



**CODE OF PROFESSIONAL CONDUCT
FARMINDUSTRIA**

SEPTEMBER 23, 2009

TABLE OF CONTENTS

1. GENERAL PRINCIPLES

2. DIRECT PROVISION OF SCIENTIFIC INFORMATION

- General principles;
- verbal information imparted to physicians;
- information material;
- promotional material;
- professional updating and scientific cooperation
- advertising in newspapers and magazines.

3. SCIENTIFIC CONGRESSES, MEETINGS AND CONVENTIONS

- General principles;
- the different types;
- international, national and regional meetings;
- local scientific meetings;
- refresher courses;
- visits to company laboratories;
- Investigator meetings.

4. RELATIONS BETWEEN THE INDUSTRY AND THE SCIENTIFIC AND HEALTH SECTORS AND PATIENT ASSOCIATION

- Scholarships and scientific consultancy;
- relations with scientific societies;
- clinical trials and drug-related studies;
- internet sites;
- relations between Pharmaceutical Companies and Patient Associations.

5. REGULATORY BODIES AND PROCEDURES IMPLEMENTING THE CODE OF PROFESSIONAL CONDUCT

- the Supervisory Committee: composition and functions;
- the Single-Judge Tribunal composition and functions;
- the Jury: composition and functions;
- sanctions;
- Secretariat, office and meetings
- amendments and supplements to the Code of Professional Conduct;
- Stipulating the undertaking to abide by the Code of Professional
- Conduct.

FARMINDUSTRIA'S 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 form of a voluntary agreement entered into 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 health sectors.

All member companies of Farmindustria must accept and comply with the provisions of the Code of Professional Conduct.

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 operators 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 health operators.

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 by companies with head offices in or outside 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 Efpia Code of Professional Conduct. Whenever Italian health operators are involved Farmindustria's Code of Professional Conduct shall apply.

- 1.9 Unless stated otherwise, the Code refers to relations between each of the member companies and health operators. The latter shall be understood to refer to the various types of physicians, pharmacists, and health directors as also technical and administrative personnel employed in public and private health 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 must 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 must be issued by entities recognised by SINCERT (the national system for the accreditation of Certification Bodies)
- 1.14 The provisions contained in this Code shall have no retroactive effect.

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 must 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 operators, scientific salesmen must always qualify themselves and state the capacity in which they are acting.
- 2.5. Scientific salesmen of medicinal products must not be engaged in health or para-health 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 scientific salesmen to impart information on the properties and characteristics of their drugs to health operators in a manner such as to allow them to be used for therapeutically correct purposes.
- 2.7 Companies will also be responsible for training scientific salesmen to collect feedback on their drugs, as this is a means to ensure the fullest information on the products being marketed.
- 2.8 Salesmen directed to provide scientific information on drugs must 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 The information material prepared by companies on their products in order to provide information to physicians must refer to official documents issued to AIFA when the drugs were registered or successively approved by the agency on the basis of existing laws.
- 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 must be made stating that a product has no collateral effects or toxicity risk.
- 2.11 Scientific citations must accurately portray the meaning intended by the author(s).

- 2.12 The texts, tables and other illustrations taken from medical reviews or scientific works must 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 must be conceded, offered or promised.

Promotional material concerning drugs and their use, sponsored by a pharmaceutical industrial enterprise shall have a negligible value, shall not be exchangeable and in any case shall be connected to the activities performed by physicians and pharmacists. This material must also clearly indicate the company or the product of the sponsoring company.

The offer of any kinds of economic incentives designed to compensate health operators for time taken from normal professional activities in order to participate in congressional events is prohibited in all circumstances.

It must 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 health structures unless the material in question has a perceivably negligible value, namely a value of less than 25 euros. Companies must 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.

Advertising in newspapers and magazines

- 2.16 In the ambit of newspaper and magazine advertising, companies must 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.

3. SCIENTIFIC CONGRESSES, MEETINGS AND CONVENTIONS

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 health operators and entail addressing a number of participants.
- The subject matter shall not include the so-called group interviews that must, instead, be conducted, free-of-charge, directly on the premises of healthcare institutions or in medical surgeries where health operators 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 conferences or congresses must, together with the operators' 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 health 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.

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 health operators to express their consent to the handling of personally identifiable information must 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 35 years of age, in line with the requirements stated under the following point 3.10.

- 3.3 Participation in conference events by the companies must 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 health operators invited to Italian conference events in Italy or abroad while the category of hotel accommodation must not exceed four stars.

In addition, companies may not invite a health operator to congresses, conferences, scientific meetings and company laboratory visits more than twice a year. However, this restriction does not apply to speakers or moderators.

In the case of participation in local ECM (continuous medical education) initiatives organised by public structures in a hospital environment, characterised by proceedings lasting no longer than one day and in the absence of any kind of invitation or hospitality for participants, with the exception of a coffee-break, the foregoing limit shall not apply.

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 health 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.

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 must be to promote scientific cooperation between physicians.

The different types of event

- 3.8 Events organised directly or indirectly by pharmaceutical companies must 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 must be chosen on an international, national or at least regional basis. Places with an exclusively 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.
- 3.9 Scientific meetings held at a local level may make provision for a limited participation of physicians: Their proceedings must be completed within a maximum overall period of 12 hours. The participants invited to such meetings will be drawn from a territorial area below that of the region.

International, national and regional meetings

- 3.10 The Pharmaceutical companies, with regard to 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, must 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 must guarantee that, on a yearly basis, 10% of the physicians participating in such events will be under 40 years of age.
- 3.11 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.
- 3.12 As concerns events taking place in Italy, hospitality can only be offered by pharmaceutical companies for general practitioners and hospital pharmacists if the meetings in question qualify for specific ECM credits.

- 3.13 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.

- 3.14 Conference events organised at a national level by pharmaceutical companies may not, in terms of their proceedings, last less than six hours per day.

Local scientific meetings

- 3.15 Only local scientific meeting that qualify for specific ECM credits can be sponsored by pharmaceutical companies. These meetings must be held in venues such as hospitals, universities, foundations with a scientific character or congressional halls that can ensure a scientific dignity for the event.

- 3.16 In the course of the meeting only a coffee break may be offered to the physicians attending.
For events involving over six hours training a small working meal may be offered between the morning and the afternoon sessions within the structure where the conference takes place.

Refresher courses

- 3.17 For medical - scientific refresher courses at any territorial level the same rules shall apply as those mentioned above for scientific congresses, conferences and meetings.
- 3.18 Companies are prohibited from organising or sponsoring the participation of operators in refresher courses that do not have a medical or scientific character, such as foreign language, IT, or tax courses or similar initiatives.

Visits to company laboratories

- 3.19 Health operators may visit company laboratories on condition that appropriate time is dedicated to information-training within the framework of the visit, that the time allocated does not exceed that strictly necessary for such visits, 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

- 3.20 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 must 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 must 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 must be made in compliance with the criteria fixed for the choice of conferences and congresses.

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

Scholarships and 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 must be stipulated between the physician and the pharmaceutical company specifying the nature of the service offered. The need for the service in question must be clearly identified and stated.
- The contract must 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 must guarantee coherence and appropriateness in respect of the objectives pursued and must be capable of being fully documented.
- The decision on such initiatives must 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.

Scientific cooperation may, in addition, also be obtained through scholarships. However, also in this case, decisions on such initiatives must be the exclusive responsibility of the executive top management of the company.

Relations with scientific societies

- 4.2 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

4.3 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 must be met:

- A written contract must be initially drawn up between the sponsoring company and the entities involved in the study and, in respect of the study, the company must detail its characteristics and the nature of the work offered by the entities and /or the participating physicians.
- The study protocol must 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 must not contain elements such as to encourage or suggest the prescription or purchase of a particular medicinal product.
- The scientific 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 must 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 the event that, for purposes of study or training initiatives undertaken directly or indirectly by companies, recourse is made to the use of instruments (such as holters, electrocardiograms and other telemedicine instruments) exclusively for the foregoing studies or initiatives, the distribution to physicians of the relevant instruments must take place through an entity or entities involved in the studies (local health offices, universities, hospital agencies and Institutes for Treatment and Research) and their use shall be regulated by the application of a specific agreement between the company in question and the foregoing entities.

In every case, it must be specified that the instruments can be used for a determined period and exclusively for the purpose of completing the study or the training initiative, that they will be withdrawn at the conclusion of the study or initiative and that they cannot be used for immediately successive enquiries to be conducted by the company with the same entities.

The withdrawal of the instruments must be specifically documented and these documents must be made available by the pharmaceutical companies if and when the Supervisory Committee requests them in the course of any fact-finding enquiries in progress.

In all cases the use of information technology instruments is expressly forbidden (such as notebook or desktop computers, handhelds and similar products).

Internet sites

- 4.4 Every internet site opened by an Italian company or a company operating in Italy that is addressed to the general public and Italian operators, 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 must 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

- 4.5 Any form of economic support, whether direct or indirect, by the pharmaceutical company towards a patient association must comply with the following criteria:

- A specific and preliminary agreement aimed at regulating the amount of financing and the reasons for its disbursement must be reached. For this reason, each pharmaceutical company must 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 must be authorised in advance by the association. In order to acquire such authorisation, the objectives for, and the manner of, using the logo must be clearly defined.
- Any form of sponsorship by the pharmaceutical companies vis à vis the patient associations must 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.
- The pharmaceutical companies must include within their own internet sites the list of the patient associations that they sustain.

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. 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 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 should 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 must 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 must 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.

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.

At the conclusion of the hearings, the Single-Court Tribunal:

- will make its ruling and communicate it to the company concerned in the event that it deem the case to have been thoroughly debated. 30 days after this communication, and in the event that the company does not lodge an appeal with the Jury, 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 must communicate this fact to its own certifying body, as set forth under point 1.13 of this Code;

- if it deems it necessary it can acquire additional elements for its investigations through the Supervisory Committee, and fix a date for the new discussions.

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.

Having received the appeal, the Jury makes provision to notify the company concerned of the date of the appeal meeting, which must 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 the request for the immediate interruption of the behaviour;
- 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, 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) must be formally approved by the Governing Council.

If the Single-Judge Tribunal were to decide to apply a sanction, other than a written warning, a request for the immediate termination of the behaviour 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, publish 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 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.

Rome, September 23, 2009