

QUESTIONS AND ANSWERS ON THE "CODE OF CONDUCT FOR THE RELATIONS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ASSOCIATIONS, PATIENT ADVOCATES, PATIENT EXPERTS, PATIENTS AND CAREGIVERS"

I. INTRODUCTION

1. The new Code of Conduct replaces the previous version of the Code approved in November 2011. What were the goals behind this review?

The review had four goals:

- To implement the new EFPIA Code with regard to interactions with Patients' Associations;
- To regulate the interactions of Apifarma member companies with Patients, Caregivers, Patient Advocates and Patient Experts;
- To regulate the types of relationships and interactions that exist between the Pharmaceutical Industry and the above-mentioned interlocutors;
- To clarify and standardise rules of conduct between the various member companies.

2. To which APIFARMA member companies does the new Code of Conduct apply?

The new Code applies to member companies of APIFARMA in the Pharmaceutical Industry that market prescription and over-the-counter medicinal products. It does not apply to member companies that market in vitro diagnostic medical devices.

3. What were the main changes introduced?

- Definition of the concepts of Patient Advocate, Patient Expert, Patient and Caregiver and regulation of the terms under which the member companies can cooperate with them;
- Introduction of the principle of privileged contact with Patients' Associations for the purpose of cooperation with Patient Advocates, Patient Experts, Patients and Caregivers;
- Regulation of the terms under which service contracts may be signed between member companies and Patient Advocates, Patient Experts, Patients and Caregivers;
- Transparency - elimination of double reporting, only reporting on Infarmed's Transparency Platform is now mandatory;
- Written agreements - mandatory for all interactions with the exception of in-kind support ≤ 60 Euros and invitations to events. Suggestions for draft contracts have been introduced and are annexed to the Code;
- Partnerships with Patients' Associations - for co-organised projects which are the responsibility of both parties;
- Financing of Patients' Associations - Companies are no longer able to request or demand to be the exclusive financing party of any event or activity of a particular Patients' Association, and are still not able to request or demand to be the exclusive financing party of a Patients' Association;
- Clarification on the terms under which member companies can provide information on pipeline and marketed medicinal products;
- Hospitality - monetary limits identical to those applicable to Healthcare Professionals.

II. SCOPE AND DEFINITIONS

4. Is a Patients' Advocate necessarily a Patient?

A Patient Advocate may or may not be a patient. It is an individual with knowledge and experience in the defence and support of a patient population living with a certain disease. He may or may not be a member of a Patients' Association.

5. What is a Patient Expert?

A Patient Expert is a patient with technical knowledge in research and development (R&D) and/or regulatory affairs, by virtue of his/her experience and/or training. It is his/her knowledge in R&D and/or regulatory affairs, not his/her condition as a patient, that may legitimise his/her provision of services as a Patient Expert under the terms of Article 11 of the Code (primarily through the Patients' Association of which he/she is a member).

6. What differentiates a Patient Expert from a Patient Advocate? Can a patient be simultaneously a Patient Expert and a Patient Advocate?

What differentiates the Patient Advocate from the Patient Expert is his or her status as a "defender" and "representative" of a particular patient population. And it is in this capacity that he or she can cooperate with the companies, particularly in the context of their activities in support of health, research and/or education, always in accordance with the provisions of Article 10 of the Code.

A Patient can display all three qualities simultaneously: being a Patient, a Patient Expert and a Patient Advocate. However, for the purposes of providing services, the companies must clearly highlight and document in what capacity they intend to hire this individual - whether as a Patient, Patient Expert or Patient Advocate - and therefore complying with Articles 10 or 11 of the Code, as applicable.

7. Should companies highlight and document the quality of a particular individual as a Patient Advocate whenever they use his/her services?

Yes. The knowledge and experience of an individual in defending and supporting a patient population should be shown through his/her CV and/or biography obtained from public sources (e.g. LinkedIn, institutional pages of associations). The following criteria illustrate, by way of example, this knowledge and experience as a Patient Advocate:

- ✓ Membership and/or participation in international, national bodies or working groups in the reference area to which the provision of services relates;
- ✓ Publications, lectures and/or public interventions on the therapeutic area/pathology/topic in question;

III. RELATIONS BETWEEN COMPANIES, PATIENTS' ASSOCIATIONS, PATIENT ADVOCATES, PATIENT EXPERTS, PATIENTS AND CAREGIVERS

8. Can a Pharmaceutical Industry company provide information to a Patients' Association on the progress achieved in the area of medicinal products and therapy?

The company may disclose this information only reactively, in response to a specific request from the Patients' Association, and provided that the information is addressed to health professionals who cooperate with them. Any response related to progress in the area of medicinal products and therapy must be coordinated and made available by the scientific areas of the company (medical or research department).

9. Can a pharmaceutical company be the sole financing party of a Patients' Association?

Under no circumstances should a company request or demand to be the exclusive financing party of a particular Patients' Association.

As a general rule, companies should avoid being the sole or majority financing parties of a given Patients' Association. However, in some cases it may be difficult to avoid that a company is not the exclusive or majority financing party of a particular Patients' Association, either because:

- a) It is the only company (within the universe of the Pharmaceutical Industry and beyond), which, at that time, is available to cooperate with the Patients' Association or
- b) the Patients' Association, of its own free will, does not intend to cooperate, at that moment, with other companies/entities (within the universe of the Pharmaceutical Industry and beyond).

10. Can a company in the Pharmaceutical Industry be the sole financing party of an event or activity organised by a Patients' Association?

Under no circumstances should a company request or demand to be the exclusive financing party of a particular event or activity organised by a Patients' Association. However, there may be situations where only one company is available to finance a particular event or activity organised by a Patients' Association or the Patients' Association, of its own free will, does not intend to cooperate at that time with other companies/entities (within the universe of the Pharmaceutical Industry and beyond). Under these conditions, it is acceptable for the Company to be the sole financing party of this event and/or activity.

11. Can verbal agreements be established with a Patients' Association?

No, unless we are dealing with non-financial support (in kind) of less than EUR 60.00 granted by a company to a Patients' Association. In this case it is not mandatory to reduce the agreement to written form. However, this support must be preceded by a written request, dated and signed by the Patients' Association and addressed to the company, which must specify the scope and purpose of the activity or event in question, as well as the required non-financial support.

12. Can companies freely use the logos, names and other materials belonging to a Patients' Association?

No. Unless there is a signed contract where this matter is previously and specifically regulated or there is a prior and clear written consent from the Patient Association in this regard, Companies may not use the logo and/or name of the Patients' Association as well as any other copyright material belonging to the latter. The same consideration is valid, according to the legal rules, for the use by the Patients' Associations of the logo, name and copyright material belonging to the Companies, the use of which must be subject to prior authorisation by the Company.

13. Are companies required to keep a record of the documentation relating to agreements with Patients' Associations and/or Patient Advocates?

Yes. Written agreements between Companies and Patients' Associations and/or Patient Advocates should be maintained for the period provided for in the applicable legislation.

14. Following the launching by a company of a digital platform on a particular pathology for the general public, a Patient contacts the company to offer his/her individual cooperation in the development of the information content of the platform. Can the company accept?

The company can only accept the cooperation of Patients, Caregivers and/or Patient Experts that is intermediated and contracted through a Patients' Association, in accordance with Article 11 of the Code of Conduct.

15. What contract model should be drawn for the interactions with Patients' Associations, Patient Advocates, Patient Experts, Patients or Caregivers?

Contracts should include the essential requirements set out in the Code of Conduct for the different types of interaction, namely:

- a) Support/sponsorship for events/activities organised by Patients' Associations: those provided for in Articles 6 and 18 of the Code and in model A in Annex I of the Code;
- b) Services provided by Patients' Associations, Patient Experts, Patients or Caregivers: those provided for in Articles 6, 9 and 11 of the Code and in model B in Annex I of the Code;
- c) Services provided by Patient Advocates: those provided for in Articles 6 and 10 of the Code and in Model C in Annex I of the Code;
- d) Partnerships with Patients' Associations: those provided for in Articles 6 and 17 of the Code.

APIFARMA makes available to its member companies, in Annex I of the Code of Conduct, suggestions for draft contracts for the interactions identified in points a), b) and c), which include, among others, the essential requirements laid down in the Code for the different types of interaction.

16. I intend to hire a representative of a Patients' Association for the purpose of providing certain services (for example, Speaker, Consultant, etc.). Can the contract be signed with the individual representative?

No. If the service to be provided is carried out by a representative of the Patients' Association, the contract should have the Patients' Association as its counterpart and not the latter's representative. In the case of a service rendered by a Patients' Association, regardless of who is the individual providing the service, the contracting parties should always be the Company and the Patients' Association. No contract should be signed with the Representative of the Patients' Association as he/she is empowered to provide services on behalf of the Patient Association and not on his own behalf. In this sense, the transfer of value, if any, must be made to a bank account belonging to the Patients' Association and not to the Representative of the Patients' Association.

17. For the purpose of the provision of services by a Patients' Association, Patient Advocate, Patient Expert, Patient or Caregiver, which one should the Company contact and with which should it formalize the respective written agreement?

The following table aims to summarise the general rules set up in the Code of Conduct with regard to contacts and agreements that may be established by Companies:

Party	Definition	Initial Contact	Contract	Relevant Articles of the Code
Patients' Association	Non-profit organisations consisting essentially of patients and/or caregivers, which represent and/or support the needs of patients and/or caregivers and develop their activity in Portugal	Allowed	Direct	Article 9
Patient	An individual living with an illness. For the purposes of this Code, he only represents himself and his opinion/experience as a patient, regardless of his/her technical knowledge in research and development and/or regulatory matter. When he/she represents the Patient Association with which he/she is affiliated, he/she appears as a Representative of a Patient Association.	Through the Patients' Association, which should make the selection and intermediation with the Patient	With the Patients' Association	Article 11/ 2 and 3
Patient Expert (PE)	Patient with technical knowledge in research and development and/or regulatory affairs, by virtue of his/her experience and/or training. For the purposes of this Code, he/she only represents him/herself as an expert in research and development and/or regulatory affairs.	Through the Patients' Association, which should make the selection and intermediation with the Patient	With the Patients' Association	Article 11/ 2 and 3
Patient Advocate (PA)	Individual with knowledge and experience in the defence and support of a population of patients living with a certain disease. May or may not be affiliated with a Patients' Association	If the PA is a member/associated of a Patients' Association, contact should be carried out via the Patients' Association	Direct or with the Patients' Association	Article 10/ 1 and 2
Representative of a Patients' Association	An individual empowered to represent and express the collective vision of the Patients' Association he represents on a given topic or therapeutic area.	Allowed, provided he/she acts as the representative of the patients' Association and not as an individual in his/her personal capacity	With the Patients' Association	Article 2/ 1 - p
Caregiver	The individuals who accompany and take care of the patient, be they family and/or friends of the patient, volunteers or persons hired to carry out this activity.	Through the Patients' Association, which should make the selection and intermediation with the Caregiver	With the Patients' Association	Article 11/ 2 and 3

18. Should Patients' Associations disclose the support or sponsorship granted by Industry companies to their events and/or activities?

In the spirit of transparency, Companies should ensure, through their contracts, that Patients' Associations make public the support given by Companies in the materials relating to the event or activity being supported.

19. On what terms should Patients' Associations, their representatives and Patient Advocates disclose that they are service providers of pharmaceutical companies?

Patient Associations, their representatives and Patient Advocates should publicly disclose that they are service providers of a particular company in the Pharmaceutical Industry, whenever they write or speak in public about matters covered by the service contract (such as in lectures, congresses, training and awareness sessions, among others) or about matters related to the Company to which they provide services.

IV. EVENTS AND ACTIVITIES ORGANISED BY MEMBER COMPANIES

20. Are companies allowed to organise Health related events targeting the general public?

Yes. Companies can organise Health related events addressed to the general public, including patients and/or caregivers. These events may not have any promotional nature.

These events can also be advertised to the Patients' Associations, which can disclose them to their members.

21. In the context of an event organised by a company in the Pharmaceutical Industry concerning the prevention of a particular disease and aimed at patients, caregivers and/or the general public, is it allowed to give t-shirts and/or other gifts to participants?

No. As stated in Article 15 of the Code of Conduct, member companies may not grant, directly or indirectly, any gifts to Patient Associations, their representatives, Patient Advocates, Patient Experts, Patients or Caregivers in their personal capacity.

22. Should the services provided to companies by Patients' Associations and/or Patient Advocates be paid, or can they be free of charge?

Patients' Associations and/or Patient Advocates are entitled to be paid for the services they provide, in a fair, reasonable manner and in compliance with the market practice, taking into account legitimate factors such as the time spent preparing/executing the service, the complexity of the service and the experience of the service provider, among others. However, the principle of contractual freedom between the parties applies and the provision of services may be free of charge if, for example, the nature of the services to be provided so justifies or if such is requested by the Patient's Association/Patient Advocate.

22. Can a member company hire a Patient's Association to participate in a Patient Advisory Board?

Yes, it can, provided that the requirements of no. 2 of Article 9 (Provision of services) are met.

22.1. What is an Advisory Board?

It is a meeting organised by a pharmaceutical company, of a necessarily non-promotional nature, which aims to collect relevant and legitimate information from third parties, considered "experts" or Advisors, on specific and predefined issues for which the company has no internal knowledge. When it involves the participation, even if not exclusive, of representatives of Patients' Associations, Patient Advocates, Patient Experts, Patients and/or Caregivers it is referred to as Patient Advisory Board.

22.2. What kind of questions and topics can be raised with Patients' Associations?

Companies may ask questions about the patient pathway, challenges in managing and living with a particular condition and other issues related to the needs of patients and their caregivers such as training, capacity building and disease awareness needs, etc. No questions can be asked about specific medicinal products.

22.3. Which companies' employees can organise and/or actively participate in Patient Advisory Boards?

Patient Advisory Boards should be organised and can actively involve staff from companies in non-commercial areas such as science, medical or patient relations.

22.4. Can employees of companies with sales-related jobs and/or responsibilities directly related to the sale/prescription of medicines (medical sales representatives, sales managers, etc.) participate in Advisory Boards or Patient Advisory Boards?

No.

22.5. What about employees in the commercial/marketing areas?

Employees in the commercial/marketing areas of companies whose responsibilities are not directly related to the sale/prescription of medicines may participate in Patient Advisory Boards when there is a legitimate need to do so, but only as observers (for instance, participation of the brand manager of a certain therapeutic area in a multidisciplinary Advisory Board, which aims to obtain information on the patient's path in the management of the disease, provided that this information is relevant to the marketing strategy).

23. Can a member company make a video with testimonies of patients and/or caregivers?

Yes, provided that the purpose of the video is to obtain greater knowledge about the personal experience of the Patient and/or his/her Caregiver with a particular pathology. The video may not have any promotional nature and no questions may be asked about the use of a particular medicinal product(s) and/or mention any brand or active substance.

a) How can patients be selected?

Patients should be selected by Patients' Organisations. In very exceptional situations, namely when there is no Patients' Association in a particular therapeutic/ pathological area, the patient may be selected by a Healthcare Professional or Patient Advocate.

b) Can patient testimonies be disclosed to healthcare professionals and/or the general public?

They can, since as explained in the previous answers, these videos cannot be of any promotional nature.

24. Can a pharmaceutical company award a gift to a Patients' Association or individual (whether Patient, Caregiver, Patient Advocate, Patient Expert or a representative of a Patients' Association)?

No. Gifts, whether direct or indirect, namely those for personal use (e.g. electronic equipment for individual use), as well as complimentary gifts (e.g. bouquet of flowers, bolo-rei (cake) and/or gifts on special occasions, such as birthdays, the birth of children or other festive occasions, such as Christmas and Easter, are totally forbidden).

25. Can a member company develop, individually or in partnership with a Patients' Association, information or educational material for patients about a particular pathology?

Yes, materials on pathologies and/or therapies for Patients can be developed, irrespective of the medium, as long as they are not related to the promotion of medicinal products. These materials may address the importance of early diagnosis, life habits that help to prevent the progression of the disease or to improve the symptoms, how to manage and value certain adverse effects of the therapy, etc.

Examples: brochures/DVDs/pens/websites/apps on the pathology or disease management. Note: Digital media should be protected from manipulation/reuse; otherwise, they may be considered as a gift to patients.

26. Can the materials mentioned in the previous question be distributed by Patients' Associations and healthcare professionals?

Yes, they can.

27. Are there value limits for this sort of materials?

Yes, there are. The unit value of each information or educational material may not exceed 60,00 Euros, VAT included.

V. EVENTS AND ACTIVITIES CO-ORGANISED BY MEMBER COMPANIES AND PATIENTS' ASSOCIATIONS

28. A member company wants to develop a project, for example, a disease awareness campaign, in partnership with a Patients' Association. Can the company do this?

Yes, this sort of initiatives is of common interest for the Pharmaceutical Industry and the Patients' Association and the two entities can contribute and cooperate in a specific way. As long as it is a one-off initiative, limited in time and scope, and not the whole activity of the Patients' Association, it is possible that this partnership is created with a single company of the Pharmaceutical Industry and the costs can be fully borne by the company.

29. How is a partnership between a member company and a Patients' Association developed?

The partnership must be identified and detailed in a written agreement, which establishes the responsibilities and tasks of each party. The implementation of the project must be accompanied by an implementation schedule, identification of costs and, at the end, an assessment of the completion of the project, including the estimate of all costs.

30. What kind of responsibilities will a Patients' Association have in a partnership with a company?

The responsibility of the Patients' Association depends on the scope and purpose of the partnership in question. Patients' Associations are best aware of the challenges and training and information needs of patients, and their contribution can be essential to tailoring the message to those for whom it is intended. Patients' Associations can also use their communication channels to reach a wider audience.

VI. EVENTS AND ACTIVITIES ORGANISED BY PATIENTS' ASSOCIATIONS SUPPORTED BY PHARMACEUTICAL COMPANIES

31. What kind of events/activities of Patients' Associations can be supported or sponsored by Companies?

The following activities organised by Patients' Associations are normally considered eligible for support or sponsorship by member companies:

- Disease awareness programmes or campaigns;
- Conferences and other educational or scientific events aimed at increasing the knowledge and awareness of diseases;
- Professional meetings of Patients' Associations, related to the fulfilment of their mission and goals;
- Awards granted by Patients' Associations the main purpose of which is to promote science or the development of scientific or educational methodologies and information.
- Initiatives to raise funds for the development of the above-mentioned activities;

Activities other than those listed above may also be considered eligible, provided that they comply with all the principles and rules set out in the Code of Conduct and in the legislation in force.

32. Can a company review and/or correct the materials produced by the Patients' Associations to which they grant financial support?

Yes. Companies may review and/or correct the materials produced by the Patients' Associations to which they grant financial support in order to correct factual and/or scientific inaccuracies, but they may not seek to influence the content of these produced materials in such a way as to favour their commercial interests.

33. Is it possible for Companies to provide support to Patient Advocates, Patient Experts, Patients or Caregivers?

No. Companies can only provide financial/sponsorship support or non-financial support to Patients' Associations.

34. Can companies bear the hospitality expenses of representatives of Patients' Associations, Patient Experts, Patient Advocates, Patients and Caregivers for the purpose of attending institutional, scientific and/or educational events they organise or sponsor?

Yes. However, hospitality costs should be limited to what is strictly necessary for the main purpose of the event and include only travel, meals, accommodation and/or registration costs. Hospitality is limited to participants in their own right, with the exception of the situation where the participant has to be accompanied by a Caregiver, who is not registered for the event. In this situation, the company can bear the costs of travel, meals, accommodation and/or registration of the accompanying person as Guest Patient Caregiver. The hospitality should not exceed the period between the day before the start and the day after the end of the event.

35. A Patients' Association requests sponsorship from a Company for an awareness-raising activity for a group of patients and/or healthcare providers. What can this sponsorship consist of and what can the Company get in return?

Sponsorship may consist of a financial or non-financial contribution (for instance, the renting of premises to carry out the activity, the provision of audio-visual media).

In return, the company may, inter alia, have the right to participate in the activity, set up an institutional stand or distribute corporate promotional materials.

No direct or indirect advertising of prescription medicinal products may be carried out in that activity.

36. Whenever a Patients' Association submits a request for support or sponsorship to a company in the Pharmaceutical Industry, should the company request the formalization of the request in writing?

Yes. The request addressed to the Company should be formalised in writing (for instance, by letter or e-mail), and must be dated and signed, even if electronically, by the Patients' Association.

37. Within the framework of support or sponsorship granted to activities/events of Patients' Associations, what kind of costs can be borne by companies in the Pharmaceutical Industry?

The actual and reasonable costs necessary to carry out the activity/event, such as: costs related to the fees of speakers or trainers, space rental, accommodation or meals of the participants (as long as justified by the meeting agenda), or costs of educational material or of disseminating the activity/event.

38. Is it compulsory to report to Infarmed, through the Transparency and Advertising Platform, the support and sponsorship granted to Patients' Associations and the amounts paid as remuneration for the provision of services by Patients' Associations and Patient Advocates?

Yes, in accordance with Article 159 of the Medicinal Products Statute.

39. Should cross-border value transfers, i.e., by other companies in the group, relating to the above-mentioned support/sponsorship and service provision also be reported to Infarmed through the Transparency and Advertising Platform?

Yes, cross-border value transfers when carried out by companies belonging to the same economic group as APIFARMA member companies, even if based in another country, should also be reported.

Final Remark:

This document may be reviewed at any time if there are changes in the applicable legal and/or ethical rules.

APIFARMA

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