CODE OF CONDUCT

FARMINDUSTRIA

18th January 2019

FARMINDUSTRIA

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FARMINDUSTRIA

THE FARMINDUSTRIA CODE OF PROFESSIONAL CONDUCT

1. GENERAL PRINCIPLES

1.1 In order to comply with the provisions of statute law and the rules laid down by the Codes of Conduct of European and international federations of the pharmaceutical industry (EFPIA and IFPMA), Farmindustria has drawn up a Code of Professional Conduct in the form of a voluntary agreement underwritten by the pharmaceutical companies belonging to Farmindustria. The Code sets out to regulate relations not only between companies but also their relations with the scientific and healthcare sectors.
All member companies of Farmindustria shall accept and comply with the provisions of the Code of Professional Conduct.
The following are excluded from the scope of this Code:

- Activities aimed at releasing non-promotional information, general information about companies (such as direct information to investors or the press), including financial data and descriptions of research and development, provided that Healthcare Professionals are not present in significant numbers.
- Institutional events organized by pharmaceutical companies on issues that go beyond promotional information, which are of interest to a variety of individuals from all areas potentially affected, which are held in right locations and in which healthcare professionals are present in amounts not prevalent.

On these occasions, however, cannot be provided for healthcare professionals present any form of hospitality or travel unless exceptional initiatives that shall be approved in advance by the Supervisory Committee.

1.2. The Code represents the commitment of the industry not only to abide by specific laws in force but also to operate on the basis of transparent standards of conduct that regulate the various circumstances in which corporate activities take place.
The regulations constituting the subject matter of the Code of Professional Conduct have been drawn up in the general interest and to safeguard the prestige and honour of the pharmaceutical industry towards the state, public opinion, the medical profession and healthcare professionals in general.

1.3 The text of the code of professional behaviour shall be issued to all relevant public institutions, entrepreneurial organisations, professional associations and professional associations of healthcare professionals.

1.4 Observance of the code by the member companies of Farmindustria entails:

- compliance with the resolutions of the governing bodies passed in conformity to the Farmindustria's byelaws, the principles of fair competition and democratic principles and abstaining from initiatives in contrast with such resolutions;

– observance of fair competition between companies and in the management of all corporate operations, in all their various aspects, in such a way as not to harm the legitimate interests of others;

– the contribution of each company towards the defence of the good name of the pharmaceutical industry towards the public at large.

1.5 In performing its activities the companies shall not damage the image of competing companies or their products. The companies shall also be ethically and professionally responsible for the behaviour of their personnel and shall, therefore, issue them with appropriate internal directives to regulate their conduct when engaged on corporate business.

1.6 The jurisdiction and activities of the Supervisory Committee and the Jury are exclusively designed to secure compliance with the Code of Professional Conduct.

1.7 Companies operating in Italy that belong to multinational groups shall be held responsible for the behaviour of their parent companies and associate companies for invitations issued to Italian physicians to attend events held either inside or outside Italy whenever such behaviour infringes the provisions of the Code of Professional Conduct.

1.8 Promotional initiatives taking place in Italy, sponsored or organized by companies with head offices in Europe, are subject to the application of the Code of Professional Conduct of the country in which the pharmaceutical companies that sponsor these initiatives are based, and to the application of the Farmindustria's Code of Professional Conduct. Promotional initiatives taking place in Italy, sponsored or organized by industries that are based on non-European territory are subject to the EFPIA Code and to the Farmindustria's Code.
In case of conflict between the provisions of the various Codes, the provision will be more narrowly.

1.9 Unless stated otherwise, the Code refers to relations between each of the member companies and healthcare professionals. The latter shall be understood to refer to the various types of physicians, pharmacists, and healthcare directors as also technical and administrative personnel employed in public and private healthcare structures.

1.10 For purposes of the application of the provisions of this Code of Professional Conduct the term "general practitioner" shall refer to a generalist physician who provides general medical services on behalf of the National Health Service, independently of any specialist qualifications that he or she may possess.

1.11 The provisions of this Code that apply to the general practitioner shall also apply to hospital pharmacists.

1.12 Pharmaceutical companies shall not, either directly or indirectly sponsor (by hiring rooms, equipment, etc.) organisations with no national or international scientific standing or whose mission is unknown. This prohibition especially applies to medical practices run by partnerships among physicians.

1.13 By February 28th of each year member companies shall acquire and submit to the President of Farmindustria a certificate attesting to the observance of procedures governing marketing and scientific information activities in the preceding year. The attestation shall be issued by entities recognised by ACCREDIA (Italian Body Of Accreditation) and may provide, exclusively for companies belonging to the National Committee of the Small Industry the use of a simplified procedure according to the instructions of the respective Certification Bodies.

1.14 The provisions contained in this Code shall have no retroactive effect.

1.15 All the data where storage in hard copy is required by this Code, alternatively, it may be stored in electronic format as well. The provisions of the Chapter 5 of this Code stand unmodified.

2. DIRECT PROVISION OF SCIENTIFIC INFORMATION

General principles

2.1. Companies are responsible for the information and promotional actions conducted on their products even if arranged and/or performed by third persons (consultants, agents, agencies, etc.).

2.2 The information contents shall always be documented and documentable. Exaggerated statements, universal and exaggerated claims and indemonstrable comparisons without any objective basis are inadmissible.

2.3 The use of email, automated calling systems and other electronic communication means to divulge promotional material regularly approved by AIFA fax is prohibited, unless the company holds a prior written and documented consent of the physician to whom the material is addressed.

Verbal information imparted to physicians

2.4 When presenting information on medicinal products to healthcare professionals, medical sales representatives shall always qualify themselves and state the capacity in which they are acting.

2.5 Medical sales representatives shall not be engaged in healthcare or para-healthcare activities, or activities in any way connected to the use of drugs, neither on a gratuitous basis nor in any form of continuous gainful employment synonymous with that of a salaried worker.

2.6 Companies are responsible for training of medical sales representatives to provide information on the properties and characteristics of their drugs to healthcare professionals in a manner such as to allow them to be used for therapeutically correct purposes.

2.7 Companies will also be responsible for training of medical sales representatives to collect feedback on their drugs, as this is a means to ensure the fullest information on the products being marketed.

2.8 Medical sales representatives directed to provide scientific information on drugs shall also verify the presence of their products in pharmacies or in other point of sale and use their best efforts to ensure their traceability.

Information material

2.9 Where the scientific information is carried out using media computing facilities, mail or telephone, including through third persons, shall be fully respected the same regulatory provisions identified by the applicable law and the present Code on scientific information.

2.10 Apart from ministerial authorisations no omnicomprehensive statements are admissible such as "the preferred drug", "absolutely innocuous", "fully tolerated" or similar and no categorical assertions shall be made stating that a product has no collateral effects or toxicity risk.

2.11 Scientific citations shall accurately portray the meaning intended by the author(s).

2.12 The texts, tables and other illustrations taken from medical reviews or scientific works shall be reproduced faithfully and in full, and with an exact indication of the source. No citations are admissible that appear partial and/ or contradictory with respect to the author's intentions when separated from the context in which they originally appeared.

Promotional material

2.13 In the framework of information activities and the presentation of medicinal products to physicians or pharmacists no prizes, pecuniary advantages or rewards in kind shall be conceded, offered or promised. Promotional material concerning drugs and their use, sponsored by a pharmaceutical industrial enterprise shall have a perceivably negligible value, shall not be exchangeable and in any case shall be connected to the activities performed by physicians and pharmacists. This material shall also clearly indicate the company or the product of the sponsoring company.
The offer of any kinds of economic incentives designed to compensate healthcare professionals for time taken from normal professional activities in order to participate in congressional events is prohibited in all circumstances.
It shall also be guaranteed that all promotional material for physicians and pharmacists shall be acquired directly by companies through a centralised function.

Professional updating and scientific cooperation

2.14 Free information material for scientific or professional consultation not specifically connected to medicinal products may only be distributed to public healthcare structures unless the material in question has a perceivably negligible value, namely a value of less than 25 euros. Companies shall procure such material directly through centralised functions.

2.15 As concerns donations, gratuitous loans for use and gratuities involving instruments directly related to the medical profession, such offers may only be made in favour of university institutes, hospitals and clinics and in compliance with the administrative procedures of the entity concerned. Outside the scope of clinical trials are not allowed in respect of the above structures donations or gratuitous loans for use involving instruments fungible - with how to use different or alternatives to diagnostic or therapeutic - such as smartphones, tablets or similar to be allocated to doctors for personal use outside the facility or to be sold to patients.

Advertising in newspapers and magazines

2.16 In the ambit of newspaper and magazine advertising, companies shall comply with the rule of transparency and thereby accept, as an essential criterion, the net separation between information and advertising and hence guaranteeing the reader to be immediately able to recognise a promotional message, whatever its editorial or columnar layout.

Samples

2.17 Medical samples can only be supplied in response to a written request from physicians qualified to prescribe that particular medicine. Written request shall be signed, stamped and dated by physicians.
Medical Representatives cannot supply more than 2 medical samples per physicians/visit of each form or dosage up to a maximum of 8 samples of each for or dosage for 18 months starting from the date of first marketing. Medical Representatives can also supply not more than 4 samples per physicians/visit up to a maximum of 10 samples per year of products chosen among those in company's products list that have been on the market for more than 18 months.

3. CONFERENCE EVENTS, COMPANY LABORATORY VISITS, TRAINING COURSES AND INVESTIGATOR MEETINGS

General principles

3.1 Without prejudice to the statutory provisions in force on this question, the subject matter of these provisions shall be conventions, congresses and scientific meetings held to discuss themes, related in a variety of ways to the use of medicinal products, that provide an occasion for an industrial enterprise to meet healthcare professionals and entail addressing a number of participants.
The subject matter shall not include the so-called group interviews that shall, instead, be conducted, free-of-charge, directly on the premises of healthcare institutions or in medical surgeries where healthcare professionals perform their professional duties. No other circumstance is admitted. No form of hospitality can be offered within the framework of such initiatives (e.g. coffee-breaks, lunches, dinners).

3.2 With reference to the statutory provisions on the subject of the safeguarding of persons and other subjects in relation to the handling of personally-identifiable information (the law on privacy), a pharmaceutical company that intends to invite physicians to congresses, conferences, scientific meetings, refresher course and company laboratory visits shall, together with the professionals' acceptance, also acquire express consent to use their names and, where necessary, disclose these names to the Supervisory Committee, together with their date of birth and the indication of any specialisations acquired as well as proof of their compliance with the general and regional laws on the obligation to inform their reference healthcare structures of their participation in such sponsored visits to conference events. These requirements are exclusively for purposes of ensuring conformity to the Code of Professional Conduct and are limited to a specific conference or congress or the visit to a company laboratory. This provision is applicable only to company laboratory visits, not CME conferences, and CME refresher courses and conferences limited to cases of direct recruitment of doctors by pharmaceutical companies.

Failure to produce the documents indicated in the foregoing subsection by a company when requested by the Supervisory Committee of the Code of Professional Practice will automatically entail the referring the case to the Jury for the application of a possible sanction.

The forms used by healthcare professionals to express their consent to the handling of personally identifiable information shall be kept by the companies for a period of three years and may be used by the supervisory bodies specified in the Code of Professional Conduct and also for the purpose of verifying companies' compliance with the annual quantitative limits fixed under points 3.3, regarding the number of invitations permitted for each physician, as well as the percentages of actual participation by physicians under 40 years of age, in line with the requirements stated under the following point 3.11.

3.3 Participation in conference events by the companies shall be related to the role performed by the industries in the field of research, development and scientific information and shall be inspired by ethical, scientific and cost-effective criteria.

In this context the pharmaceutical companies may only offer economy-class air travel to Italian healthcare professionals invited to Italian conference events in Italy or abroad while the category of hotel accommodation shall not exceed four stars. In the case of rail transport is allowed all travel classes except for class Executive.

On the occasion of international conferences involving intercontinental flights longer than 6 consecutive hours of flight will be possible to offer the travel business class only for speakers and moderators included in the official program of the conference with the exception of those involved with the presentation of Posters.

In addition, companies may not invite a healthcare Professional to congresses, conferences, scientific meetings, refresher course and company laboratory visits more than twice a year. However, this restriction does not apply to speakers or moderators and the provision is applicable only to company laboratory visits, not CME conferences, and CME refresher courses and conferences limited to cases of direct recruitment of doctors by pharmaceutical companies.
Similarly, the limit shall not apply in the case of educational or training events concerned with specific pathologies, and taking place in concomitance with a public pronouncement by the World Health Organisation of potential healthcare crises higher than the IV alert level. In this case derogation from the limit can only refer to initiatives:

- exclusively designed to update physicians on the pathology;
- organised by public organisations;
- held on the premises of the foregoing public organisations;
- that have acquired ECM credits;
- that do not make provision for any kind of hospitality;
- for which prior information was sent to Farmindustria.

3.4 No meetings or congresses may be directly or indirectly organised by a company outside Italy if it is to be mainly attended by Italian physicians.

3.5 As concerns the choice of venue for meetings organised directly by a company, the latter shall provide the Supervisory Committee, in the course of an investigation, good scientific, organisational and logistic reasons for the choice of the locality.
In no event may scientific initiatives be organised that also serve tourist purposes. And 'forbidden organization or sponsorship of congresses that are held or which provide the hospitality of the participants in structures that, by the type of services offered, are in conflict with the principles of the Code of Conduct as may occur, for example, for: Resorts, Ships, Castles that are outside the urban context, Masseria Farms, Agritourisms, Farms, Golf Clubs, Museums, Stadiums, Aquariums, Health Spas or facilities that have as a main activity services dedicated to Wellness or Spa.

3.6 Invitations issued to physicians by pharmaceutical companies to attend conferences and congresses are subject to the condition that the theme of the congressional meeting shall be pertinent to the specialisation of the physicians who will attend.

3.7 The primary objective of the participation in or organisation of international, national and regional conferences and congresses shall be to promote scientific cooperation between physicians.

The Conference venue

3.8 Events organised directly or indirectly by pharmaceutical companies shall be held in places and venues chosen for logistic, scientific and organisational reasons, which shall exclude venues in catering or restaurant facilities and they shall be characterised by a scientific programme that qualifies the event as an expert meeting. The participants invited to meetings shall be chosen on an international, national, interregional, regional or local basis. Places with tourist vocation are rigorously prohibited in the periods June 1st - September 30th, as concerns seaside resorts and from 1 December 1st- March 31st and July 1st - August 31st , as concerns mountain resorts.
The Italian places that are on the sea and which are Regional Capitals or Province, headquarters also Universities and major Hospitals, are exempt from this prohibition. This, provided that the congress and the hospitality of the participants are concentrated in the urban context of the capital with the exclusion, however, of structures that are close to sea-equipped and accessible for bathing.

Regional events and scientific meetings at the local level

3.9 Regional events and scientific meetings at the local level are characterized by a geographical area of origin of the participants at the provincial level or the individual region. The events will have acquired CME credits and on this occasion may not be offered or hospitality except for the coffee break. For events that include a number of training hours than 6 may be offered a "light lunch" in the interval between the morning session and the afternoon session in the conference structure where the event takes place. Such events shall be held in locations such as hospitals, universities, foundations of scientific and conference rooms that ensure scientific dignity.

The interregional events

3.10 The interregional events are characterized by a 'balanced representation of physicians from at least three regions and may not require more than an overnight stay. These initiatives follow the same rules laid down in this Code for national events.

International and national meetings

3.11 The Pharmaceutical companies, with regard to non-CME conferences in Italy or abroad organised by scientific societies or public or private institutions and entities as well as conferences in Italy directly organised by companies, shall endeavour to ensure that at least 10% of the physicians chosen by them to attend the meetings will be under 40 years of age. In any event the companies shall guarantee that, on a yearly basis, 10% of the physicians participating in such events will be under 40 years of age.

3.12 The involvement of companies in the hospitality offered to participants in congressional events cannot exceed a 12-hour time period prior to and immediately after the congress and such hospitality may not have characteristics such as to overshadow the technical-scientific characteristics of the event.

3.13 Any costs to be borne by the hospitality pharmaceutical companies may cover General practitioners, hospital pharmacists, pharmacists of the territory and, where applicable nurses, only in relation to CME events that are held in Italy.

3.14 In the context of conference meetings in or outside Italy it is forbidden to arrange or sponsor autonomous initiatives with social, cultural or tourist purposes, including gala dinners. Social dinners organised by the conference for the participants as a whole are allowed and shall be included in the inscription fees for the conference.
No hospitality of any kind or form can be offered to companions of the persons invited.

3.15 Non-CME Conference events organised at a national level by pharmaceutical companies may not, in terms of their proceedings, last less than six hours per day. The provision of this paragraph shall not apply to events organized directly by national and international scientific Societies.

3.16 Hospitality offered by pharmaceutical companies on occasion of congress events shall be limited to travel, accommodation and payment of the registration fees to the congress. During the days of the congress the hospitality offered may also include meals and drinks up to a threshold of 60 Euro per each Professional per meal for all events in Italy. As for events held abroad, referral shall be made to the amounts and thresholds mentioned in the relative country's Code of Professional Conduct, where applicable. In any other case, the limit remains fixed at 60 Euro also for events held abroad. The respect of the principle of sobriety shall, however, be guaranteed and the meal shall be offered preferably in the same hotel where the guests are staying or in contiguous structures.

Promotional materials used at the conference

3.17 During the conference events will be distributed gadget of negligible value and relevant to the profession of the doctor or the pharmacist with the exception of objects that recall graphically packaging of medicinal products. On gadgets will be written the name of medicinal products and / or the name of the active ingredient and / 0 the name pharmaceutical company

Updating and web-based training

3.18 The training and updating medical science made through the electronic instrument such as web meetings, e-meetings and similar events or FAD, cannot provide any form of hospitality and are not subject to any restriction in terms of the duration of the work.

Refresher courses

3.19 For medical - scientific refresher courses at any territorial level the same rules shall apply as those mentioned above for scientific congresses, conferences and meetings.

3.20 Companies are prohibited from organising or sponsoring the participation of professionals in refresher courses that do not have a medical or scientific character, such as foreign language, IT, or tax courses or similar initiatives. It's 'instead allowed the sponsorship of initiatives directed at healthcare professionals update identified in section 1.9 of this Code and relating to matters directly related to the

healthcare management directly related to the drugs, provided that they are take in Italy, are organized by qualified entities, to take place in venues hospital or university or at least capable of ensuring scientific dignity and be completed within the course of a day with a forecast of at least 6 hours of actual work. In these cases, companies will not be able to bear any burden of hospitality except for a light lunch. It 's also allowed the sponsorship of initiatives whose duration is more than just a day in the case of national level events organized by companies qualified in relation to the subject matter. In this case pharmaceutical companies may also support the costs of travel and hospitality to the participants with a maximum of one night. These initiatives are subject to the provisions of this Code relating to national events.

The satellite symposia

3.21 If pharmaceutical companies shall ensure the organization of satellite symposia in conjunction with conference events in Italy or abroad, shall be complied with current regulations and ethical rules on Conferences and Meetings and, where applicable, the rules of Continuing Education in Medicine. These initiatives will be implemented or in the main event, or in half a day before the start or following the end of it. If it starts in the afternoon the satellite symposium will be held in the morning of the same day or in the afternoon of the last day in the event that the main event will end at mid-day.

Visits to company laboratories

3.22 Healthcare Professionals may visit company laboratories on condition that appropriate time is dedicated to information-training within the framework of the visit, that the duration of the visit does not exceed the period of one day, that the hospitality offered is limited to a period of time not in excess of twelve hours prior to and immediately successive to the conclusion of the initiative and that its character shall not be such as to compromise the technical purposes of the visit. For such visits, pharmaceutical companies may only provide economy air travel and accommodation in hotels of no more than four stars. Moreover, no hospitality of any kind can be offered, in any circumstance, to any accompanying persons. The organisation of any type of social, cultural or tourist initiative, including gala dinners, is prohibited.

The Investigator meetings

3.23 The term Investigator Meetings shall refer to study meetings called by investigators for the purpose of pre-clinical, clinical or observational studies.
In the event that a company takes steps to organise specific Investigator meetings, such meetings shall comprise a number of participants proportionate to the number of centres involved in the study, address the formulation of a protocol to be filed at the local Ethical Committee or be attested to by the existence of a specific protocol filed with the local Ethical Committee, and have no promotional implications.

The duration of the initiative shall comply with a programme of work that excludes elements of tourism or recreation as well as hospitality for accompanying persons of any type.

The choice of the venue shall be made in compliance with the criteria fixed for the choice of conferences and congresses as well as the identification of the limits of hospitality. Do not allow the organization or sponsorship of initiatives that take place abroad where they concern studies involving mostly Italian centers or if you participate mainly Italian doctors.

Where to get the seat Investigator meetings are necessary intercontinental flights longer than 6 consecutive hours of flight will be possible to provide for participants traveling in business class. This possibility is not applicable to Investigator Meetings related to observational studies.

The initiatives of Professional Relations

3.24 PR initiatives with Healthcare Operators (such as business lunches and dinners) may be carried out by pharmaceutical companies only if the following conditions are met:

- a modest number of Operators generally no more than 6;
- company directors, possibly accompanied by an Area Manager or similar, with the absolute exclusion of operational territorial roles.

Such initiatives must, moreover, be inspired by the principles of sobriety and shall not be of a repetitive nature.

4. RELATIONS BETWEEN THE INDUSTRY AND THE SCIENTIFIC AND HEALTHCARE WORLDS

Scientific consultancy

4.1 Pharmaceutical companies may avail themselves of the cooperation of physicians as consultants for services such as rapporteurs and moderators at conferences or invite them to participate in observational studies or training and education services. Such forms of cooperation entail that the following criteria be fully complied with:

- A written contract shall be stipulated between the physician and the pharmaceutical company specifying the nature of the service offered. The need for the service in question shall be clearly identified and stated.

- The contract shall also stipulate that the consultant undertakes to disclose his or her relationship with the pharmaceutical company whenever he or she writes or speaks in public on the subject matter to which the cooperative relationship refers. The same obligation also applies in the event that the pharmaceutical company employs physicians on a part-time basis who are also practising medical professionals.

- The company is required to keep the documentation on the services offered by consultants for a period of at least 3 years.

- The consideration paid by pharmaceutical companies for the services provided shall meet cost-performance criteria and reflect the market value of such services. The initiative shall guarantee coherence and appropriateness in respect of the objectives pursued and shall be capable of being fully documented.

- The decision on such initiatives shall be reserved to the executive top management.

- Whenever journeys or any form of hospitality are provided, the provisions set forth under subsection 3 of this Code, concerning conferences and congresses, shall apply.

Scholarships

4.2 The collaboration between pharmaceutical companies and scientific world can also be activated through scholarships. In this case, the bags shall be designed to a project of considerable scientific interest with specific and measurable goals, and shall be subject to prior conclusion of a specific agreement with the facility where the beneficiary is active, in which are indicated all applicable requirements; shall have unique character and not normal not being able to repeat with the same structure with the same hospital or operating unit / Department before 3 years.
This time limit does not apply, therefore, in the case of different Operating Units / Departments, even if they belong to the same Hospital Structure. The decision-making aspect related to the granting of scholarships must be reserved for the company's top management.
Finally, pharmaceutical companies must publish, through their websites, by June 30th of each year, the list of scholarships awarded for each single centre, in the previous calendar year, together with the economic value of each individual loans.

Relations with scientific societies

4.3 Pharmaceutical companies may establish relations of cooperation with scientific societies and medical associations on condition that they serve the exclusive purpose of divulging scientific knowledge and improving professional knowledge and are undertaken with entities of proven reliability and national standing, and whose mission is well known.

Clinical trials and drug-related studies

4.4 In the phase immediately following the issue of marketing authorisations for medicinal specialities, only clinical trials authorised pursuant to the law governing such activities will be allowed.
Clinical studies, post marketing surveillance studies and surveys conducted after the marketing of a drug shall be exclusively conducted for scientific purposes.
The performance of observational clinical studies by pharmaceutical companies shall comply with the provisions laid down in the circular of the Ministry of Health of 2 September 2002, n° 6, and the resolution of AIFA of 20 March 2008 setting out the guidelines for the classification and management of drug observational studies.

The following criteria shall be met:

- A written contract shall be initially drawn up between the sponsoring company and the entities involved in the study and, in respect of the study, the company shall detail its characteristics and the nature of the work offered by the entities and /or the participating physicians.

- The study protocol shall be approved by the Corporate Scientific Service or by the head medical office which shall also make provision to ensure that the study is conducted in compliance with the law on privacy.

- Any remuneration provided for participating in the study shall meet cost-performance criteria and reflect the market value of the work performed.

- The study shall not contain elements such as to encourage or suggest the prescription or purchase of a particular medicinal product.

- Medical sales representatives may only be involved in observational studies in a logistical capacity, with the total exclusion of any economic or financial involvement on their part. Furthermore, their involvement, if any, can only take place under the supervision of the Corporate Scientific Service or the medical head office and shall be subject to appropriate prior training.

It shall be understood that a company shall, in any case, remain responsible for all activities related to these studies even if conducted with the assistance of third parties.

In case for the purpose of the study, carried out directly or indirectly by the companies, it is necessary to use electromedical equipment aimed exclusively at the study itself (such as holter, electrocardiograms and other telemedicine devices), the distribution to doctors of these instruments will have to be carried out through the body/bodies involved in the study (ASL, Universities, hospitals and institutions IRCCS) and its use shall be regulated under a special agreement between the company and such bodies. In any case, the use of the devices must be for a limited period of time, exclusively for the duration of the study. Re-use in subsequent immediate investigations, carried out by the company with the same bodies, is forbidden.

The effective withdrawal must be clearly documented and made available by the pharmaceutical companies if so requested by the Control Committee within preliminary investigation.

Always as part of these studies, it is not allowed to use IT tools (both hardware and software) unless the tool is absolutely essential to the conduct of the study and there is functional incompatibility between such tools and those used by the organizations where the study in question takes place, ie there is no risk of confusion between the data functional to the conduct of the study - or otherwise obtained during the same - with the date already present in the equipment used by these bodies. Such tools will, in any case, only be used for the purpose of the specific study for which it was intended.

The distribution to doctors of such hardware and software tools, must be carried out through the body/bodies involved in the study (ASL, Universities, Hospitals and Institutions IRCCS), and must be regulated as part of a specific agreement between the company and the aforementioned bodies.

The above mentioned material must, however, be returned to the Sponsor/Promoter at the end of the study with trace of effective return. The Control Committee may carry out specific checks to verify proper compliance with the provisions referred to in this paragraph.

Internet sites

4.5 Every internet site opened by an Italian company or a company operating in Italy that is addressed to the general public and Italian professionals, in addition to complying with the requisites laid down under the regulations and the pertinent laws in force, shall also guarantee that the sponsor, the source of all information set forth in the site, the designated recipients of such information and the objectives of the site are all clearly identified and/or specified. In all cases it shall be guaranteed that access to sections containing promotional information on the company's products shall be exclusively reserved to pharmacists and physicians.

Relations between Pharmaceutical Companies and Patient Associations

4.6 Any form of economic support, whether direct or indirect, by the pharmaceutical company towards a patent association shall comply with the following criteria:

- A specific and preliminary agreement aimed at regulating the amount

of financing and the reasons for its disbursement shall be reached. For this reason, each pharmaceutical company shall develop a standard internal procedure for the approval of this category of agreements.

- The public utilisation by a pharmaceutical company of the logo or material owned by a patient association shall be authorised in advance by the association. In order to acquire such authorisation, the objectives for, and the manner of, using the logo shall be clearly defined.
- Any form of sponsorship by the pharmaceutical companies vis à vis the patient associations shall be transparent and without promotional objectives.

- No company can request to be the sole financier of a patient association.
- In all cases in which journeys or other forms of hospitality are provided, the provisions set out under subsection 3 of the Code on conferences and congresses shall apply.

– Companies shall make publicly available on their own internet sites, at least for a period of 3 months coinciding with the first 3 months of each year, a list of Patient Associations to which it provides financial support, referred to the previous year, including the monetary value of financial support for each Association..

Contracts between companies and Patient association under which they provide any type of Services to companies are only allowed if such Services are provided for the purpose of supporting healthcare or research. Patient Associations may be engaged as experts and advisors for Services such as participation at advisory board meetings and speaker services.

A written contract or agreement shall be agreed in advance which specifies the nature of the Services to be provided and the basis for payment of those Services. A legitimate need for the Services shall be clearly identified and documented in advance of requesting the Services. The compensation for the Services shall be reasonable and not exceed the fair market value of the Services provided. Companies shall make publicly available each year a list of Patient Associations that they have engaged to provide contracted Services.

Patient Support Program

4.7 The Patient Support Program (PSP) is a healthcare program designed for the benefit of the patient in treatment with a drug with a marketing authorization: e.g. telephone and home support services therapy, therapy monitoring services, also through diagnostic activities, etc.).

The PSP must, however, guarantee the management of pharmacovigilance, privacy, the responsibility for the management of materials and the responsibility for compliance and labour law (it is not possible to outsource labour).

The corporate function that has the responsibility for decision-making of the PSP must not be commercial and must operate with the supervision of the company's compliance function.

Data collected in the PSP should only be used for the purposes of patient support. Any use for other purposes must be separately contracted, in compliance with the relevant legal and ethical provisions. The subject responsible for supporting the patient must be a doctor or a qualified operator with the necessary skills.

5. THE TRANSPARENCY OF TRANSFERS OF VALUE AMONGST PHARMACEUTICAL COMPANIES, HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Obligation of transparency

5.1 On an annual basis, each pharmaceutical company shall document and render public, by using the template that constitutes part of this code (att. 1) , all transfers of value carried out directly or indirectly to Healthcare Professionals and Organisations, as identified in the Definitions Attachment (att. 2). The disclosure of this data shall come about on an individual basis and any eventual disclosure in aggregate form, as per the following point 5.5, shall represent an exceptional circumstance.
Data shall be published on the company's website. Companies are required to keep, alternatively also in electronic format, the appropriate documentation for at least 3 years where it states that consensus has been requested from the Healthcare Professional on the disclosure of data. The verification on the existence of a policy aimed at the systematic acquisition of the above mentioned consensus' will be carried out annually and this is included in the activities of Certification as laid

down in point 1.13 of the general principles of the Code of Professional Conduct.

5.2 The exclusion of the obligation to disclosure is on transfers of value connected to OTC medicines and those related to promotional materials referred to in point 2.13 of this Code, to meals and drinks and to medical samples.

Method of application

5.3 The disclosure of the information connected to the transfers of value shall be carried out on an annual basis starting from 2016 with reference to economic data regarding 2015.
Pharmaceutical companies may indicate the transfers of value exclusively by choosing exclusively cash-based or accruals-based criteria. These criteria must be followed for a period of no less than 3 years.

The pharmaceutical companies shall disclose the transfers of value carried out during each year, within the first six months of the following year. The information shall remain public domain for a period of at least 3 years from the moment of disclosure. The companies shall, moreover, conserve, alternatively also in electronic format, the documentation to support the data disclosed for a period of at least 5 years and make it available also in detailed form to any requests from the Healthcare Professionals involved.

Applicability of the national Codes

5.4 The data regarding the transfers of value shall be disclosed in the state where the recipient has their own domicile and will be governed by the rules laid down in the Code of Professional Conduct of that state. When a company does not have a subsidiary or affiliate in the country where the recipient has their own domicile, the providing company shall, however, disclose the data regarding the transfers of value to that person according to the rules and regulations of the Code where the recipient is domiciled.

Disclosure of data on an individual and aggregate basis

5.5 Each pharmaceutical company shall disclose, on an individual basis for every recipient, the amount of the transfers of value carried out during the previous year with reference to:

a) expenses for the participation at conferences and congresses regarding registration fees, travel and accommodation (excluding meals and drinks);

b) expenses for consultancy and professional activities not otherwise covered in letter a), resulting from a specific contract between the company and individual Healthcare Professionals where the type of service is stated.

To this end, pharmaceutical companies shall do the utmost possible to obtain consensus from the Healthcare Professionals. If the Healthcare Professional does not give their consensus on data privacy, the company shall disclose the data on an aggregate basis.

If this is this case, for each of the categories listed in the previous letters a) and b), the following data shall be identifiable:

- the number of recipients on an absolute basis and as a percentage of the total recipients;
- the aggregate data attributable to those Healthcare Professionals;
- the percentage of the transfers of value as an aggregate of the total transfers.

5.6 Each company shall disclose the amount of the transfers of value carried out for each Healthcare Organisation, as laid down in the definitions in attachment 2 to this Code, during the previous year with reference to:

a) donations and grants (including free-of-charge leases) both in cash and benefits in kind;

b) direct or indirect contribution to congress events carried out through healthcare structures or third parties, including the sponsorship of doctors to conferences and congresses with the payment of the registration fees and the expenses of travel and accommodation;

c) economic transactions related to consultancy and professional activities resulting from a written contract between the company and the Institute/Organisation or Association that provide any type of service not covered in a) or b).

Duplication

5.7 In the case a transfer of value has been made to an individual Healthcare Professional indirectly via a Healthcare structure or third party, this data shall be disclosed on an individual basis where possible, and only once.

Research & Development expenses

5.8 The annual expenses that pharmaceutical companies incur for activities shall be disclosed in aggregate form. These include those related to planning and actuation of:

a) non-clinical studies, as defined in the Good Laboratory Practices;

b) clinical studies, as defined in the Directive 2001/20/CE;

c) observational prospective studies, according to point 4.4 of this Code, that involve the gathering of data on patients by individuals or groups of doctors.

5.9 Expenses related to Investigator Meetings, Advisory Boards or hospitality where they are connected to the activities according to point 5.8 above shall be disclosed on an aggregate basis.

Methodology

5.10 Each pharmaceutical company shall disclose a note summarising the methodology used to lay down data with reference to information regarding VAT, currency or possible fiscal aspects connected to the transfers of value in individual or aggregate form.

FARMINDUSTRIA

ATTACHMENT 1

		Full Name *(Art. 1.01)*	**HCPs:** City of Principal Practice HCO**s:** city where registered *(Art. 3)*	Country of Principal Practice *(Schedule 1)*	Principal Practice Address *(Art. 3)*	Unique country local identifyer *OPTIONAL* *(Art. 3)*	Donations and Grants to HCOs *(Art. 3.01.1.a)*	Contribution to costs of Events *(Art. 3.01.1.b & 3.01.2.a)*			Fee for service and consultancy *(Art. 3.01.1.c & 3.01.2.c)*		Transfers of Value re Research & Development as defined *(Art. 3.04)*	**TOTAL** *OPTIONAL*
								Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract		
INDIVIDUAL	HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP*** *(i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
		Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
		Aggregate amount attributable to transfers of value to such Recipients *- Art. 3.2*					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate) - Art. 3.2*					N/A	N/A	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of total transfers of value to individual HCPs *- Art. 3.2*					N/A	N/A	%	%	%	%	N/A	N/A
		% on total of Recipients *- Art. 3.2*					N/A	N/A	%	%	%	%	N/A	N/A
	HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO*** *(i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
		HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
		Aggregate amount attributable to transfers of value to such Recipients *- Art. 3.2*				*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate) - Art. 3.2*				*number*	*number*	*number*	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of total transfers of value to individual HCOs *- Art. 3.2*				%	%	%	%	%	%	%	N/A	N/A
AGGREGATE		***AGGREGATE DISCLOSURE***												
		N/A	N/A	N/A	N/A	N/A	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*TOTAL AMOUNT*	*OPTIONAL*

FARMINDUSTRIA

ATTACHMENT 2

DEFINITIONS RELATING TO POINT 5 OF THE CODE ON TRANSPARANCY OF THE TRANSFERS OF VALUE

Recipient

Any Healthcare Professional or Organisation that carries out a profession or principle activity or that has the main domicile or legal head office in Europe.

Donations and Grants

By donations and grants (including free-of-charge leases) these must include all the supplies, in cash or kind, destined either directly or indirectly to the Healthcare Organisations as defined hereafter.

Events

All the events of a promotional nature whether scientific or professional such as congresses, conferences, symposiums and other similar initiatives (including as examples Advisory Boards, visits to company plants, Investigator Meetings finalised towards clinical studies and not interventional) organised or sponsored by pharmaceutical companies.

Healthcare Professionals

Any person who carries out their activity in the medical sector, dentistry, public, private or hospital pharmacies, any nurses, Administrators or staff of Local Health Authorities, any technical or administrative personnel of public or private healthcare structures and any other person within the scope of their professional activity can prescribe, dispense, purchase or administer a medicinal speciality and that has their activity mainly in Europe. Intermediary pharmaceutical distributors are however excluded.

Healthcare structures

Any structure whether it is an association or medical, scientific, healthcare or research organisation, (independently from its legal form) such as Hospitals, Clinics, Foundations, Universities, specialisation and training schools (except for patient associations) that have their legal headquarters or main office or activity in Europe, or through which a Doctor may practice.

Research and Development

The transfers of value connected to the research and development include those activities planned or carried out with the aim of developing non-clinical studies as defined in the Good Laboratory Practices, clinical studies, as governed by Directive 2001/20/CE, and non-intervention studies that are prospective in their nature and that involve the gathering of information on patients by doctors for the study itself.

Subjects that must respect the obligations of transparency

The pharmaceutical companies associated to Farmindustria and all their subsidiaries and affiliates are bound to respect the obligations laid down in point 5 of the Professional Code of Conduct. The pharmaceutical entities that are legally separate but part of the same group are also bound to respect the Code.

Transfers of value

Economic transfers whether direct or indirect, both in cash or kind, carried out for either promotional aims or for the development and commercialisation of pharmaceuticals for human use subject to medical prescription. The direct transfers are those carried out directly between the company for the benefit of the recipient. The indirect transfers are those carried out on behalf of the company by a third party.

FARMINDUSTRIA

REGULATORY BODIES AND PROCEDURES FOR IMPLEMENTING THE CODE OF PROFESSIONAL CONDUCT

Article 1

The Bodies

The bodies set up to supervise and execute procedures for the code of self-regulation are the Supervisory Committee, the Single-Judge Tribunal and the Jury.

Article 2

Supervisory Committee

The Supervisory Committee is made up of 15 members including the Chairman The Chairman of the committee is appointed by the Presiding Judge of the Supreme Court of Cassation from judges in pension in the most representative districts within the national territory who have had important management responsibilities. He remains in office for three years and is re-elected only once. The other 14 members are appointed by the Governing Council of Farmindustria and chosen from the legal representatives of the member companies (or their permanent delegates who are members of the management or board of directors of the company) of whom 7 representing national companies and 7 representing companies whose share capital is non-Italian. The members of the committee shall hold office for two years and can be re-appointed. The legal representative of a member company can be elected as a member of the Supervisory Committee on condition that the Single-Judge Tribunal or the Jury has made no specific ruling against the company in the last twelve months and no investigations concerning it are pending before the Single-Judge Tribunal or the Jury. In the exercise of its functions the Supervisory committee can avail itself of consultants chosen according to specific circumstances. A member who fails to participate in three meetings of the committee in the course of one year will be replaced.

Article 3

Single-Judge Tribunal

The Single-Judge Tribunal is constituted by a member of the Jury as stated in the following article 4, chosen by the Jury itself from among its members. He or she may avail him/herself of a consultant appointed by the National Federation of Medical Associations from independent physicians of recognised standing who no longer perform professional work and a consultant chosen from representatives of the pharmaceutical sector who hold no positions of corporate responsibility. The consultants do not have voting rights.
The judge is chosen, hearing-by-hearing, in rotation, from the members of the Jury on the basis of age, commencing from the youngest and he or she shall not participate in any appeal hearings before the Jury to discuss the decisions that he or she took.
The judge shall consider the sanctions proposed to him or her by the Supervisory Committee and deliver his/her decisions concerning the sanctions in conformity to the following article 14.

Article 4

The Jury

The Jury is made up of the Chairman and three members.
The Chairman of the Jury is appointed by the Presiding Judge of the Court of Cassation and is chosen among retired judges in the most representative districts within the national territory who have had important management responsibilities. Two members are appointed by the Presiding Judge of the Court of Milan and chosen from retired judges. One member is appointed by the National Council of the Bar and chosen from qualified and retired lawyers.
The Jury shall also avail itself of the services of a consultant appointed by the National Federation of Medical Associations to be chosen from independent physicians of recognised standing and who no longer perform professional work, and an industrial consultant chosen from representatives of the pharmaceutical sector who no longer hold positions of corporate responsibility. The consultants do not have voting rights. The President, members of the jury and Advisors hold office for 3 years and can be reconfirmed once. During the initial application of this provision after 3 years after its entry into force will proceed to the renewal of half of the members of the Jury and half of consultants. The Chairman of the Jury shall adopt measures at his/her own discretion to decide organisational and management matters referring to the Jury and the Single-Judge Tribunal.

He/she is responsible for relations with the Supervisory Committee, the Single-Judge Tribunal and the Presidency of the Association.
The members of the Jury and the Chairman of the Supervisory Committee, upon acceptance of the office, shall expressly declare that they have no current professional relations or interests with the member companies and undertake not to establish such relations during the tenure of their office.
In agreement with the secretariat, the Jury fixes the dates of its hearings and those of the Single-Judge Tribunal and draws up the internal regulations governing the working of the Jury and the Single-Judge Tribunal.
At the request of associate bodies, the Jury provides opinions on the Code of Professional Conduct and where necessary can convene the Supervisory Committee and the Jury in a joint sitting.
The Jury decides appeals on the basis of all the elements collected by the Supervisory Committee and the Single-Judge Tribunal.

Article 5

The investigative, proactive and consultative functions of the Supervisory Committee

The Supervisory Committee shall:

- draw up internal regulations to protect the confidentiality of the work conducted by the committee;
- order - upon receipt of a circumstantial report received from a recognised source - investigations into cases related to presumed infringements of the code;
- submit to the Single-Judge Tribunal proposals in order to sanction alleged infringements of the code, which, in its opinion, have been proven.
- express non-binding opinions at the request of members or the Chairman of the Jury.

Article 6

Fact-finding function of the Supervisory Committee

The Supervisory Committee can carry out, within the framework of the ascertainment to be made in the investigative phase, fact-finding activities on the premises of the companies, for the sole purpose of the investigation in hand, by means of an auditing company to be specifically appointed on a case-by-case basis. Furthermore, the Supervisory Committee, for its fact-finding mission regarding alleged violations of the Code of Professional Conduct, may appoint a specialised company of proven integrity, to carry out specific investigations on congressional events and promotional activities conducted within the territory, with exclusive reference to the field of application of the Association's Code of Professional Conduct and the specific laws in force regulating the provision of scientific information on drugs.

Article 7

Guideline-setting function of the Supervisory Committee

The Supervisory Committee performs a preventive advisory function with regard to cases that while not representing blatant infringements of the code do not appear to comply with the general principles of the code and members' ethical standards.
In such circumstances it shall inform all members - while guaranteeing the anonymity of the companies involved – that the behaviour in question does not comply with the principles indicated in this subsection and, whenever necessary, shall submit adjustments and supplements to the Code of Professional Conduct that regulate such cases to the Governing Council for approval in line with the provisions of the following article 17.

Article 8

Secretariat

A Secretariat for the Supervisory Committee and the Jury is instituted. The secretariat is made up of a secretary chosen from the functionaries of the Association. The secretariat's functions are as follows:

- to receive and prepare the documentation on the reports received;

- to prepare an explanatory report for the Supervisory Committee, the Single-Judge Tribunal and the Jury;

- to provide assistance to the collective bodies in their operations by appropriately storing the documentation and filing the relative acts.

Article 9

Office and Meetings

The Supervisory Committee, the Single-Judge Tribunal the Jury and the offices of the secretariat are situated in the offices of Farmindustria.
The Supervisory Committee, the Single-Judge Tribunal and the Jury shall meet whenever required upon convocation by their respective chairmen, which shall be notified at least three days before the date fixed for the meeting.
In cases of particular urgency this term may be waived. The meetings of the Supervisory Committee, the Single-Judge Tribunal and Jury are held in camera.
The Supervisory Committee and Jury shall be validity constituted when attended by a majority of their members.
The Supervisory Committee and Jury shall pass resolutions with a majority vote of the members in office. In the event of a tied-vote whoever chairs the meeting shall have the casting vote.
The Supervisory Committee and Jury shall be assisted by a secretary who is bound to observe the secrecy of the proceedings.

Article 10

Petitions to the Supervisory Committee

The Supervisory Committee examines the reports and documents submitted to it from identified sources as well as the verbal statements rendered by members of the committee or formulated directly by the companies during hearings before the Supervisory Committee, the Single-Judge Tribunal or the Jury.

Written reports shall be sent to the Chairman of the Supervisory Committee of Professional Conduct by recorded delivery, at the head office of Farmindustria in Rome, where the receipt of the communication will be registered on a special internal protocol. Will be considered valid only reports concerning events that took place during the 12 months preceding the date of its receipt.
Following receipt of the communication - if the information therein is not manifestly unfounded - the committee will commence an investigation, for which technical consultants can be appointed according to the circumstances involved. In the event that a more detailed investigation is called for, the Chairman can appoint one or more representatives of the committee, chosen ad hoc, to make such an enquiry.
As soon as the Supervisory Committee commences its investigation it will notify the company in question through the offices of the secretariat, requesting it to provide written explanations and present itself for a hearing. The hearing is exclusively reserved to the legal representative of the company in question, who may, however, be accompanied by an officer of the company. In the event that the committee decides on a specific sanction, the preliminary hearing of the company in question is obligatory. Together with the request for clarifications, the company is also requested to provide whatever relevant documentation it possesses that can make a significant contribution towards the decision-making process of the committee.
Furthermore, in the course of any such hearing the Supervisory Committee will enquire about all the probative documents that the company may possess.
The investigation will lead either to the shelving of the case or to the proposal of a specific sanction. Minutes will be drawn up during the meetings of the Supervisory Committee, which, in observance of the regulations concerning information on associate members, shall guarantee the anonymity of the companies involved in the proceedings.

Article 11

Decisions Proposed by the Supervisory Committee

If the Supervisory Committee, upon concluding the investigation procedure, establishes that a specific infringement of the code has taken place, it will decide to propose a specific sanction and notify the company concerned.

In the event that the company recognises its own responsibility and simultaneously and formally undertakes to change its conduct the Supervisory Committee will inform the Single-Judge Tribunal of these undertakings and may make a reasoned proposal for a less severe sanction than that originally proposed.

Article 12

Proceedings before the Single-judge tribunal

Upon receipt of a formal communication proposing sanctions against a given company by the Supervisory Committee, the Single-Judge Tribunal instructs that the company in question be notified that proceedings have been initiated against it and assigns it a period of between eight to fifteen days to file a defence brief. Subject to the receipt of this communication, the company, in the person of its legal representative, may participate in discussions before the judge. The legal representative of the company may also be accompanied, if necessary, by a trusted assistant. The submission of additional information not previously provided by the company to the Supervisory Committee cannot be admitted during proceedings before the Single-Judge Court, unless exceptional circumstances persuade the Judge him/herself to request it as a supplement to the investigation. A representative of the Supervisory Committee, specially appointed by this committee, will participate in the discussions.

On conclusion of the hearings, the Single-Court Tribunal will make its ruling and communicate it to the company concerned, 30 days after the communication, and in the event that the company does not lodge an appeal with the Jury, the information will be imparted on the decision taken by Farmindustria's Governing Council. In this case, the decision will be immediately executive - unless the circumstance stated under the following article 14, letter d)) applies - and all member companies will be duly informed. The company receiving the sanction shall communicate this fact to its own certifying body, as set forth under point 1.13 of this Code.

At any time during these hearings the Single-Judge Tribunal can ask the Supervisory Committee for its opinions.

Article 13

Appeal procedure

Within 30 days from the date of communication of the decisions of the Single-Judge Tribunal, the company can lodge an appeal before the Jury together with any additional documentation. In that regard, the jury will consider only those appeals that are properly motivated.
Having received the appeal, the Jury makes provision to notify the company concerned of the date of the appeal meeting, which shall be fixed within 30 days from the date on which the appeal was filed.
Subject to the receipt of this communication, the company, in the person of its legal representative, may participate in discussions before the Jury.
The Jury may request new documentation or arrange for a supplementary investigation through the Supervisory Committee.
A specially appointed representative of the Supervisory Committee, who may also file written briefs, will participate in the discussions.
When the discussions are terminated, the Jury will make a ruling and communicate it to the company concerned and to the Governing Council of Farmindustria. All member companies will be apprised of the decision by a specific circular.

Article 14

Sanctions

The sanctions that may be applied by the Single-Judge Tribunal in the event of proven infringements of the provisions of the Association's Code of Professional Conduct are as follows:

a) warning with a request to cease any behavior, if still in use, and ban it completely if necessary;
b) written reprimand;
c) temporary suspension;
d) expulsion.

In addition to the sanctions stated under the foregoing letters b), c) and d) a graduated pecuniary sanction may also be applied, whose amount will depend upon the seriousness of the violation as well as the damage to the image and reputation of the sector, the number and nature of previous and, whenever quantifiable, the expenditure borne by the company for the carrying out the initiative forming the subject matter of the judgement.

The sanction may not, in any case, exceed the sum of €200,000.00 (two hundred thousand). In the event that a company accept the decision of the single-judge and thereby expressly waive its right of appeal to the jury, it will be accorded a reduction of one quarter of the pecuniary sanction.

In the event of a violation committed within a 12-month period successive to any violation for which a company had already been required to pay the full pecuniary sanction, the foregoing €200,000.00 (two hundred thousand), will not apply.
The application of the sanction referred to under d) shall be formally approved by the Governing Council.
If the Single-Judge Tribunal were to decide to apply a sanction different from the warning with a request to cease any behavior and / or with disqualification of the same or a written censure without pecuniary sanctions, twice against the same company for infringements committed in the space of 24 months, it will, through the offices of the Association, disclose the decision on a newspaper with national circulation along with the name of the offending company. In the event that the date of the infringement could not be ascertained, reference will be made to the date of the violation's report in order to determine whether the foregoing 24-month period has elapsed.

Article 15

Loss of office of a member of the Supervisory Committee

The member of the Supervisory Committee whose company is formally sanctioned by the Jury or by Single Judge will automatically forfeit office as soon as the decision is notified to him.

Article 16

Procedural costs for the ruling

All the costs sustained by the Association shall be for the account of the company in question.

Article 17

Amendments and supplements to the Code of Professional Conduct

Amendments and supplements to the Code of Professional Conduct that represent an integral part of the byelaws of the Association shall be approved by the Governing Council at the proposal of the Supervisory Committee.

Article 18

Stipulating and undertaking to abide by the Code of Professional Conduct

When the Code of Professional Conduct is issued each member company belonging to Farmindustria in the person of its legal representative shall, as an essential condition for their membership of the Association, be required to make a specific undertaking that it accepts the code and will not impede the work of the bodies set up to monitor and enforce it.