CODE OF CONDUCT GOVERNING THE RELATIONS BETWEEN PHARMACEUTICAL INDUSTRY AND PATIENTS' ORGANIZATIONS

APIFARMA – Associação Portuguesa da Indústria Farmacêutica keeps a partnership with Portuguese Patients' Organizations since the year 1999. At the same time it has been developing its work with European Patients' Organizations in a close relation with EFPIA – *European Federation of Pharmaceutical Industries and Associations*.

Pharmaceutical Industry recognizes it has common objectives with Patients' Organizations, which represent and/or provide support to the patients' needs and/or the health care providers.

With a view to ensure the relations between the pharmaceutical industry and patients' organizations are developed in an ethical and transparent manner, EFPIA approved, in October 2007, a Code of Conduct on the Relations between Pharmaceutical Industry and Patients' Organizations.

This Code is based on the following principles, which have been updated by EFPIA and pan-European patients' organizations, the last time in June 2011:

1. The independence of Patients' Organizations regarding their political decisions, their policies themselves and their activities must be guaranteed.

2. All partnerships between Patients' Organizations and the Pharmaceutical Industry should be based on mutual respect, each partner's point of view being valued the same way.

3. Pharmaceutical Industry should not request the promotion of prescription only medicinal products and Patients' Organizations should not be engaged in those activities.

4. The objectives and scope of the partnerships should be transparent. The financial and non financial support provided by the Pharmaceutical Industry should be disclosed.

5. Diversified financing of Patients' Organizations by multiple entities is welcome by Pharmaceutical Industry.

APIFARMA transfers this Code of Conduct to Portugal as to bind the relations between its member companies and any patients' organization, irrespective of having or not having been incorporated as an organization.

The rules sanctioned here were freely discussed and voluntarily accepted, and are binding for all the member companies of APIFARMA.

Article 1

Scope

1. This Code of Conduct aims at establishing a set of standards to govern the relations between the companies of Pharmaceutical Industry members of APIFARMA and Patients' Organizations and/or Associations.
2. The provisions of this Code are binding for all the member companies of APIFARMA.
3. For the purposes of this Code of Conduct it should be understood as:
a) "Companies" – member companies of APIFARMA;
b) "Patients' Organizations" – the non-profit organizations comprising patients and/or health care providers, representing and/or providing support to the patients and health care providers' needs and develop their activity in Portugal.

c) "relations between companies of Pharmaceutical Industry and Patients' Organizations" – any interaction among these entities, including the granting of funds by a company to a Patients' Organization.

Article 2

Promotion of prescription only medicinal products

Under this Code, European and national legislation and regulations and the Code of Ethics of APIFARMA are applicable to Promotional Practices of Pharmaceutical Industry, namely as far as the prohibition of promotion of prescription only medicinal products among the general public is concerned.

Article 3

Agreements

1. Companies which want to provide direct or indirect financial support and significant non financial support to Patients' Organizations should put it in writing, by means of an agreement signed by both parties, according to the form included in Appendix of this Code.
2. The agreement mentioned in the previous number should mention the express amount of the financing, as well as its purpose or a description of the significant non financial support as the case may be.
3. Each company should establish internal proceedings of formal approval of the agreements mentioned in the previous numbers.

Article 4

Contracts between Companies and Patients' Organizations

1. Companies and Patients' Organizations may celebrate contracts under which Patients' Organizations may provide services to Companies with the purpose to support health and/or research.
2. Companies are allowed to contract Patients' Organizations to be speakers, experts and/or consultants during meetings held by them.
3. In situations provided for in no. 1 the following criteria should be complied with:

a) to specify the nature of services to provide and the payment conditions;
b) to identify, in a clear way, the legitimate need for those services;
c) the criteria to select the services should relate directly with the need identified in the previous subparagraph and people in charge for its selection should have the suitable experience and knowledge to assess if the speakers, experts and/or consultants meet those criteria;
d) the extent of the service provided cannot exceed what is reasonably necessary to meet the identified needs;
e) the contracting Company should keep the records regarding the services provided and use that information in a suitable way;
f) the contracts signed with Patients' Organizations cannot be an incentive for the recommendation of a particular medicinal product;
g) the payment of the services provided should be reasonable and reflect the market practice in a fairly manner.

Contracts should include the obligation for Patients' Organizations to declare they provide paid services to a Company every time they write or speak in public on subjects covered by the contract or matters related to the Company.

Article 5

Use of logos and materials subject to copyright

1. The public use by a Company, in the scope of the agreements mentioned in article 3, of a logo and/or materials subject to copyright belonging to a Patients' Organization is subject to a previous written authorization given by the latter.
2. The authorization request mentioned in the previous number should clearly indicate the specific objective and the way the logo and/or materials subject to copyright are to be used by the company.

Article 6

Materials produced by Patients' Organizations

1. Companies should not try to influence the contents of materials produced by Patients' Organizations they sponsor, so as to favour their commercial interests.

2. The obligation provided for in the previous number does not prevent companies to correct evidence-based and/or scientific inaccuracies existing in produced materials.

3. The companies may contribute to the preparation of texts of scientific nature, upon request of the Patients' Organizations.

Article 7

Transparency

1. The list of Patients' Organizations sponsored by each Company within the scope of the agreements mentioned in article 3 should be disclosed, each year, and should mention:

a) the nature of the provided support;

b) the monetary value of the provided support;

c) the benefits received, as far as significant non-financial supports to which no monetary value can be ascribed are concerned.

2. The disclosure mentioned in the previous number should not compromise any confidential information.

3. Companies should make sure the information on the sponsorship of Patient's Organizations is made available in a clear and transparent manner, upon request of any stakeholder or through the institutional website of the Company, until 31st of May, each year.

Article 8

Financing

No company can impose itself as to being the exclusive sponsor of a Patients' Organization or of its main programs.

Article 9

Events and hospitality

1. Any event organized or sponsored by a Company, or on its behalf, within the scope of articles 3 and 4, should be carried out in a suitable venue according to the main purpose of the event.

2. Companies should not choose places and/or tourism complexes known for their leisure, entertainment or sports facilities to hold the events.

3. The events mentioned in the previous numbers should be held in Portugal, unless it is more reasonable, in logistic terms, to hold the event in a foreign country:

a) taking into account the home countries of most of the guests.

b) taking into account the location of the relevant resources or knowledge which are the subject-matter or the topic of the event.

4. Hospitality provided by Companies to Patients' Organizations and their members should be of a reasonable level and be restricted to the main objective of the event, irrespective of being organized by the Patients' Organization or the Company.

5. Provided hospitality should be restricted to travels, meals, accommodation and registration fees, and limited to the participants in own right.

6. In case of clear need to assist the participant, the Companies may bear the costs with travelling, meals, accommodation and register of the participant's companion in the quality of the patient's carer.

7. Hospitality cannot include the sponsorship or the organization of events of entertainment nature (i.e. leisure, entertainment or sports).

Article 10

Offences to the Code

1. 1. The implementation of the provisions of this Code should be supervised by the Council of Ethics of APIFARMA.

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

3. The violation of the rules of this Code by a Company is considered as a disciplinary offence, and the sanctions provided for in APIFARMA Articles of Association shall apply.

4. The sanction applied, as well as the nature of the offence shall be published by APIFARMA.

Version approved in Special Session of General-meeting of 28 November 2011

This Code of Ethics shall come into force on 1 January 2012

Appendix I

Model of the written agreement between the Pharmaceutical Industry and Patients' Organizations

This model comprises the essential aspects to include in a written agreement, under the provisions of Article 3. Companies may use this model as a whole or adjust it to the specific case.

I – **Object of the Agreement**:

- **Identification of the parties** (Pharmaceutical Company, Patients' Organization and third parties called to cooperate;
- Type of support
  - if the agreement has to do with subsidies not subject to conditions, meetings or specific publications, etc
  - amount of financing
  - purpose
  - description of the indirect or significant non financial support (for instance, time granted by public relations agencies, free training programs)
- Objectives
- Duration and rules on suspension, revocation or termination of the agreement;
- Rules on the use of the logo and material subject to copyright;
- Confidentiality clause of (when appropriate)
- Transparency clause of (mentioning that the Pharmaceutical Company shall disclose, publicly, the supports granted to Patients' Associations under the provisions of article 7.)

II - Applicable legislation and/or codes of conduct

III – Signature of the Parties

IV - Date of the agreement