CODE OF ETHICS FOR PROMOTION PRACTICES OF THE PHARMACEUTICAL INDUSTRY AND INTERACTION WITH HEALTHCARE PROFESSIONALS AND HEALTH ORGANISATIONS

PREAMBLE

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 the 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.

APIFARMA's Code of Ethics aims to encourage cooperation between pharmaceutical companies and the various entities in the health field, such as health professionals and health organisations, in order to work for the patient and thus promote access to better and more innovative therapies.

The Code of Ethics does not aim to restrict the promotion of medicinal products or *in vitro* diagnostic devices in a manner that harms free competition, but to ensure that member companies promote their products and services ethically in compliance with applicable laws and regulations, for the sake of the name and prestige of the Pharmaceutical Industry.

This Code of Ethics also strives for objective scientific information, allowing a rational and safe use of the medicinal products and *in vitro* diagnostic devices marketed by the Pharmaceutical Industry companies which are members of APIFARMA.

The aim is to create an environment in which the general public can be confident that choices regarding medicinal products and *in vitro* diagnostic medical devices are made on

the basis of the characteristics and benefits of each one and the clinical needs of the patients.

This Code incorporates the principles and standards included in the Codes of Ethics of the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations), EFPIA (European Federation of Pharmaceutical Industries and Associations) and MedTech Europe, and in national and EU legislation on the promotion of in vitro diagnostic medicines and medical devices.

This revision aims to align the wording of the Code of Ethics with that of the EFPIA, IFPMA and MedThec Codes in order to create a uniformity of regulated matters.

The self-regulation system allows APIFARMA and its member companies to define, implement, comply with and ensure compliance with the highest ethical standards, particularly those that constitute the *ethos* set out in the IFPMA and EFPIA Codes, which are assumed to be part of this Code, as well as the founding principles of the MedThec Europe Code, which can be summarised in the following principles:

1. The principle of the primacy of the patient in the activity of pharmaceutical companies - pharmaceutical companies focus their activity on the patient and contribute, through research, development, manufacture and marketing of medicinal products and *in vitro* diagnostic means, to their rational use and to the well-being of the patient;

2. The principle of integrity - companies are accountable for their decisions, actions and interactions with other stakeholders in the medicinal products and *in vitro* diagnostic medical devices' value chain and should ensure that their interventions and communications are accurate, legitimate, balanced and based on ethical principles and encourage all entities and individuals with whom they engage to follow the same high ethical principles and standards;

3. The principle of mutual respect and reciprocity - companies carry out their activity with all the stakeholders in society, respect the different opinions and decisions of each entity

and, in their decisions, comply with the laws and regulations in force, starting with the processing of personal health data;

4. **The principle of diversified financing** of health organisations of pharmaceutical companies to health organisations and other entities, as a way of safeguarding the independence and credibility of all parties;

5. **The principle of transparency** in all activities and relationships established, including disclosure of all benefits in kind or in cash (value transfers) provided to health professionals and health organisations.

The relationships of the Pharmaceutical Industry with Patients' Organisations, Patient Advocates, Patient Experts, Patients and Caregivers are governed by the Code of Ethics for the relations between the Pharmaceutical Industry and Patients' Organisations, Patient Advocates, Patient Experts, Patients and Caregivers and therefore refers to that Code for its discipline.

The rules set out herein were freely discussed and voluntarily accepted, binding all APIFARMA member companies.

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 medical devices and to the interactions between healthcare professionals, and Health Organizations carried out by pharmaceutical

companies members of APIFARMA (hereinafter referred to as member companies), directly or with the intervention of other entities based on general principles of patient first, integrity, mutual respect and reciprocity, diversified financing of Health Organisations and transparency.

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 Patient Advocates, Patient Experts, Patients and Carers.

Article 2

Definitions

For the purpose of this Code of Ethics it is understood that:

(A) **Practical education and training action**: aims at providing practical education and training on the safe use of medicines and *in vitro* diagnostic medical devices or related services. The training may be organized by the company itself or by third parties and is aimed at health professionals or others. Examples: demonstration of machine operation; demonstration of new technique; hands-on training; demonstration of medicinal product administration, through or without medical device.

B) **Support**: a contribution, financial or in kind, granted by a company to a natural or legal person, for a specific purpose of its initiative and responsibility, without any compensation for the company.

C) **Personal benefit**: any benefit, regardless of its amount, which is not related to a legitimate activity under the terms set forth in APIFARMA's Code of Ethics or in the legislation in force.

D) **Service provision contract**: contract by which one of the parties undertakes to provide the other with a certain result of its intellectual or manual work, with or without remuneration.

E) **Personal Health Data**: any information, including that obtained through health service providers, relating to the physical, mental or genetic characteristics of an identified or identifiable natural person, as well as to his or her physiology or state of health which in any way or form allows an individual to be identified.

F) **Member companies**: companies associated to APIFARMA that market prescription only medicinal products, over-the-counter medicinal products and *in vitro* diagnostic medical devices;

G) **Event companies**: Companies contracted by pharmaceutical companies or health organizations to organize an event.

H) **Events**: All professional, promotional, scientific, educational meetings, congresses, conferences, symposia, training and education events and other similar events (including, but not limited to, advisory boards, factory and research and development facilities' visits, researchers' meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a member company.

I) **Scientific or educational event:** event aimed at conveying scientific knowledge on health and/or pathologies and/or providing professional education or training in areas related to the activity of the health professional. The event can be organised by the company itself or by third parties and is aimed at health professionals.

J) Promotional Event: event aimed at promoting products. The event can be organized by the company itself or by third parties and is aimed at healthcare professionals.

K) Hospitality: logistic support granted by pharmaceutical industry companies to health professionals or representatives of health organizations to participate in events and activities organized by the companies themselves and/or by third parties, namely by supporting the cost of meals, travel, accommodation and registration.

L) Health Organizations: legally established corporate bodies, regardless of their form of incorporation, which may or may not comprise health professionals, engaged in the provision of health care, research, teaching and scientific activities, with the exception of Patient Associations, such as hospitals and clinics, public and private, scientific societies, foundations, medical associations, universities and other teaching institutions, professional associations in the health field.

M) **Interactions with health care organizations**: any type of relationship established between a Pharmaceutical Industry company and a health care organization,

N) **Interactions with health care professionals**: any type of relationship established between a pharmaceutical company and a health care professional. In these interactions the promotion of medicinal products and *in vitro* diagnostic medical devices requiring the intermediation of a health care professional is permitted.

O) **Items of medical utility:** objects intended for the provision of health care to the patient, not related to the promotion of medicinal products, which are relevant to the activity of the healthcare professional and which may contribute to assisting the patient in the administration of the medicinal product and/or the management of the illness. These items must not constitute a personal benefit for the healthcare professional nor correspond to items that the healthcare professional normally purchases in the course of his daily professional activity (e.g. office supplies, gloves, stethoscopes, sphygmomanometer).

P) **Venue:** space where the event is organised (e.g. hotel, congress centre).

Q) **Location:** geographical area where the event is organized (e.g. city or town).

R) Gifts: benefit in kind that does not configure an item of medical utility, informative or educational material. Promotional gift is a good in kind granted for promotional purposes (which does not include promotional materials as defined in Chapter II).

S) Partnerships: collaboration between one or more member companies and one or more, health organizations for the development of a specific project (event or other activity), of the responsibility of both parties, limited in time and scope of activity. In a partnership the parties have specific and documented responsibilities and derive a legitimate benefit from the implementation of the project.

T) **Sponsorship:** a contribution, financial or non-financial, granted by a company to a corporate body, for a specific purpose, with a compensation (promotional or other).

U) **Health Professional:** the person legally qualified to prescribe, dispense or administer medicinal products, namely medical doctors, dentists, veterinary doctors, odontologists, pharmacy technicians, pharmacists or nurses. In the field of *in vitro* diagnostic medical devices, health professionals are also, in addition to those referred to, diagnostic technicians and laboratory technicians who, in the course of their professional activities, may directly or indirectly prescribe, recommend, administer, use, supply, order or decide on the purchase or rental of *in vitro* diagnostic medical devices or related services.

V) **Personal services to health professionals:** any sort of service outside the profession which confers a personal benefit to the health professional.

Article 3

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 health organizations 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 Portuguese 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 healthcare organizations.
4. Member companies should ensure that the companies of the economic group to which they belong to 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. The provisions of article 24, no. 2, should be exempted from the application of the preceding paragraph

Article 4

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 rules 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 make 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 final form and that they consider they are in compliance with the requirements of the Code of Ethics and with the legislation and other rules in force, including those regarding advertising;
   b) are in accordance with the summary of the medicinal product's 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 rules in force are complied with.

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

Article 5

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.
2. Promotion of prescription only medicinal products is only allowed to health professionals.
3. Promotion of medicinal products should comply with the summary of the medicinal product's characteristics.
4. 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.
5. The direct distribution of medicinal products to the public is forbidden.
6. The word "safe" should never be used to describe a medicinal product.
7. The word "new" should not be used to describe a medicinal product a presentation, a therapeutic indication or another characteristic of the medicinal product, which has been available in the market for more than one year.
8. No medicinal product should be presented mentioning that it has no side-effects, toxicity, addiction or dependency risks.
9. 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.
10. Promotion should not be deceitful, subliminal or hidden.
11. 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.

12. 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 6

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 describe 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 devices and should be carried out for scientific or educational purposes.

Article 7

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.
2. The information included in promotional material must be accurate, up-to-date, verifiable and described in a sufficiently comprehensive manner to enable the recipient to have a

correct idea of the therapeutic value of the medicinal product or of the value of the *in vitro* diagnostic medical device.

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) not lead to any incorrect or unclear 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 efficiency and safety 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's characteristics.
6. Promotion should encourage the rational use of medicinal products or the safe use of *in vitro* diagnostic medical devices presenting them in an objective manner without overstating their properties.
7. All elements included in promotional materials, including charts, pictures and tables of studies, should: a) clearly mention the exact source or sources of the promotional features; 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 8

Promotion among 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 among 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 among 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 among the public should not include any aspect which:
   a) leads to conclude that the medical appointment or the surgical procedure is unnecessary, in particular by suggesting 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 are concerned;
   f) is exclusively or mainly addressed to children;

g) refers to a recommendation from scientists, healthcare professionals or another person who, due of their celebrity, may encourage the consumption of medicinal products or in *vitro* diagnostic medical devices;

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 anamnesis, lead to a false 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 9

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 essential information compliant with the summary of product's characteristics, stating the date when the latter were 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 10

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 11

Comparative advertising

1. Comparative advertising of medicinal products and *in vitro* diagnostic medical devices is only permitted among 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 information included in the respective summary of products characteristic, or the respective instructions for use and technical documentation or on credible scientific data or objective features, such as the price of the medicinal products or *in vitro* diagnostic medical devices.

Article 12

Dissemination of information to Healthcare Professionals

1. Information regarding prescription only medicinal products and *in vitro* diagnostic medical devices which require the mediation of a health professional should only be addressed to health professionals.
2. The healthcare professionals' databases must always be 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 13

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 and the promotion rules provided for in this Code.
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 14

Interdiction of advice on personal medical matters

1. Member companies marketing medicinal products or *in vitro* diagnostic medical devices cannot respond to general public requests for advice on personal medical matters and should refer these requests to a healthcare professional.
2. Excluded from the provisions of no. 1 is the possibility for pharmaceutical companies to respond to requests for clarification on the medicinal product within the scope of the information included in the package leaflet and Labelling and, in this situation, the consultation of a health care professional should be recommended.
3. Member companies should guarantee the confidentiality of possibe conveyed clinical data.

Article 15

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 trademark or the trademark of the *in vitro* diagnostic medical device.
4. If with the promotional gifts, additional information on the medicinal product is provided, this information must be compliant with the provisions of article 8, no. 1 of this Code.
5. Promotional gifts should not be an incentive nor a compensation to recommend, prescribe, purchase, supply, dispense, sell, administer or use medicinal products or *in vitro* diagnostic medical devices.

Article 16

Information or educational materials and items for medical use

1. The member companies may provide health professionals with information or educational materials intended for the training of health professionals provided that, cumulatively, they are of low monetary value, relevant to the practice of their professional activity and directly benefit the provision of healthcare to the patient.

2. Member companies can provide healthcare professionals with items for medical use aimed at the provision of healthcare to the patient as long as they are of low monetary value, relevant to the practice of their professional activity and do not consist of a personal benefit for the healthcare professional nor correspond to items that the healthcare professional would normally purchase as part of his or her daily professional activity.

3. For the purposes of this article, "low monetary value" is understood as the value defined in existing national legislation.

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

Article 17

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 such 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 18

Events organized by health organizations

1. Member companies may support or sponsor scientific or educational events organized by health organizations, provided they respect the rules set up by this Code, namely articles 23 and 24, and by the legislation and other provisions in force.
2. Support or sponsorship of any event must be clearly announced prior to the commencement of and during the event and must be included in all event documentation, as well as all information material that may result from the event.
3. The compensation for event sponsorship, when applicable, must constitute a tangible benefit. The mere placing of the Company's logo on the event's publicity materials or the receipt of written or verbal acknowledgements from the event organisers does not constitute a tangible benefit.
4. The member company granting support or sponsorship must retain all documentation relating to them for the legal period in force

Article 19

Events organised by events' companies

The rules provided for in this chapter, as well as the other rules of the Code of Ethics, in particular those relating to hospitality, apply to the organisation of events carried out by events' companies.

Article 20

e4ethics

1. Member companies should check for a positive evaluation on the e4ethics online event pre-assessment platform before sponsoring or supporting an event or supporting the participation of healthcare professionals within that event where the event:
   a) Is a European event organised by a Third Party
   (b) More than 500 (five hundred) healthcare professionals are participating;
   (c) The participating healthcare professionals come from at least 5 (five) different countries from among the countries covered by the EFPIA Code.
   (d) Events conducted exclusively by virtual means are outside the scope of this Article.
   e) The decisions of e4ethics are binding on the member companies.
   f) The member companies cannot support an event that has not been approved or has been qualified as non-compliant by e4ethics.

2. The submission of events for evaluation must be done proactively on the e4thics website by the event organiser, and member companies may also submit third party events for evaluation.

3. Paragraphs b) and c) of the previous number shall only apply to companies that promote and market medicinal products for human use.

4. Member companies that market *in vitro* diagnostic medical devices can only sponsor or support an event following a positive evaluation on the e4ethics online event pre-evaluation platform.

Article 21

Training activities on *in vitro* diagnostic medical devices

1. Member Companies marketing *in vitro* diagnostic medical devices may organize activities with the purpose of providing 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 providing training on the use of products or services, and the provisions of the previous article should apply adapted as necessary.

Article 22

Events' programme

1. The programme of events organized, supported or sponsored by member companies should be directly related to the professional activity of the participating 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. The events organized, supported or sponsored by member companies cannot include entertainment activities (for example, leisure, recreation or sports).

Article 23

Events' venue and location

1. Events organized, supported or sponsored by member companies should be held in suitable venues for the main purpose of the event and the venues should not be places and/or complexes which are known for their leisure, entertainment, sport or luxury and extravagance facilities.

2. The events 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.

Article 24
Hospitality

1. Hospitality granted in connection with events and training activities:

(a) should be restricted to the cost of meals, travel, accommodation and registration

b) should only be granted to health professionals who participate in the event as of their own right;

c) should not exceed the period between the day before the beginning and the day after the end of the event;

(d) should be restricted to the main purpose of the event

e) cannot include events of an entertainment nature (e.g. leisure, amusement or sporting events);

(f) should be of a reasonable level and not exceed what healthcare professionals participating in the event would be willing to pay for themselves;

(g) should not be provided as compensation for the time spent by the health professionals participating in the event

2. The cost of the meals provided to health professionals shall not exceed €60.00 in events taking place on national territory and €90.00 in international events, unless the country in which the event takes place has a different Code of Ethics or national legislation, in which case this amount shall apply, even if it is higher.

CHAPTER 4. INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND HEALTH ORGANIZATIONS

Article 25

General principles

1. Any interaction with healthcare professionals or organizations or associations comprising healthcare professionals must aim to support health care provision, research or professional/scientific training and should not constitute an incentive nor compensation to recommend, prescribe, purchase, supply, dispense, sell, administer or use medicinal products or *in vitro* diagnostic medical device.

Article 26

Prohibition to give 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 27

Financing health organisations

Companies should not request or require to be the exclusive financier or sponsor of a health organisation, or of any event or activity organised by it.

Article 28

Provision of services by healthcare professionals or health organizations

1. Member Companies may enter into service provision 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 medical/scientific studies, clinical trials, training programs, advisory boards and market research, or with health organizations comprising healthcare professionals.

2. The selection of healthcare professionals as consultants should be based on objective criteria related to their professional experience and scientific, clinical or technical knowledge. Member companies should ensure that their employees responsible for selecting healthcare professionals as consultants have the necessary knowledge and experience to ensure that selection is based on those criteria.

3. The service provision agreements referred to in paragraph 1 shall be made in writing prior to the beginning of the service provision, and should specify the nature of the services, their legitimate need and the payment conditions, when applicable.

4. The provision of services may be remunerated in so far as it is not in return for the prescription or dispensing of medicinal products or *in vitro* diagnostic medical devices. The remuneration should be reasonable and reflect the market value of the services provided. By agreement of the Parties, the provision of services may be free of charge.

5. In case a healthcare professional provides services as a speaker or moderator in an event the suitable provisions of articles 23 and 24 apply.

6. The number of selected healthcare professionals should not exceed the reasonable number of professionals required to achieve the identified purpose.

7. The Member Company should keep all records related to the services provided, for the legal timeframe in force.

8. 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.

9. Random 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 29

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, by a third party, or by events companies provided they respect the rules set up by this Code and by the legislation and other provisions in force, in particular those provided for in article 20.
2. Member companies marketing *in vitro* diagnostic medical devices may only directly support, in the form of hospitality under the provisions of article 27, the participation of Healthcare Professionals in scientific or educational events organized by the Company or in training activities organized by the Company, a third party or events companies provided they comply with the rules set up by this Code and by the legislation and other provisions in force, in particular those provided for in article 19.
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 and 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 provisions of article 27, 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 timeframe in force.

Article 30

Support to health organizations in the scope of continuous education

1. Member companies may grant support to health organizations 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 or by third parties.
2. The support mentioned 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 entered, 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 support granted in the scope of continuous training should be included in the promotional documentation relating to it
7. The member company that grants the support should keep all documentation regarding the latter during the legal term in force.

Article 31

Support and sponsorship of health organizations in the scope of health care provision or scientific research

1. Member companies may grant support and sponsor health organizations comprising healthcare professionals providing health care or engaged in scientific research with the purpose of supporting healthcare provision or scientific research or educational and/or training activities related to health.
2. The support and sponsorship mentioned 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 entered specifying the scope and purpose of the support and the conditions under which it is granted.
5. The support and/or sponsorship mentioned in the previous numbers may be financial or non-financial contributions.
6. When the support and sponsorship is a benefit in kind they should not bear the name or the logo of a medicinal product or *in vitro* diagnostic medical device.
7. Any support or sponsorship provided in connection with the activities carried out under this article should be included in any promotional literature concerning the former, as well as in any reports or information material disseminated or published after those activities have taken place
8. The member company that grants the support should keep all documentation regarding it during the legal term in force.
9. The support provided for in this article should not be granted to healthcare professionals individually.

Article 32

Partnerships between Companies and health organizations

1. Companies and health organizations may enter partnerships that are based on a legitimate and common interest and that are developed, planned and implemented with the input of the parties, and in accordance with their legitimate interests.
2. Partnerships may involve one or more member companies and one or more health organizations and should always be supported by a contract with detailed information on the project and the responsibilities assigned to each Party.
3. Partnerships can be established for the development of specific projects, with activities and tasks limited in time and assigned to each party.
4. For the development of the projects, a time schedule should be established with the implementation steps, regular checks on the fulfilment of the project and, at the end, a joint evaluation and final reconciliation of the activities and costs should be made.
5. Companies may bear the total direct costs of the project, not including costs associated with the operational expenses of the health organisations or others that are not associated with the said project.

Article 33

Use of logos and copyrighted materials

1. The use by a company of a logo, name and/or copyrighted materials belonging to healthcare professionals, healthcare organisations or a third party is subject to that third party's prior written consent.

2. The request for authorisation referred to in the previous number should clearly state the specific purpose and the way in which the logo, name and/or copyrighted materials are used by the Company.

Article 34

Medicinal products' samples

1. Member companies may provide, free of charge and under exceptional circumstances, to each healthcare professional qualified to prescribe four free samples, per year, of a specific medicinal product in response to a written request 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" and "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 35

Samples and demonstration products of *in vitro* diagnostic medical devices

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 written request, 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" and "not for sale", or similar indications, and should be labelled and accompanied by a copy of the instructions for use.

Article 36

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

1. Non-interventional studies of a marketed medicinal product or *in vitro* diagnostic medical devices are defined as studies where these products are prescribed in a usual manner according to the provisions of the market authorization. The indication of a patient for a specific therapeutic strategy 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 diagnostic 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 on medicinal products must be carried out with a scientific purpose and may not be used as an incentive for the recommendation, prescription or use of a medicinal product or *in vitro* diagnostic medical device.
3. 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) A protocol to develop the study must be drawn;

   b) The protocol must be submitted to and approved by the respective Health Ethics Committee(s);

   c) The development of the study should be supervised by the Company's scientific department

d) A written contract must be signed between the healthcare professionals and/or the 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;

e) The remuneration should be reasonable and reflect the market value of the carried out work;

f) Member companies should comply with the legislation in force on personal data protection;

g) The results of the study should be analysed by the sponsor and the summaries resulting from the study should be made available to the researchers, as soon as possible;

h) The records of the reports should be kept for the legal period of time;

i) The sponsor should send the executive summary of the study's report 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

4. Whenever applicable member companies are encouraged to comply with the standards provided for in nos. 2 and 3 for all the other sorts of studies covered by this article, including epidemiological records and studies and other studies of retrospective nature.

CHAPTER 5. REPRESENTATIVES OF MEMBER COMPANIES

Article 37

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 member 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 the 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 resort 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 38

Representatives of *in vitro* diagnostic medical devices

1. Each Member Company should guarantee that its representatives, regardless of their 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 other legislation and 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 other legislation and provisions in force, and member companies are responsible for their compliance.
4. Member company's 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, 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 all 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 resort 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

CHAPTER 6 - TRANSPARENCY

Article 39

Disclosure obligation

Member Companies should publicly disclose any benefits in kind or pecuniary benefits (value transfers) they directly or indirectly grant to a healthcare professional or to a health organization, as provided for by national legislation.

CHAPTER 7. FINAL PROVISIONS

Article 40

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 ethical offence against it.
3. It is incumbent on the Ethics Committee to decide on the existence or not of ethical offences and, in case of an offence, to apply the corresponding disciplinary 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 41

Coming into force

This Code of Ethics should come into force on 1st January 2023.

Version approved at the Special General Meeting of 25th November 2022