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## Code of deontology

Approved by the Board of pharma.be of 11 December 2013

– to be approved by the General Assembly of 28 March 2014

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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.

## 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.

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

#### **article 29bis**

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, events to promote medicinal products, 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.

### 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.
- 2bis. 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 or scientific studies as referred to under article 43, the companies that made the aforementioned means available are subject to the advance visa procedure as referred to under articles 72 and 73 of the present Code.

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.

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

## 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.

## 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 5bis: Transparency

### article 44bis

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<sup>quater</sup> 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, paragraph 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 44<sup>quater</sup> 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<sup>quater</sup> 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<sup>quater</sup> 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 44 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<sup>quater</sup> 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.

#### **article 44<sup>quinquies</sup>**

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 49bis**

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 permissible for patient organisations to call on 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.

## Chapter 7:

# Supervision – Measures upon non-observance of the Code

## Section 1: Generalities

### article 52

§ 1. With a view to guaranteeing respect for the proper application of the rules of this Code, a number of disciplinary or controlling bodies are set up, namely:

1. a Secretariat,
2. a Bureau of Proceedings,
3. a Visas Bureau,
- 3bis. a Bureau for Control on Written Communication, hereinafter the BCWC,
4. a Chamber of Investigation,
5. a Deontological and Pharmaceutical Ethics Committee (hereinafter "the DEP Committee"),
6. a Chamber of Appeal.

§ 2. Unless the Code lays down an explicit exception, a mandate to serve on one of these disciplinary or monitoring bodies is incompatible with a function on any other (disciplinary or monitoring) bodies of pharma.be.

§ 3. The president of each disciplinary or monitoring body shall have sovereign authority on matters of procedure. He may have recourse to the services of an expert of his choice in order to settle any particular issue.

§ 4. The members of the various disciplinary or monitoring bodies explicitly undertake, on pain of possible exclusion decided by the Board of Directors, to guarantee the confidentiality of all the data, information, evidence, acts, documents or any other information that comes to their knowledge in the exercising of their mandate.

§ 5. Any member of one of these disciplinary or monitoring bodies who fails to attend three consecutive ordinary meetings is deemed to have resigned, save in exceptional circumstances. Arrangements are then made for a replacement.

§ 6. All decisions, reports or other official documents are signed by the president of the body in question of the disciplinary or monitoring body or by any other person duly mandated by him. Failing exception provided for by the Code, the aforementioned documents are communicated to the parties, as stated under article 56 of the present Code.

§ 7. All members of a disciplinary or monitoring body will act in total independence. If there is a conflict of interests, the member will refrain from taking part in any phase in the procedure or handling of the case concerned. The president, vice president or, failing this, the other members of the disciplinary or monitoring body if the president is in called into question, can automatically or at the request of one of the parties, remove from the procedure or handling of the case in question any member in a situation of conflict of interests.

The decision taken on this subject shall be communicated immediately and there is no possibility of appeal against it.

§ 8. When the disciplinary or monitoring body of pharma.be takes decisions, it does not accept any instructions from members of pharma.be or from any bodies of pharma.be.

## **article 53**

At regular intervals, the presidents of the various bodies accompanied by members who so desire, as well as the Director General of pharma.be, will meet to consider the development of the deontology, especially in the light of the legislation and jurisprudence. They will submit to the Board of Directors any proposal to modify the present Code that they may deem necessary.

## **article 54**

Outside of any disciplinary procedure, any member-company may request from the DEP Committee an opinion on the activities or project that it envisages carrying out, in order to check that it complies with the present Code. This request for opinion must be precise, complete and permit the adoption of a position in full knowledge of the facts.

The opinion procedure as described in this article may not under any circumstances concern any of the activities that, by virtue of the present Code, are subject to the advance visa procedure as described under articles 72 to 78 of the present Code.

## **article 55**

A compilation of anonymous and representative jurisprudence shall be available to the members of pharma.be, comprising the final decisions taken by the Bureau of Proceedings, the Visas Bureau, the DEP Committee and the Chamber of Appeal. This jurisprudence is regularly updated and is the subject of a communication, and at least once every year.

## **article 56**

Unless otherwise specified in the present Code, any correspondence may be sent to the parties by regular mail, e-mail, telefax or any other means of communication. The final decisions by the DEP Committee and the Chamber of Appeal will in contrast, have to be communicated to the parties involved by registered letter.

## **article 57**

Any document (complaint, statement, exhibit, decision, etc.) that is communicated to the parties in connection with a case is strictly confidential and cannot be circulated by the parties without the explicit agreement in writing by the president of the body in question. Under no circumstances may it be used for commercial purposes.

## **article 58**

1. Except for provision to the contrary, the time limits referred to in the present Code are absolute time limits. They run from the day after the act, at zero hours, and expire on the last day of the time limit, at 24.00 hours.
2. If this last day is a Saturday or Sunday or a public holiday, the expiry of the time limit is automatically postponed until the first subsequent working day.
3. Acts that must be fulfilled at the Secretariat can only be carried out during office opening days and times.

## **article 59**

Any correspondence in connection with this Code is to be addressed to the:

**Secrétariat du Code de déontologie/ Secretariaat van de Code voor deontologie**  
**pharma.be**  
**Chaussée de La Hulpe 166**  
**1170 Brussels**

## **Section 2: Bodies**

### **§ 1. The Secretariat**

#### **article 60**

The Secretariat is charged with general support and administrative management of the deontological device. It will always act in strict neutrality and independence. It will not be involved in the decision-making processes of the various disciplinary or monitoring bodies.

#### **article 61**

pharma.be is responsible for the material organisation of the Secretariat. This will be assured by qualified staff who bear the title of Secretary. They may assist one another or stand in for one another.

### **§ 2. The Bureau of Proceedings**

#### **article 62**

The Bureau of Proceedings:

- a. consults all dossiers that come in under article 79 of the present Code;
- b. pronounces in a sovereign capacity and in the final resort on the admissibility of any incoming dossier and on the subsequent course of action, as laid down in particular under article 91 of the present Code; under no circumstances will the Bureau of Proceedings adjudicate on the merits of the dossiers.

#### **article 63**

1. The Bureau of Proceedings includes one serving member, a lawyer who is not active in the pharmaceutical industry.
2. The Bureau of Proceedings includes one substitute member, a lawyer who is not active in the pharmaceutical industry. The substitute member replaces the serving member in the event of the absence or unavailability of the latter or in the circumstances intended in article 52, § 5 of the present Code.
3. Members of the Bureau of Proceedings are appointed by the pharma.be Board of Directors. The mandates are remunerated.
4. These mandates run concurrently with those of the DEP Committee, as laid down under article 69.5 of the present Code.
5. The Bureau of Proceedings will meet as often as is required for the consideration of dossiers.

## § 3. The Visas Bureau

### article 64

The Visas Bureau pronounces on requests for advance visas as referred to in article 73 of the present Code.

### article 65

1. The Visas Bureau is composed of two chambers. One of these chambers is charged exclusively with appeals as referred to in article 77 of the present Code and shall be known as the “Chamber of Appeal”. Each chamber consists of three serving members, namely:
  - a. a lawyer, who is not active within the industry, as president;
  - b. a member representing the pharmaceutical industry who, having acquired wide experience in the sector, is no longer in the service of any pharma.be member company;
  - c. a member drawn from the scientific, academic, medical or pharmaceutical world.
2. The same person may not hold mandates within different chambers of the Visas Bureau at the same time.
3. The rules regarding the quorums needed are as follows. The chamber that handles the requests for visa in the first instance is validly convened when its president and at least one of the two other members are present. However, the Chamber of Appeal must include the three members referred to under point 1. Decisions are reached by consensus.
4. There are as many substitute members as there are serving members. Mandates are remunerated.
5. The members referred to under points 1.a and 1.b of this article are appointed by the pharma.be Board of Directors. The same applies to the corresponding substitute members.

The member referred to under point 1.c of this article is appointed by a representative organisation of the scientific, academic, medical or pharmaceutical world. The same applies to the corresponding substitute member.
6. These mandates will run concurrently with those of the DEP Committee, as laid down under article 69.5 of the present Code.
7. Each chamber of the Visas Bureau will meet as often as is required for the consideration of dossiers.

## § 3bis. The Bureau for Control on Written Communication

### article 65bis

The BCWC has the task, in accordance with the procedure described in articles 78bis and following of the present Code, of exercising control over the compliance of the written communication of companies addressed to healthcare professionals with the provisions of the present Code and with the legal and regulatory provisions applicable in this matter.

## **article 65ter**

1. The BCWC consists of three serving members, namely:
  - a. a lawyer, who is not active in the pharmaceutical industry, as president,
  - b. a member representing the medical profession with no connection with the industry,
  - c. a member representing the pharmaceutical profession with no connection with the industry.
2. There are as many substitute members as serving members. The mandates are remunerated.
3. The BCWC is validly convened when its president and at least one of the two other members are present. Decisions are reached by consensus.
4. Both the serving and substitute members of the BCWC are appointed by the pharma.be Board of Directors.
5. The mandates run concurrently with those of the DEP Committee, as laid down under article 69.5 of the present Code.

## **§ 4. The Chamber of Investigation**

### **article 66**

The Chamber of Investigation carries out, on the instructions of the Bureau of Proceedings, the investigations necessary to collect incriminating or exonerating elements in cases where the facts have not been assembled of sufficient elements of proof of a violation of the rules of behaviour of the present Code.

Its powers of investigation are determined by article 94 of the present Code.

### **article 67**

1. The Chamber of Investigation has one serving member, a lawyer who is not active in the pharmaceutical industry.
2. The Chamber of Investigation has one substitute member, a lawyer who is not active in the pharmaceutical industry. The substitute member replaces the serving member if the latter is absent or unavailable.
3. Members of the Chamber of Investigation are appointed by the pharma.be Board of Directors. The mandates are remunerated.
4. The mandates run concurrently with those of the DEP Committee, as laid down under article 69.5 of the present Code.
5. The Chamber of Investigation meets as often as is required for the consideration of cases.

## § 5. The Committee for Deontology and Ethics in the Pharmaceutical Industry (DEP Committee)

### article 68

The DEP Committee:

- a. considers complaints on the grounds as intended in article 79 of the present Code;
- b. considers, if applicable, complaints for summary consideration as stated under article 104 of the present Code;
- c. pronounces on an appeal against a decision to refer a case to the Federal Agency for Medicinal and Health Products (FAMHP);
- d. takes action on the requests as intended in article 54 of the present Code.

### article 69

1. The DEP Committee has 12 members, namely:
  - a. one member, a lawyer who is not active in the pharmaceutical industry, the president;
  - b. one member, a lawyer who is not active in the pharmaceutical industry, the vice president;
  - c. five members representing the pharmaceutical industry;
  - d. three members representing the medical profession, who have no connection with the industry;
  - e. one member representing the pharmaceutical profession, who has no connection with the industry;
  - f. one member drawn from the scientific or academic world, who is not active in the industry.
2. There are as many substitute members as serving members. Furthermore, for the members referred to under point 1.c, a reserve shall be set up to ensure replacements in case of unfilled mandates or the unavailability of serving or substitute members.
3. The rules concerning the quorums required are as follows. The DEP Committee is validly convened when, in addition to the president, six of its members are present. Decisions are taken by a simple majority of votes of the members present. If there is a tied vote, the president has the casting vote. At the request of at least one member and subject to the casting of the president's vote in the case of a tied vote, the vote will be by secret ballot. Only members present are entitled to vote. Voting by power of attorney is not permitted.
4. The members referred to under points 1.a and 1.b are appointed by the other members of the DEP Committee from a list submitted by the Board of Directors. The same applies to the corresponding substitute members.

The members referred to under point 1.c. are elected by the Board of Directors from among the members of pharma.be, by secret ballot and according to the highest number of votes cast in their favour. The five with the highest number of votes cast in their favour become the serving members, the next five the substitute members and the others constitute the reserve group, the order of precedence being determined by the number of votes cast in their favour. In the case of a tied vote, the priority will go to the most senior in terms of the exercising of the mandate or most senior in terms of age.

The members referred to under points 1.d and 1.e are appointed by one or several associations or organisations concerned. The same applies to the corresponding substitute members. As far as possible, the allocation of mandates referred to under points 1.d and 1.e shall take into account the representativeness of the associations to which the above-mentioned members belong.

The member referred to under point 1.f is appointed by an organisation that is representative of the academic or scientific world. The same applies to the corresponding substitute member.

5. Members of the DEP Committee have a three-year renewable mandate.

6. Only one person per member-company can sit as a serving or substitute member as referred to under point 1.c. The rule continues to apply if, following a merger, take-over or any other operation involving the rapprochement or restructuring of companies, or following a change of employer, two members of the same member-company or same group of interests sit on the DEP Committee. In this case only one of the members in question may retain his mandate. The management of the member-company decides which member retains his mandate.
7. If one of the members representing the pharmaceutical industry as referred to under point 1.c resigns or is no longer able to exercise his mandate, he is replaced by the member who was immediately next in terms of the number of votes obtained during the election referred to under point 4, paragraph 2 of this article; the order of priority as referred to under point 4, paragraph 2 is then adapted to this effect.
8. If the president is absent or unable to attend, the meetings of the DEP Committee are chaired by the vice president and the vice presidency is taken by the substitute president or by the substitute vice president.  
  
If the vice president is absent or unable to attend, he is replaced by the substitute president or by the substitute vice president.  
  
If both the president and vice president are absent or unable to attend, the meetings of the DEP Committee are chaired by the substitute president and the vice presidency is taken by the substitute vice president.
9. The meetings are monthly. The dates of these meetings are set and communicated annually in advance to the pharma.be members.

Approval by the President of the DEP Committee president is required for any change to the dates set.

## § 6. The Chamber of Appeal

### article 70

1. Notwithstanding point 2 of this article, the Chamber of Appeal pronounces on appeals against the merits of a decision taken by the DEP Committee. A further appeal charges the Chamber of Appeal itself with considering the merits of the case. The Chamber rules to confirm or amend the decision referred to it. Under no circumstances does it send the case back to the DEP Committee.
2. The Chamber of Appeal pronounces on appeals submitted against a decision taken by another body pursuant to article 88 of the present Code.

### article 71

1. The Chamber of Appeal has 12 effective members, that is:
  - a. one member, a lawyer who is not active in the pharmaceutical industry, the president;
  - b. one member, a lawyer who is not active in the pharmaceutical industry, the vice president;
  - c. five members representing the pharmaceutical industry;
  - d. three members representing the medical profession, who have no connection with the industry;
  - e. one member representing the pharmaceutical profession, who has no connection with the industry;
  - f. one member drawn from the scientific or academic world, who is not active in the industry.
2. There are as many substitute members as serving members. Furthermore, for the members referred to under point 1.c, a reserve shall be set up to ensure replacements in case of unfilled mandates or the unavailability of serving or substitute members.

3. The rules concerning the quorums required are as follows. The Chamber of Appeal is validly convened when, in addition to the president, six of its members are present. Decisions are taken by a simple majority of votes of the members present. If there is a tied vote, the president has the casting vote. At the request of at least one member and subject to the casting of the president's vote in the case of a tied vote, the vote will be by secret ballot. Only members present are entitled to vote. Voting by power of attorney is not permitted.
4. The members referred to under points 1.a and 1.b are appointed by the other members of the Chamber of Appeal from a list submitted by the Board of Directors. The same applies to the corresponding substitute members.

The members referred to under point 1.c are elected by the Board of Directors from among the members of the Association, by secret ballot and according to the highest number of votes cast in their favour. The five with the highest number of votes cast in their favour become the serving members, the five next the substitute members and the others constitute the reserve group, the order of precedence being determined by the number of votes cast in their favour. In the case of a tied vote, the priority will go to the most senior in terms of the exercising of the mandate or most senior in terms of age.

The members referred to under points 1.d and 1.e are appointed by one or several associations or organisations concerned. The same applies to the corresponding substitute members. As far as possible, the allocation of mandates referred to under points 1.d and 1.e shall take into account the representativeness of the associations to which the above-mentioned members belong.

The member referred to under point 1.f is appointed by an organisation that is representative of the academic or scientific world. The same applies to the corresponding substitute member.

5. Members of the Chamber of Appeal have a mandate that runs concurrently with those of the DEP Committee, as stipulated under article 69.5.
6. Only one person per member-company can sit as a serving or substitute member as referred to under point 1.c. The rule continues to apply if, following a merger, take-over or any other operation involving the rapprochement or restructuring of companies, or following a change of employer, two members of the same member-company or same group of interests sit on the Chamber of Appeal. In this case only one of the members in question may retain his mandate. The management of the member-company decides which member retains his mandate.
7. If one of the members representing the pharmaceutical industry as referred to under point 1.c resigns or is no longer able to exercise his mandate, he is replaced by the member who is immediately next in terms of the number of votes obtained during the election referred to under point 4, para. 2 of this article; the order of priority as referred to under point 4, para. 2 is adapted to this effect.
8. If the president is absent or unable to attend, the meetings of the Chamber of Appeal are chaired by the vice president and the vice presidency is assumed by the substitute president or by the substitute vice president.

If the vice president is absent or unable to attend, he is replaced by the substitute president or by the substitute vice president.

If both the president and vice president are absent or unable to attend, the meetings of the Chamber of Appeal are chaired by the substitute president and the vice presidency is assured by the substitute vice president.

9. The meetings take place on each occasion that an appeal is lodged.

## Section 3: Advance visa procedure

### Sub-section 1: Scientific events

#### article 72

The invitation of healthcare professionals to and the defrayment of the costs of participating in a scientific event as referred to under article 30 that involves at least one overnight stay, 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.

### Sub-section 2: Non-interventional studies

#### article 73

1. The non-interventional studies referred to under article 43 of the present Code, with the exception of the experiments referred to in the law of 7 May 2004 concerning experiments on human persons and that are subject to the advice of an ethics committee, are subject to an advance visa procedure.

To this end, pharmaceutical companies are bound to obtain the visa from the Visas Bureau of pharma.be prior to the inclusion of the first investigator.

Only the studies cited in the first paragraph and that cumulatively meet the following conditions are submitted to the visa procedure:

- they are carried out or supported directly or indirectly by a pharmaceutical company;
- they relate to one or more of the characteristics of the medicinal product(s) studied;
- they involve one or more persons from outside the company.

2. Proceedings in regard to the Visas Bureau are conducted in writing only.

#### article 74

Companies introduce an application for visa by submitting the duly completed model dossier as drawn up by the Secretariat, together with all information and documents attesting to compliance with article 43 and 44 of the Code.

The model dossier drawn up by the Secretariat includes the following elements:

- general identification data,
- the starting and closing dates of the study,
- the detailed scientific protocol including the following elements: the objective, methodology, possible approval by the company's scientific service referred to under article 6 of the present Code and added value,
- the detailed financial protocol including the following elements: the amount and methods of remuneration for the investigators, the detailed description of the services requested of the investigators who receive the remuneration and the model contract concluded with the investigators,
- the methods for the supply and distribution of the medicinal products studied,
- the description of the future use of the data collected,
- the scientific justification, biostatistical if applicable, for the number of patients and investigators included as well as their geographical distribution,
- any other information deemed to be useful by the applicant company.

On pain of being declared inadmissible, three copies of the application file must be submitted by post.

The Secretariat acknowledges reception of each dossier received and at the same time issues a dossier number to the applicant company. This dossier number may only be used by the applicant company in accordance with the conditions laid down under article 75, paragraph 2, and article 76, paragraph 2.

## **article 75**

The Visas Bureau decides whether or not the project complies with articles 43 and 44 of the present Code.

If the Bureau considers that the project complies with the aforementioned articles, it issues a visa. In this case, the applicant company is bound to indicate the dossier number referred to under article 74, last paragraph, above, known as the "visa number", on all documents concerning the project drawn up following reception of the Bureau's decision.

If the Bureau considers that the project does not comply with articles 43 and 44 of the present Code or if it judges the application to be incomplete, it delivers a negative opinion. All negative opinions must be furnished with reasons.

Any visa issued by the Bureau constitutes presumption of compliance of the project with articles 43 and 44 above, provided the application submitted by the company is complete and a true reflection of reality, notwithstanding the last paragraph of article 78.

## **article 76**

The Visas Bureau notifies the applicant company of its decision no later than the tenth working day following that on which the Secretariat receives the application.

If, at the end of the tenth working day following that on which the Secretariat receives the application, the Visas Bureau has not notified the applicant company of its decision, the visa is deemed to have been granted. In which case, the applicant company is bound to indicate the dossier number referred to under article 74, last paragraph, of the present Code, known as the "visa number", on all documents concerning the project in question drawn up after the expiry of the aforementioned term.

## **article 77**

1. It is possible to appeal to the Visas Bureau Chamber of Appeal against the Visas Bureau's decision taken pursuant to article 75 of the present Code.
2. On pain of inadmissibility and at the latest on the 30<sup>th</sup> day following notification of the contested decision taken by the Visas Bureau, the applicant company must submit its appeal, giving reasons, in an ordinary letter deposited with the Secretariat or a registered letter. The date of the postmark serves as proof of the date of posting for the second alternative.
3. In this case, the procedure will be as described under articles 74 to 76 of the present Code. The applicant must attach to its request a letter setting out its arguments.
4. Procedures shall be conducted in writing only.

## **article 78**

The president of the Visas Bureau is charged with ensuring that the procedures for the advance visa as described in this Sub-section are respected.

To this end and notwithstanding the competences of the other disciplinary or monitoring bodies of the deontological device, the Visas Bureau president takes any useful measure, on his own initiative or at the request of a third party, in particular when the scientific study takes place without the company having obtained an advance visa or under conditions that do not correspond to those mentioned in the dossier as referred to under article 74 of the present Code.

He can also, in particular:

- ask the companies concerned for a copy of the advance opinion delivered by the competent ethics committee in cases where they have not been notified of the visa application to the Visas Bureau;
- ask the companies in question for an explanation and/or to take the necessary corrective measures;
- submit the dossier to the Bureau of Proceedings with the express request to initiate a complaints procedure.

In cases when the company in question is granted a visa, it must submit a new visa application if substantial changes are made to the project between the time of submitting the visa application and the time of the inclusion of the first investigator.

By “substantial” change is meant any change that one could reasonably expect would have had to have been taken into account by the Visas Bureau in order to make its decision in full knowledge of the facts.

## Section 3bis: Procedure for control on written communication

### article 78bis

Every month the Secretariat selects at random five medicinal products belonging to five different pharmaceutical companies and invites the latter, through their person responsible for information, to provide it with a copy of every written communication that relates to these medicinal products that is destined for healthcare professionals and that is in circulation at that moment.

### article 78ter

Written communication should be understood as any written message, irrespective of the support, used by medical informants to present or explain the properties of a medicinal product.

### article 78quater

At the same time as the written communication referred to under article 78bis, the company communicates for each written communication for which professional category it is intended. The company also provides the Secretariat with an outline of the internal procedure foreseen for the latter's approval.

### article 78quinquies

At the latest on the 15<sup>th</sup> day following the date of dispatch of the invitation referred to under article 78bis, the companies shall communicate to the Secretariat the documents and data set out in articles 78ter and 78quater. The dossier must be transmitted to the Secretariat in electronic form (e.g. by e-mail, on CD-ROM, by USB, etc.).

The Secretariat provides each member of the BCWC with a copy of the dossier mentioned in the above paragraph.

### article 78sexies

To fulfil its mission as referred to under article 65bis the BCWC will consider whether:

- the company has adequate internal procedures for approving the written communication,
- the written communication contains all the text components imposed by the Royal Decree of 7 April 1995 concerning information and publicity relating to medicinal products for human use,
- the written communication contains clear references in case of reference to published studies or when citations are given,
- the properties of the medicinal products described are presented without exaggeration and if the written communication incites a rational use of medicinal products only,
- no use is made of terms such as "safe" or "without danger" or any other term that expresses a similar concept, without these terms being defined clearly,
- the layout is sober and its principal aim is to present information in summary form and to render it more accessible,
- the texts are clear and the typefaces used make it easy to read,
- the sections of the written communication whose presence is required by laws and regulations are an inherent part of the other elements of the message,
- the written communication is addressed only to persons who can reasonably be supposed to be in need of or interested in it.

The BCWC communicates its conclusions to the company concerned through the intermediary of the Secretariat within one month following the expiry of the 15-day period referred to under article 78quinquies, paragraph one.

## **article 78septies**

The BCWC can ask the company for additional information through the Secretariat. At the latest on the 15<sup>th</sup> day following the day of the request, the company shall provide the Secretariat with this additional information. In the event of a request for additional information, the period of one month referred to under article 78sexies, paragraph two, is suspended until the company complies with this request.

## **article 78octies**

A summary rendered anonymous of the BCWC conclusions is communicated annually to the pharma.be members and published on the pharma.be website.

## **article 78nonies**

Any company that does not agree with the BCWC conclusions shall send to the Secretariat its observations in writing at the latest on the 15<sup>th</sup> day following the dispatch of these conclusions.

The BCWC examines these observations and communicates its final conclusions to the company through the intermediary of the Secretariat at the latest on the 15<sup>th</sup> day that follows receipt of these observations.

## **article 78decies**

The companies are bound to take into account the BCWC conclusions.

## **article 78undecies**

The BCWC president is charged with ensuring that the companies respect the obligations that arise out of this section. To this end and notwithstanding the competences of the other bodies of the deontological device, the BCWC president can take any useful measure. He can, for example:

- ask a company to give an explanation and/or to take the necessary corrective measures,
- submit the dossier to the Bureau of Proceedings with the express request to initiate a complaints procedure.

## Section 4: Complaints procedure

### Sub-section 1: General rules of procedure

#### article 79

Any natural person or legal entity who notes a failure to respect the rules of deontology intended in the present Code may bring this to the attention of the Secretariat in writing.

The present Sub-section does not apply to the advance visa procedure as described in articles 72 to 78 of the present Code, or to the procedure for control on written communication as described in articles 78*bis* to 78*undecies* of the present Code.

#### article 80

Before initiating disciplinary proceedings before a disciplinary body of pharma.be, the parties will seek to resolve their dispute amicably.

During a complaints procedure, the president of each disciplinary body may fulfil a conciliation mission or appoint a member to this effect. If necessary, the presidents of the disciplinary bodies may consult on this subject.

#### article 81

1. As an exception to the provisions of the language legislation, on one hand, the parties are free to instigate proceedings in Dutch or in French, as they choose, whatever the place of establishment of the opposing party, the language in which any incriminated infraction took place, the place where the infraction may have occurred, etc.

On the other hand, the defending party can also, irrespective of the language in which the proceedings are brought, establish its defence in either Dutch or French.

At the sessions of the DEP Committee and of the Chamber of Appeal – for consideration of the merits and for summary consideration – everybody, both the representatives of the parties and their counsels and members of the DEP Committee and of the Chamber of Appeal, can express themselves in the (national) language of their choice.

The decisions of the DEP Committee and of the Chamber of Appeal will be drawn up in the language in which the initial complaint was submitted (Dutch/French), unless during the proceedings the parties express a preference for them to be drawn up in the other language (Dutch/French).

2. Each president of the disciplinary body concerned opens, manages and closes the debates. He can also order debates to be reopened. He takes all measures he deems necessary for the smooth running of the proceedings. In the event that the Code is silent the President takes a sovereign decision about the consequences that must be given to each procedural incident. Unless the President decides to refer to them, the provisions of the Judicial Code do not apply.

#### article 82

1. The parties cooperate on the smooth running of the proceedings and respect the rights of defence.

In the case of absence of one of the parties in proceedings on the merits of a case and notwithstanding article 104.6 of the present Code, both sides are considered to have been heard and no objection is possible.

2. In principle, no postponement will be granted. Nevertheless a substantiated request can be submitted to the president of the body concerned; he has the sovereign right to pronounce, without any recourse, while taking into account the right of defence of the parties.

Moreover, the party summoned can exceptionally obtain a postponement if all the parties qualified to represent it are prevented from so doing for serious reasons that existed before receipt of the summons to appear. The president of the body in question pronounces in a sovereign capacity and without any possibility of appeal on the request for postponement.

## **article 83**

The parties must be summoned to appear before the body concerned within a reasonable period of time, counting from submission of the complaint. They can be assisted. The decision to summon them states the date, time and the disciplinary body before which the party involved must appear.

## **article 84**

1. Within 15 days of the Secretariat notifying the parties of the summons to appear before the DEP Committee or before the Chamber of Appeal, the latter are bound to notify the Secretariat if they will be submitting pleadings or other documents in the framework of the proceedings. If such is the case, they must confirm simultaneously to the Secretariat whether or not an agreement has been concluded between the parties concerning a timetable for submitting the said documents and/or pleadings.

The parties communicate to the other parties all documents or pleadings at the same time as they submit these documents or pleadings with the Secretariat.

2. A party that wishes an involved third party to be heard can submit a substantiated request to the president of the body concerned; the latter has a sovereign right of decision with no recourse. If appropriate, taking into account the rights of defence, he will ask the rival party about their arguments in favour of or against the hearing.
3. When drawing up the timetable referred to in paragraph one, the parties must ensure mutual respect for the rights of the defence. They must also take into account that no document or pleading can be submitted after the seventh working day that precedes the date of appearance before the body in question.

If the parties consider that the time between the date of communicating the date of the hearing and the date of the hearing itself is too short to handle the necessary business, the latter may:

- a. Either request that an exception be made to the limit set out above according to which the documents and pleadings must be submitted and communicated no later than the seventh working day before the appearance before the body in question.
- b. Or ask for the case to be dealt with at the next DEP Committee session, provided that this session has not already been set aside for dealing with other cases. As regards the appeal procedure, a later date applies that is to be determined by the Secretariat.

The president of the disciplinary body in question will respond as soon as possible to this request. This is a sovereign decision by the president against which no appeal is possible.

If the parties fail to reach agreement in setting a timetable in accordance with the regulation established above, the requesting party will ask the president of the disciplinary body in question to set on his own initiative a timetable and determine a date on which the case will be heard.

The president of the disciplinary body in question will respond as soon as possible to this request. This is a sovereign decision by the president against which no appeal is possible.

The president of the disciplinary body in question decides in a sovereign capacity and without any possibility of appeal on the action to be taken if the documents or pleadings are submitted

late or in violation of the timetable or in case of failure to communicate or late communication of the documents and pleadings to the other parties.

## **article 85**

If a member of one of the disciplinary bodies is a member of the same company – or the same group of interests as indicated under article 9.3 of the by-laws – as one of the parties in a dossier submitted for complaint, he will not participate at any stage in the proceedings for considering the dossier in question.

## **article 86**

The disciplinary bodies will remove from the dossier any element of proof obtained by illicit means.

## **article 87**

The parties can consult the dossier at the Secretariat at any time by making an appointment.

## **article 88**

If the same case is brought before the disciplinary bodies of pharma.be and before a body external to pharma.be, for example a judicial or administrative authority or body of arbitration, its consideration by the disciplinary bodies is deferred until the judicial or administrative authority has taken its decision, on the understanding that appeals against the decisions of the disciplinary bodies of pharma.be cannot be instituted with a judicial or administrative authority until the “internal appeals” within pharma.be have been exhausted.

When the same case has already been brought before a body external to pharma.be it can no longer be brought before the disciplinary bodies.

By “the same case” is understood any complaints dossier the subject of which, in full or in part, refers to identical or similar facts originating in the same member companies.

Any party involved in a case brought before the deontological bodies will inform the latter without delay if the same case is brought before a body external to pharma.be.

The application of article 88 gives rise to a separate decision on the part of the president of the disciplinary body. It is possible to appeal against this decision to the Chamber of Appeal. On pain of inadmissibility the parties must submit their substantiated appeal either by means of a normal letter deposited with the Secretariat, or by a registered letter sent to the Secretariat, at the latest on the seventh day following the day when the president’s disputed decision was made known. The date of the postmark serves as proof of the date of posting for the second alternative. The Chamber of Appeal then pronounces on the application of this article 88. The case is then sent to the disciplinary body in question that acts in accordance with the decision taken by the Chamber of Appeal.

## Sub-section 2: Consideration of the merits of a complaint

### 1. Consideration of the merits of a complaint by the Bureau of Proceedings

#### article 89

1. Any legal entity or natural person who notes a failure to respect the rules of deontology intended in this Code may submit a complaint to the Bureau of Proceedings via the Secretariat, provided this complaint is in writing, furnished with reasons and its initiator is identified.
2. Unless he already adheres to this Code by virtue of the rules laid down under article 112, the initiator must, at the same time as his complaint, also provide a statement undertaking to respect the rules laid down in this Code.
3. Complaints that are not accompanied by any element of proof are admissible provided they are in writing, furnished with reasons and their initiator is identified.
4. Anonymous complaints that are not accompanied by elements of proof are not under any circumstances admissible.
5. Before initiating proceedings, the legal entity or de facto association submitting a complaint must deposit an amount of EUR 650 before commencement of the proceedings. The Bureau of Proceedings will not act on a complaint that is not accompanied by proof of this deposit. The bodies referred to under article 38 and natural persons are not bound to deposit this amount.

#### article 90

The Bureau of Proceedings pronounces in a sovereign capacity on any action to be taken following simple communication of information that is not accompanied by a complaint, as well as on cases that do not satisfy the conditions for the admissibility of a complaint as set out in article 89 of the present Code.

Under no circumstances will the Bureau take any action on the basis of the simple communication of information that is anonymous and not accompanied by any element of proof.

#### article 91

Without pronouncing on the merits of the complaint, the Bureau of Proceedings assesses what course of action should be taken regarding it, namely:

- discontinuance of the proceedings, according to the conditions laid down under article 93,
- referral to the Chamber of Investigation, according to the conditions laid down under article 94,
- referral to the DEP Committee, according to the conditions laid down under article 95,
- referral to the Federal Agency for Medicinal and Health Products (FAMHP), according to the conditions laid down under article 108.

#### article 92

The Bureau of Proceedings can itself be the initiator of a complaint when information that comes to its attention concerns a serious violation of the rules of deontology that threatens the interests of the pharmaceutical sector in general. In this case, it shall give detailed reasons for its decision and becomes a party to the complaint.

When assessing whether a violation is serious or not in the sense of the above paragraph, the Bureau of Proceedings refers to the directives on this subject that are attached as Annex 1 to the present Code.

The Bureau of Proceedings cannot however be the initiator of a complaint when the information available to it is anonymous and lacking any element of proof.

## article 93

Explicit reasons must be given for any decision to discontinue the proceedings. This decision is not subject to appeal. The decision is communicated in writing to the parties.

In this case, the company against which the complaint or information was directed is entitled, in regard to the Bureau of Proceedings, to express *ex post* its point of view concerning the alleged facts.

## 2. Consideration of a complaint by the Chamber of Investigation

### article 94

1. If the dossier is not accompanied by sufficient elements of proof for it to be the subject of referral to the DEP Committee, the Bureau of Proceedings may refer it to the Chamber of Investigation. The latter investigates the case to either incriminating or exonerating effect and can, among other things:
  - summon and hear the parties concerned,
  - examine any useful document (approval forms, invoices, etc.) that the parties may have submitted for the purposes of the investigation,
  - summon an involved third party and hear him.
2. Within 30 days of receipt of the dossier from the Bureau of Proceedings, the Chamber of Investigation submits a detailed investigation report to the Bureau of Proceedings setting out the tasks it has undertaken. This term may be extended if necessary provided justification is provided.
3. On the basis of this investigation report, the Bureau of Proceedings assesses in a sovereign capacity the action to be taken regarding the dossier (that is to say either dismissing the case as intended in article 93 of the present Code, or referring it to the DEP Committee as intended in article 95 of the present Code). It communicates its decision to the parties at the same time as a copy of the investigation report from the Chamber of Investigation.

## 3. Consideration of a complaint by the DEP Committee

### article 95

If the dossier is accompanied by a sufficient number of elements of proof of the existence of a violation of the present Code, the Bureau of Proceedings can transmit this dossier to the DEP Committee. Referral to the DEP Committee charges the latter with considering the merits of the case.

In that case the dossier can under no circumstances it be the subject of referral to the Federal Agency for Medicinal and Health Products (FAMHP) as stated under article 108. The Bureau of Proceedings can indeed only refer to the FAMHP when it complies with the cumulative conditions summarised in article 108 of the present Code.

## article 96

1. The DEP Committee may request additional investigating measures from the Chamber of Investigation. Within 30 days of reception of the dossier from the DEP Committee, the Chamber of Investigation submits a copy of the detailed investigation report to the DEP Committee setting out in full the tasks it has undertaken. This term may be extended if necessary provided justification is provided. A copy of the report is moreover communicated in writing to the parties at the same time.
2. The DEP Committee can also summon and hear the parties concerned or the presidents of the other bodies within a reasonable period of time.

## 4. Consideration of a complaint by the Chamber of Appeal

### article 97

1. An appeal can be made to the Chamber of Appeal against any decision taken on the merits by the DEP Committee. Notwithstanding article 88 in fine, no appeal can be made against procedural incidents.
2. On pain of inadmissibility, the parties (or one of them) must have submitted their appeal, either by means of an ordinary letter deposited with the Secretariat or by means of a registered letter sent to the Secretariat, at the latest on the 15<sup>th</sup> day following the day on which the disputed decision of the DEP Committee was sent to parties by registered letter in accordance with article 56 of the Code. The date of the postmark serves as proof of the date of sending.
3. At the latest on the 30<sup>th</sup> day after an appeal is lodged with the Chamber of Appeal, the Secretariat summons the parties concerned to appear before the Chamber of Appeal. This appearance takes place at the earliest on the 20<sup>th</sup> day after being summoned to appear.

### article 98

1. The Chamber of Appeal can, either automatically or at the request of the parties, request additional measures from the Chamber of Investigation. Within 30 days of reception of the dossier from the Chamber of Appeal, the Chamber of Investigation submits a copy of the detailed investigation report to the Chamber of Appeal setting out in full the tasks it has undertaken. This term may be extended if necessary provided justification is provided. The investigation report is attached to the dossier. A copy of the report is moreover communicated in writing to the parties at the same time.
2. The Chamber of Appeal can also summon and hear the parties concerned or the presidents of the other bodies.
3. The Chamber of Appeal can itself describe or redescribe the facts.

## 5. Decisions and measures to be taken upon non-observance of the Code

### article 99

The consideration of the merits, before the DEP Committee and before the Chamber of Appeal, can lead to the following decisions:

- the complaint is well founded and a violation of the Code is established, possibly with the pronouncing of one of the measures provided for under article 100,
- the complaint is not justified,
- confirmation that the dispute is ended.

The decision of the DEP Committee and/or the decision of the Chamber of Appeals is/are imparted with full reasoning and in writing to the parties involved.

## article 100

§ 1. If, in the case of a decision on the merits, the DEP Committee or the Chamber of Appeal declare a violation to be confirmed, they order the immediate cessation of the incriminated activities and order the member concerned to undertake in writing not to repeat these activities.

§ 2. If the DEP Committee or the Chamber of Appeal declares the violation to be confirmed in a decision on the merits, they can also impose the following measures on the members that they declare to have violated the deontological rules intended in the present Code:

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

§ 3. By “corrective measure” as intended in §2, is understood, for example:

- correction to the incriminated material,
- insertion of a correcting statement,
- direct communication of the decision taken by the DEP Committee or the Chamber of Appeals, or an extract thereof, by letter to members of the medical/pharmaceutical profession.

§ 4. By “supervisory measure” as intended in §2, is understood, for example:

- the communication of the modified version of the incriminated material,
- the communication of the details of the arrangements for a future event and of the list of participants,
- recommendations regarding transparency and readability,
- the removal of a link to a website.

§ 5. By “financial indemnification” is taken to mean a reasonable one-off financial recompense for the damage that the member of the pharmaceutical industry suffers as the result of the violation of the deontology rules intended in the present Code. The size of this measure is unilaterally decided by the DEP Committee or by the Chamber of Appeal. When deciding on this sum the DEP Committee or the Chamber of Appeal takes into consideration the damage that the pharmaceutical industry is suffering, including the effect on its reputation. This measure consists of a contribution to a fund intended to finance actions that contribute to the advancement of the pharmaceutical industry's reputation; the decisions in regard to the use of the funds deposited to this fund shall be taken in agreement with the statutes of pharma.be. The amount of this measure varies between 5,000 euro and 50,000 euro depending on the violation.

§ 6. 1. Any decision by the DEP Committee or the Chamber of Appeal that a violation of the rules of deontology intended in the present Code has been established is published as described below.

For decisions by the DEP Committee, the publication takes place only after the expiry of the appeal period set out in article 97, §2, of the present Code and provided no appeal has been lodged.

By “publication” is understood the nominative publication of a summary of the decision.

The publication must at least appear in the following journals, and on each occasion in Dutch and in French:

- De Artsenkrant/le Journal du Médecin,
- Het Apothekersblad/les Annales Pharmaceutiques.

The DEP Committee or the Chamber of Appeal can also order publication in other journals.

In the case of a repeat violation within two years of a violation of the present Code being confirmed in a final decision of the DEP Committee or the Chamber of Appeal or in the case of a serious violation of the rules of deontology intended in the present Code, that jeopardises the interests of the pharmaceutical sector in general, the publication also appears in English in SCRIP.

In assessing whether a failing is serious or not in the sense of the above paragraph, the DEP Committee or the Chamber of Appeal refers, depending on the case, to the directives on this subject that are attached as Annex 1 to the present Code.

2. Each publication contains the following statement: *The DEP Committee and the Chamber of Appeal are bodies established by pharma.be to ensure the good observance of the rules of its Code of deontology. These committees consist of members who are not connected with the pharmaceutical industry but who come from the medical or pharmaceutical professions or from the scientific or academic world, of lawyers, and of representatives of the pharmaceutical industry. All these members act in complete independence in implementing the Code.*

*The decision of the DEP Committee and of the Chamber of Appeal are taken by a simple majority of the members present, having solely regard for the facts set before them and only concern the parties to the disputed matter.*

*pharma.be undertakes the administrative management of the deontological tool. To consult pharma.be's Code of deontology please visit the website [www.pharma.be](http://www.pharma.be).*

- § 7. The costs linked to a cessation order, to measures, to publication and, if applicable, to the translation of the decision summary in English with a view to publication in SCRIP, are borne by the company against which they are pronounced, notwithstanding the application of article 111.
- § 8. Upon non-observance of an order to stop, of the reprimand, of the corrective measure or the supervisory measure imposed by the DEP Committee or Chamber of Appeal in agreement with article 100, § 1 - § 4 of the present Code, within the time limit imposed by the DEP Committee or by the Chamber of Appeal, the DEP Committee or the Chamber of Appeal (as the case may be) has the right to review its decision and impose a financial indemnification.
- § 9. In execution of the decision of the DEP Committee or of the Chamber of Appeal to impose a financial indemnification on a specified member in agreement with § 2, § 5 and § 8 of the said article 100, the member involved shall deposit the financial recompense as determined by the DEP Committee or the Chamber of Appeal into the account of pharma.be (as communicated by the Secretariat) within 30 days counting from the day of the written report that was made available by the Secretariat.

If payment is not forthcoming, interest will be charged for the delay.

## **article 101**

If, during the three years following notification of the decision by the DEP or Chamber of Appeal, a member of pharma.be is condemned definitively for identical or similar facts, the disciplinary body that took the final decision can submit the dossier to the pharma.be Board of Directors with a view to application of article 102 of the present Code. It can also order publication of its decision in SCRIP.

## article 102

Notwithstanding the measures provided for under article 100, the pharma.be Board of Directors can, in accordance with article 7 of the by-laws, initiate exclusion proceedings against any member that, through its attitude, constitutes an obstacle to the aims pursued by pharma.be in the field of ethics and professional relations, or refuses to comply with the internal regulations, of which the present Code is an inherent part.

## article 103

(...)

### Sub-section 3: Summary consideration of a complaint

## article 104

1. If it is to be considered, a complaint submitted for summary consideration must satisfy the following conditions:
  - a. it must be submitted in the form of a written request to the Secretariat by a pharma.be member; it can also be initiated by the Bureau of Proceedings pursuant to article 92 of the present Code, possibly following the referral of the case by the president of the Visas Bureau in accordance with article 78, paragraph 3 or by the president of the BCWC in accordance with article 78*undecies*;
  - b. it must be accompanied by available evidence;
  - c. it must contain grounds; the grounds must clearly demonstrate an imminent risk of serious damage to the interests of the initiator of the complaint; if the complaint is submitted by the Bureau of Proceedings, the grounds must clearly demonstrate an imminent risk of serious damage to the interests of the pharmaceutical sector in general.
2. The secretary submits the request for summary consideration to the vice president, assisted by two members of the DEP Committee. The persons thus designated undertake the summary consideration. They do not participate in other stages of the proceedings in a case in which they are charged with the summary consideration.
3. Members who are charged with summary consideration may have recourse to any measure they deem useful in fulfilling their mission. They will summon the parties and hear them within a period of time and in the manner appropriate to the circumstances.
4. The summary proceedings can result in the following decisions:
  - discontinuance of the proceedings,
  - order for immediate cessation or cessation within a given term of the improper fact; the cessation applies at the latest until the parties are notified of the decision on the merits taken by the DEP Committee.
5. Decisions taken in summary proceedings are communicated to the parties.
6. Summary decisions may be contested by any parties that did not attend the hearing. On pain of being declared inadmissible and no later than two working days after being notified of the decision, the parties must submit their request to have the decision set aside in writing to the Secretariat, either by means of an ordinary letter deposited with the Secretariat or a registered letter sent to the Secretariat, at the latest on the second day following the day on which the disputed decision was announced. The date of the postmark serves as proof of the date of posting for the second alternative. The objection is addressed to the vice president and members who were charged with the summary consideration; in the event of the unavailability of one of these two members, the president will replace him or them by one or two other members of the DEP Committee.

7. If the summary consideration results in a discontinuance of the proceedings without further action, the DEP Committee in question will submit the dossier to the Bureau of Proceedings that will decide on any further action.

If the summary consideration results in a cessation order, the DEP Committee in question will submit the dossier to the next ordinary meeting of the DEP Committee that will consider the merits of the case.

#### **Sub-section 4: Implementation of decisions**

##### **article 105**

Decisions on merits taken by the DEP Committee can only be implemented on expiry of a term allowed for appeal intended in article 97, § 2, of the present Code. Except in regard to publication as referred to in article 100, § 6 of the Code, the DEP Committee may, however, on stating the grounds and in the pharmaceutical industry's general interest, declare its decision to be immediately enforceable in full or in part, notwithstanding any appeal against the decision to the Chamber of Appeal in accordance with articles 97 and 98 of the Code.

##### **article 106**

Decisions taken in summary consideration are not in principle immediately enforceable. The DEP Committee in question may, however, on stating the grounds, declare its decision to be immediately enforceable in full or in part, notwithstanding any contesting of the decision in accordance with article 104, § 6, of the Code.

##### **article 107**

The president of the disciplinary body that takes the final or enforceable decision may, on his own initiative or at the request of one of the parties, take any measure he may deem useful to ensure compliance with his decision.

He can thus, by way of example, submit the dossier to the pharma.be Board of Directors with a view to application of article 102.

#### **Sub-section 5: Referral of a case to the Federal Agency for Medicinal and Health Products (FAMHP)**

##### **article 108**

Any decision by the terms of which the Bureau of Proceedings refers the case to the Federal Agency for Medicinal and Health Products (FAMHP) must explicitly state grounds.

A dossier, following a complaint as referred to under article 89, can only be referred in this way if it satisfies all the following conditions:

- the complaint satisfies the conditions laid down by article 89.1;
- the case concerns facts that are liable to constitute a violation of the laws and regulations on medicinal products, provided these facts also lie within the field of application of this Code;
- the case includes the beginnings of proof of the existence of a violation of the abovementioned laws and regulations;
- the case is not liable to be referred to the DEP Committee by the terms of the conditions laid down under article 95.

##### **article 109**

1. Any decision by the Bureau of Proceedings for referral to the Federal Agency for Medicinal and Health Products (FAMHP) can be the subject of an appeal to the DEP Committee by the parties concerned. The parties involved are informed of the decision to refer in writing.

On pain of inadmissibility, the appealing party must have submitted his appeal in writing, either by means of an ordinary letter deposited with the Secretariat or by means of a registered letter sent to the Secretariat, at the latest on the 15th day following the day on which the decision for referral was notified in writing. The date of the postmark serves as proof of the date of posting for the second alternative.

The decision for referral does not take effect until the 15<sup>th</sup> day following that which follows the date of notification. An appeal has suspensive effect.

2. If it declares the appeal to be admissible, the DEP Committee examines whether the three conditions laid down under article 108, paragraph 2 of the present Code are satisfied.

Before making this examination, the DEP Committee may request additional investigating measures from the Chamber of Investigation. Within 30 days of receiving the dossier from the DEP Committee, the Chamber of Investigation will submit a detailed investigation report to the DEP Committee setting out all the tasks it has undertaken. This term can be increased as required and on the basis of justification. A copy of the report is communicated to the parties.

In order to undertake the examination referred to under the first paragraph of this point 2, the DEP Committee can summon and hear the parties concerned as well as the presidents of the other bodies within a reasonable time period.

On the basis of the elements that it may have obtained, the DEP Committee pronounces in a sovereign capacity, after the investigation, on whether or not the conditions laid down under article 108, paragraph 2 of the present Code have been respected.

The appeal procedure can culminate in the following decisions:

- confirmation of referral,
- cancellation of referral.

This decision takes immediate effect; it is not subject to appeal. It is communicated to the parties in writing.

3. If the referral is cancelled, the DEP Committee discontinues proceedings. This discontinuance of proceedings is not subject to appeal.

As an exception to that which is stipulated in the previous paragraph, if, following the examination referred to under point 2 of the present article 109, the DEP Committee considers that the dossier contains sufficient elements of proof, the DEP Committee can consider the merits of the dossier. The decision taken by the DEP Committee on the merits of the dossier is subject to appeal on the basis of the conditions set out under articles 97 and 98 of the present Code.

## article 110

1. Referral to the Federal Agency for Medicinal and Health Products (FAMHP) has the effect of permanently stopping any deontological procedures concerning the referred file for the disciplinary bodies of pharma.be.
2. The Bureau decides in a sovereign capacity to communicate to the Federal Agency for Medicinal and Health Products (FAMHP) any dossier involving a company that is not a member of pharma.be.

## Chapter 8: Costs of proceedings and financing

### article 111

1. In the sense of this article, "costs of proceedings" are understood to be all costs relating to the proceedings referred to in chapter 7, section 4.

The costs of proceedings are established per dossier introduced for a complaint as referred to under article 89 of the present Code, on the basis of the real costs incurred by each disciplinary body individually. A detailed statement of expenses is to be submitted to the parties that bear the costs of proceedings.

The sum deposited pursuant to article 89.5 of the present Code, is reimbursed at the time of calculating the final amount of the costs of the proceedings. The sum deposited may be set against the costs of proceedings.

The costs of proceedings always amount to at least the sum as deposited pursuant to article 89.5.

2. The president of each disciplinary body may, in exceptional circumstances and provided justification is given, depart from the rules concerning the costs of proceedings as set by the present Code.

The president of each body can, in cases not provided for by the present Code, decide in what way the costs of proceedings are to be shared between the parties.

3. The party that is found guilty of a violation by a final decision and, if applicable, against which a measure is pronounced, bears the costs of proceedings.

The complainant bears the costs of proceedings when, the merits of the case having been considered, no violation or measure is noted in regard to the defending party.

Failing agreement to the contrary between the parties, the complainant bears the costs of proceedings when the president of the disciplinary body in question rules that the dispute has ended before a decision is taken on the merits of the case.

The complainant bears the costs of proceedings if the complaint is set aside with discontinuance of proceedings by the Bureau of Proceedings.

The parties bear no costs of proceedings if the case is referred definitively to the Federal Agency for Medicinal and Health Products (FAMHP). In the latter case, the sum deposited will be refunded to the complainant.

As an exception to the above rules, disciplinary bodies and natural persons bear no costs of proceedings.

4. The party found guilty of a violation and against which a measure may have been pronounced bears the costs of proceedings plus a fixed amount obtained by the addition of the following amounts:
  - EUR 1,250 for an order to cease activities pursuant to article 100, § 1, of the present Code;
  - EUR 1,250 per corrective measure pronounced pursuant to article 100, § 2, of the present Code;
  - EUR 1,250 for publication provided for by article 100, § 6, of the present Code.

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

### article 112

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 113

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 114

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 115

§ 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 40.1, last paragraph, 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 115bis

The first reporting period referred to in article 44*ter*.1 shall be the 2015 calendar year.

### article 116

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

## Annex 1

**Directives concerning the determination of facts that must be considered as a "serious violation of the rules of deontology jeopardising the interests of the pharmaceutical sector in general" pursuant to articles 92 and 100, § 4 of the Code**

### Context

In regard to application of the Code of deontology, the notion of "serious violation of the rules of deontology jeopardising the interests of the pharmaceutical sector in general", hereinafter expressed as "serious violation", is important at two levels:

- Pursuant to article 92 of the Code, the **Bureau of Proceedings** can itself initiate a complaint provided the information available to it and on which the complaint is based relates to a "serious violation". If the information is accompanied by the beginnings of proof, the complaint can even be based on information from an anonymous source but always provided that they are facts amounting to a "serious violation". If the Bureau decides to submit a complaint it must provide reasons for such a decision and becomes a party to the case.
- In accordance with article 100, § 4, of the Code, if the **DEP Committee** or the **Chamber of Appeal** declare a "serious violation" established in the sense as set out above, the decision is not only published in *Le Journal du Médecin / De Artsenkrant* and *Les Annales Pharmaceutiques / Het Apothekersblad* (or another journal) but also 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 (Bureau of Proceedings, DEP Committee, 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.<sup>1</sup> Although in principle it is sufficient for a violation to fall within just one of the categories mentioned hereunder for it to be considered to be a "serious violation", the fact that the violation can be regarded as falling within two or more of the categories mentioned hereunder would naturally play a part in making the assessment.

- 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 must 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,<sup>2</sup>

<sup>1</sup> These examples are for information purposes only; each case must always be considered on the basis of the circumstances peculiar to the specific case.

<sup>2</sup> Provided the study carried out falls within the material field of application of the Code.

- 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 must be considered to be a "serious violation".

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

- the granting to the doctor of a benefit in cash or in kind per prescription he makes out.
- For adequate health care it is also important for patients, the authorities and healthcare professionals to have confidence in the pharmaceutical industry and in its products in general. Consequently, violations with high visibility, for healthcare professionals, the general public or the authorities, will very often have a very big (negative) impact on general confidence in the pharmaceutical industry and must 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 must 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 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<sup>3</sup> -

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<sup>3</sup> 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.

which prohibits the pharmaceutical industry, save in certain exceptional cases, from granting premiums or benefits – therefore constitutes 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.

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§ 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”.

Annex 2

Annex 2 - TEMPLATE - DISCLOSURE OF TRANSFERS OF VALUE													
Art. 44ter.3											Date of publication: .....		
	Full Name  <i>(Art. 44bis)</i>	HCPs: City and zip code of Principal Practice HCOs: City and zip code of Headquarters  <i>(Art. 44quater)</i>	Country of Principal Practice  <i>(Art. 44bis.2)</i>	Principal Practice / Headquarters Address (street/n°/post. box)  <i>(Art. 44quater)</i>	Unique country local identifier <i>OPTIONAL</i>  <i>(Art. 44quater)</i>	Donations and Grants <i>(Art. 44quater.2.1.a)</i>	Contribution to costs of scientific events <i>(Art. 44quater.2.1.b &amp; 44quater.2.11.a)</i>			Fee for service and consultancy <i>(Art. 44quater.2.1.c &amp; 44quater.2.11.b)</i>		TOTAL <i>OPTIONAL</i>	
							Sponsorship agreements with HCOs / third parties appointed by HCO's to manage a scientific event	Registration Fees	Travel & Accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accomodation relevant to the contract		
<i>INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, upon request)</i>													
HCPs	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	<i>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</i>												
	Aggregate amount					N/A	N/A	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount		Optional
Number of Recipients (named list, where appropriate) - Art. 44quater.3					N/A	N/A	number	number	number	number		Optional	
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 44quater.3					N/A	N/A	%	%	%	%		N/A	
<i>INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, upon request)</i>													
HCOs	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	<i>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</i>												
	Aggregate amount attributable to transfers of value to such Recipients - Art. 44quater.3					Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	
Number of Recipients (named list, where appropriate) - Art. 44quater.3					number	number	number	number	number	number	number		Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 44quater.3					%	%	%	%	%	%	%		N/A
<i>AGGREGATE DISCLOSURE</i>													
R&D	Transfers of Value re Research & Development as defined in art. 44quater.5										TOTAL AMOUNT	OPTIONAL	

pharma.be

Terhulpesteenweg 166 Chaussée de La Hulpe | Brussel 1170 Bruxelles  
info@pharma.be | www.pharma.be | fax 02 661 91 99

BTW - TVA BE 0407.622.902 | Ondernemingsnummer - Numéro d'entreprise 0407.622.902  
Bank - Banque J. Van Breda & C° 645-1621206-80 | IBAN BE47 6451 6212 0680 | BIC JVBABE22