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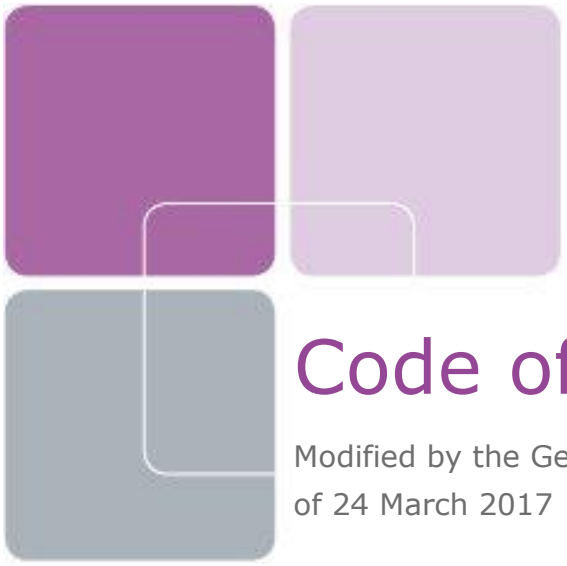

Code of deontology

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Chapter 1: Preamble

article 1
Medicinal products help maintain and restore man's most valuable possession: his health and quality of life.

It is the mission of the pharmaceutical industry to harness all the necessary human and financial resources with which to develop, produce and market medicinal products.

To this end, the pharmaceutical industry develops a unique expertise and know-how based on the most advanced sciences and technologies.

The pharmaceutical industry is therefore ideally placed to provide information on its products. It also plays an essential role in continuous training and scientific research, also after the medicinal products are marketed.

In this capacity, the pharmaceutical industry endeavours to establish a lasting partnership with the other health care players, including academic, medical and pharmaceutical bodies as well as the patient organisations.

This is why members of pharma.be have subscribed to the present Code of deontology (hereafter "the Code" or "the present Code"). This set of rules guarantees that the activities of the pharmaceutical companies in providing information on or advertising the medicinal products they market takes place within a quality scientific framework that takes due account of the justified interests and expectations of the various health care players, including those of patients. The Code is also designed to ensure that the contribution of the pharmaceutical industry to continuous training and research on medicinal products is of the very highest standard.

article 2
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. Reagents and diagnostic products as well as 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, pharmaceutical 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 pharmaceutical companies and healthcare professionals and to the relationships between pharmaceutical companies and patient organisations. It consequently includes rules regarding:

a. oral communication (medical informants),
b. written communication,
c. samples,
d. diffusion of scientific information on stands etc.
e. data storage and data transmission,
f. granting of subsidies, premiums and advantages, and sponsoring,
g. invitation of healthcare professionals to scientific events,
h. invitation of patients to events,
i. remuneration by pharmaceutical companies of scientific services rendered by healthcare professionals,
j. non-interventional scientific studies to which healthcare professionals consent.

The field of application of the Code does not cover the information and documents referred to under Article 9, § 1, part 6 of the law of 25 March 1964 on medicines.

article 3

1. The present Code supplements all legal and regulatory provisions on the subject of promoting and providing information on medicinal products for human use, which must be respected under all circumstances.

2. The present Code also supplements the provisions of the EFPIA Code on the Promotion of Prescription-only Medicines to, and interaction with, Healthcare Professionals, of the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, of the IFPMA Code of Pharmaceutical Marketing Practices and of the Code of deontology of the non-profit association Mdeon. In case of contradiction between the codes, the most constraining provision shall always apply.

3. Notwithstanding the application of §§ 1 and 2 above, if the promotion, information or interaction with healthcare professionals does not take place in Belgium, the promotion, information or interaction must not only be in accordance with the provisions of this Code, but also with the provisions of the Code of deontology that applies in the country where the promotion, information or interaction takes place.

   Likewise, when a pharmaceutical company maintains relationships with or supports activities of patient organisations outside Belgium, these relationships or activities must not only be in accordance with the provisions of the present Code but also, notwithstanding the application of paragraph 1 and paragraph 2 above, in accordance with:

   a. In the case of relationships or activities taking place in a particular country within Europe, the provisions of the Code of deontology applicable in that particular country,

   b. In the case of cross-border relationships or activities, the provisions of the code of deontology applicable in the country in which the patient organisation has its main European location.

   "Europe" as referred to in the previous paragraph includes all the countries where the Codes of Deontology of the member-associations of EFPIA are applicable.

   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.

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Chapter 2: Basic rules

A. General rules

article 4
Any communication aimed at presenting the properties of a product may only encourage a rational use of the product and must be based on observations that are:

- correct,
- objective,
- sufficient,
- fair,
- verifiable,
- in accordance with the most recent content of the approved dossier concerning marketing authorisation,
- a reflection of generally accepted scientific knowledge,
- where appropriate, backed up by bibliographical references, which are to be mentioned in the communication.

The communications referred to in the previous paragraph must be well founded. Justifying elements must be communicated to any healthcare professional who has addressed a reasonable request to this effect to the company. However, there is no obligation to provide a justification of the validity of the elements that were accepted at the time of the granting of marketing authorisation.

article 5
Notwithstanding the legal obligations, and with the exception of "reminder" advertising, mention shall be made of:

- the product's composition,
- its therapeutic indications,
- contra-indications and precautionary measures,
- adverse reactions,
- dosage and method of administration,
- available packaging,
- the name and address of the company responsible for marketing the product.

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

article 6
Within companies, the information shall be examined and approved by scientifically and professionally qualified persons.

The holder of the marketing authorisation shall establish a permanent connection with a scientific service charged with providing information on the medicinal products that it markets and which 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.

Regardless of the way the scientific service is organised, this service should include a medical doctor or a pharmacist who will approve any promotional material before release.

In addition, the scientific service must include a medical doctor or a pharmacist who will be responsible for the supervision of all non-interventional studies which are carried out or sponsored by the company.

article 7
Irrespective of the internal organisation of companies, the head of the company (or head of the pharmaceutical division) is the person who, in respect to the deontology, assumes responsibility for all matters relating to information and promotion.

article 8
Whenever published studies are mentioned, clear references shall be given.

Citations shall make a clear reference to sources. They shall not be invoked in a tendentious manner out of context and shall remain true to the spirit of their author. References must be clearly identifiable.

The elements cited and all the other elements necessary for ensuring compliance with the provisions of the previous paragraph must be communicated to the healthcare professionals who so request it.

article 9
Notwithstanding the legal obligations, comparisons with competing products – if necessary or useful – must establish the particular characteristics of the product with which it is compared in a manner that is fair, complete and scientific. They shall be based on the most recently available data insofar as these comply with Article 4.

article 10
1. The frequency of the provision of information or promotion will depend on the real need for it and may not in any way inconvenience the recipient.

2. The content and form of the information or promotion shall respect the dignity of the persons to whom it is addressed.

   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.

3. The terms "safe" and "without danger" or any other term expressing a similar concept may not be used unless clearly defined. It may not be said that a medicinal product presents neither adverse reactions nor risk of dependency.

article 11
If visual material, such as graphs, illustrations, photographs or tables are used that come from published studies, the source must always be mentioned. This visual material must be faithfully reproduced.

In particular, attention must be paid to ensure that the visual material 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).

article 12
Information or promotion relating to medicinal products may only be aimed at persons who can reasonably be supposed to need them or to be interested in them.

article 13
Address lists must be kept up-to-date. If a recipient wants his or her name to be deleted from an address list, this must take place immediately.

article 14
Information or promotion from abroad is treated in the same way as that which originates in Belgium. Companies based in Belgium will ensure that messages and material dispatched from their parent company, subsidiary or principal comply with these regulations even if they are based outside the Kingdom of Belgium.

article 15
When pharmaceutical companies have recourse to third parties, they remain responsible for ensuring that these third parties respect the rules of this Code.

article 16
Companies shall refrain from jeopardising the reputation of the industry in general or of a sector partner in particular.

B. Specific rules

1. Oral communication (medical informants)

article 17
Every company shall ensure that medical informants, 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 this Code, as well as with the applicable legal provisions and regulations. They must also respect these provisions.

article 18
The medical informant reflects the image of his company in particular and of the pharmaceutical industry in general in regard to members of the medical and pharmaceutical profession.

article 19
Companies exercise control over and assume responsibility for the actions of their personnel. This responsibility continues to apply even if the medical informants fail to respect the instructions they are given.

The medical informants must be properly trained by the company that employs them and possess sufficient scientific knowledge to give information on the medicinal products they present that is as accurate and as complete as possible.

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

article 20
The medical informants shall attach the greatest value to proper conduct that invites respect and regard for their profession. They will be courteous, loyal and correct. They will visit the authorised sites at a prearranged or most convenient time. They will act as a guest and without disturbing normal activities.

The medical informants shall respect scrupulously the wishes of persons visited as regards frequency and, where appropriate, other stipulations.

article 21
When making visits they will be in possession of visiting cards mentioning their own name and their company's name.

At the time of each visit, the medical informants must, for each of the medicinal products that they present to the person visited, provide or make available a summary of the product characteristics, possibly by means of the pharma.be Compendium.

article 22
The medical informants shall base their presentation on scientific documentation that does not depart from the elements included in the summary of the product characteristics. They may supplement their presentation with other data that were accepted at the time of the procedure for obtaining marketing authorisation and that are included in a technical file signed and dated by the information manager.

The medical informants must notify the information manager of any information imparted by the persons visited that relates to the use of the medicinal products that they are promoting, in particular concerning adverse reactions, of which they are informed.

article 23
The medical informants are bound to respect confidentiality regarding any information that is covered by medical secrecy.

2. Written communication

article 24
The presentation and illustration of information is the responsibility of companies.

article 25
The layout must be sober. It will endeavour to summarize the information, to make it more accessible or easier to retain. It will avoid any excess.

article 26
The texts will be clear and the typeface used must make it easy to read.

article 27
The sections of a message that are required by law or regulations must be an integral part of the other sections of the message.

article 28
When a company pays to have promotional material published in a magazine or similar publication, this promotional material must be clearly distinguishable from independent journalistic articles.

3. Samples

article 29
1. Notwithstanding the legal and regulatory obligations, samples shall only be given to persons qualified to prescribe medicinal products, after the latter have submitted a written, signed and dated request to the company.

2. Notwithstanding the legal or regulatory exceptions, samples may only be supplied in order to familiarise the medical doctor with the medicinal product and only during the period necessary for this purpose.

3. Samples must not be given as an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products.

4. Each sample must be accompanied by the summary of the product characteristics.

5. Companies must have an appropriate system for controlling the distribution of samples of medicinal products.

6. The words "free sample – may not be offered for sale" or any other words of similar meaning must appear on the outer packaging of the sample.

3*bis*. Informational or educational materials, and items of medical utility

article 29*bis*

1. Pharmaceutical companies may only provide healthcare professionals 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.

   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.

2. Items of medical utility may only be provided for healthcare professionals when these items are:
   (i) intended directly for the training of healthcare professionals and the care of patients;
   (ii) of limited value; and
   (ii) not part of the basic material or basic equipment which every healthcare professional needs for his or her routine practice.

3. The term "of limited value" as mentioned above under points 1 and 2 is defined in the relevant guidelines.

4. Scientific events

article 30

Scientific events that are directly or indirectly supported or organised by pharmaceutical companies and that are attended by healthcare professionals shall take place within a framework of quality, as required by Articles 31 to 35. When a scientific event does not take place in Belgium, it must also, in accordance with Article 3, § 3, 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.

This applies, for example, to events of an exclusively professional and scientific nature, symposiums, international scientific congresses, advisory board meetings, visits to research or manufacturing facilities, investigator meetings for clinical or other scientific studies and any other form of scientific meeting held in Belgium or abroad.

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, pharmaceutical companies are obliged to obtain the visa from the Visas Bureau of the non-profit association Mdeon.

article 31 Hospitality

1. Hospitality made directly or indirectly available during scientific events must always be kept at a reasonable level and remain secondary to the principal scientific purpose of the meeting. It must not damage the good name of the industry.

2. The hospitality made available will be limited to the organisation and/or defrayment of the costs of travel, meals, accommodation and registration and will not extend beyond the official duration of the scientific event.

2*bis*. The value of the meals provided, drinks included, may under no circumstances exceed the limits laid down in the guidelines in this matter.

3. 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.

4. The hospitality made available will not under any circumstances include payment for or the organisation of sports or leisure activities or any other form of entertainment.

article 32 Scientific nature of the meeting – place, date and duration

1. Scientific events will always be predominantly scientific in nature. In all cases, from the moment of arrival at the place until the moment of departure, activities with a scientific purpose will, in terms of time, take up the greater part of each day of the event.

2. The events will be organised and the travel made in connection with medical and pharmaceutical sciences and not as an end in themselves.

3. The scientific events must take place at a suitable venue that aids the scientific purpose of the event. The place, date and duration of the events and travel must not in any case be of a nature to create any confusion as to their scientific nature.

4. It must be possible to reasonably justify the place and travel, especially when the event is held outside Belgium.

   Scientific events outside Belgium cannot be organised or sponsored unless:

   a. the majority of those invited do not originate from Belgium and, given the country of origin of most of those invited, it makes more sense logistically to have the event in another country, or

   b. relevant expertise or infrastructure is available at the place of the event, so that, from a logistics point of view, it makes more sense to have the event in another country.

5. When organising scientific events, companies must avoid places known for their entertainment opportunities or that are extravagant. Similarly, they shall refrain from sponsoring scientific events – or participating in them – that are held in such places.

article 33 Travelling, registration and organisational expenses

Companies may pay travelling, registration and organisational expenses provided the conditions laid down under Articles 30 to 35 are respected.

article 34 Accompanying persons – extension of the stay

1. Invitations to attend scientific events as well as their organisation or support by pharmaceutical companies are limited to healthcare professionals.

   The partners of healthcare professionals may accompany the latter if they make an explicit request.

   Neither the costs of hospitality, travel, registration, organisation nor any other costs may be met for these accompanying persons. Pharmaceutical companies shall take all the necessary measures to ensure the greatest possible transparency and clarity in this respect.

2. If the healthcare professionals invited to attend scientific events want to prolong their stay in a private capacity, under no circumstances may pharmaceutical companies make any contribution to the costs involved. Pharmaceutical companies shall take all the necessary measures to ensure the greatest transparency and clarity in this respect.

5. Dissemination of information at events

article 35

When companies participate in exhibitions, information days or any other event at which several companies come together to show their products to healthcare professionals and to provide information about these products, they must respect not only the above Articles but also and as a matter of priority the following:

a. The way in which the stand is laid out, the decoration and the informative material will be such that the scientific nature is most in evidence. Companies will charge qualified staff with this task.

b. The information and the various elements that serve to disseminate it (whether written material, audio-visual presentations, posters or any other means or media) will always comply with the laws and regulations on medicinal products as well as the provisions of the Code.

6. Use of audio-visual resources

article 36

Communications transmitted orally or by means of slides or posters shall comply with the aforementioned stipulations.

Any additional information must be made available to interested persons when the pictures or words only relate to the principal elements.

7. Data storage and data transmission

article 37

The storage and transmission of data will also be in accordance with the stipulations of this Chapter. They will also comply with legal requirements in terms of confidentiality and the protection of privacy.

8. Grants, subsidies and sponsoring

article 38

Notwithstanding Article 40 of the present Code and notwithstanding the legal provisions, the pharmaceutical companies are free to make any 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, grants, allowances, scientific prizes, 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.

article 39

The 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 as referred to under Article 2, para. 2, the pharmaceutical 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 as referred to under Article 30, the companies that made the aforementioned means available are subject to the advance visa procedure as referred to under that Article.

When a pharmaceutical 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.

Pharmaceutical companies are encouraged to make available publicly to third parties information about financial means and other operating means.

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Chapter 3: Premiums and benefits

article 40

1. It is forbidden, in connection with the supply, prescribing, issuing or administration of medicinal products, to promise, offer or grant, directly or indirectly, premiums or benefits in money or in kind to wholesalers or persons qualified to prescribe, issue or administer medicinal products as well as to the institutions in which the prescribing, issue or administration of medicinal products takes place.

Among other things, it is forbidden to offer or grant any form of hospitality except as part of a scientific event as referred to under Article 30 of the present Code

2. However, the prohibition referred to in point 1 of the present Article does not apply to:

1° premiums or benefits of negligible value and that relate to the exercising of the medical profession, dental profession or pharmaceutical profession and that concern medicinal products that are not subject to prescription. However, in regard to medicinal products that can only be supplied on prescription, the offer, granting or promise of any gift to a healthcare professional is prohibited, even when it is of negligible value and concerns the exercising of the medical profession, dental profession or pharmaceutical profession;

2° samples made available to healthcare professionals in accordance with Article 29 of the present Code;

3° informational or educational material and items of medical utility made available to healthcare professionals in accordance with Article *29bis* of the present Code;

4° invitations to and the defrayment of the costs of participating in a scientific event, including hospitality, by healthcare professionals provided the event complies with the conditions described under Articles 30 to 35 of the present Code;

5° remuneration for legitimate services of a scientific nature, provided that this remuneration remains within reasonable limits. However, under no circumstances can a payment be made purely to remunerate time spent by healthcare professionals on attending a scientific event as referred to under Article 30 of the present Code.

Chapter 4: Contracts

article 41

Notwithstanding Article 40 of the present Code and notwithstanding the legal provisions, contracts between pharmaceutical 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:

1° support healthcare or research,

2° do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products.

article 42

1. Notwithstanding Article 40 of the present Code and notwithstanding the legal provisions, a pharmaceutical company may use one or more healthcare professionals as consultants or advisors 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, in which the healthcare professionals concerned receive a remuneration and/or are expected to travel.

   The arrangements made in this respect, if relevant to this subject, must satisfy the following conditions:

   a. a legitimate need for the services is clearly identified before retaining the healthcare professionals and making arrangements in this respect;

   b. the criteria for selecting consultants are directly related to the identified legitimate need as referred to in clause a and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the contacted healthcare professionals meet those criteria;

   c. the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

   d. 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 g. hereafter;

   e. the pharmaceutical company maintains records concerning the services provided and makes appropriate use of them;

   f. the hiring of the healthcare professionals to provide the services is not an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products and

   g. the compensation for the services is reasonable and reflects the usual market value of the services provided.

2. For the purposes of transparency, pharmaceutical companies are strongly encouraged to include in the written contract as mentioned above in paragraph 1.d. 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 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, pharmaceutical 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.

3. The provisions mentioned under paragraph 1.d. do not apply to limited market research, such as one-off phone interviews or surveys by post, e-mail or internet, provided that the healthcare professionals concerned are not consulted repeatedly, whether in the context of the same or another survey, and that the remuneration for their collaboration is of token value.

4. When a healthcare professional attends a scientific event in the capacity of consultant or advisor, the Articles 30 to 35 of the present Code apply.

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Chapter 5: Non-interventional studies

article 43
Non-interventional studies 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 44
In carrying out the scientific studies referred to under Article 43, companies shall ensure, notwithstanding the legal and regulatory provisions on this subject, that the following conditions are respected, to the extent that they are relevant to the case in question:

- the study is conducted with a clear scientific purpose;
- 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;
- the scientific protocol must be approved in advance by the company's scientific service as referred to under Article 6 of the present Code and this service has to supervise the conduct of the study;
- 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;
- the remuneration is commensurate with the services requested and reflects the market value thereof;
- the procedures for supplying the medicines studied shall be described in detail in the protocol; they shall be coherent in regard to the stated purpose and methodology;
- the future use of the data collected shall be stated clearly in the protocol;
- the study results must be analysed and reports thereof must be submitted within a reasonable period of time to the company's scientific service which shall maintain these reports for a reasonable period of time;
- the company must send the study results to all healthcare professionals who participated in the study; the study results should also be kept at the disposal of the bodies of pharma.be as referred to under Article 52, paragraph 1 of the present Code and must be submitted following a request on their part; 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;
- the number of patients requested for inclusion as well as the number of investigators included shall be justified in a scientific manner in the protocol, for example by means of a biostatistical calculation;
- the study must not constitute an inducement to recommend, prescribe, purchase or sell, supply or administer medicinal products;
- medical informants may only intervene in a study to perform administrative tasks under the supervision of the company's scientific service; this service will ensure that the medical informants are adequately trained for this purpose; their involvement in scientific studies must not be linked to the promotion of medicinal products.

Chapter 5*bis*: Transparency

article 44*bis*

1. Notwithstanding the application of legal and regulatory provisions, and in particular those that relate to the protection of privacy, pharmaceutical companies shall document and disclose transfers of value they make, directly or indirectly, for the benefit of a healthcare professional or organisation.

   When the recipient has its principal professional address or place of incorporation in Belgium, the documenting and disclosure of the transfers of value must be made in accordance with the rules and procedures as set out below.

2. For the application of the provisions in this Chapter, the following terms are to be understood as defined below:

   - Transfers of value: any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products for human use;

   - Direct transfers of value: transfers of value made directly by a pharmaceutical company for the benefit of a healthcare professional or organisation;

   - Indirect transfer of value: transfers of value made on behalf of a pharmaceutical company for the benefit of a healthcare professional or organisation, or transfers of value made through an intermediate and where the pharmaceutical company knows or can identify the healthcare professional or organisation that will benefit from the transfer of value.

   - Healthcare professional: any natural person who is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. This definition of healthcare professional includes (i) any official or employee of a government agency or other organisation (whether in the public or private sector) who may prescribe, purchase, supply, recommend or administer medicinal products and (ii) any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional. All other employees of a pharmaceutical company and wholesalers or distributors of medicinal products are excluded from this definition.

   - Healthcare organisation: (i) any association or organisation active in the field of healthcare or at the medical or scientific level, irrespective of the legal or organisational form, such as a hospital, foundation, university or other teaching institution or learned society, except for patient organisations within the scope of Chapter 6 of the Code whose business address, place of incorporation or primary place of operation is in Europe or (ii) any legal entity through which one or more healthcare professionals provide services.

3. The obligation described under point 1 of this Article does not apply to transfers of value that (i) *either* are solely related to non-prescription medicinal products, (ii) *or* are not listed in Article 44*quater* of the present Code, such as items of medical utility governed by Article 29*bis*, § 2, meals and drinks governed by Article 31, § 2*bis*, and samples governed by Article 29 of the Code, (iii) *or* are part of ordinary course purchases and sales of medicinal products by and between a pharmaceutical company and a healthcare professional, such as a pharmacist, or a healthcare organisation.

4. In regard to transfers of value that relate solely to non-prescription medicinal products, pharmaceutical companies are, however, strongly encouraged to comply with the obligation set out under point 1 of this Article in regard to their other products.

article 44*ter*

1. The transfers of value as referred to in Article 44*bis*, § 1, must be disclosed on an annual basis. Each period for which a report is made shall cover a full calendar year (the "reporting period").

2. Disclosures shall be made within 6 months after the end of the relevant reporting period. Without prejudice to the application of the legal and regulatory provisions, in particular concerning the protection of privacy, the information must remain accessible to the public for at least three years after the date when such information is first disclosed, in accordance with Article 44*ter*, § 4.

3. For consistency purposes, disclosures will be made using a structure set forth in annex 2 of the present Code.

4. Transfers of value shall be disclosed on or via the website of a central platform set up for this purpose. The practical aspects linked to this platform will be determined by means of guidelines.

5. The information shall be disclosed in Dutch and French. Pharmaceutical companies are encouraged to also make disclosures in English.

6. Pharmaceutical companies must document all transfers of value that must be disclosed in accordance with Article 44*bis*, § 1. They must retain the relevant proof that they have respected their disclosure obligations correctly and in full for a minimum of 5 years after the end of the relevant reporting period, notwithstanding the legal and regulatory provisions concerning the protection of privacy and other matters.

article 44*quater*

1. Except in the cases referred to in Article 44*quater*, §§ 3 and 5, transfers of value shall be disclosed on an *individual* basis. Each pharmaceutical company shall disclose for each identifiable recipient the amounts attributable to transfers of value during the reporting period for the benefit of this recipient which can be reasonably classed under one of the categories set out below. Such transfers of value may be aggregated on a category-by-category basis, provided that itemised disclosure is made available upon request by the relevant recipient, or the relevant authorities.

2. The categories of transfers of value referred to in Article 44*quater*, § 1, are as follows:

    I. In regard to transfers of value to healthcare organisations:

        a. Donations and grants that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare, as referred to in Article 38, § 3, of the Code.

        b. Contribution to costs of scientific events, including sponsoring of healthcare professionals to enable them to attend these events, such as:
            i. Registration fees;
            ii. Sponsorship agreements with healthcare organisations or with third parties appointed by these organisations to manage a scientific meeting; and
            iii. Travel and accommodation as referred to in Article 31 of the Code.

c. Fees for services and consultancy. This category includes transfers of value resulting from or related to contracts between pharmaceutical companies and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to the reimbursement of expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

II. In regard to transfers of value to healthcare professionals:

a. Contributions to costs related to scientific events, such as:
   i. Registration fees; and
   ii. Travel and accommodation as referred to in Article 31 of the Code.

b. Fees for services and consultancy. This category includes transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare professionals under which such healthcare professionals provide a service to a pharmaceutical company, as well as any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to the reimbursement of expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

3. For transfers of value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Article 44quater 2 above, cannot be disclosed on an individual basis for legal reasons, the pharmaceutical company shall disclose the amounts attributable to such transfers of value for each reporting period on an *aggregate* basis. Such aggregate disclosure shall identify, for each category, (i) the number of beneficiaries covered by such disclosure, on an absolute basis and as a percentage of all recipients, and (ii) the aggregate amount attributable to transfers of value to such recipients.

4. Where a transfer of value required to be disclosed pursuant to Article 44*quater*, § 1 or 3 above, is made to an individual healthcare professional indirectly via a healthcare organisation, such a transfer of value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made in the name of the individual healthcare professional in accordance with the categories set forth in Article 44*quater*, § 2, II, above.

5. Transfers of value relating to research and development in each reporting period shall be disclosed by each pharmaceutical company on an *aggregate* basis. Costs related to scientific events that are clearly related to activities covered by this paragraph can be included in the aggregate amount under the "Research and Development" transfers of value category.

   "Research and Development" transfers of value include transfers of value to healthcare professionals or healthcare organisations related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in European Directive 2001/20/EC); or (iii) non-interventional studies as defined in Article 43 of the Code.

6. Each pharmaceutical company shall publish a note summarizing the methodologies used in preparing the disclosures and identifying transfers of value for each category described in Article 44*quater*, § 2. The note shall include a description of the valuation methods applied and of the way in which, depending on the case, an agreement for more than one year, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of the transfers of value were handled.

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article 44*quinquies*

When transferring values to healthcare practitioners or organisations, pharmaceutical companies are strongly encouraged to include, in their contracts with them, provisions relating to the recipients' consent to disclose transfers of value in accordance with this Chapter. In addition, companies are strongly encouraged to renegotiate existing contracts to include clauses to this effect.

Chapter 6: Relationships with patient organisations

article 45
Notwithstanding the application of legal provisions and regulations, in particular those relating to the advertising of medicines to the general public, pharmaceutical companies are allowed to provide direct or indirect, financial or other support to patient organisations.

By patient organisation is understood: any not-for-profit organisation, 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.

article 46
When a pharmaceutical company provides financial support to a patient organisation, a written agreement must be drawn up. The same rule applies when significant indirect support, such as paying for the services of a public relations agency, or significant non-financial support, such as making available manpower or space, is provided to a patient organisation.

This written agreement must as a minimum include the following:

- the amount of the funding or, in case of indirect or non-financial support, a precise description of the support,
- the purpose of the funding, such as the allocation of an "unrestricted grant", support for a particular meeting or publication, etc. and
- the code or codes of deontology applicable to the support pursuant to Article 3, § 3, second paragraph, of the present Code.

Each pharmaceutical company shall have an internal approval process in place for these agreements.

article 47
Notwithstanding the application of legal provisions and regulations, a pharmaceutical 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 48
A pharmaceutical company will always respect the independence of the patient organisations when drawing up the text of the material it is sponsoring. This does not preclude the company from correcting factual inaccuracies.

article 49
1. Each pharmaceutical company shall make available to the public once a year a list of patient organisations to which it provided support during the past calendar year as referred to under Article 46, first paragraph, of the present Code. It mentions for each patient organisation the nature of the support provided. The description must be sufficiently complete to allow the average user to form a picture of the scope of the support. The description must state the amounts of money involved if the support is financial and the costs invoiced. If considerable non-financial support is involved that cannot be ascribed a meaningful financial value, the non-financial benefit received by the patient organisation must be described clearly.

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

3. Each pharmaceutical company likewise publishes an annual list of patient organisations to which it has provided considerable services on a contractual basis. This list must contain a description of the nature of the services provided sufficiently complete to allow the average user to form a picture of

the scope of the support, however without thereby disclosing confidential information. Moreover the companies must make known the total amount that they have paid per patient organisation in the period concerned.

article 49*bis*

Contracts between pharmaceutical companies and patient organisations in which the latter undertake to perform particular services for the former are only allowed if these services are provided to support health care or research.

It is permitted to call on patient organisations as experts and advisers to perform these services, such as participating in advisory board meetings or giving talks. Contracts in which consultancy or other services are regulated must, insofar as they are relevant, comply with the following conditions:

a. 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, without prejudice to what is stated hereafter in clause g, the basis for the remuneration for these services;

b. the justified necessity for the services is clearly identified and documented before the services are requested and contracts are made regarding them;

c. the criteria for the selection of services is directly linked to the justified necessity mentioned in clause b. and the people who are responsible for selecting the service possess the necessary expertise to check that the experts and advisors contacted satisfy the criteria;

d. the scope of the service is not greater than that which is reasonably necessary to realise the identified need;

e. the pharmaceutical company keeps a report of the services provided and makes appropriate use of it;

f. the assistance given to the patient organisations is rendered in such a way that the provision of services does not constitute a means of encouraging the recommendation of a particular medicinal product;

g. the remuneration for the services is reasonably in line with the fair market value of the services provided. Consultancy contracts made may not be used as justification for remunerating patient organisations;

h. the pharmaceutical companies are strongly encouraged to put a clause in their written contracts with patient organisations under which the patient organisation undertakes to report that they have provided paid services for the company whenever they speak about in public or advertise the matters that form the subject of the contract or about any other matter in connection with the company;

i. every pharmaceutical company must publish an annual list of patient organisations which it has called on to perform services for payment as set out in Article 49, § 3, of the Code.

article 50
No pharmaceutical company may require that it be the sole funder of a patient organisation or any of its projects.

article 51
1. Pharmaceutical companies may financially support events that are organised for 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.

2. Events for patients that are sponsored or organised by or on behalf of a pharmaceutical company will always be held in a suitable location that advances the purpose of the event and the exchange of information. Locations that are known for entertainment or that are extravagant must be avoided.

3. Hospitality that is extended by the pharmaceutical companies to patient organisations and their members must always be reasonable and remain subordinate to the main purpose of the event, regardless of whether the event is organised by a patient organisation or by the industry.

4. The hospitality that is offered in connection with an event shall be limited to the organisation and/or defrayment of the costs of travel, meals, accommodation and registration.

5. Hospitality may only be offered to participants in the event. In exceptional cases, if there is a clear need on the grounds of hospitality (e.g. disability) the costs of travel, meals, accommodation and registration of an accompanying carer may be paid.

6. All hospitality that is offered to patient organisations and their representatives will always be reasonable and remain strictly limited to the purpose of the event.

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

8. A pharmaceutical company may not organise or sponsor events that take place outside Belgium unless:

    - 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

    - given the relevant expertise or infrastructure at the location of the event, it makes greater logistical sense to hold the event in another country.

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Chapter 7: Supervision – Measures upon non-compliance with the Code

Section 1: Generalities

article 52

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

1. A Secretariat;
2. A supervisory body: the Bureau for Control on Written Communication, hereinafter referred to as the "BCWC";
3. Two disciplinary bodies:
   a. the Committee for Deontology and Ethics in the Pharmaceutical Industry, hereinafter referred to as the "DEP Committee"; and
   b. the Chamber of Appeal.

article 53

1. 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.

2. 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 54

1. 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.

2. The president of each disciplinary or supervisory body shall have sole discretion for ruling on procedural issues.

3. 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.

4. 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.

5. 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 by-laws – 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 85, § 2, 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.

6. 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 55
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 56
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 57
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 58
Without prejudice to the publication and communication measures referred to in Articles 56, 96 and 98 of this Code, 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 59
1. 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.

2. 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.

3. 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.

4. 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.

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article 60
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 61
In accordance with the procedure described in the current section, the BCWC has the task to review the conformity of the written communication of companies intended for healthcare professionals with the provisions of this Code and with the relevant legal provisions and regulations.

article 62
1. The BCWC comprises three full members, namely:

   a. a lawyer, not employed within the pharmaceutical industry, as president;
   b. a member representing the medical profession, not involved in the industry;
   c. a member representing the pharmaceutical profession, not involved in the industry.

2. The number of substitute members must be equivalent to that of full members. The mandates are remunerated.

3. The BCWC is validly convened when its president and at least one of the two remaining members are present. Decisions are taken by consensus.

4. Both full and substitute members of the BCWC are designated by the Board of Directors of pharma.be.

5. 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 63
Each month, the Secretariat selects *at random* five human medicinal products from five different pharmaceutical 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 64
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 65
At the same time as the written communications referred to in Article 63, the company shall specify the relevant category of professionals targeted for each piece of written communication. Furthermore, the company shall provide the Secretariat with an overview of its internal procedure for the approval of the same.

article 66
1. The companies shall communicate the documents and data listed in Articles 64 and 65 to the Secretariat no later than the fifteenth day after the invitation referred to in Article 63 was sent. The file must be emailed to the Secretariat, which shall acknowledge receipt of the same.

2. 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 67

1. To fulfil its duty pursuant to Article 61, the BCWC shall ascertain whether:
   - the 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.

2. The BCWC shall communicate its findings to the company concerned via the Secretariat within one month following the expiry of the fifteen-day period referred to in Article 66, § 1.

article 68

The BCWC may request through the Secretariat that the company provide additional information. The company shall provide the additionally requested information to the Secretariat no later than the fifteenth day following the date of the request. If additional information is requested, the period of one month referred to in Article 67, § 2, shall be suspended until the company has complied with the request.

article 69

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

article 70

1. Any 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.

2. The BCWC shall consider these observations and pass on its final conclusions to the company through the Secretariat no later than the fifteenth day following the date of their receipt.

article 71

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

article 72

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:
   - requesting an explanation from a company;
   - 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 73
The DEP Committee:

- adjudicates the admissibility of any complaint;
- handles complaints;
- ensures the conciliation tasks pursuant to Article 80, § 2.

article 74
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 75
1. To be validly convened, the chambers of the disciplinary bodies must respectively comprise:

   a. a president, a lawyer and not actively involved within the pharmaceutical industry;
   b. a member representing the industry for pharmaceutical products for human or veterinary use (according to the type of product/issue concerned); and
   c. a member, not involved in the industry, representing either the medical profession or the pharmaceutical profession or having a scientific or academic background.

2. 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 83, from among those persons included in the reserve referred to in Article 76.

   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 54, § 5. The Secretariat shall annex said declaration to the notice of hearing referred to in Article 85, § 2, to ensure the parties are made aware of the same.

article 76
1. A reserve is established to allow the setting up of the chambers of the disciplinary bodies called upon to decide, in accordance with Article 75 of this Code. This reserve comprises the following full members:

   a. three lawyers, not actively involved in the pharmaceutical industry;
   b. six members representing the industry for pharmaceutical products for human use;
   c. three members representing the industry for pharmaceutical products for veterinary use;
   d. six members representing the medical profession, not involved in the industry;
   e. two members representing the pharmaceutical profession, not involved in the industry; and
   f. three members with a scientific or academic background, not active in the industry.

2. 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.

3. The members referred to in § 1, point a, 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 § 1, points b and c, 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 in point c 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 § 1, points b and c, 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 § 1, points d and e, 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 § 1, points d and e, are allocated while taking into account how representative the associations from which the abovementioned members originate actually are.

   The members referred to in § 1, point f, are designated by one or more representative organisation(s) from academic or scientific backgrounds. The same applies for the corresponding substitute members.

article 77

1. 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)*.

2. Mandates are remunerated, except for members who are active in industry.

3. Where a member representing the industry of pharmaceutical products for human or veterinary use, as referred to in Article 76, § 1, points b and c, resigns or can not/no longer continue its mandate, said member shall be automatically excluded from the reserve referred to in Article 76 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 76, § 3, subparagraph 2. Any replacement member of a disciplinary body shall be appointed for the remaining term of mandate of its predecessor.

4. 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 78
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 79
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 80
1. Before initiating a complaint procedure before the DEP Committee, the parties must attempt to settle their disputes amicably.

2. 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 81
1. Any individual or legal entity who/that observe a violation of the rules of deontology as laid down in this Code 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).

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

3. 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).

4. The Secretariat shall confirm receipt of the complaint with the relevant parties as soon as possible.

article 82

1. 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 100; and
   (iv) be accompanied by evidence that conciliation, e.g. as referred to in Article 80, § 1, has been attempted or, where applicable, evidence of the defendant's refusal to participate in said conciliation.

2. The plaintiff must also specify which measures are being requested in its complaint, as referred to in Article 96 of the present Code.

article 83

1. 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.

2. 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 81, § 4 (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 § 1 of this Article.

   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 84

1. No later than the seventh calendar day following confirmation by the Secretariat of the registration of complaint in accordance with Article 81, § 4, 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.

2. 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 § 1 of this Article.

In the absence of agreed timetable notified to the Secretariat within the time limit referred to in § 1 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 85

1. 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.

2. 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 75, § 2.

   If a party wishes to remove a member of the disciplinary body pursuant to Article 54, § 5, 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 54, § 5.

article 86

1. 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.

2. Except where exceptional circumstances apply, any briefs or exhibits filed or notified belatedly or outside the established timetable shall be excluded from the debates.

3. The briefs of the parties may not exceed 25 pages (A4, Verdana 9, single-spaced).

article 87

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

§ 4. Handling of the complaint by the disciplinary bodies

article 88

1. 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.

2. 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 89

1. 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.

2. 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.

3. The parties may be represented by an advisor or a lawyer.

article 90

1. The hearings of the disciplinary bodies shall not be in public, unless otherwise asked by the defendant at the start of the hearing.

2. 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.

3. The debates shall be held in the language of the proceedings, as determined per Article 83, unless the president of the relevant body authorises the parties or third parties concerned to express themselves in another language.

article 91

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 92

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

article 93

1. 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.

2. 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 93 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 94

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

2. 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 95, § 2, of the Code.

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

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

4. 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).

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

6. 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 96 of the present Code.

7. 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 § 5 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).

8. 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 75, § 2.

   If a party wishes to remove a member of the disciplinary body pursuant to Article 54, § 5, 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 54, § 5.

Sub-section 3: Decisions and measures upon non-compliance with the Code

article 95

1. The proceedings before the DEP Committee and the Chamber of Appeal may give rise to the following decisions:

   - 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 96;
   - The lack of admissibility or grounds for the complaint/appeal;
   - 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.

2. 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.

3. The decisions of the DEP Committee are deemed final in the absence of any appeal filed within the period referred to in Article 94, § 2, of this Code.

article 96

1. 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.

2. 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:

   - a reprimand; and/or
   - a corrective measure; and/or
   - a supervisory measure; and/or
   - a financial indemnification measure.

3. The term "corrective measure", as referred to in § 2, includes for example:

   - correction of infringing material;
   - insertion of a corrective statement and/or issuing an amended version of the infringing material;
   - recall of any infringing material already distributed;
   - 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;
   - removal of a link to a website.

4. The term "supervisory measure", as referred to in § 2, includes for example:

   - communicating the details of the organisation of an upcoming event and any other relevant information relating thereto;
   - recommendations for transparency or clarity;
   - 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.

5. 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.

6. 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 94, § 2, 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 1.

   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."

7. 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 99.

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Sub-section 4: Execution of decisions

article 97

Except in the case of publications referred to in Article 96, § 6, 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 98

1. 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.

2. The measures which may be imposed under Chapter 7 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 by-laws.

Chapter 8: Costs of proceedings

article 99

1. In the sense of the present Article, the term "costs of proceedings" refers to all costs linked to the proceedings referred to in Chapter 7, section 3.

2. 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.

3. The party bearing the costs of proceedings is obliged:

   (i) to make payment of the lump sum as published each year on the public website of pharma.be;

   (ii) where applicable, to make payment of expert fees arising pursuant to Article 54, § 3, of this Code; and

   (iii) where applicable, to refund the plaintiff /appellant for the equivalent amount spent by the latter on registry fees, as referred to in Articles 81, § 3, and 94, § 4, of this Code.

4. 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.

5. Each disciplinary body may, in any case not provided for under this Code, fix the allocation of costs of proceedings to the parties.

6. In derogation of the preceding rules, individuals shall not be required to bear any costs of proceedings.

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Chapter 9: General provisions – Entry into force – Interim measures

article 100
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 101
Notwithstanding the application of Articles 3, § 3, and 30 of the present Code, 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 102
The resignation or exclusion of a member 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 also remains liable for any costs of proceedings (or other sums) established in accordance with Article 111.

article 103
1. 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, with the exception of Article 40, § 2, 1°, 2nd sentence, which enters into force six months after its approval by the pharma.be General Assembly.

2. 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 104
1. The first reporting period referred to in Article 44*ter*, § 1, shall be the 2015 calendar year.

2. In derogation of § 1, in the event of the affiliation of a new member or the merger/acquisition of a non-member company by a member of pharma.be, the first reference period referred to in Article 44*ter*, § 1 shall coincide, for said new member or the merged/acquired company, at the latest, with the calendar year respectively following the initial year of membership or the year of the merger/acquisition.

article 105
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.

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Annex 1

Directives concerning the determination of facts that must be considered as a "*serious violation of the rules of deontology*" pursuant to Article 96, § 6, of the Code

Context

In accordance with Article 96, § 6, 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 reflection.[1]

- 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 results,[2]
  - 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.

[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.*

- 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 organisation of a competition for patients who use a particular medicinal product;

  - the introduction of a system by which, after the tenth purchase, the pharmaceutical company offers a patient an eleventh medicinal product free of charge.

- Article 10[3] 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 -

[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".

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.

Annex 2

Click here to download the template for disclosure.

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