheme. It assists the disciplinary and supervisory bodies in their duties. Since strict neutrality and independence must be maintained at all times, it does not intervene in the decision-making process of any of the disciplinary or supervisory bodies.
- B.** pharma.be assumes material responsibility for the Secretariat. Qualified individuals in the form of designated secretaries ensure the function of the latter. Each can assist or replace their peers as required, on a reciprocal basis.

ARTICLE 39.

- A.** Except where derogation is expressly specified under this code, a mandate within one of the disciplinary or supervisory bodies is not compatible with a mandate in any of the other (disciplinary or supervisory) bodies of pharma.be.
- B.** The president of each disciplinary or supervisory body shall have sole discretion for ruling on procedural issues.
- C.** The president of the disciplinary or supervisory bodies may call in, at its own initiative or at the request of the parties, an expert of its choice, at any stage of the proceedings, to provide an opinion on any specific question, noting that said individual shall be bound by a confidentiality obligation.
- D.** The members of the various disciplinary or supervisory bodies expressly undertake, under penalty of possible exclusion from the relevant body decided by the Board of Directors, to guarantee the confidentiality of all data, information,

exhibits, acts, documents and any other elements of which they become aware in the course of exercising their mandate.

- E.** Each member of a disciplinary or supervisory body must act with complete neutrality, independence and impartiality. In the event of any (perceived) lack of neutrality, independence or impartiality, the relevant member shall refrain from participating in any phase of the proceedings or handling of the case at stake. On this basis, for example, where a member of one of the disciplinary bodies belongs to the same company – or the same interest group as indicated in Article 9 of the bylaws – as one of the parties involved in the proceedings, said member shall refrain from involvement in the relevant phase of the proceedings or the handling of the case at stake. The president – or the other members of the disciplinary or control body if the president is targeted – may, on his/her/their own initiative or following a substantiated request made by one of the parties, if applicable in accordance with Article 70, B, of this code, exclude any member of the relevant body from the proceedings or the handling of the case at stake in the event of any lack of neutrality, independence or impartiality.

Any decision taken in this context shall be promptly notified and cannot be appealed.

- F.** The relevant disciplinary or supervisory body of pharma.be, when making the decision, shall not accept any instruction from any members or other bodies of pharma.be.

ARTICLE 40.

Where necessary, the presidents of the various bodies, accompanied by any other members of these bodies wishing to attend, and the CEO of pharma.be, shall meet to study how ethics have evolved, particularly in light of legislation and case law. They shall submit any proposed modification of this code that they consider necessary to the Board of Directors, with subsequent submission to the General Assembly in mind.

ARTICLE 41.

While ensuring compliance with privacy regulations, the final decisions taken by the DEP Committee and the Chamber of Appeal shall be publicly disclosed on the extranet of pharma.be. These decisions are also referenced on the pharma.be public website, with the option of obtaining an excerpt of the decision on request. Disclosure of an excerpt of the decision is contingent on consent being provided by the relevant parties.

The decisions (whether or not in the form of excerpts) are solely intended for internal use and may not be disclosed to any third parties except with the consent of the parties involved.

ARTICLE 42.

Unless otherwise specified in this code, all correspondence may be sent to the relevant parties by postal mail, email, fax or any other means of communication.

ARTICLE 43.

Without prejudice to the publication and communication measures referred to in Articles 41, 81 and 83, any document (complaint, brief, exhibits, decision, etc.) communicated to the parties in the course of any proceedings is strictly confidential and may not be disclosed by the parties except with the express written consent of the president of the relevant body and, where applicable, the party having originally issued said document. It cannot, under any circumstances, be used for commercial purposes.

ARTICLE 44.

- A.** Except where otherwise specified, the time limits referred to in this code are absolute. They run from zero hours on the day following that of the act and expire as of midnight on the final day of the specified period.
- B.** If the latter day is a Saturday, Sunday or public holiday, the expiry of the period shall be automatically extended to the next working day.
- C.** Any period due to commence or expire during the months of July and August shall be suspended until 1 September and deemed to recommence from said date, unless otherwise decided by the president of the relevant body.
- D.** Any acts having to be fulfilled at the Secretariat can only be carried out during the opening hours of the pharma.be offices, namely between 9am and 5pm.

ARTICLE 45.

Any correspondence concerning the application of this code shall be sent to:

Secretariat of the code of Deontology
 pharma.be
 Chaussée de La Hulpe 166
 1170 Brussels
 deonto@pharma.be

Section 2. Bureau for Control on Written Communication

ARTICLE 46.

In accordance with the procedure described in the current section, the BCWC has the task to review the conformity of the written communication of Member Companies intended for Healthcare Professionals with the provisions of this code and with the relevant legal provisions and regulations.

ARTICLE 47.

- A.** The BCWC comprises three full members, namely:
 - I.** a lawyer, not employed within the pharmaceutical industry, as president;
 - II.** a member representing the medical profession, not involved in the industry;
 - III.** a member representing the pharmaceutical profession, not involved in the industry.
- B.** The number of substitute members must be equivalent to that of full members. The mandates are remunerated.
- C.** The BCWC is validly convened when its president and at least one of the two remaining members are present. Decisions are taken by consensus.
- D.** Both full and substitute members of the BCWC are designated by the Board of Directors of pharma.be.
- E.** The mandates of the BCWC members shall be three years and may be renewed. The mandates may be revoked ad nutum (at any time).

ARTICLE 48.

Each month, the Secretariat selects **at random** five human medicinal products from five different Member Companies. These companies are then requested - via their responsible for information person - to send a copy of each written correspondence relating to these medicinal products, which is intended for Healthcare Professionals and currently in circulation.

ARTICLE 49.

The term 'written communication' refers to any written message, regardless of which medium is used, which medical informants use to present or explain the properties of a medicinal product.

ARTICLE 50.

At the same time as the written communications referred to in Article 48, the Member Company shall specify the relevant category of professionals targeted for each piece of written communication. Furthermore, the Member Company shall provide the Secretariat with an overview of its internal procedure for the approval of the same.

ARTICLE 51.

- A.** The Member Companies shall communicate the documents and data listed in Articles 49 and 50 to the Secretariat no later than the fifteenth day after the invitation referred to in Article 48 was sent. The file must be emailed to the Secretariat, which shall acknowledge receipt of the same.
- B.** The Secretariat shall submit a copy of the file referred to in the preceding paragraph to each member of the BCWC in charge of the file.

ARTICLE 52.

- A.** To fulfil its duty pursuant to Article 46, the BCWC shall ascertain whether:
 - the Member Company has an adequate internal procedure for the approval of written communication;
 - the written communication includes all the text components required to comply with the Royal Decree of 7 April, 1995 concerning information and advertising for medicinal products for human use;
 - the written communication includes clear references when reference is made to published studies or when citations are mentioned;
 - the properties of the medicinal products described are presented without exaggeration and the written communication encourages only rational use of the medicinal products;
 - any terms such as "safe" or "harmless" or any other similar equivalent are used, without these terms being clearly defined;
 - the layout remains discreet and is mainly intended to present the information in summary form and make it more accessible;
 - the texts are clear and the selection of characters used allows effortless reading;
 - the portions of the written communication concerning statements required by laws and regulations constitute a whole along with the remainder of the message;
 - the written communication is only sent to recipients who could reasonably be expected to need or have an interest in it.

- B.** The BCWC shall communicate its findings to the Member Company concerned via the Secretariat within one month following the expiry of the fifteen-day period referred to in Article 51, A.

ARTICLE 53.

- A.** The BCWC may request through the Secretariat that the Member Company provide additional information. The Member Company shall provide the additionally requested information to the Secretariat no later than the fifteenth day following the date of the request.
- B.** If additional information is requested, the period of one month referred to in Article 52, B, shall be suspended until the Member Company has complied with the request.

ARTICLE 54.

An anonymised overview of the files examined by the BCWC is published annually on the pharma.be extranet.

ARTICLE 55.

- A.** Any Member Company that disputes any of the conclusions of the BCWC shall submit its observations in writing to the Secretariat, no later than the fifteenth day following that on which said conclusions were submitted.
- B.** The BCWC shall consider these observations and pass on its final conclusions to the Member Company through the Secretariat no later than the fifteenth day following the date of their receipt.

ARTICLE 56.

The Member Companies are obliged to take the conclusions of the BCWC into account.

ARTICLE 57.

The president of the BCWC is tasked with ensuring the companies comply with any obligations imposed on them as a result of this section. For this purpose and without prejudice to the competences of the other bodies of pharma.be, the president of the BCWC may take any measure deemed expedient. This may include, for example:

- A.** requesting an explanation from a Member Company;
- B.** informing the Board of Directors of pharma.be of any non-compliance with the provisions of the present section.

Section 3. Complaint Procedure

Sub-section 1. Disciplinary bodies

ARTICLE 58.

The DEP Committee:

- A.** adjudicates the admissibility of any complaint;
- B.** handles complaints;
- C.** ensures the conciliation tasks pursuant to Article 65, B.

ARTICLE 59.

The Chamber of Appeal shall adjudicate any appeal made against decisions taken by the DEP Committee. In the event of an appeal, the Chamber of Appeal is tasked with assessing the merits of the case and shall reconsider whether to confirm or reform the decision incumbent on it. It shall under no circumstances refer the case back to the DEP Committee.

ARTICLE 60.

- A.** To be validly convened, the chambers of the disciplinary bodies must respectively comprise:
 - I.** a president, a lawyer and not actively involved within the pharmaceutical industry;
 - II.** a member representing the industry for pharmaceutical products for human or veterinary use (according to the type of product/issue concerned); and
 - III.** a member, not involved in the industry, representing either the medical profession or the pharmaceutical profession or having a scientific or academic background.
- B.** The president to the linguistic role corresponding to the language of the proceedings shall designate the individuals who will sit in the chamber of the disciplinary body convened to issue decision, in accordance with the preceding paragraph and the designated language of the proceedings as determined pursuant to Article 68, from among those persons included in the reserve referred to in Article 61.

Each member of the disciplinary body, at the time of designation, must report in writing that he/she does not have any conflict of interests with regard to the case he/she has been seized upon and shall report any circumstances which

may raise doubts over its neutrality, independence or impartiality in the sense of Article 39, E. The Secretariat shall annex said declaration to the notice of hearing referred to in Article 70, B, to ensure the parties are made aware of the same.

ARTICLE 61.

- A.** A reserve is established to allow the setting up of the chambers of the disciplinary bodies called upon to decide, in accordance with Article 60 of this code. This reserve comprises the following full members:
 - I.** three lawyers, not actively involved in the pharmaceutical industry;
 - II.** six members representing the industry for pharmaceutical products for human use;
 - III.** three members representing the industry for pharmaceutical products for veterinary use;
 - IV.** six members representing the medical profession, not involved in the industry;
 - V.** two members representing the pharmaceutical profession, not involved in the industry; and
 - VI.** three members with a scientific or academic background, not active in the industry.
- B.** The number of substitute members must be equivalent to that of full members. Furthermore, for each category referred to in the previous paragraph, there should be both French- and Dutch-speaking members. However, any member is free to declare having a sufficient knowledge of the other language and sit in both the French and Dutch-speaking chambers accordingly.
- C.** The members referred to in point A, I, are designated by the other members of the disciplinary bodies on the basis of a list presented by the Board of Directors. The same applies for the corresponding substitute members.

The members referred to in point A, II and III, are elected by the Board of Directors (subject to approval of the Bureau of the Animal Health Group as far as the members referred to point A, III, are concerned) from among the members of pharma.be, after obtaining a majority of votes. To the extent possible, attempts shall be made to ensure that at least one third of the members of the disciplinary bodies elected in this manner are not employees of companies represented in the Board of Directors of pharma.be (on the day of the election).

Among the elected individuals, those ranked most highly shall become full members and all subsequent individuals shall become substitute members, taking into account, to the extent possible, the allocation key of a third of employees of companies that are not represented in the Board of Directors

of pharma.be (on the day of the election) for each list of full/substitute members. In the event of a voting tie, the vote cast by the most senior individual in terms of the exercising of the mandate or the most senior shall prevail. The surplus members shall be placed on a waiting list, with an order of precedence determined on the basis of total votes obtained, to ensure replacements in the event that the position of a serving member becomes vacant or any full or alternate members are rendered unavailable.

The members referred to in point A, II and III, may under no circumstances exercise a commercial position or function within the marketing department of a pharma.be member. In contrast, however, admissible roles include individuals designated as responsible for information persons, who act in the capacity of compliance officers, or who are part of the medical or legal department of a pharma.be member.

The members referred to in point A, IV and V, are designated by one or more of the relevant association(s) or organisation(s). The same applies for the corresponding substitute members. To the extent possible, the mandates referred to in point A, IV and V, are allocated while taking into account how representative the associations from which the abovementioned members originate actually are.

The members referred to in point A, VI, are designated by one or more representative organisation(s) from academic or scientific backgrounds. The same applies for the corresponding substitute members.

ARTICLE 62.

- A.** The mandates of the members of the disciplinary bodies shall be three years and may be renewed. The mandates may be revoked ad nutum (at any time).
- B.** Mandates are remunerated, except for members who are active in industry.
- C.** Where a member representing the industry of pharmaceutical products for human or veterinary use, as referred to in Article 61, A, II and III, resigns or can not/no longer continue its mandate, said member shall be automatically excluded from the reserve referred to in Article 61 and replaced by the next incumbent member in the relevant category, in terms of the total votes obtained in the election referred to in Article 61, C, subparagraph 2. Any replacement member of a disciplinary body shall be appointed for the remaining term of mandate of its predecessor.
- D.** If the president is absent or otherwise incapacitated, the meetings of the disciplinary bodies shall be presided by the relevant substitute president to the same linguistic role.

ARTICLE 63.

Decisions are taken by a simple majority of votes of the members. Only the members present during the most recent hearing and who were present throughout the relevant discussions shall be entitled to vote. If the composition of a disciplinary body varies between two hearings, all debates must be restarted from scratch. Votes by procuration are prohibited.

ARTICLE 64.

The members of the disciplinary bodies are not allowed to sit in both the DEP Committee and the Chamber of Appeal when both entities are addressing the same case. The same applies to members belonging to the same company or organisation as a member who has already sat in the concerned case.

Sub-section 2. General rules of procedure

1. Conciliation

ARTICLE 65.

- A.** Before initiating a complaint procedure before the DEP Committee, the parties must attempt to settle their disputes amicably.
- B.** At any stage of the complaint procedure, the president of each disciplinary body may engage in conciliation attempts or appoint a member to do likewise. The president may convoke the parties for this purpose.

2. Filing of a complaint

ARTICLE 66.

- A.** Any individual or legal entity who/that observe a violation of the rules of deontology as laid down in the present code, except in the preamble section, may file a written complaint against any member of pharma.be with the Secretariat, for the attention of the DEP Committee.

The plaintiff must substantiate its complaint with the available evidence.

The complaint must be filed in person or sent by registered mail to the Secretariat. It must also be emailed to the Secretariat. It cannot exceed 25 pages (A4, Verdana 9, single-spaced).

- B.** The plaintiff must also concomitantly send a copy of the complaint and any annexes to the defendant by registered mail.

- C.** The complaint shall only be registered and conveyed to the DEP Committee after receipt of payment of the registry fee in the bank account of pharma.be. The plaintiff shall include proof of said payment with the complaint.

The registry fees shall amount to:

- 1,250 euros for legal entities (excl. VAT);
- 60 euros for individuals (excl. VAT).

- D.** The Secretariat shall confirm receipt of the complaint with the relevant parties as soon as possible.

ARTICLE 67.

- A.** To be declared admissible, the complaint must:
- I.** clearly identify the plaintiff and the defendant;
 - II.** include a statement of relevant facts and a description of the alleged claims, making explicit reference to the relevant provisions of this code of Deontology;
 - III.** be accompanied by a declaration with which the plaintiff undertakes to comply with the rules prescribed by this code unless adherence to the present code is already confirmed in accordance with the rules laid down in Article 85; and
 - IV.** be accompanied by evidence that conciliation, e.g. as referred to in Article 65, A, has been attempted or, where applicable, evidence of the defendant's refusal to participate in said conciliation.
- B.** The plaintiff must also specify which measures are being requested in its complaint, as referred to in Article 81 of the present code.

ARTICLE 68.

- A.** Under penalty of inadmissibility, the plaintiff is obliged to formulate its complaint:
- In French, if the registered office or main place of establishment of the defendant is located in the Walloon region;
 - In Dutch, if the registered office or main place of establishment of the defendant is located in the Flemish region;
 - In French or Dutch, at the choice of the plaintiff, if the registered office or main place of establishment of the defendant is located in the Brussels region;
 - In French or Dutch, according to the official language of the country in which the defendant is established, or, if neither French nor Dutch are said official language, at the choice of the plaintiff.

- B.** Unless the parties agree in writing to run the proceedings in another language (French or Dutch) and notify this agreement to the Secretariat no later than the seventh calendar day following confirmation by the Secretariat of the registration of the complaint in accordance with Article 66, D (in which case, said notification shall be accompanied by a translation of the complaint into that other language), the proceedings shall be carried out exclusively in the language in which the complaint was drawn up in accordance with point A. of this Article.
- C.** The briefs and any other observations of the parties sent to the disciplinary bodies and other parties must be communicated in the language of the proceedings, under penalty of exclusion from the debates. Unless otherwise specified by the president of the relevant disciplinary body, the exhibits brought by the parties must also be prepared or translated in the language of the proceedings, except for documents originally drawn up in English.

3. Preparation and setting up of a hearing

ARTICLE 69.

- A.** No later than the seventh calendar day following confirmation by the Secretariat of the registration of complaint in accordance with Article 66, point D, the parties must inform the Secretariat whether or not they intend to file written briefs and/or exhibits during the proceedings and, if necessary, whether they have mutually concluded and agreed on a timetable for the exchange of their written briefs/exhibits.
- B.** The maximum period allowed for the exchange of briefs/exhibits shall be 4 weeks from the date of notifying said timetable to the Secretariat. However, subject to mutual agreement, the parties may arrange a shorter or longer timetable, as required.

Provided the parties agree on a timetable, they shall notify the details to the Secretariat within the period referred to in point A of this Article.

In the absence of agreed timetable notified to the Secretariat within the time limit referred to in point A. of this Article, the president of the DEP Committee shall impose, at its sole discretion and without any recourse, a timetable, which shall in any event not exceed 4 weeks (as from the time the decision is communicated to the parties). The president may, where applicable, impose very strict time limits for the exchange of briefs/exhibits based on the circumstances of the case.

ARTICLE 70.

- A.** The parties shall be convoked before the DEP Committee within a time limit and in a manner commensurate with the circumstances and, where applicable, depending on the established timetable. Efforts shall be made, depending on circumstances, to ensure a reasonable period of time is allowed between the filing of the last brief and the date of appearance at the hearing.
- B.** The notice of hearing indicates the date, time and composition of the chamber of the disciplinary body before which the relevant parties must appear. Annexed to this is the declaration referred to in Article 60, B.

If a party wishes to remove a member of the disciplinary body pursuant to Article 39, E, of this Code, it shall notify the specific reasons for its request to the members of the disciplinary body, through the Secretariat, as well as all parties involved as soon as it is informed of the composition of the seat of the body, in accordance with this paragraph and no later than the time of commencement of the first hearing. This request shall be handled in accordance with Article 39, E.

ARTICLE 71.

- A.** Each party shall provide all other parties with a copy of its entire set of exhibits or briefs at the same time it submits such exhibits or briefs to the Secretariat.

The exhibits and briefs must in any event be emailed to the Secretariat (in WORD format for briefs and PDF format for exhibits). The exhibits must be properly itemised and numbered.
- B.** Except where exceptional circumstances apply, any briefs or exhibits filed or notified belatedly or outside the established timetable shall be excluded from the debates.
- C.** The briefs of the parties may not exceed 25 pages (A4, Verdana 9, single-spaced).

ARTICLE 72.

The parties may consult the file in the Secretariat at any time by appointment.

4. Handling of the complaint by the disciplinary bodies**ARTICLE 73.**

- A.** The president of the disciplinary body shall open, preside over and close the debates. The president may also order the reopening of discussions. The president shall take all measures deemed necessary to ensure the proceedings function smoothly. If nothing is specified in the code, the president shall have sole discretion to decide how to follow up each procedural issue. Although the provisions of the Judicial code are not applicable, the president may nevertheless decide to proceed in line with the same.
- B.** At any stage of the proceedings, the president of the disciplinary body may convoke and hear the relevant parties within a reasonable time. The president may also order the production of documents within a specified time limit to obtain additional information.

ARTICLE 74.

- A.** The parties shall cooperate to ensure the proceedings function smoothly and shall respect the rights of the defence and the adversarial principle.

If a party convoked in due form is not present at the hearing, the debates are deemed to be adversarial without any opposition recourse possible.
- B.** As a general rule, no postponement shall be granted. Nevertheless, a substantiated request may be submitted to the president of the relevant body, who shall then decide at its own discretion and without any recourse, while respecting the right of defence.
- C.** The parties may be represented by an advisor or a lawyer.

ARTICLE 75.

- A.** The hearings of the disciplinary bodies shall not be in public, unless otherwise asked by the defendant at the start of the hearing.
- B.** Any party who wishes a third party to be heard may lodge a substantiated request with the president of the disciplinary body, who shall decide at its sole discretion and without any recourse. In light of the rights of defence, the president shall ask the opposing party to provide its arguments over whether or not said hearing should proceed.
- C.** The debates shall be held in the language of the proceedings, as determined per Article 68, unless the president of the relevant body authorises the parties or third parties concerned to express themselves in another language.

ARTICLE 76.

At the request of a party and after adversarial scrutiny, the disciplinary bodies shall exclude any evidence gathered by unlawful means from the file.

ARTICLE 77.

The disciplinary bodies may qualify the facts themselves or otherwise requalify them.

ARTICLE 78.

A. When the same case is heard between the same parties before disciplinary bodies and any body external to pharma.be, for example a judicial or administrative authority or an arbitration body, handling of the same case by the disciplinary bodies can be suspended until a verdict is rendered by the relevant judicial or administrative authority.

B. Any party involved in a case brought before the disciplinary bodies shall promptly notify the latter if the same case is brought before a body external to pharma.be.

The application of this Article 78 leads to a separate decision by the president of the disciplinary body. There is no right of appeal against this decision before the Chamber of Appeal.

5. Specific rules governing the appeal procedure**ARTICLE 79.**

A. Any decision taken by the DEP Committee can be appealed against to the Chamber of Appeal. Decisions made on procedural issues cannot be appealed.

B. Under penalty of inadmissibility, the appeal must be made in the language of the disputed decision and either hand-delivered to the Secretariat or sent to the Secretariat by registered mail, within ten calendar days from the date of receipt of the decision of the DEP Committee sent in accordance with Article 80, B, of the code.

The appeal shall also be notified to the Secretariat by email.

C. The appellant is also obliged to send a copy of its appeal and any annexes by registered mail to the defendant in appeal.

D. The appeal shall only be registered and conveyed to the Chamber of Appeal after receipt of payment of the registry fee in the bank account of pharma.be. The appellant shall include proof of said payment with the appeal.

The registry fees shall amount to:

- 3,000 euros for legal entities (excl. VAT);
- 100 euros for individuals (excl. VAT).

E. The Secretariat shall confirm receipt of the appeal with the relevant parties as soon as possible.

F. To be deemed admissible, the appeal must outline the set of claims put forward by the appellant in response to the decision of the DEP Committee.

The appellant must also specify which measures are being requested in its appeal, as referred to in Article 81 of the present code.

G. Under penalty of exclusion from the debates, the defendant in appeal shall have a maximum period of 10 days from the notification of the Secretariat referred to in point E of this Article to transmit to the latter and the other relevant parties its written observations, the scope of which must be limited to the grievances set out in the appeal.

The appeal and observations, as well as any exhibits, must at least be emailed to the Secretariat (in WORD format for briefs and PDF format for exhibits). The exhibits must be properly itemised and numbered.

The appeal of the appellant and the observations of the defendant in appeal may not exceed 25 pages (A4, Verdana 9, single-spaced).

H. The parties shall be convoked before the Chamber of Appeal within a time limit and in a manner commensurate with the circumstances. Efforts shall be made, depending on circumstances, to ensure a reasonable period of time is allowed between the filing of the observations of the defendant in appeal and the date of appearance at the hearing.

The notice of hearing indicates the date, time and composition of the chamber of the disciplinary body before which the relevant parties must appear. Annexed to this is the declaration referred to in Article 60, B.

If a party wishes to remove a member of the disciplinary body pursuant to Article 39, E, of this code, it shall notify the specific reasons for its request to the members of the disciplinary body, through the Secretariat, as well as all parties involved as soon as it is informed of the composition of the seat of the body, in accordance with this paragraph and no later than the time of commencement of the first hearing. This request shall be handled in accordance with Article 39, E.

Sub-section 3. Decisions and measures upon non-compliance with the code

ARTICLE 80.

- A.** The proceedings before the DEP Committee and the Chamber of Appeal may give rise to the following decisions:
- I.** The complaint/appeal, being declared admissible, is well founded and a violation of the code is established, possibly with the pronouncing of one of the measures provided for in Article 81;
 - II.** The lack of admissibility or grounds for the complaint/appeal;
 - III.** The statement that the dispute has ended, where applicable, by implementing an amicable agreement between the parties. In the latter case, the parties are solely responsible for reaching such agreement, even after conciliation by the president.
- B.** The decisions of the DEP Committee and the Chamber of Appeal are expressly substantiated and notified to the parties by registered mail with acknowledgment of receipt.
- C.** The decisions of the DEP Committee are deemed final in the absence of any appeal filed within the period referred to in Article 79, B, of this code.

ARTICLE 81.

- A.** When the DEP Committee or the Chamber of Appeal declares that a violation is established, it shall order immediate cessation of the infringing activities and shall urge the relevant party to undertake in writing to take the necessary measures to prevent any recurrence.
- B.** When the DEP Committee or the Chamber of Appeal declares that a violation is established, it may also impose the following measures against the party that it deems to have contravened the rules of deontology referred to in this code:
- I.** a reprimand; and/or
 - II.** a corrective measure; and/or
 - III.** a supervisory measure; and/or
 - IV.** a financial indemnification measure.
- C.** The term "corrective measure", as referred to in point B., includes for example:
- I.** correction of infringing material;
 - II.** insertion of a corrective statement and/or issuing an amended version of the infringing material;

- III.** recall of any infringing material already distributed;
- IV.** direct notification by letter to the medical and/or pharmaceutical profession of the decision of the DEP Committee or the Chamber of Appeal or an excerpt from the same;
- V.** removal of a link to a website.

- D.** The term "supervisory measure", as referred to in point B, includes for example:
- I.** communicating the details of the organisation of an upcoming event and any other relevant information relating thereto;
 - II.** recommendations for transparency or clarity;
 - III.** requiring the submission, by a specified deadline, of a detailed plan of concrete measures that the relevant party intends to undertake to comply with the decision or to improve its internal control process.
- E.** The term "financial indemnification measure" refers to a reasonable financial compensation for any damage suffered by the pharmaceutical industry as a result of a violation of the rules of deontology referred to in this code. The amount of the latter shall be fixed at the sole discretion of the DEP Committee or the Chamber of Appeal. When determining said amount, the DEP Committee or the Chamber of Appeal shall take account of any damage suffered by the pharmaceutical sector, including to its reputation. The amount of compensation shall vary between 5,000 euros and 50,000 euros depending on the violation and must be paid in the bank account of pharma.be specifically reserved for this purpose (as communicated by the Secretariat) within a period of 30 calendar days from the date of the written notice issued by the Secretariat. If this is not done, late payment interest shall be levied at the legal interest rate applicable to civil matters.

The financial indemnification referred to in this paragraph shall be repaid by pharma.be to the King Baudouin Foundation.

- F.** The DEP Committee or the Chamber of Appeal may also order the nominative publication of a summary of the decision, in Dutch and/or French, in certain journals, subject to the agreement of the journal in question.

As regards the decisions of the DEP Committee, any publication shall only take place after time limit for appeal, as referred to in Article 79, B, of this code, has elapsed and provided that no appeal has been filed.

In the event of a subsequent violation within two years after a breach of this code has been established by the DEP Committee or the Chamber of Appeal in a final decision or in the event of a serious breach of the rules of deontology referred to in this code, the nominative publication of a summary of the decision shall also proceed in English in SCRIP.

In assessing whether or not a breach is serious in the context of the preceding paragraph, the DEP Committee or the Chamber of Appeal, whichever is applicable, may refer to the guidelines on this subject, appended to this code in annex.

All publications shall include the following reference: "The DEP Committee and the Chamber of Appeal are bodies established by pharma.be to ensure the rules of its code of Deontology are properly applied. These committees comprise both members not involved in the pharmaceutical industry (lawyers and members of the medical profession, the pharmaceutical profession, or from scientific or academic backgrounds), and a representative of the pharmaceutical industry; all of whom operate with total independence pursuant to the code.

The decisions of the DEP Committee and the Chamber of Appeal are taken by a simple majority of members present, relate solely to the facts submitted to them and concern only the parties directly involved in the cited dispute.

pharma.be oversees the administrative management of the deontological system. To consult the code of Deontology of pharma.be, refer to the www.pharma.be website."

- G.** Costs linked to the order of cessation, measures, publication and, where applicable, translation of the summary of the decision, shall be borne by the party against whom they are delivered, without prejudice to the application of Article 84.

Sub-section 4. Execution of decisions

ARTICLE 82.

Except in the case of publications referred to in Article 81, F, of the code, decisions taken by the DEP Commission are in principle enforceable by provision, notwithstanding appeal, unless the DEP Commission decides otherwise, by way of a specially substantiated decision. The provisional execution of the decision shall take place at the sole risk of the party pursuing the same.

ARTICLE 83.

- A.** The Board of Directors shall be informed of any final decision of the disciplinary bodies which results in a violation of this code being established.
- B.** The measures which may be imposed under Chapter 5 of this code shall not, regardless of circumstances, prejudice the possibility for the Board of Directors of pharma.be to propose the exclusion of any member to the General Assembly pursuant to Article 7 of the bylaws.

Chapter 6.

Costs of proceedings



ARTICLE 84.

- A.** In the sense of the present Article, the term "costs of proceedings" refers to all costs linked to the proceedings referred to in Chapter 5, section 3.
- B.** The party deemed to have committed a violation by a final decision and, where applicable, against which a measure is imposed, shall bear the costs of proceedings.

The plaintiff shall bear the costs of proceedings where, after a final decision, no violation is established or measure imposed against the original defendant.

Unless otherwise agreed by the parties, the plaintiff shall bear the costs of proceedings when the disciplinary body concerned acknowledges that the dispute has ended before a decision has been made.

- C.** The party bearing the costs of proceedings is obliged:
- to make payment of the lump sum as published each year on the public website of pharma.be;
 - where applicable, to make payment of expert fees arising pursuant to Article 39, C, of this code; and
 - where applicable, to refund the plaintiff /appellant for the equivalent amount spent by the latter on registry fees, as referred to in Articles 66, C, and 79, D, of this code.
- D.** In view of the circumstances, the disciplinary body may order the party that has committed a violation to pay a procedural allowance of between 1,500 and 4,500 euros.

In its assessment, the disciplinary body shall take account of:

- the complexity of the issue;
 - any patently unreasonable aspect of the situation.
- E.** Each disciplinary body may, in any case not provided for under this code, fix the allocation of costs of proceedings to the parties.
- F.** In derogation of the preceding rules, individuals shall not be required to bear any costs of proceedings.

Chapter 7.

General provisions - Entry into force - Interim measures



ARTICLE 85.

Adhesion to the code, that is an inherent part of the pharma.be by-laws, becomes effective at the time of membership of pharma.be. It is a necessary condition for becoming a member of pharma.be.

ARTICLE 86.

Notwithstanding the application of the definition of "Applicable code(s)" and of Section 4 of Chapter 2 of the present code, Member Companies are obliged, if they invite Healthcare Professionals to participate in a scientific event held abroad or if they sponsor the participation of Healthcare Professionals at such events, to notify any local company concerned that is connected to them or, if applicable, to request advice locally.

ARTICLE 87.

The resignation or exclusion of a Member Company when a case of concern to it is in progress does not halt the proceedings, or the implementation of measures pronounced against it. This Member Company also remains liable for any costs of proceedings (or other sums) established in accordance with Article 84.

ARTICLE 88.

- A.** The code of Deontology, as drawn up originally, entered into force on 15 April 1976. The present revised version of the code enters into force the day after its approval by the pharma.be General Assembly. Member Companies have until 1 September 2020 to comply with the new code.
- B.** All members of bodies set up by virtue of the previous version of the code will continue to exercise their mandate until a decision to the contrary is taken on the part of the competent body on the matter.

ARTICLE 89.

pharma.be will be responsible for communication in connection with the present code. This communication will be addressed to all interested parties as well as to members of the pharmaceutical industry, Healthcare Professionals, including representative organisations, patients and the authorities.

Annex

Directives concerning the determination of facts that must be considered as a "serious violation of the rules of deontology" pursuant to Article 81, F, of the Code

CONTEXT

In accordance with Article 81, F, of the Code, if the **DEP Committee** or the **Chamber of Appeal** declare a "serious violation" established in the sense as set out above, a summary of the decision is published in English in SCRIP.

DIRECTIVES

Clearly the question as to whether or not certain facts constitute a "serious violation" in the above-mentioned context must always be judged on a case-by-case basis and it is ultimately for the deontological body charged with considering the case (DEP Committee or Chamber of Appeal) to pronounce on this question in total independence but also furnishing reasons for its decision.

Without seeking to call into question the freedom of judgement of the above-mentioned bodies, a certain number of elements are proposed hereunder as a basis for reflection¹.

- Medicinal products are supposed to help maintain and restore man's most valuable possession: his health and quality of life. The pharmaceutical industry bears a great responsibility in this respect. This is why all facts that could jeopardise the patient's health can be considered to be "serious violations".

May be considered to be facts likely to jeopardise the patient's health:

- the deliberate falsification of study results²,
- the falsification of the expiry date of medicinal products.

- The information furnished by pharmaceutical companies concerning products they market must be correct and objective. It must be possible for the patient to be sure of receiving the medicinal product that is most suitable for him. Consequently, any instance in which a company tries to influence the prescribing or issuing behaviour of Healthcare Professionals and that if it were brought to the attention of patients, would risk compromising the relationship of individual trust between the latter and Healthcare Professionals can be considered to be a "serious violation".

The following may be considered to be a violation designed to influence the prescribing or issuing behaviour of a Healthcare Professional and that, if it were brought to the attention of patients would risk compromising the relationship of individual trust between the latter and Healthcare Professionals:

- the granting to the doctor of a benefit in cash or in kind per prescription he makes out
- For adequate health care it is also important for patients, the authorities and Healthcare Professionals to have confidence in the pharmaceutical industry and in its products in general. Consequently, violations with high visibility, for Healthcare Professionals, the general public or the authorities, will very often have a very big (negative) impact on general confidence in the pharmaceutical industry and can consequently be considered as a general rule to be "*serious violations*". In this context, the fact that the violation could be the subject of media coverage must therefore be taken into consideration.

The following may be considered to be violations with high visibility:

- sponsoring of/ support for a meeting for a large number of Belgian doctors abroad (for example in the French Champagne region), with no justification being given for the location;
- the inviting of a large number of doctors to attend a sports or cultural event.
- A medicinal product is not a simple consumer good. It can only be placed on the market following a searching procedure aimed at guaranteeing the quality, safety and effectiveness of the product (AMM/VHB = marketing authorisation). At the same time as an AMM/VHB, an RCP/SKP (= summary of product characteristics) and an insert are drawn up to inform both the Healthcare Professional and the patient. Any marketing technique aimed at inciting patients to use medicinal products by offering them gifts or any economic advantage and due to which the purchasing and, if applicable, the prescribing or the issuing of the medicinal product would no longer be (principally) motivated by the reasons given in the insert/RCP/SKP but rather by commercial incentives can consequently be considered to be a "*serious violation*".

The following may be considered to be violations that consist of encouraging the use of medicinal products by offering benefits to the patient:

- the inviting of Healthcare Professionals to sports or cultural events;
- the inviting of Healthcare Professionals to a conference abroad, without it being possible to justify the location in any way;
- Article 10³ of the law on medicinal products provides a cornerstone on which interactions between the pharmaceutical industry and Healthcare Professionals are based. A violation of this Article 10 - which prohibits the pharmaceutical industry, save in certain exceptional cases, from granting premiums or benefits - can therefore constitute a "*serious violation*".

The following may be considered to be violations of Article 10 of the law on medicinal products:

- the inviting of Healthcare Professionals to sports or cultural events;
- the inviting of Healthcare Professionals to a conference abroad, without it being possible to justify the location in any way;
- excessive remuneration for a doctor for his contribution to a scientific study, characterised by the granting of a remuneration that is out of proportion to the nature and duration of the work provided;
- the inviting of Healthcare Professionals to the restaurant, insofar as this is not in connection with medical or pharmaceutical science or insofar as the medico-pharmaceutical communication is secondary to the facts as a whole.

The notion of "*serious violation*" as described above is an inherent part of the pharma.be deontological arsenal. The actions of which a party stands accused must therefore constitute a violation of the provisions of the *Code of deontology*, and this whether or not they are the subject of legal sanctions. However, the fact that actions of which a party stands accused are open to legal sanctions because they also infringe one or more legal provisions is an element to be examined when assessing their seriousness.

- 1 These examples are for information purposes only; each case must always be considered on the basis of the circumstances peculiar to the specific case.
- 2 Provided the study carried out falls within the material field of application of the code.
- 3 Art. 10 § 1. It is prohibited, in connection with the supply, prescribing, issuing or administration of medicinal products, to promise, offer or grant, directly or indirectly, premiums, pecuniary benefits or benefits in kind to wholesalers, persons qualified to prescribe, issue or administer medicinal products as well as to institutions in which the prescribing, issuing or administration of medicinal products takes place.

§ 2. However, the prohibition as referred to under § 1 does not apply to:

- 1° premiums or benefits of negligible value or which relate to the exercising of the medical profession, the dental profession, the pharmaceutical profession or veterinary medicine;
- 2° the invitation and defrayment of the participation costs, including hospitality, of legal entities or natural persons as referred to under § 1, including in the veterinary sector, relating to a scientific event, provided that this satisfies all of the following conditions:
 - A. the event is of an exclusively scientific nature, in connection in particular with the medical and pharmaceutical sciences;
 - B. the hospitality offered is limited strictly to the scientific purpose of the event;
 - C. the place, date and duration of the event creates no confusion as to its scientific nature;
 - D. the payment of the costs of participation, including hospitality, is limited to the official duration of the event;
 - E. the defrayment of the costs of participation, including hospitality, cannot be extended to legal entities or natural persons other than those referred to under § 1;
- 3° notwithstanding article 18, § 2, of Royal Decree n° 78 of 10 November 1967 concerning the exercising of health care professions, remuneration for legitimate services of a scientific nature, provided they remain within reasonable limits. This applies in particular to clinical trials referred to under article 2, 7°, of the law of 7 May 2004 concerning experiments on human persons.

For the application of para. 1, 1°, the King can further define the notion of "*negligible value*".

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