Code of Deontology

Modified by the General Assembly of 14 December 2005
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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.

This is why members of pharma.be have subscribed to the present Code of Deontology. 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 ensue that the contribution of the pharmaceutical industry to continuous training and research on medicinal products is of the very highest standard.

article 2
The Code of Deontology concerns medicinal products for human consumption, as defined by article 1 of the law of 25 March 1964, whether subject to prescription of 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.

The Code of Deontology applies to all means implemented with a view to promoting or providing information on medicinal products, including:

a. oral communication (medical informants),
b. written communication,
c. samples,
d. collective scientific meetings,
e. exhibitions and audiovisual presentations,
f. subsidies, grants and sponsoring,
g. scientific studies carried out after registration of the medicinal products.

The field of application of the Code does not cover the information and documents referred to under article 2 § 2 of R.D. of 7 April 1995 concerning information and advertising in connection with medicinal products for human use.

**article 2bis**
§ 1. This Code supplements all legal and regulatory provisions on the subject of promoting and providing information on medicinal products for human use that must be respected under all circumstances.

§ 2. This Code also supplements the provisions of the Code of Practice on the Promotion of Medicines of the EFPIA and of the FIIM Code on marketing practices for pharmaceutical products. 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 or information does not take place in Belgium, the promotion or information 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 or information takes place.

When, on the basis of the previous paragraph, 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 3
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 health 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 4
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,
- side effects,
- dosage and method of administration,
- available packagings,
- the name and address of the company responsible for marketing the product

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

article 5
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.

**article 6**
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 7**
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 health professional who so requests it.

**article 8**
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 3.

**article 9**
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 side effect nor risk of dependency.
article 9bis
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 9ter
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 9quater
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 10
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 11
When pharmaceutical companies have recourse to third parties, they remain responsible for ensuring that these third parties respect the rules of this Code.

article 12
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 13
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 health 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 14**
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 15**
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 precise 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 16**
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 17**
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 18**
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 concerning any of the medicinal products that they are promoting, in particular concerning unwanted side effects of which they are informed by the persons visited.
article 19
The medical informants are bound to respect confidentiality regarding any information that is covered by medical secrecy.

2. Written communication

article 20
The presentation and illustration of information is the responsibility of companies.

article 21
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 22
The texts will be clear and the typeface used must make it easy to read.

article 23
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 24
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 25
Notwithstanding the legal and regulatory obligations, samples shall only be given to persons qualified to prescribe medicinal products, after the later have submitted a written, signed and dated request to the company.

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

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

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.

4. Collective scientific meetings
**article 26**
Collective scientific meetings that are directly or indirectly supported or organised by pharmaceutical companies and that are attended by health sector professionals shall take place within a framework of quality, as required by articles 27 to 31. When a collective scientific meeting does not take place in Belgium, it must also, in accordance with article 2bis, § 3 of this Code, comply with the application criteria laid down by the Code of Deontology that applies in the country where the meeting takes place.

This applies, for example, to meetings of an exclusively professional and scientific nature, meetings to promote medicinal products, symposiums, international scientific congresses and any other form of scientific meeting held in Belgium or abroad.

**article 27 Hospitality**
1. Hospitality made directly or indirectly available at the time of collective scientific meetings must always be of 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 expenses linked to travel, meals, accommodation and registration and will not extend beyond the official duration of the collective scientific meeting.

3. The hospitality made available will always be limited to that which the health sector professionals who benefit from it would reasonable 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 28 Scientific nature of the meeting – place, date and duration**
1. Collective scientific meetings 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 meeting.

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

3. The collective scientific meetings must take place at a suitable venue that aids the scientific purpose of the meeting. The place, date and duration of the meetings 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 meeting is held outside Belgium.

Meetings 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 meeting in another country, or

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

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

**article 29 Travelling, registration and organisational expenses**
Companies may pay travelling, registration and organisational expenses provided the conditions laid down under articles 26 to 31 are respected.

**article 30 Accompanying persons – extension of the stay**
§ 1. Invitations to attend collective scientific meetings as well as their organisation or support by pharmaceutical companies are limited to professionals from the health sector.

The partners of health sector 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 health sector professionals invited to attend collective scientific meetings 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.

**article 31**
When companies participate in exhibitions, information days or any other meeting at which several companies come together to show their products to health sector 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, audiovisual presentations, posters or any other means or support) will always comply with the laws and regulations on medicinal products as well as the provisions of the Code.

5. Exhibitions and audiovisual presentations

**article 32**

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

The storage and transmission of data will also be in accordance with these stipulations. They will also comply with legal requirements in terms of confidentiality.

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

6. Grants, subsidies and sponsoring

**article 33**

Notwithstanding the legal provisions, the pharmaceutical companies are free to make any financial resources or other means of functioning available to third parties.

In this case they must take all useful measures to be 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 collective scientific meetings as referred to under article 26 or scientific studies as referred to under article 36, the companies that made the aforementioned means available are subject to the advance visa procedure as referred to under articles 58 and 64.

For the purposes of this article, it is understood by “financial means or other operating means”: subsidies, grants, scientific prizes, sponsoring, provision of services for humanitarian purposes.

**article 34 (…)**
Chapter 3: 
Premiums and benefits

article 35
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.

It is consequently forbidden to:

• offer or give presents in the personal interest of the beneficiary’s personnel, such as tickets for private sports events or other entertainment events;

• offer or grant any form of hospitality, except as part of a collective scientific meeting as referred to under article 26.

However, the prohibition referred to in the first paragraph 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;

2° invitations to and the defrayment of the costs of participating in a collective scientific meeting, including hospitality, by health sector professionals provided the meeting complies with the conditions described under articles 26 to 31 of this Code;

3° 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 health sector professionals on attending a collective scientific meeting as referred to under article 26.
Chapter 4: Scientific studies carried out after registration of the medicinal products

article 36
Scientific studies carried out after registration of medicinal products shall be conducted within a quality framework in which the remuneration proposed to health sector professionals is proportional to the services provided.

This chapter refers only to the studies cited in the first paragraph and that meet all the following conditions:

- 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 an individual outside of the company.

article 37
In carrying out the scientific studies referred to under article 36, companies shall ensure that the following elements are respected, to the extent that they are relevant to the case in question:

- a scientific protocol shall provide a detailed description of the objective sought and methodology implemented; the aforementioned objective and methodology shall always be coherent, the one in regard to the other;

- a financial protocol shall provide a detailed description of the amount and the procedures for remunerating the investigators; the protocol shall attest to the fact that the remuneration is commensurate with the service requested;

- the procedures for supplying the medicines studied shall be described in detail in the protocol; they shall be coherent in regard to the stated objective and methodology;

- the future use of the data collected shall be stated clearly in the protocol;

- 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.
Chapter 5:  
Supervision – Sanctions

Section 1: Generalities

article 38
§1. With a view to guaranteeing respect for the proper application of the rules of this Code, a number of bodies are set up, namely:

1. a Secretariat,
2. a Bureau of Proceedings,
3. a Visas Bureau,
4. a Chamber of Investigation,
5. a Deontological and Pharmaceutical Ethics Committee (hereinafter "the DEP Committee"),
6. a Chamber of Appeal.

§2. Failing explicit exception laid down by this Code, a mandate to serve on one of these bodies is incompatible with a function on any one of the other bodies.

§3. The President of each body shall have sovereign authority without appeal on matters of procedure. He may have recourse to the services of any expert in order to assist in deciding on any particular issue.

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

§5. Any member of one of these bodies who fails to attend three ordinary consecutive 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 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 42.

§7. All members will act in total independence. If there is a conflict of interest, the member will refrain from taking part in any phase in the procedure or handling of the case that may be concerned. The president, vice president or, failing this, the other members of the 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.

**article 39**
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 Code of Deontology that they may deem necessary.

**article 40**
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 Code of Deontology. 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 this Code, are subject to the advance visa procedure as described under articles 58 to 69.

**article 41**
An anonymous and representative jurisprudence shall be available to the members, giving the final decisions taken by the Bureau of Proceedings, the Visas Bureau, the DEP Committee and the Chamber of Appeal. This jurisprudence is updated and communicated at regular intervals, and at least once every four months.

**article 42**
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 shall be communicated by registered letter.

**article 43**
Any document (complaint, pleading, 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 44**
1. Except for provision to the contrary, the time limits referred to in this Code of Deontology 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 45**
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**
**Square Marie-Louise 49**
**1000 Brussels**

**Section 2: Bodies**

§1. The Secretariat

**article 46**
The Secretariat is charged with general support and administrative management of the deontological device. It will always act in strict neutrality. It will not be involved in the decision-making processes of the various bodies.

**article 47**
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 48**
The Bureau of Proceedings:

a. consults all incoming dossiers, except in case of a request for opinion as referred to under article 40, in the field of summary consideration, advance opinion procedure as referred to under section 3 of this chapter and appeal to the Chamber of Appeal;

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 82; under no circumstances will the Bureau of Proceedings adjudicate on the merits of the dossiers.

**article 49**

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.

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 55, point 5.

5. The Bureau of Proceedings will meet as often as is required for the consideration of dossiers.

**§3. The Visas Bureau**

**article 50**

The Visas Bureau pronounces on requests for advance visas as referred to under articles 58 and 64.

**article 51**

1. The Visas Bureau is, if necessary, organised into various chambers. One or more of these chambers is (will be) charged exclusively with appeals as referred to under articles 62 and 68 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 hold mandates within different chambers of the Visas Bureau at the same time. However, when a dossier is being considered on appeal as stated under articles 62 and 68, members who sit on the Chamber of Appeal may not have been members of the chamber that handled the dossier in the first instance.

3. The rules regarding the quorums needed are as follows. Each chamber of the Visas Bureau 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 55, point 5.

7. Each chamber of the Visas Bureau will meet as often as is required for the consideration of dossiers

§4. The Chamber of Investigation

article 52
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 there are insufficient elements of proof of the existence of a violation.

Its powers of investigation are determined by article 85.

article 53
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 for concurrently with those of the DEP Committee, as laid down under article 55, point 5.

5. The Chamber of Investigation meets as often as is required for the consideration of cases.
§5. The Deontological and Pharmaceutical Ethics Committee (DEP Committee)

article 54
The DEP Committee:

a. considers the merits of complaints;
b. considers, if applicable, complaints for summary consideration as stated under article 95;
c. pronounces on an appeal against a decision to refer a case to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen [Federal Public Services, Security of the Food Chain and Environment – Medicines Directorate-General];
d. acts following requests as referred to under article 40

article 55
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 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 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 company or same group of interests sit on the DEP Committee. In which case only one of the members in question may retain his mandate. The management of the company or group of companies decides which member retains his mandate.

7. If one of the members representing the pharmaceutical industry as referred to under article 55, point 1, c) resigns or is no longer able to exercise his mandate, he is replaced by the member who, in terms of the number of votes obtained during the election referred to under article 55, point 4, para. 2, is immediately next; the order of priority as referred to under article 55, point 4, para. 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 assured 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 assured by the substitute vice president.

9. The meetings are monthly.

§6. The Chamber of Appeal
article 56
1. Notwithstanding point 2 of this article, the Chamber of Appeal pronounces on appeals against a decision on the merits taken by the DEP Committee. The appeal charges the Chamber of Appeal 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 against a decision taken by another body pursuant to article 79.

article 57
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 55, point 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 company or same group of interests sit on the Chamber of Appeal. In which case only one of the members in question may retain his mandate. The management of the company or group of companies decides which member retains his mandate.

7. If one of the members representing the pharmaceutical industry as referred to under article 57, point 1, c) resigns or is no longer able to exercise his mandate, he is replaced by the member who, in terms of the number of votes obtained during the election referred to under article 57, point 4, para. 2, is immediately next; the order of priority as referred to under article 57, 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 assured 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: collective scientific meetings**
article 58
1. The collective scientific meetings referred to under article 26 are subject to an advance visa procedure if the event involves at least one overnight stay on the part of the participating health professionals.

In which case, pharmaceutical companies are obliged to obtain the visa from the Visas Bureau before the start of the meeting.

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

article 59
Companies make a visa application by submitting the duly completed model dossier drawn up by the secretariat, accompanied with all information and documents establishing compliance with articles 26 to 31 of the Code.

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

- general identification data,
- the dates of the meeting,
- the place of the meeting and justification thereof,
- a summary of the scientific and social programme, with details of what takes place on each day and the precise employment of time,
- travel arrangements, with precise indication of the employment of time,
- the number of participants and their professional speciality,
- the amount of the contribution by the company, participants and their partners towards the costs of hospitality, travel, registration and organisation of the meeting,
- the role played by a services company, if any,
- the request for INAMI/RIZIV [National Institute of Sickness and Disability Insurance] accreditation,
- any extension, in a private capacity, of the stay on the part of the health professionals outside the framework of the collective scientific meeting.

To be admissible, five copies of the dossier 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 60, para. 2 and article 61, para. 2.

article 60
The Visas Bureau decides whether or not the project complies with articles 26 to 31 of this Code.
If the Visas 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 59 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 Visas Bureau considers that the project does not comply with articles 26 to 31 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 Visas Bureau constitutes presumption of compliance of the project with articles 26 to 31 above provided the application submitted by the company is complete and a true reflection of reality, notwithstanding the last paragraph of article 63.

**article 61**
The Visas Bureau communicates its decision to the applicant company no later than the fifth working day following that on which the secretariat receives the application.

If, at the end of the fifth 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 59, known as the “visa number”, on all documents concerning the project in question drawn up after the expiry of the aforementioned term.

**article 62**
1. It is possible to appeal to a Visas Bureau Chamber of Appeal against the Visas Bureau’s decision taken pursuant to article 60.

2. On pain of inadmissibility and at the latest on the 30th day following notification of the contested decision, the applicant company must have submitted its appeal with reasons in writing, either sent by registered post or handed in at the secretariat.

3. In this case, the procedure will be as described under articles 59 to 60. The applicant must attach to its request a letter setting out its arguments.

4. The Visas Bureau Chamber of Appeal communicates its decision to the applicant company no later than the 10th working day following that on which the secretariat receives the request.

If at the end of the 10th working day that follows the day on which the secretariat receives the request, the Visas Bureau Chamber of Appeal 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 59 last paragraph, known as the “visa number”, on all documents relating to the project in question drawn up after the expiry of the said term.
5. Proceedings shall be conducted in writing only.

**article 63**
The president of the Visas Bureau is charged with ensuring that the procedures for the advance visa as described in the first sub-section are respected.

To this end and notwithstanding the competences of the other 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 collective scientific meeting 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 59.

He can also, in particular:

- 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 holding of the collective scientific meeting; 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.

**Sub-Section 2: scientific studies carried out after registration of the medicinal products**

**article 64**
1. The scientific studies referred to under article 36, with the exception of the experiments referred to under article 2, 11° of the law of 7 May 2004 concerning experiments on human persons, are subject to an advance visa procedure.

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

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

**article 65**
Companies introduce a visa application by submitting the duly completed model dossier as drawn up by the secretariat, together with all information and documents attesting to compliance with article 36, § 1, par. 1 and 37 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 a board of experts 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, five 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 66, para. 2 and article 67, para. 2.

**article 66**
The Visas Bureau decides whether or not the project complies with articles 36 § 1, para.1 and 37 of this 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 65 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 36 § 1, para.1 and 37 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 36 § 1, para.1 and 37 above, provided the application submitted by the company is complete and a true reflection of reality, notwithstanding the last paragraph of article 69.

**article 67**
The Visas Bureau communicates its decision to the applicant company 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 65, last paragraph, known as the “visa number”, on all documents concerning the project in question drawn up after the expiry of the aforementioned term.

**article 68**
1. It is possible to appeal to a Visas Bureau Chamber of Appeal against the Visas Bureau’s decision taken pursuant to article 66.

2. On pain of inadmissibility and at the latest on the 30th day following notification of the contested decision, the applicant company must have submitted its appeal with reasons in writing, either sent by registered post or handed in at the secretariat.

3. In this case, the procedure will be as described under articles 65 to 67. The applicant must attach to its request a letter setting out its arguments.

4. Procedures shall be conducted in writing only.

**article 69**
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 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 65.

He can also, in particular:

- ask the companies concerned for a copy of the advance opinion delivered by the approved 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 4: Complaints procedure

Sub-Section 1: general rules of procedure

article 70
Any natural person or legal entity who notes a failure to respect the rules of deontology may bring this to the attention of the deontological bodies.

The present sub-section does not apply to the advance visa procedure.

article 71
Before initiating disciplinary proceedings, the parties will seek to resolve their dispute amicably.

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

article 72
Each president 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.

article 73
The parties cooperate on the smooth running of the proceedings.

In the case of absence of one of the parties in proceedings on the merits of a case and notwithstanding article 95, point 6, both sides are considered to have been heard and no objection is possible.

In principle, no postponement will be granted. However, 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 74**
The parties must be summoned with reasonable notice. They can be assisted.

**article 75**
The parties can deposit at the secretariat any pleadings or other document that they judge to be useful. If they use this option, they must do so while respecting the timetable agreed in advance between all the parties and that respects the rights of defence. The parties communicate to the other parties all documents or pleadings at the same time as they deposit these documents or pleadings with the secretariat. No document or pleadings may be deposited after the seventh working day prior to that of appearance before the body in question.

The president decides in a sovereign capacity and without any possibility of appeal on the action to be taken if the documents or pleadings are deposited 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 76**
If a member of one of the 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 77**
The deontological bodies will remove from the dossier any element of proof obtained by illicit means.

**article 78**
The parties can consult the dossier at the Secretariat.

**article 79**
When the same case is brought before the deontological bodies and before a body external to pharma.be, for example a judicial or administrative authority or body of arbitration, it can no longer be considered by the deontological bodies.

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

By “the same case” is understood any dossier the subject of which, in full or in part, is 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 this article gives rise to a separate decision on the part of the president of the body in question. It is possible to appeal against this decision to the Chamber of Appeal, which then pronounces on the application of this article. The case is then sent to the 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 80
1. Any legal entity or natural person who notes a failure to respect the rules of deontology may submit a complaint, provided it 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 105, 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 Chamber will not act on a compliant 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 81
The Bureau 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 the previous article.

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 82
Without pronouncing on the merits of the case, the Bureau assesses what course of action should be taken, namely:

- discontinuance of the proceedings, according to the conditions laid down under article 84,
- referral to the Chamber of Investigation, according to the conditions laid down under article 85,
- referral to the DEP Committee, according to the conditions laid down under article 86,
- referral to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments/FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen, according to the conditions laid down under article 99.

**article 83**
The Bureau 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 refers to the directives on this subject that are attached to this Code.

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

**article 84**
Reasons must be given for any decision to discontinue the proceedings. It is not subject to appeal. The decision is communicated to the parties.

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

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

**article 85**
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.

2. Within 30 days of receipt of the dossier, the Chamber 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. It communicates its decision to the parties at the same time as a copy of the investigation report.

3. Consideration of a complaint by the DEP Committee

article 86
If the dossier is accompanied by a sufficient number of elements of proof of the existence of a violation of the Code of Deontology, the Bureau of Proceedings can transmit this to the DEP Committee. Referral to the DEP Committee charges the latter with considering the merits of the case.

If the dossier is accompanied by a sufficient number of elements or proof of the existence of a violation of the Code of Deontology, under no circumstances can it be the subject of referral to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments/ FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen as stated under article 99.

article 87
1. The DEP Committee may request additional investigating measures from the Chamber of Investigation. Within 30 days of reception of the dossier, 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 communicated to the parties.

2. The DEP Committee can also summon and hear the parties concerned or the presidents of the other bodies.

4. Consideration of a complaint by the Chamber of Appeal

article 88
1. An appeal can be made to the Chamber of Appeal against any decision taken on the merits by the DEP Committee. Notwithstanding article 79 in fine, no appeal can be made against incidents or decisions of internal order.

2. On pain of inadmissibility and at the latest on the 15th day following that of notification of the disputed decision, the parties must have submitted their appeal by letter, to be deposited either at the Secretariat or sent by registered post.

3. At the latest on the 30th day after the lodging of an appeal, the secretary summons the parties concerned to appear. This appearance takes place at the earliest on the 20th day after being summoned to appear.
article 89
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, 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 communicated to the parties.

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 sanctions

article 90
The consideration of the merits, before the DEP Committee and before the Chamber of Appeal, can lead to the following decisions:

• the confirmation of the violation, possibly with the pronouncing of one of the sanctions provided for under article 91,
• the non-confirmation of the violation,
• confirmation that the dispute is ended.

article 91
§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 company concerned to undertake in writing not to repeat these activities.

§2. If the DEP Committee or the Chamber of Appeal declare the violation to be confirmed in a decision on the merits, they can also pronounce the following sanctions to be imposed on the companies that they declare to have violated the deontological rules:

• reprimand,
• corrective measure.

§3. By “corrective measure” is understood, for example:

• correction to the incriminated material,
• insertion of a correcting statement,
• direct communication by letter to members of the medical/pharmaceutical profession of the decision or a copy of the decision.
§4. Any decision by the DEP Committee or the Chamber of Appeal on the merits of a case confirming a violation is published.

For decisions by the DEP Committee, the publication takes place only after the expiry of the appeal period 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,
- De Huisarts/Le Généraliste,
- 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 being confirmed in a final decision or in the case of a serious failing that jeopardises the interests of the pharmaceutical sector in general, the publication also appears 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 appended to this Code.

§5. The costs linked to a cessation order, to sanctions and to publication are borne by the company against which they are pronounced, notwithstanding the application of article 102.

**article 92**

If, during the three years following notification of the decision, a company is condemned definitively for identical or similar facts, the body that took the final decision can submit the dossier to the pharma.be Board of Directors with a view to application of article 93. It can also order publication of its decision in SCRIP.

**article 93**

Notwithstanding the sanctions provided for under article 91, 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 the Association in the field of ethics and professional relations, or refuses to comply with the internal regulations, of which this Code is an inherent part.

**article 94**

Any decision may be accompanied by a guidance measure.
Sub-Section 3: summary consideration of a complaint

**article 95**

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 by a pharma.be member company; it can also be initiated by the Bureau of Proceedings pursuant to article 83, possibly following the referral of the case by the president of the Visas Bureau pursuant to articles 63, para. 3 and 69, para. 3;
   
   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 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; 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 in the most appropriate manner.

6. They 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 have submitted in writing their request to have the decision set aside. 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 96
Decisions on merits taken by the DEP Committee can only be implemented on expiry of a term allowed for appeal. The DEP Committee in question may, however, on stating the grounds and in the sector’s general interest, declare its decision to be immediately enforceable in full or in part, notwithstanding any appeal against the decision.

article 97
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.

article 98
The president of the 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 93.

Sub-section 5: referral of a case to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen

article 99
Any decision by the terms of which the Bureau of Proceedings refers the case to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen must contain grounds.

A dossier, following a complaint as referred to under article 80, can only be referred in this way if it satisfies all the following conditions:
• the complaint satisfies the conditions laid down by 80.1;
• 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 86.

**article 100**

1. Any decision for referral to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen can be the subject of an appeal to the DEP Committee by the parties concerned.

On pain of being declared inadmissible and at the latest on the 15th day following the date of notification of the referral decision, the appealing party must have submitted his appeal in writing, to be deposited either at the Secretariat or sent by registered post.

The decision for referral does not take effect until the 15th 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 99 para. 2 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, 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.

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 99, para. 2 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.

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, 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 88 and 89.

**article 101**

1. Referral to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen has the effect of permanently stopping any deontological procedures concerning the referred file.

2. The Bureau decides in a sovereign capacity to communicate to the SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen any dossier involving a company that is not a member of pharma.be
Chapter 6: Costs of proceedings and financing

article 102 Complaints procedure: costs of proceedings
1. In the sense of this article, “costs of proceedings” are understood to be all costs relating to the proceedings referred to in chapter V, section 4.

The costs of proceedings are established per dossier introduced for a complaint as referred to under article 80, on the basis of the real costs incurred by each 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 80, point 5, 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 80, point 5.

2. The president of each 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 sanction 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 sanction 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 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 SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement - Direction générale Médicaments / FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – Directoraat-generaal Geneesmiddelen. In the latter case, the sum deposited will be refunded to the complainant.
As an exception to the above rules, deontological bodies and natural persons bear no costs of proceedings.

4. The party found guilty of a violation and against which a sanction 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 91, § 1;
- EUR 1 250 per sanction pronounced pursuant to article 91, § 2;
- EUR 1 250 for publication provided for by article 91, § 4.

**article 103 (…)**

**article 104 (…)**
Chapter 7:  
General provisions – Entry into force – Interim measures

article 105  
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 the Association.

article 105bis  
Notwithstanding the application of articles 2bis, § 3, and 26 of this Code, companies are obliged, if they invite health professionals to participate in a collective scientific meeting held abroad or if they sponsor the participation of health professionals at such meetings, to notify any local company concerned that is connected to them or, if applicable, to request advice locally.

article 106  
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 sanctions pronounced against it. This member also remains liable for any costs of proceedings (or other sums) established in accordance with articles 102 and 103.

article 107  

§2. The following interim measures are taken:

1. Dossiers submitted in connection with the complaints procedure before the present revised version enters into force will be dealt with in accordance with the basic and procedural rules that were in force at the time of the events.

2. Dossiers submitted in connection with the visa procedure before 1 January 2006 will be dealt with taking into account the provisions of the Code version in force at the time, even if the request relates to a collective scientific meeting that takes place after this date or a study that closes after this date. Dossiers submitted after 1 January 2006 will be dealt with taking into account the provisions of the present revised version of the Code.

3. 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.

4. The DEP Committee and the Chamber of Appeal set up by the revised and corrected version of the present Code will legitimately exercise all their responsibilities attributed to them by the Code.
from 1 April 2003, and this while implementing, if applicable, any rules of composition and of quorum that may depart from those laid down in the Code if, on this date, a sufficient number of members representing the medical profession, the pharmaceutical profession and the scientific and academic world have not been duly appointed by their representative associations or organisations. Members of the body in question who are validly appointed will decide by simple majority on the above-mentioned exceptional rules. This will continue for as long as the above-mentioned situation applies.

**article 108**
The Internal Regulations of the DEP Committee as approved by the General Assembly of 29 March 2002 are repealed.

**article 109**
The FIIM Code of marketing practices for pharmaceutical products, as approved by the FIIM General Assembly of 31 August 1994 and as adopted by the pharma.be General Assembly of 24 March 1995, is an inherent part of this Code.

**article 110**
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, health professionals, including representative organisations, patients and the authorities.
Annex

Directives concerning the determination of facts that must be considered as a “serious violation of the rules of deontology jeopardising the interests of the pharmaceutical sector in general” pursuant to articles 83 and 91, § 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 83 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 91, § 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, Le Généraliste / De Huisarts 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.\(^1\) Although in

\(^1\) These examples are for information purposes only; each case must always be considered on the basis of the circumstances peculiar to the specific case.
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 seen to fall within several 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,
- 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 health professionals and that if it were brought to the attention of patients, would risk compromising the relationship of individual trust between the latter and health 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 health professional and that, if it were brought to the attention of patients would risk compromising the relationship of individual trust between the latter and health 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 health professionals to have confidence in the pharmaceutical industry and in its products in general. Consequently, violations with high visibility, for health 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.

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2 Provided the study carried out falls within the material field of application of the Code.
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 health 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 health professionals are based. A violation of this article 10\(^3\) - which prohibits the pharmaceutical industry, save in certain exceptional cases, from granting premiums or benefits – therefore constitutes a “serious violation”.

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\(^3\) Art. 10 § 1. It is prohibited, in connection with the supply, prescribing, issuing or administration of medicinal products, to promise, offer or grant, directly or indirectly, premiums, pecuniary benefits or benefits in kind to wholesalers, persons qualified to prescribe, issue or administer medicinal products as well as to institutions in which the prescribing, issuing or administration of medicinal products takes place. § 2. However, the prohibition as referred to under § 1 does not apply to:

1° premiums or benefits of negligible value or which relate to the exercising of the medical profession, the dental profession, the pharmaceutical profession or veterinary medicine;

2° the invitation and defrayment of the participation costs, including hospitality, of legal entities or natural persons as referred to under § 1, including in the veterinary sector, relating to a scientific event,
The following may be considered to be violations of article 10 of the law on medicinal products:

- the inviting of health professionals to sports or cultural events;
- the inviting of health 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 health 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.

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”.