CODE OF ETHICS FOR PROMOTION PRACTICES OF THE PHARMACEUTICAL INDUSTRY AND INTERACTION WITH HEALTH CARE PROFESSIONALS AND INSTITUTIONS, ORGANIZATIONS OR ASSOCIATIONS COMPRISING HEALTH CARE PROFESSIONALS

Ethical issues should be, 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 changes as a result of the changes of national and community legislation and 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 our association is a member, as well as the experience of the Council of Ethics.
This version merges in a single body the previous version of the Code and the EFPIA Codes: Code of Ethics *on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals* and *Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations* approved in July 2013, integrating also the aspects regarding advertising of medicinal products according to Decree-Law no. 176/2006, of 30 August, as revised by Decree-Law no. 128/2013 of 5th September.

For the first time rules on information and promotion of in vitro diagnosis, clearly aiming at standardizing the ethical conduct of the companies associated of APIFARMA are included in the Code of Ethics. Ethical standards applying to information and promotion of over-the-counter medicinal products were also systematized.

The main goal of the Code of Ethics is to stand up for objective scientific information enabling a rational use of medicinal products and in vitro diagnosis marketed by the Pharmaceutical Industry companies associated with 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* diagnosis medical devices are made based on the characteristics and benefits of each of them and the patients' clinical needs.

This code also addresses a group of transparency rules aiming at disclosing the sponsorships and supports granted by the Pharmaceutical Industry companies to health care professionals and associations representing health care professionals and Patients, respectively.

APIFARMA Code of Ethics does not aim at restraining the promotion of medicinal products and in vitro diagnosis devices in such a way as to hinder free competition, seeking rather to ensure that member pharmaceutical companies engage in an ethical promotion, restraining from deceitful practices and potential conflicts of interest with health care professionals, whilst complying with applicable laws and regulations to the benefit of the name and prestige of the Pharmaceutical Industry.

The relations of Pharmaceutical Industry with Patients Associations are governed by the *Code of Conduct for the relations between Pharmaceutical Industry and Patients Associations*, for which reason its subject is referred to this 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 which represent the application to the promotion and marketing practices of over-the-counter and prescription only medicinal products and in vitro diagnosis medicinal devices and the interaction with health care professionals, based on suitable independence and transparency criteria in relating with health care professionals 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 fully 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 diagnosis 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 diagnosis 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 surveillance, 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 companies' institutional advertising, such as financial data, description of research and development programs and the analysis of normative developments affecting the society and its products.

g) the relations between Pharmaceutical Industry and Patients Associations.

Article 2

Pharmaceutical Company Staff

1- All staff and personnel under contract with third parties related to the preparation or approval of promotional materials or activities should be familiar with the requirements of the Code of Ethics and other applicable rules.

2- 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 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 non-interventional study has been examined and it is in compliance with all requirements provided for in this Code.

3- Companies marketing *in vitro* diagnosis medical devices should have a person in charge of the supervision of the promotional materials.

4- The professionals mentioned in nos. 2 and 3 have to declare that:

   a) They have examined the promotional materials in their finished form and consider they are in compliance with the requirements of the Code of Ethics and all the rules in force including those regarding advertising;

   b) They are in accordance with the summary of the product characteristics or the instructions of use and the technical documentation of the *in vitro* diagnosis medical devices; and

   c) They are a true and fair presentation of the facts on the medicinal product or the *in vitro* diagnosis medical device.

5- Each company should appoint at least one senior employee who shall be responsible for the supervision of the company and their affiliates, so as to ensure the Code of Ethics and the other rules are complied with.

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

Article 3

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. The promotion of medicinal products should comply with the elements identified in the summary of the 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 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. The 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 in newspapers or magazines, by one company, should not resemble independent editorial articles, and should be clearly identified as being of advertisement nature.

11. The materials regarding medicinal products and their uses, whether of promotional nature or not which are sponsored by a company should clearly display the name of the sponsor.
12. The studies or programs on the use of medicinal products, namely pharmacovigilance programs, post-marketing experiences and post-authorization studies may not be used as a disguised way of promoting a medicinal product and should be carried out for scientific or educational purposes.

Article 4
General rules for the promotion of in vitro diagnosis medical devices

1. An in vitro diagnosis medical device can only be promoted after having been assessed as to its conformity or after notification of the competent authority.
2. The promotion of in vitro diagnosis medical devices should be compliant with the instructions for use and the technical documentation.
3. The promotion should be adjusted to the recipient and made according to suitable ethical standards, so that the social value of the medicinal product can be disclosed and its special nature understood acknowledged.
4. Promotion should not be deceitful, subliminal or hidden.
5. Promotional materials published in newspapers or magazines, by one company, should not resemble independent editorial articles, and should be clearly identified as being of advertisement nature.
6. The materials regarding in vitro diagnosis medical devices and their uses, whether of promotional nature or not, which are sponsored by a company should clearly display the name of the sponsor.

Article 5

Promotion and its substantiation

1. The information on the characteristics of the medicinal products or in vitro diagnosis 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, 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 in vitro diagnosis medical devices.
3. The information included in promotional material or the one intended for the suitable use of the medicinal product or in vitro diagnosis 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 the product characteristics, the instructions for use and the technical documentation of the in vitro diagnosis medical device;

   b) be in accordance with the marketing authorization in the case of the medicinal products and according to the conformity assessment in the case of the in vitro diagnosis medical devices; and

   c) does not lead to any incorrect or wrong conclusions.
4. Scientific data supporting statements on the medicinal product characteristics or *in vitro* diagnosis medical device should be made available to health care providers 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. Companies don't have to provide substantiation regarding the validity of the elements approved in the summary of the medicinal product characteristics.
6. Promotion should encourage the rational use of medicinal products, or the safe use of in vitro diagnosis medical device introducing them in an objective manner without overstating their properties.

7. All promotional elements, including charts, pictures and tables of studies published and integrated in promotional materials 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 6

Promotion among the general public

1- Only the following items may be promoted among the general public:
   a) Non reimbursed over-the-counter medicinal products :
   b) In vitro diagnosis medical devices the use of which does not require the mediation and decision of a health care professional, as well as those authorized by law.
2- The promotion among the general public should be identified unequivocally as such, stating clearly it is a medicinal product or an in vitro diagnosis medical device.
3- Promotion among the general public should include, legibly, the information included in the legal system in force.
4- Promotion among 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 person's normal health condition may be improved by means of the use of the medicinal product or the in vitro diagnosis medical device:
   d) Suggests that the person's normal health condition may be impaired in case the medicinal product or the in vitro diagnosis medical device is not used, except as

far as the vaccination campaigns approved by the competent authority is concerned;

e) Is exclusively or mainly addressed to children;

f) Refers to a recommendation from scientists, health care professionals or other persons, who, because of their celebrity, may encourage the consumption of medicinal products or in vitro diagnosis medical device;

g) suggests the medicinal product or *in vitro* diagnosis medical device is food, cosmetic or personal hygiene products, or any other consumption product;

h) suggests that the safety or efficacy of the medicinal product or in vitro diagnosis medical device is due to the fact that it is a natural product.

i) Could, through a detailed description or representation of the patient history, lead to an erroneous self-diagnosis;

j) Refers, in improper, alarming or misleading terms to claims or guarantees of recovery;

k) Uses in improper, alarming or misleading terms representations of changes in the human body or parts of the human body, caused by diseases or injury or of the action of a medicinal product or in vitro diagnosis medical device

Article 7

Promotion of prescription only medicinal products among health care professionals

1. All promotional materials regarding prescription only medicinal products should include, in a clear and legible way, the following:

   a) The trade name or the international non-proprietary name of the medicinal product;

   b) Duly referenced information, compliant with the summary of the product characteristics, stating the date when the later was prepared or reviewed the last time;

   c) The classification of the medicinal product according to the dispensing scheme;

   d) The reimbursement scheme;

e) 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 8

Promotion of in vitro diagnosis medical devices

The in vitro diagnosis medical devices requiring mediation or decision of a health care professional may only be advertised or publicised in technical publications or information materials intended and accessible to physicians and other health care professionals.

Article 9

Comparative advertising

1. Comparative advertising of medicine products and *in vitro* diagnosis medical devices is only permitted among health care professionals.
2. Comparisons among different medicinal products and *in vitro* diagnosis 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* diagnosis medical devices can only be made based on the elements included in the respective summary of the products characteristics, or the respective instructions for use and technical documentation, or on credible clinical data.

Article 10

Dissemination of promotion

1. Information regarding prescription only medicinal products 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 use of faxes, email, automatic call systems, text messages and other means of electronic communication are allowed only with the previous authorization or request of the health care professional.

3. The lists to send correspondence have to be always updated, and should be prepared according to national law in force. The health care professionals' requests to be removed from promotional mails lists should be respected.

Article 11

Promotion on the internet

1. Internet promotion of medicinal products or in vitro medical devices should be based on technical, scientific and professional principles, and in compliance with the national legislation of force.
2. Companies should adopt such measures so as to guarantee that the promotion of prescription only medicinal products or in vitro medical devices requiring a health care professional's mediation or decision is accessed only by health care professionals.

Article 12

Interdiction of advice on personal medical matters

1. Companies which trade on medicinal products or in vitro diagnosis medical devices cannot respond to general public requests for advice on personal medical matters, and should refer these requests to a health care professional.
2. Companies should guarantee the confidentiality on possibly conveyed clinical data.

Article 13

Gifts and other benefits

1. No gifts, prizes, bonuses, cash benefits or benefits in kind can be given, offered or promised to health care professionals, except for the provisions of article 21.
2. Notwithstanding the provisions of the previous number, within the scope of the promotion of over-the-counter medicinal products and in vitro diagnosis, gifts or benefits in kind may be given, offered or promised to health care professionals only if they have a low cash value and are relevant for the practice of medicine or pharmacy and/or involve a benefit for the patient.

3. According to the provisions of the previous number gifts may only include the 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 diagnosis medical device. If gifts are aimed at providing additional information on the product this information has always to be compliant with the provisions of article 7 no. 1.
4. For the purposes of the provisions of number 2, low cash value should be understood as a value not exceeding twenty five Euros.
5. Gifts for the health care professionals' personal benefit, such as tickets for entertainment events, should not be given.

Article 14

Medicinal products samples

1. Following a request in writing, dated and signed by a health care professional that is qualified to prescribe, a reasonable number of samples may be provided to the latter, in order to make him familiar with the product and acquire the necessary experience to use it during a period and in a quantity legally provided .
2. Each health care professional qualified to prescribe should receive, per year, no more than four free samples of a specific prescription only medicinal product.
3. The provision of free samples is only permitted within the two years after the date when the medicinal product starts to be effectively marketed.
4. Companies should have control and accounting systems in place for all the samples they dispense regarding all medicinal products handled by their representatives.
5. Samples cannot be larger than the smallest marketed package.
6. Samples should display the mention of "free medical sample – not for sale" or words with the same purpose and should be accompanied with a copy of the summary of the product characteristics.
7. Samples should not be provided as an incentive for the prescription or administration of a medicinal product.
8. No samples of the following medicinal products should be provided:

a) medicinal products containing such substances defined as psychotropic or narcotic substances by an international convention, such as the United Nations Convention of 1961 and 1971;

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 15

Samples of in vitro diagnosis medical device

1- Following a request in writing, dated and signed by a health care professional that is qualified to prescribe, a reasonable number of samples may be provided to the latter, in order to make him familiar with the *in vitro* diagnosis medical device, and to acquire experience to use it.

2- Companies should have control and accounting systems in place for all the samples they dispense.

3- Samples should display the mention of "free medical sample – not for sale" or words with the same purpose and should be labelled and accompanied by a copy of the instruction for use.

4- Samples should not be provided as an incentive for the prescription nor the use of an *in vitro* diagnosis medical device.

CHAPTER 3 – PROMOTIONAL, SCIENTIFIC OR EDUCATIONAL EVENTS

Article 16

Promotional, scientific or educational events

1. Pharmaceutical Industry companies may organize promotional, scientific or educational events with the purpose of promoting their products or conveying scientific knowledge, provided they respect the rules set up by this Code and other applicable national legislation.
2. All printed, audiovisual or computerized information material that may result from these events should reflect accurately the communications and discussions held there.

Article 17

Event venue

1. The events mentioned in the previous article should be held in suitable venues for the main purpose of the event and the venues should not be places and/or tourism complexes which are known for their leisure, entertainment or sport facilities.
2. The events 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 resources or relevant knowledge which are the object or topic of the event.
3. When the events are held in another country ("international events") the following rules should be complied with:

   a) regarding the promotion of prescription only medicinal products, the rules of the Code of Ethics in force in the country where the promotion takes place, except if the rules of the Code of Ethics of the home country of the company which organizes or sponsors the event are stricter, in which case the latter should apply.

   b) regarding the interactions with health care professionals within the scope of that event, the rules of the Code of Ethics in force in the country where the health care professional works, except for the provisions of article 18 no.5.

Article 18

Hospitality

1. Hospitality provided for promotional, scientific or educational events, should be limited to travel, meals, accommodation and registration costs.
2. Hospitality:

   a) should be restricted to the main purpose of the event.

   b) may only be provided to health care professionals which are participants in their own right;

c) should not be conditioned to the obligation of prescribing any medicinal product or *in vitro* diagnosis medical device;

d) should not be provided as a compensation for the time spent by the health care professionals when participating in the events;

e) should not exceed the period between the day prior to the beginning of the event and the day after the end of it;

f) should be of a reasonable level and should not exceed what health care professionals attending the event would be willing to pay for themselves.

g) cannot include the sponsorship or the organization of events of an entertainment nature (e.g. leisure, entertainment or sports events).

3. The social aspects which may exist in parallel may not coincide with any work meeting.
4. The payment of fees and the reimbursement of expenses regarding hospitality to the speakers and moderators of the events are considered to be suitable.
5. The cost of the meals provided to health care professionals should not be greater than € 60.00 in national events 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.

Article 19
Sponsorship of events organized by third parties

1. A sponsorship is understood as a financial or non-financial contribution granted to a third party for a specific purpose and which requires compensation.
2. Pharmaceutical Industry companies may sponsor third parties events, provided the rules established by this Code are complied with, namely articles 17 and 18 and the other applicable legislation.
3. The sponsorship should be preceded by a written request of the beneficiary entity, dated and signed, addressed to the company which grants the sponsorship.
4. The sponsorship of any event should be clearly announced prior to its beginning and for its duration.

5. The company granting the sponsorship should keep all documentation regarding it.
6. The sponsorship granted cannot be an incentive, nor the contribution for the recommendation, prescription, purchase, supply, selling or administration of medicinal products, nor the use, prescription, dispensing, selling, purchase or the consumption of *in vitro* diagnosis medical devices.

CHAPTER 4. INTERACTIONS WIH HEALTH CARE PROFESSIONALS AND INSTITUTIONS, ORGANIZATIONS OR ASSOCIATIONS COMPRISING HEALTH PROFESSIONALS

Article 20

Granting Support to health care provision or scientific research

1. Pharmaceutical Industry companies may provide support to institutions, organizations or associations of Health Professionals providing health care or are engaged in research if:

   a) they are made with the purpose to support health care provision or research;

   b) they are preceded by a written request of the beneficiary entity, dated, signed and addressed to the donor;

   c) they are documented and recorded by the donor;

   d) they are not an incentive nor the contribution to the recommendation, prescription, purchase, supply, sale or administration of certain medicinal products, nor the use, prescription, dispensing, selling, purchase or the consumption of *in vitro* diagnosis medical devices.
2. The supports mentioned in the previous number may be financial or non financial contributions.
3. When the supports are benefits in kind they should not bear the name or the logo of a medicinal product.
4. No supports should be granted to health care professionals individually.

Article 21

Informational or educational materials and items of medical utility

1. The Pharmaceutical Industry companies may supply informational or educational materials to health care professionals, provided that they are, simultaneously, of low cash value, relevant for the practice of their professional activity and bring direct benefits to the provision of health care to the Patient.
2. The Pharmaceutical Industry companies may give to health care professionals items of medical utility intended for the health care professional's education and the provision of health care to the Patient, provided they are of low cash value, are not for the health care professional's personal benefit nor correspond to items the Health Professional usually purchases within the scope of his/her daily professional activity.
3. The supply of informational or educational materials and items of medical utility mentioned in the previous numbers may not be an incentive to the prescription, purchase, and administration or dispensing of medicinal products or a way of compensation for the latter.

Article 22

Consultants

1. Pharmaceutical companies are allowed to hire health care professionals such as consultants to participate, among others, in lectures, meetings, take part in medical/scientific studies, clinical trials, training programs, follow up of counselling and market research committees.
2. The participation of consultants should be rewarded.
3. In situations provided for in no. 1 a written contract or written agreement should be signed between the companies and the health care professionals before starting to provide the services, which should comply with the following criteria:

   a) specify the nature of the contract or agreement and the terms of payment of the provided services;

   b) identify clearly, the services to be provided and the legitimate need for the services.

4. The criteria to select the consultants should be directly related with the need identified in the previous number, and the people in charge of their selection should have the required experience and knowledge to evaluate if the mentioned health care professionals meet the established criteria.
5. The number of selected health care professionals should not exceed the reasonable number of professionals required to achieve the identified purpose.
6. The contracting company should keep all records related to the services provided by the health care professionals.
7. The recruitment of a health care professional as a consultant should not result in an incentive nor compensation or to recommend, prescribe, purchase, supply, selling or administration of medicinal products, or the in vitro diagnosis medical devices.
8. The obligation of the health care professional to identify himself/herself as a company's consultant, whenever he/she writes or lectures in public on subjects which are the object of the contract or agreement, or even on any subjects related to the company, should be included in any contract or agreement signed between the company and the health care professionals, both in the scope of this article or the scope of an employment relationship.
9. In case a health care professional is attending a national or international event as a consultant, the suitable provisions included in articles 17 and 18 apply.
10. Limited market studies, such as phone interviews or questionnaires sent by mail /e-mail/internet, are excluded from the scope of this article provided the health care professional is not consulted in a recurrent manner and the payment for the service is suitable and not excessive.

Article 23

Non-interventional studies of marketed medicinal products

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 means of an evaluation with a clinical

trial protocol, but by the current clinical practice and the prescription of the medicinal product is clearly separated from the decision to include the participant in the study or not. No diagnosis or additional monitoring 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 involving the collection of patients' data through, or on behalf of, a health care professional, or a group of them, should comply with the following criteria:

2.1. The study must be carried out under a scientific objective;

2.2. A protocol to develop the study must be drawn;

2.3. A written contract must be signed between health care professionals and/or Institutions where the study will be developed and the sponsoring company, in which the nature of the services to be provided and the reasons for those services to be paid should be specified;

2.4. The payment should be reasonable and reflect the market value of the carried out work;

2.5. The protocol of the study must be submitted and approved by the respective Health Ethics Committee;

2.6. The companies should comply with legislation on personal data protection;

2.7. The study should not be an incentive for the recommendation or prescription of a specific medicinal product;

2.8. 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;

2.9. 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;

2.10. The records of the reports should be kept for the legal period of time;

2.11. The sponsor should send the executive summary to the health care professionals who took part in the study and should make it available 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 the 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.

Article 24

Medical Sales Representatives

1.Each company should guarantee that its medical sales representatives, including personnel employed under a third party contract and other representatives of the company who visit health care professionals, pharmacies, hospitals or other health facilities in connection within the context of the promotion of medicinal products (individually a "medical sales representative") are familiar with the requirements of the Code of Ethics and all applicable provisions.

2. Medical sales representatives should be duly trained by 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 all applicable provisions, 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 health care professionals with a summary of products characteristics (SPC), or have it available for use.

6. Medical sales representatives should immediately convey to their 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. The companies and the medical sales representatives should ensure that the frequency, scheduling and duration of the visits to health care 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 all applicable rules.

8. Medical sales representatives should not turn to incentives or pretexts to arrange for an interview. During an interview or at the time of arranging for one, medical sales representatives should ensure they do not lead health care professionals of health institutions into error as to their identity or the identity of the company they represent.

Article 25

Commercial representatives of in vitro diagnosis medical devices

1. Each company should guarantee that its commercial representatives, including personnel employed under a third party contract and other representatives of the company who visit health care professionals, pharmacies, hospitals or other health facilities in connection within the context of the promotion of *in vitro* diagnosis medical devices are familiar with the requirements of the Code of Ethics and all applicable provisions.
2. Commercial representatives should be duly trained by companies and have enough scientific knowledge to be able to provide precise and complete information on the *in vitro* diagnosis medical devices they promote.
3. Commercial representatives should comply with all the principles of the Code of Ethics and all applicable provisions, and companies are responsible for their compliance.
4. Commercial 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, commercial representatives should provide health care professionals with a copy of the labelling and instructions of use, or have them available for use.

6. Commercial representatives should immediately convey to the manufacturer or the company they are bound to by contract, any information they get on the use of the *in vitro* diagnosis medical devices they promote, especially regarding incidents.
7. The companies and the commercial representatives should ensure that the frequency, scheduling and duration of the visits to health care 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 all applicable rules.
8. Commercial representatives should not turn to incentives or pretexts to arrange for an interview. During an interview or at the time of arranging for one, Commercial representatives should ensure they do not lead health care professionals of health institutions into error as to their identity or the identity of the company they represent.

CHAPTER 5. TRANSPARENCY

Article 26

Disclosure obligation

1. The Pharmaceutical Industry companies marketing medicinal products have, under the provisions of national legislation, to document and disclosure to the general public any information on any directly or indirectly granted subsidies, gifts, supports, sponsorships or any other sum, asset or right with cash value, to a health care professional or an institution, organization or association comprising health care professionals, according to the following articles.
2. The disclosure of the information mentioned in the previous number should be made individually, identifying the respective recipient.

Article 27

Disclosure Periodicity

1- The information disclosed on the value transfers shall have the previous year as a reference.

2- The disclosure of information mentioned in the previous number should be made annually until 30th June each year, unless some other more restrictive provision results from national law.

Article 28

Dissemination platform

The information mentioned in article 26 shall be disseminated through an electronic platform of public access.

Article 29

Personal data

The disclosure of information mentioned in article 26, which involves mentioning personal data should be compliant with the provisions of the personal data protection law.

CHAPTER 6. FINAL PROVISIONS

Article 30

Offences against the Code and sanctions

1. The implementation of the provisions of this Code should be supervised by the Council of Ethics of APIFARMA.
2. In the case a violation of the provisions of this Code is detected, the claim shall be sent to the Council of Ethics following the steps in the proceedings provided for in the Regulation of the Council of Ethics.

3. In the case of a violation of the provisions of the Code, the Association should ask the offender to immediately put an end to the irregular activity and to undertake, in writing, the obligation to not relapse in that practice.
4. The violation of the provisions of this Code by a company is considered as a disciplinary offence, and the applicable sanctions are provided for in APIFARMA Statutes.
5. The sanction applied, as well as the nature of the offence, shall be published by APIFARMA.

Article 31

Transitional Provisions

The provisions of article 13, no. 1 applies only as of 1st July 2014.

Article 32

Coming into force

This Code of Ethics shall come into force on 1st January 2014.

Version approved in Special Session of General Assembly of 09 December 2013