

## CODE OF ETHICS FOR PROMOTION PRACTICES OF THE PHARMACEUTICAL INDUSTRY AND INTERACTION WITH HEALTHCARE PROFESSIONALS AND INSTITUTIONS, ORGANISATIONS OR ASSOCIATIONS COMPRISING HEALTHCARE PROFESSIONALS

Ethical issues are, and have been throughout the years, a real concern for the Portuguese Pharmaceutical Industry.

Since 1987 APIFARMA is governed by Codes of Ethics which, as time goes by, have undergone amendments as a result of the national and community legislation development and of the ongoing need to clarify concepts and practices.

The various versions of Code of Ethics were also influenced by the Code of Ethics of IFPMA (*International Federation of Pharmaceutical Manufacturers and Associations*) and EFPIA (*European Federation of Pharmaceutical Industries and Associations*) of which APIFARMA is a member.

This revision is justified by the obligation to transpose the new MedTech Europe Code of Ethical Business Practice, of which APIFARMA is a member, which entered into force on January 1<sup>st</sup> 2017.

Taking this opportunity, some concepts were also clarified, namely within the scope of promotional, scientific or educational events.

APIFARMA Code of Ethics does not aim at restraining the promotion of medicinal products and *in vitro* diagnostic medical devices for in such a way as to hinder free competition, but at ensuring that member companies engage in an ethical promotion of their products and services, whilst complying with applicable laws and regulations to the benefit of the name and prestige of the Pharmaceutical Industry.

The main goal of the Code of Ethics is to stand up for objective scientific information enabling a rational and safe use of medicinal products and *in vitro* diagnostic medical devices marketed by the Pharmaceutical Industry companies that are members of APIFARMA.

The goal is to create an environment where the general public may be sure that the choices regarding their medicinal products and *in vitro* diagnostic medical devices are made based on the characteristics and benefits of each of them and the patients' clinical needs.

The relationships between Pharmaceutical Industry and Patients Organisations are governed by the *Code of Conduct for the relationships between Pharmaceutical Industry and Patients Organisations*, for which reason its subject is referred to that Code.

The rules sanctioned here were freely discussed and voluntarily accepted and are binding for all APIFARMA members.

## CHAPTER 1. GENERAL PRINCIPLES

### Article 1

#### Scope

1. This Code of Ethics aims at establishing a set of standards applicable to the promotion and marketing practices of prescription only and over-the-counter medicinal products and *in vitro* diagnostic medicinal devices and to the interactions between healthcare professionals, institutions, organizations or associations comprising Healthcare professionals and the Pharmaceutical Industry companies members of APIFARMA (hereinafter referred to as member Companies), based on suitable independence and transparency criteria, respecting the health and life of the patients and the image and reliability of the Pharmaceutical Industry.
2. This Code should be complied with notwithstanding the integral respect of the applicable legal and regulatory provisions, which, from an ethics point of view, should also be equally complied with.
3. This Code does not apply to:
  - a) labelling and package leaflets of medicinal products, which are subject to the applicable legal provisions;
  - b) labelling, instructions for use and technical documentation of *in vitro* diagnostic medical devices, which are subject to applicable legal provisions;

- c) correspondence, possibly accompanied by non promotional material, required to answer a specific question on a specific medicinal product or a specific *in vitro* diagnostic medical device;
- d) evidence-based informative advertisements and reference materials regarding, for instance, changes in package, warnings as to adverse reactions as part of general precautions, safety warnings on incidents within the scope of pharmacovigilance, commercial catalogues and price lists, provided they do not include messages regarding attributes or properties of the products;
- e) non promotional information regarding human health or diseases;
- f) the member Companies' institutional advertising;
- g) the relationships between Pharmaceutical Industry and Patients Organisations.

## Article 2

### Rules about the Code applicability

1. Member Companies undertake to fully respect and comply with the provisions of this Code in all initiatives and interactions with healthcare professionals who pursue their activities in Portugal or with institutions, organizations or associations comprising healthcare professionals incorporated in Portugal, irrespective of the place where the initiative or the interaction takes place.
2. Member Companies further undertake to fully respect and comply with the provisions of this Code in all initiatives and interactions which take place in the national territory with healthcare professionals or with institutions, organizations or associations comprising healthcare professionals that pursue their activities outside the national territory.
3. Member Companies belonging to multinational economic groups with head offices, subsidiaries or other type of establishments located abroad are responsible for the compliance by the latter with the provisions of this Code regarding any initiative carried out in the national territory, irrespective of its nature (promotional, scientific or educational) or the means through which it is carried out, with respect to:
  - a) products approved or not in Portugal ;

- b) interactions with healthcare professionals or with institutions, organizations or associations comprising healthcare professionals.
4. Member Companies should ensure that the companies of the economic group to which they belong comply with the provisions of this Code when they carry out abroad any initiative or interaction with healthcare professionals who pursue their activities in Portugal or with institutions, organizations or associations comprising healthcare professionals incorporated in Portugal, unless the rules of the country where the initiative or the interaction takes place are more restrictive, in which case they should be applied.
  5. The provisions of article 24, no. 2, should be exempted from the application of the preceding paragraph.

### **Article 3**

#### **Member companies' staff**

1. Member Companies staff, regardless of the legal relationship, and third parties acting on their behalf should be familiar with the requirements of the Code of Ethics and with the legislation and other provisions applicable.
2. Member Companies marketing medicinal products should have a scientific department comprising a physician or a pharmacist responsible for:
  - a) The information on their medicinal products;
  - b) The approval of all the information or promotional material before they are distributed;
  - c) The supervision of any non-interventional study, including all revisions regarding those studies. The department must be sure the protocol of the non-interventional study has been examined and it is in compliance with all requirements provided for in this Code.
3. Member Companies marketing *in vitro* diagnostic medical devices should have a person in charge of the supervision of the information or promotional materials.
4. The professionals mentioned in nos. 2 and 3 have to declare that the information or promotional materials:

- a) have been reviewed in their finished form and that they consider they are in compliance with the requirements of the Code of Ethics and with the legislation and other provisions in force, including those regarding advertising;
  - b) are in accordance with the summary of product characteristics or with the instructions of use and the technical documentation of the *in vitro* diagnostic medical device; and
  - c) are a true and fair presentation of the facts on the medicinal product or the *in vitro* diagnostic medical device.
5. Each Member Company should appoint at least one senior employee who should be responsible for the supervision of the Member Company and their affiliates, so as to ensure the Code of Ethics, the legislation and other provisions in force are complied with.

## **CHAPTER 2. PROMOTION OF MEDICINAL PRODUCTS AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES**

### **Article 4**

#### **General rules for the promotion of medicinal products**

- 1. A medicinal product can only be promoted for the respective approved indications after it has been granted a marketing authorization which enables its sale or dispensing.
- 2. Promotion of medicinal products should comply with the elements identified in the summary of product characteristics.
- 3. The right of pharmaceutical companies to inform the scientific community about the advances in the field of medicinal products and therapeutics is excluded from the application of nos. 1 and 2; those companies may disclose the results of scientific research they are carrying out for that purpose.
- 4. The direct distribution of medicinal products to the public is forbidden.
- 5. The word "safe" should never be used to describe a medicinal product.

6. The word "new" should not be used to describe a medicinal product or presentation available for more than one year, nor a therapeutic indication which has been promoted or launched for more than one year.
7. No medicinal product should be presented mentioning that it has no side-effects, toxicity risks, addiction or dependency risks.
8. Promotion should be adjusted to the recipient and made accordingly to suitable ethical standards, so that the social value of the medicinal product can be disclosed and its special nature acknowledged.
9. Promotion should not be deceitful, subliminal or hidden.
10. Promotional materials published at the initiative of a Member Company, in any printed or digital means of communication, should not resemble independent editorial articles and should be clearly identified as being of advertisement nature.
11. The studies or programs on the use of medicinal products, namely pharmacovigilance programs, post-marketing experiences and post-authorization studies should not be used as a disguised way of promoting a medicinal product and should be carried out for scientific or educational purposes.

## **Article 5**

### **General rules for the promotion of *in vitro* diagnostic medical devices**

1. An *in vitro* diagnostic medical device can only be promoted after having been assessed as to its conformity by the manufacturer or after notification to the competent authority.
2. The promotion of *in vitro* diagnostic medical devices should:
  - a) be compliant with the respective instructions for use and the technical documentation;
  - b) be adjusted to the recipient and made according to suitable ethical standards
3. The word "safe" should never be used to qualify an *in vitro* diagnostic medical device.
4. Promotion should not be deceitful, subliminal or hidden.

5. Promotional materials published at the initiative of a Member Company, in any printed or digital means of communication, should not resemble independent editorial articles, and should be clearly identified as being of advertisement nature.
6. The studies or programs on the use of *in vitro* diagnostic medical devices, namely vigilance programs, post-marketing experiences and post-authorization studies should not be used as a disguised way of promoting an *in vitro* diagnostic medical device and should be carried out for scientific or educational purposes.

## Article 6

### Promotion and its substantiation

1. The information on the characteristics of the medicinal products or *in vitro* diagnostic medical devices should not exceed the limits guaranteed by available scientific proof and it must be prepared free of ambiguity.
2. The information included in promotional material has to be accurate, up-to-date and verifiable and described in a sufficiently comprehensive manner to enable the recipient to have a correct idea of the therapeutic value of the medicinal products or of the value of the *in vitro* diagnostic medical devices.
3. The information included in promotional material or the one intended for the suitable use of the medicinal product or *in vitro* diagnostic medical device should:
  - a) be grounded on an updated evaluation of all available scientific proof and in compliance with the provisions of the summary of product characteristics or with the instructions for use and the technical documentation of the *in vitro* diagnostic medical device;
  - b) be in accordance with the marketing authorization in the case of medicinal products and in accordance to the conformity assessment in the case of *in vitro* diagnostic medical devices; and
  - c) does not lead to any incorrect or wrong conclusions.
4. Scientific data supporting statements on the medicinal product or *in vitro* diagnostic medical device characteristics should be made available to Healthcare Professionals when they request them.

5. Information on side-effects of medicinal products should reflect the available proof and be likely to be substantiated through clinical experience. Member Companies don't have to provide substantiation regarding the validity of the elements approved in the summary of medicinal product characteristics.
6. Promotion should encourage the rational use of medicinal products or the safe use of *in vitro* diagnostic medical device introducing them in an objective manner without overstating their properties.
7. All elements integrated in promotional materials, including charts, pictures and tables of studies, should:
  - a) clearly indicate the exact source or sources of the promotional elements;
  - b) be faithfully reproduced. In case of need they may be adjusted, mentioning the introduced adjustment.
8. Quotes of medical or scientific literature or personal communications should be faithfully reproduced and dully referenced.

## Article 7

### Promotion to the public

1. Only the following products may be promoted to the general public:
  - a) non reimbursed over-the-counter medicinal products :
  - b) *in vitro* diagnostic medical devices the use of which does not require the mediation and decision of a Healthcare Professional, as well as those authorized by law.
2. Promotion to the general public should be identified unequivocally as such, clearly stating it is a medicinal product or an *in vitro* diagnostic medical device.
3. Promotion to the general public should include, legibly, the information required by legislation and other provisions in force.
4. Any form of comparative advertising is prohibited.
5. Promotion to the general public should not include any element which:



- a) leads to conclude that the medical appointment or the surgical procedure is unnecessary, in particular by offering a diagnosis or suggesting treatment by mail;
- b) suggests that the effect of the medicinal product is guaranteed, with no adverse reactions or side effects, with results greater or equivalent to those of another treatment or medicinal product;
- c) suggests that the effect of the *in vitro* diagnostic medical device is guaranteed, with better or equivalent results to those of another *in vitro* diagnostic medical device;
- d) suggests that the person's normal health condition may be improved by means of the use of the medicinal product or the *in vitro* diagnostic medical device;
- e) suggests that the person's normal health condition may be impaired in case the medicinal product or the *in vitro* diagnostic medical device is not used, except as far as the vaccination campaigns approved by the competent authority is concerned;
- f) is exclusively or mainly addressed to children;
- g) refers to a recommendation from scientists, Healthcare Professionals or other persons who, because of their celebrity, may encourage the consumption of medicinal products or *in vitro* diagnostic medical device;
- h) suggests that the medicinal product or *in vitro* diagnostic medical device is food, cosmetic or personal hygiene products, or any other consumption product;
- i) suggests that the safety or efficacy of the medicinal product or *in vitro* diagnostic medical device is due to the fact that it is a natural product;
- j) could, through a detailed description or representation of the patient history, lead to an erroneous self-diagnosis;
- k) refers in improper, alarming or misleading terms to claims or guarantees of cure;
- l) uses in improper, alarming or misleading terms visual representations of changes in the human body or parts of the human body, caused by diseases or injuries or of the action of a medicinal product or *in vitro* diagnostic medical device

## **Article 8**

### **Promotion of prescription only medicinal products to Healthcare Professionals**

1. All promotional materials regarding prescription only medicinal products should include, in a clear and legible way, the following:
  - a) the brand name or the international non-proprietary name of the medicinal product;
  - b) duly referenced information compliant with the summary of product characteristics, stating the date when the latter was prepared or reviewed the last time;
  - c) the classification of the medicinal product according to the dispensing scheme;
  - d) the reimbursement scheme;
  - e) the date when they were prepared or reviewed the last time.
2. When the information is intended exclusively to call the attention to the name of the medicinal product the provisions of no. 1 are exempted.

## **Article 9**

### **Promotion of *in vitro* diagnostic medical devices to Healthcare Professionals**

The *in vitro* diagnostic medical devices requiring mediation or decision of a Healthcare Professional may only be advertised or publicised in technical publications or information materials intended and accessible exclusively to physicians and other Healthcare Professionals.

## **Article 10**

### **Comparative advertising**

1. Comparative advertising of medicinal products and *in vitro* diagnostic medical devices is only permitted to Healthcare Professionals.
2. Comparisons between different medicinal products and different *in vitro* diagnostic medical devices should be based on relevant and comparative aspects of the former and should neither be deceitful nor defamatory.

3. Comparisons between different medicinal products and different *in vitro* diagnostic medical devices can only be made based on the elements included in the respective summary of products characteristic, or the respective instructions for use and technical documentation or on credible clinical data.

## **Article 11**

### **Dissemination of promotion to Healthcare Professionals**

1. Information regarding prescription only medicinal products and *in vitro* diagnostic medical devices should only be addressed to people who, within reason, may be assumed as to be in need or have interest on that information.
2. The Healthcare Professionals databases have to be always updated, and should be prepared according to national law in force.
3. The Healthcare professionals' requests to be removed from databases must be respected.

## **Article 12**

### **Promotion on the internet or other digital channels**

1. Promotion of medicinal products or *in vitro* diagnostic medical devices on the internet or other digital channels should be based on technical, scientific and professional principles and in compliance with the national legislation in force.
2. Member Companies should adopt such measures so as to guarantee that the promotion on the internet or other digital channels of prescription only medicinal products or *in vitro* diagnostic medical devices requiring a Healthcare Professional's mediation or decision is accessed only by Healthcare Professionals.

## **Article 13**

### **Interdiction of advice on personal medical matters**

1. Member Companies marketing medicinal products or *in vitro* diagnostics medical devices cannot respond to general public requests for advice on personal medical matters, and should refer these requests to a Healthcare professional.

2. Member Companies should guarantee the confidentiality of possibly conveyed clinical data.

## **Article 14**

### **Promotional gifts**

1. Promotional gifts are prohibited within the scope of the promotion of prescription-only medicinal products.
2. Within the scope of the promotion of over-the-counter medicinal products and *in vitro* diagnostic medical devices, promotional gifts can be given to Healthcare Professionals provided they consist of benefits in kind the value of which does not exceed € 25.00 and are relevant for their professional activity and/or involve a benefit for the Patient.
3. Promotional gifts may only include the member Company's name and logo, the name of the medicinal product and/or its international non-proprietary name, if it exists, or its trade mark or the trade mark of the *in vitro* diagnostic medical device.
4. If with the promotional gifts is provided additional information on the medicinal product this information has to be compliant with the provisions of article 8, no. 1.
5. Promotional gifts should not constitute an incentive nor a compensation to recommend, prescribe, purchase, supply, dispense, sell, administer or use medicinal products or *in vitro* diagnostic medical device.

## **CHAPTER 3. PROMOTIONAL, SCIENTIFIC OR EDUCATIONAL EVENTS AND TRAINING ACTIVITIES**

## **Article 15**

### **Events organized by member Companies**

1. Member Companies may organize promotional, scientific or educational events intended for Healthcare Professionals with the purpose of, namely, promoting their products or conveying scientific knowledge, provided they respect the rules set up by this Code and other applicable national legislation.

2. All information material that may result from these events should reflect accurately the communications and discussions held there.
3. Member Companies should keep all documentation regarding the event during the legal term in force.

## **Article 16**

### **Events organized by third parties**

1. Member Companies may support or sponsor scientific or educational events organized by third parties, provided they respect the rules set up by this Code, namely articles 19 and 24, and by the legislation and other provisions in force.
2. For the purposes of this article, a sponsorship is understood as a financial or non-financial contribution given to a third party, for a specific purpose and which entails a compensation.
3. For the purposes of this article, a support is understood as a financial or non-financial contribution given to a third party, for a specific purpose and which does not entail a compensation.
4. The support or sponsorship should be preceded by a written request of the organising entity, dated and signed, addressed to the Member Company which grants the support or sponsorship, specifying its scope and purpose.
5. The support or sponsorship of any event should be clearly announced prior to its beginning and for its duration and should be included in all documentation of the event as well as in all information materials that may result from those events.
6. The Member Company granting the support or sponsorship should keep all documentation regarding it during the legal term in force.

## **Article 17**

### **Training activities on *in vitro* diagnostic medical devices**

1. Member Companies marketing *in vitro* diagnostic medical devices may organize activities with the purpose of give training on the safe use of their products and services.

2. Member Companies marketing *in vitro* diagnostic medical devices may support or sponsor activities organized by third parties with the purpose of give training on the use of products and services, and the provisions of the previous article should apply adapted as necessary.

## **Article 18**

### **Events and training activities' programme**

1. The programme of promotional, scientific or educational events and training activities, organized, supported or sponsored by Member Companies should be directly related to the professional activity of the participants Healthcare Professionals or be relevant enough to justify their attendance.
2. The programme mentioned in the previous number may include as social aspects the lunches and dinners that take place during the event or activity.
3. Promotional, scientific or educational events and training activities, organized, supported or sponsored by Member Companies cannot include entertainment activities (for example, leisure, recreation or sports).

## **Article 19**

### **Events and training activities' venue**

1. Promotional, scientific or educational events and training activities organized, supported or sponsored by Member Companies should be held in suitable venues for the main purpose of the event or training activity and the venues should not be places and/or complexes which are known for their leisure, entertainment or sport facilities.
2. The events and training activities organized by Member Companies should be held in Portugal, unless it is logistically more reasonable to hold the event in another country:
  - a) taking into account the home countries of most of the participants; or
  - b) taking into account the location of the relevant resources or knowledge which are the object or topic of the event.
3. When the events organized, supported or sponsored by Member Companies are held in another country ("international events") the rules of this Code and the rules of the

Code of Ethics in force in the country where the event takes place should be complied with, and in case of conflict the more restrictive rule should prevail.

## **CHAPTER 4. INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND INSTITUTIONS, ORGANIZATIONS OR ASSOCIATIONS COMPRISING HEALTHCARE PROFESSIONALS**

### **Article 20**

#### **General principles**

1. Any interaction with Healthcare Professionals and institutions, organizations or associations comprising Healthcare Professionals should not constitute an incentive nor a compensation to recommend, prescribe, purchase, supply, dispense, sell, administer or use medicinal products or *in vitro* diagnostic medical device.
2. Whenever required, in the scope of interactions with Healthcare Professionals, the necessary authorizations or approvals of the entities with which they have a legal relationship must be obtained.

### **Article 21**

#### **Prohibition of giving benefits for personal use**

It is prohibited to give, direct or indirectly, to Healthcare Professionals financial benefits or benefits in kind for their personal use.

### **Article 22**

#### **Provision of services by Healthcare Professionals or institutions, organizations or associations comprising Healthcare Professionals**

1. Member Companies may enter into service agreements with Healthcare Professionals, namely for their participation as speakers or moderators in promotional, scientific or educational events or for their participation as consultants in in medical/scientific studies, clinical trials, training programs, advisory boards and

market research, or with institutions, organizations or associations comprising Healthcare Professionals.

2. The service agreements foreseen in the previous number should specify the nature of the services, its legitimate need and the terms of payment, when applicable.
3. The provision of services may be remunerated, in which case it must be reasonable and reflect the market value of the services provided.
4. In case a Healthcare Professional provide services as a speaker or moderator in an event the suitable provisions of articles 19 and 24 apply.
5. The number of selected Healthcare Professionals should not exceed the reasonable number of professionals required to achieve the identified purpose.
6. The Member Company should keep all records related to the services provided.
7. The obligation of the Healthcare Professional to identify himself/herself as a Member Company's service provider or employee, whenever he/she writes or lectures in public on subjects which are the object of the agreement or contract or on any subjects related to the Member Company, should be included in any contract or agreement signed between the Member Company and the Healthcare Professionals, both in the scope of this article or the scope of an employment relationship.
8. Limited market studies, such as phone interviews or questionnaires sent by any means of communication, are excluded from the scope of this article provided the Healthcare Professional is not consulted in a recurrent manner and the payment for the service is suitable and not excessive.

## **Article 23**

### **Support to Healthcare Professionals in the scope of events or training activities**

1. Member Companies marketing medicinal products may directly support, in the form of hospitality under the terms of article 24, the participation of Healthcare Professionals in promotional, scientific or educational events organized by the Company or by a third party, provided they respect the rules set up by this Code and by the legislation and other provisions in force.



2. Member Companies marketing *in vitro* diagnostic medical devices may only directly support, in the form of hospitality under the terms of article 24, the participation of Healthcare Professionals in scientific or educational events organized by the Company or in training activities organized by the Company or a third party, provided they respect the rules set up by this Code and by the legislation and other provisions in force.
3. Member Companies marketing *in vitro* diagnostic medical devices may only directly support travel and accommodation costs of Healthcare Professionals in the scope of promotional events organized by the Company when justified by the location of the relevant resources or knowledge (for example, demonstrations of non-portable equipment).
4. Member Companies marketing *in vitro* diagnostic medical devices cannot directly support, in the form of hospitality under the terms of article 24, the participation of Healthcare Professionals in scientific or educational events organized by a third party (for example, congresses, conferences).
5. The Member Company granting the support should keep all documentation regarding the event during the legal term in force.

## **Article 24**

### **Hospitality**

1. Supports granted under the terms of the previous article:
  - a) should be limited to travel, meals, accommodation and registration costs;
  - b) may only be granted to Healthcare Professionals which are participants in their own right;
  - c) should not exceed the period between the day prior to the beginning of the event and the day after the end of it;
  - d) should be restricted to the main purpose of the event, and cannot include events of an entertainment nature (for example, leisure, recreation or sports);
  - e) should be of a reasonable level and should not exceed what Healthcare Professionals attending the event would be willing to pay for themselves;

- f) should not be provided as a compensation for the time spent by the Healthcare Professionals when participating in the events.
2. The value of the meals provided to Healthcare Professionals should not be greater than € 60.00 in events taking place in national territory and € 90.00 in international events, except if in the country where the event takes place the Code of Ethics or the national legislation establishes a different amount, in which case the mentioned amount is to be applied, whether it is greater or not.

## **Article 25**

### **Support to institutions, organizations or associations comprising Healthcare Professionals in the scope of continuous education**

1. Member Companies may grant support to institutions, organizations or associations comprising Healthcare Professionals with the purpose of supporting Healthcare Professionals continuous education through their participation in scientific or educational events or in training activities relevant to their professional activity organized by them/ Member Companies or by third parties.
2. The support referred in the previous number may be granted upon request of the beneficiary entity or at the company's initiative.
3. When the support is requested by the beneficiary entity it should be preceded by a written request, dated and signed, addressed to the member Company which grants the support, specifying its scope and purpose.
4. Whenever possible, an agreement between the member Company and the beneficiary entity should be concluded specifying the scope and purpose of the support and the conditions under which it is granted.
5. The member Company that grants the support cannot have any influence on the individual selection procedure of the Healthcare Professionals that will participate in the event or in the activity.
6. The member Company that grants the support should keep all documentation regarding it during the legal term in force.

## **Article 26**

### **Support to institutions, organizations or associations comprising Healthcare Professionals in the scope of health care provision or scientific research**

1. Member Companies may grant support to institutions, organizations or associations of Healthcare Professionals providing health care or engaged in scientific research with the purpose of supporting health care provision or scientific research.
2. The support referred in the previous number may be granted upon request of the beneficiary entity or at the company's initiative.
3. When the support is requested by the beneficiary entity it should be preceded by a written request, dated and signed, addressed to the member Company which grants the support, specifying its scope and purpose.
4. Whenever possible, an agreement between the member Company and the beneficiary entity should be concluded specifying the scope and purpose of the support and the conditions under which it is granted.
5. The support mentioned in the previous numbers may be financial or non-financial contributions.
6. When the support is a benefit in kind it should not bear the name or the logo of a medicinal product or an *in vitro* diagnostic medical device.
7. The member Company that grants the support should keep all documentation regarding it during the legal term in force.
8. The support provided for in this article should not be granted to Healthcare Professionals individually.

## **Article 27**

### **Informational or educational materials and items of medical utility**

1. Member Companies may provide to Healthcare Professionals or to institutions, organizations or associations comprising Healthcare Professionals informational or educational materials intended for the Healthcare Professional's education, provided that they are, simultaneously, of low cash value, relevant for the practice of their

professional activity and bring direct benefit to the provision of health care to the Patient.

2. Member Companies may provide to Healthcare Professionals or to institutions, organizations or associations comprising Healthcare Professionals items of medical utility intended for the provision of health care to the Patient, provided they are, simultaneously, of low cash value, relevant for the practice of their professional activity and are not for the healthcare professional's personal benefit nor correspond to items the Healthcare Professional usually purchases within the scope of his/her daily professional activity.
3. For the purposes of this article low cash value means the value set in the national legislation in force.

## **Article 28**

### **Medicinal products samples**

1. Member Companies may provide, free of charge, to each Healthcare Professional qualified to prescribe four free samples, per year, of a specific medicinal product in response to a request in writing, dated and signed, in order to make him/her familiar with the product and acquire the necessary experience to use it.
2. The provision of free samples is only permitted within the two years after the date when the medicinal product starts to be effectively marketed.
3. Member Companies should have control and accounting systems in place for the samples they provide and should keep records of all the related documentation.
4. Samples cannot be larger than the smallest marketed package.
5. Samples should display the mention "free medical sample – not for sale", or similar indications, and should be accompanied by a copy of the summary of product characteristics.
6. No samples of the following medicinal products should be provided:
  - a) medicinal products containing substances defined as psychotropic or narcotic by international conventions and national legislation;

- b) other medicinal products for which the supply of samples is not deemed to be suitable, according to what competent authorities may establish at each moment.

## **Article 29**

### **Samples and demonstration products of *in vitro* diagnostic medical device**

1. Member Companies may provide, free of charge, to each Healthcare Professional qualified to decide about the use of *in vitro* diagnostic medical devices which request his/her mediation and decision a reasonable number of samples or demonstration products, in response to a request in writing, dated and signed, in order to make him/her familiar with the *in vitro* diagnostic medical device and acquire the necessary experience to the safe, effective and appropriate use and functioning of the product or service related to it.
2. Member Companies should have control and accounting systems in place for the samples and demonstration products they provide and should keep records of all the related documentation.
3. Samples should display the mention "free medical sample – not for sale", or similar indications, and should be labelled and accompanied by a copy of the instructions for use.

## **Article 30**

### **Medical sales representatives**

1. Each Member Company should guarantee that its medical sales representatives, regardless of the legal relationship, who visit Healthcare Professionals, pharmacies, hospitals or other healthcare institutions within the context of medicinal products promotion are familiar with the requirements of the Code of Ethics and with the legislation and other provisions in force.
2. Medical sales representatives should be duly trained by Member Companies and have enough scientific knowledge to be able to provide precise and complete information on the medicinal products they promote.

3. Medical sales representatives should comply with all the principles of the Code of Ethics and with the legislation and other provisions in force, and companies are responsible for their compliance.
4. Medical sales representatives should stand up to their duties with a sense of responsibility and ethics.
5. During each visit and according to the provisions of the applicable laws and regulations, medical sales representatives should provide to Healthcare Professionals, or have it available for their use, a summary of product characteristics they are presenting.
6. Medical sales representatives should immediately convey to their Member Company's scientific departments, any information they get on the use of the medicinal products they promote, especially regarding adverse events conveyed to them.
7. Member Companies and the medical sales representatives should ensure that the frequency, scheduling and duration of the visits to Healthcare Professionals, pharmacies, hospitals or other healthcare facilities, as well as the way they are conducted, are in accordance with the ethics, the Code of Ethics and the legislation and other provisions in force.
8. Medical sales representatives should not turn to incentives or pretexts to arrange for an interview.
9. During an interview or at the time of arranging for one, medical sales representatives should ensure they do not lead Healthcare Professionals of healthcare institutions into error as to their identity or the identity of the Member Company they represent.

### **Article 31**

#### **Representatives of *in vitro* diagnostic medical devices**

1. Each Member Company should guarantee that its representatives, regardless of the legal relationship, who visit Healthcare Professionals, pharmacies, hospitals or other health facilities within the context of the promotion of *in vitro* diagnostic medical

devices are familiar with the requirements of the Code of Ethics and with the legislation and other provisions in force.

2. Representatives of the Member Company should be duly trained by companies and have enough scientific knowledge to be able to provide precise and complete information on the *in vitro* diagnostic medical devices they promote.
3. Representatives of the Member Company should comply with all the principles of the Code of Ethics and with the legislation and other provisions in force, and Member Companies are responsible for their compliance.
4. Representatives of the Member Company should stand up to their duties with a sense of responsibility and ethics.
5. During each visit and according to the provisions of the applicable laws and regulations, representatives of the Member Company should provide Healthcare Professionals with precise and complete information about the *in vitro* diagnostic medical devices they promote under the terms of the respective instructions of use.
6. Representatives should convey to the Member Company any information they get on the use of the *in vitro* diagnostic medical devices they promote, especially regarding incidents.
7. Member Companies and their representatives should ensure that the frequency, scheduling and duration of the visits to Healthcare professionals, pharmacies, hospitals or other health facilities, as well as the way they are conducted, are in accordance with the ethics, the Code of Ethics and the legislation and other provisions in force.
8. Member Companies' representatives should not turn to incentives or pretexts to arrange for an interview.
9. During an interview or at the time of arranging for one, Member Companies' representatives should ensure they do not lead Healthcare Professionals of health institutions into error as to their identity or the identity of the Member Company they represent.

## Article 32

### Non-interventional studies of marketed medicinal products or *in vitro* diagnostic medical devices

1. A non-interventional study of a marketed medicinal product is defined as a study where the medicinal product(s) is (are) prescribed in an usual manner according to the provisions of the market authorization. The indication of a patient for a specific therapeutic option is not previously decided by a protocol for a clinical trial, but by the current clinical practice and the prescription of the product is clearly separated from the decision to include the participant in the study or not. No diagnosis or monitoring additional procedures should be used on the participants and only epidemiological methods should be used for the analysis of the collected data.
2. Non-interventional studies of marketed medicinal products or *in vitro* diagnostic medical devices involving the collection of patients' data through, or on behalf of, a Healthcare Professional, or a group of them, should comply with the following criteria:
  - a) The study must be carried out under a scientific objective;
  - b) A protocol to develop the study must be drawn;
  - c) A written contract must be signed between Healthcare Professionals and/or Institutions where the study will be developed and the study's sponsor, in which the nature of the services to be provided and the reasons for those services to be paid should be specified;
  - d) The payment should be reasonable and reflect the market value of the carried out work;
  - e) The protocol of the study must be submitted and approved by the respective Health Ethics Committee;
  - f) Member Companies should comply with the legislation in force on personal data protection;
  - g) The study should not be an incentive for the recommendation or prescription of a specific medicinal product;



- h) The protocol of the study should be approved by the scientific department of the sponsor and the study development should be supervised by the same department;
  - i) The results of the study should be analysed by the sponsor and the summaries resulting from the study should be made available to the researcher as soon as possible;
  - j) The records of the reports should be kept for the legal period of time;
  - k) The sponsor should send the executive summary to the Healthcare Professionals who took part in the study and to the self-regulatory bodies of the Pharmaceutical Industry, if so required. In case the study reveals important results for the risk-benefit assessment, the executive summary should be immediately sent to the competent authority.
3. Whenever applicable Member Companies are encouraged to comply with the standards included in no. 2 for all the other sorts of studies covered by this article, including epidemiological records and studies and other studies of retrospective nature.

## CHAPTER 5. TRANSPARENCY

### Article 33

#### Disclosure obligation

Member Companies should publicly disclose any benefits in kind or pecuniary benefits they directly or indirectly grant to a Healthcare Professional or to an institution, organization or association comprising Healthcare Professionals, as provided for by national legislation.

## CHAPTER 6. FINAL PROVISIONS

### Article 34

#### Offences against the Code of Ethics

1. The supervision of the application and compliance with this Code's provisions by Member Companies is incumbent on the Ethics Committee of APIFARMA, as laid down in its Regulation and the Association's articles of association.
2. Any action or omission that maliciously or culpably violates the obligations arising from the rules of this Code is considered to be an offence against it.
3. It is incumbent on the Ethics Committee to decide the existence or not of offences against the Code of Ethics and, in case of offence, to apply the corresponding sanction.
4. The sanctions applied by the Council of Ethics are:
  - a) Simple warning;
  - b) Reprimand;
  - c) Penalty up to the amount of five years membership fees.
5. The sanction applied, as well as the nature of the offence, should be published by APIFARMA.

### Article 35

#### Coming into force

This Code of Ethics should come into force on 1<sup>st</sup> January 2018.

Version approved in Special Session of General Assembly of 18<sup>th</sup> December 2017