Index

Introduction .......................................................... 04
Definitions ............................................................ 06
Definition and object of the Code................................. 07
Scope of the Code ...................................................... 07

TITLE I PROVISIONS OF THE CODE

Chapter I Promotion of Prescription-Only Medicines .................................................. 10
1. Marketing Authorization for Medicines .............................................................. 10
2. Information on Medicines to be Made Available ................................................. 10
3. Information on Medicines and its Substantiation .................................................. 11
4. Acceptability of Promotional Material ............................................................... 11
5. Transparency in Promotion of Medicines ............................................................ 12
6. Use of Quotations............................................................................................... 12
7. Distribution of Promotional Material for Medicines ............................................ 12
8. Digital Environment............................................................................................. 13
9. Scientific Department and Review of Promotional Material on Medicines .................. 14

Chapter II Interaction with Healthcare Professionals and Organisations .................. 14
10. Guarantees of Independence............................................................................... 14
11. Scientific and Professional Meetings .................................................................. 16
12. Pharmaceutical Company Personnel.................................................................. 18
13. Medical Samples................................................................................................. 20
14. Studies................................................................................................................ 20
15. Donations and Grants.......................................................................................... 23
16. Services Provided by Healthcare Professionals or Healthcare Organisations ............ 24

Chapter III Relationships with Patient Organisations .......................................... 25
17. Relationships with Patient Organisations............................................................ 25

Chapter IV Transparency of the Pharmaceutical Industry's Relationships ................ 28
18. Transparency of the Pharmaceutical Industry's Relationships ................................ 28

Chapter V Rules of Application, Monitoring, Breaches and Sanctions ..................... 31
19. Rules of Application............................................................................................ 31
20. Queries................................................................................................................ 32
21. Monitoring of Compliance with the Code............................................................ 32

22. Breaches and Sanctions...................................................................................... 33
23. Supplementary Rules......................................................................................... 34
24. Publication and Collection of Resolutions......................................................... 35

TITLE II RULES OF PROCEDURE FOR THE CONTROL BODIES

Chapter I The Code of Practice Committee of the Pharmaceutical Industry in Spain .. 37
25. Structure and Functions...................................................................................... 37
26. Meetings............................................................................................................ 38
27. Authorities.......................................................................................................... 38

Chapter II The Code of Practice Surveillance Unit of the Pharmaceutical Industry in Spain .................................................. 38
28. Structure, Organisation, Operation Principles and Authorities................................ 38

Chapter III The Jury of AUTOCONTROL ......................................................... 40
29. The Jury............................................................................................................... 40
30. Notifications and Execution of Resolutions of the Jury........................................ 40

Chapter IV Procedures ............................................................................................ 41
31. General Rules...................................................................................................... 41
32. Complaint Procedure.......................................................................................... 41
33. Procedure for Communicating Events and Scientific Meetings .......................... 42
34. Procedure for Communicating Studies............................................................... 44
35. Procedure for Communicating Services Provided by Healthcare Professionals or Healthcare Organisations.......................................................... 45
36. Queries Procedure.............................................................................................. 46
37. Investigation Procedure....................................................................................... 46

TITLE III COMING INTO EFFECT OF THE CODE

38. Coming into Effect of the Code........................................................................... 51

ANNEX I
Disclosure Template................................................................................................. 53

ANNEX II
Queries (Questions and Answers) on the Interpretation of the Code of Practice............. 57

These texts are the non-official translation of the Spanish version of the texts approved by Farmaindustria General Assembly. The Spanish versions shall always prevail.
Code of Practice for the Pharmaceutical Industry
2014

Introduction

The Spanish pharmaceutical industry is committed to promoting patient well-being and high-quality healthcare by conducting its activities according to ethical criteria of professionalism and responsibility. As an integral part of the healthcare system, pharmaceutical companies can and must collaborate in creating and maintaining confidence that decisions made in relation to prescribing medicines are based on the best quality of patient care.

Farmaindustria, the Association of the Pharmaceutical Industry in Spain, brings together the vast majority of innovative pharmaceutical companies that represent practically all of prescription-only medicine sales in Spain. They are largely responsible for the value medicines provide to social progress and quality of life in the country. The commitment of the Spanish pharmaceutical industry in providing medicines of the highest quality and efficacy provides a very important benefit to the country, both from a health perspective as well as an economic perspective.

In order to ensure that the conduct of companies is ethical, professional and responsible, respecting the legitimate right of companies to promote their products, it is necessary to identify and establish the balance between the needs of patients, Healthcare Professionals and the general public. In view of the political and social environment in which the pharmaceutical industry operates, with the administrative control that exists for medicines, the availability of complete, accurate and objective information on medicines is essential to ensure their rational use.

As a proof of this commitment, Farmaindustria adopted the European Code of Practice on the Promotion of Medicines of the European Federation of Pharmaceutical Industries and Associations (EFPIA) as the Spanish Code in 1991. Since this first version, the Code has been revised on a regular basis in order to adapt to and anticipate the new requirements of a constantly evolving society. This process of evolution and continuous improvement is motivated, among other factors, by the obligation to adapt its terms and conditions to regulatory changes and new initiatives on self-regulation, and by the need to provide coverage to all of the activities conducted by pharmaceutical companies with those stakeholders with which they interrelate and interact, as well as the desire to strengthen their compliance and provide the Code with greater credibility and transparency. Our system must guarantee to Healthcare Professionals that the information, medical education and promotion of medicines embody as central elements scientific rigor, transparency and ethics.

This has led to a new self-regulation system in the Pharmaceutical Industry with this new version of the Code of Practice for the Pharmaceutical Industry, approved by the Governing Bodies of Farmaindustria in December 2013 and ratified by Farmaindustria General Assembly in June 2014. The Code incorporates, among others, the principles provided for in:

• Law 29/2006, of 26 July, on Guarantees and Rational Use of Medicinal Products and Medical Devices.


• European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes on Interactions with Healthcare Professionals, Relationships with Patient Organisations and Disclosure of Transfers of Value.¹

• International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices.²

The new Code essentially addresses three areas:

(i) **Promotion of Prescription-Only Medicines.**
Respecting the right of the scientific community to be completely informed about medical and scientific progress, on one hand, and the legitimate interest of companies to inform and promote their products, on the other hand. This section of the Code provides for a series of regulations designed to guarantee that the information provided in the context of the promotion of prescription-only medicines is appropriate, honest, precise, objective, complete, accurate, and truthful.

(ii) **Relationships with Healthcare Professionals and Healthcare Organisations.** The interactions between Healthcare Professionals and the pharmaceutical industry have a fundamental influence on patient care and research development; for this reason, it is necessary to establish criteria and guidelines to guarantee that these activities are conducted in a professional and responsible manner.

(iii) **Relationships with Patient Organisations.** Patient Organisations and the pharmaceutical industry share common interests, such as improving the quality of life of patients and attention to their interests. The rules included in this section guarantee that the manner in which companies interact with patients and with the organizations that represent them is appropriate and in compliance with, among others, the principles of independence, mutual respect and transparency.

The continuous commitment of pharmaceutical companies to the development, efficacy and rigor of the self-regulation system is the result of the responsible attitude of Farmaindustria members and those companies that have decided to adhere to the Code voluntarily. This commitment is proved by the implementation by the companies of robust internal procedures designed to guarantee compliance with the Code, with the aim of ensuring appropriate training of their employees.

The transparency of the self-regulation system is offered as an essential tool for promoting and strengthening confidence in the pharmaceutical industry, facilitating public access to their actions. Proof of this commitment is the publication of the Resolutions of the Jury of the Association for Self Regulation of Commercial Communications in complaint procedures, information related to clinical trials, collaboration provided to Patient Organisations and, more recently, the disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organisations.

The monitoring functions of the Code are conducted by three Control Bodies: the Code of Practice Surveillance Unit, the Code of Practice Committee and the Jury of the Association for Self Regulation of Commercial Communications. These Bodies are responsible for monitoring compliance with the Code, providing consultation and orientation on the interpretation of the Code to members, mediating in the case of complaints and issuing resolutions for those disputes in which a mediation agreement has not been reached.

¹ EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interaction with, Healthcare Professionals.
² EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.
² EFPIA Code on Disclosures of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations.
² International Federation of Pharmaceutical Manufacturers & Associations Code of Practice.
Definitions

For the purposes of this Code, the terms listed below are understood to have the following definitions:

**Recipient:** Any Healthcare Professional or Healthcare Organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Spain.

**Donation (Monetary Grant or Benefit in Kind):** An act of generosity through which a company (donor) makes an amount of money, goods or services (donation in kind) freely available to a third party (donee), which accepts it. It is considered final if for those cases in which the money, goods or services are intended for the fulfillment of a given objective, the execution of a project or the completion of an activity by the donee. In all cases, the donor will not receive or request any compensation from the donee (regulated by article 15 of the Code).

**Events:** Any promotional meeting, scientific-professional meeting, congress, conference, symposium, in-person or distance educational courses, or any other type of similar activity (including but not limited to expert meetings, visits to manufacturing and research facilities, as well as training meetings for investigators conducting clinical trials and post-authorization studies) organised or sponsored by a pharmaceutical company or under its control.

**Interaction:** Activities performed, organised or sponsored by a pharmaceutical company, or under its control — subsidiaries, foundations, associations, institutes, agencies, third-party providers, etc. — from which direct or indirect collaboration, support and/or compensation of any kind may be derived by a third party.

**Research and Development:** Activities related to the planning or conduct of (i) non-clinical studies (as defined by the OECD “Principles of Good Laboratory Practices”), (ii) clinical trials (as defined by Directive 2001/20/EC and considered in article 14.1 of the Code) and (iii) post-authorization studies (considered in article 14.2 of the Code).

**Medicinal Product for Human Use:** Any substance or combination of substances that is presented as having properties for the treatment or prevention of disease in humans, or that may be used in humans or administered to humans for the purpose of restoring, correcting or modifying physiological functions by exercising pharmaceutical, immunological or metabolic action, or for the purpose of establishing a medical diagnosis. Any mention in this Code to medicines is understood to refer to a medicinal product for human use.

**Patient Organisation:** A non-profit organisation — including umbrella organisations to which they belong — composed primarily of patients and/or their caregivers that represents and/or supports the needs of patients and/or their caregivers.

**Healthcare Organisation:** Any legal body or entity (i) that is a medical or scientific organisation, healthcare institution (of any legal status or organisation), such as hospitals, clinics, foundations, universities and other academic entities, scientific societies (excluding Patient Organisations covered by article 17 of this Code), or (ii) through which one or more Healthcare Professionals provide services.

**Market Price:** The amount a private party should generally have to pay in order to acquire a unit of a good, product, material, article or similar in Spain.

**Healthcare Professionals:** Any member of the medical, dental, pharmaceutical, nursing or podiatric profession, any other person legally considered as such, or any other person who, in exercising their profession, may perform or participate in the prescription, purchase, supply, dispensation or administration of medicinal products for human use. For the purpose of this Code veterinarians are excluded from this concept.

**Promotion:** Any activity performed, organised or sponsored by a pharmaceutical company, or under its control — subsidiaries, foundations, associations, institutes, agencies, etc. — designed to favour, either directly or indirectly, the prescription,
dispensation, recommendation, sale or consumption of medicinal products for human use.

**Transfers of Value:** Any direct or indirect Transfers of Value, whether in cash, in kind or otherwise, regardless of its purpose.

Direct: Transfers of Value are those made directly by a company for the benefit of a Recipient.

Indirect: Transfers of value are those made by a third party (provider, agent, partner or affiliate – including foundations -) acting on behalf of a company for the benefit of a Recipient when the company knows or can identify such Recipient.

Transfers of Value made as part of commercial transactions between companies and distributors, pharmacy offices and Healthcare Organisations are excluded from this concept.

**Definition and Object of the Code**

This code constitutes the collection of ethical rules through which, making use of their self-regulation power and in accordance with the stipulations of paragraph 5 of article 97 of Directive 2001/83/EC, which establishes a Community code relating to medicinal products for human use, Farmaindustria has agreed to be bound in both the promotion of medicinal products for human use and the interactions with Healthcare Professionals, Healthcare Organisations and Patient Organisations, with the intent of guaranteeing that these activities be conducted while respecting the most stringent ethical principles of professionalism and responsibility, signing to this effect an Agreement with the Association for Self-Regulation of Commercial Communications (autocontrol).

Compliance with the principles of the Code ensures that the information provided in the area of promotion of prescription-only medicines is complete, accurate and truthful, all to benefit both the interests of the Health Administration as well as those of the pharmaceutical industry in the name of protecting and improving public health. The activities or materials related to promotion, as well as the interactions with Healthcare Professionals, Healthcare Organisations and Patient Organisations must contribute, in their content or nature, to improving confidence in the pharmaceutical industry.

**Scope of the Code**

The Code covers all forms of: (i) promotion of prescription-only medicines, (ii) interactions between pharmaceutical companies and Healthcare Professionals and Healthcare Organisations, and (iii) relationship between pharmaceutical companies and Patient Organisations.

In matters of the promotion of medicinal products for human use, it covers all methods of promotion including the press and direct mail advertising, activities of company employees, the Internet, the use of audiovisual materials such as movies, videos, data storage systems and other means that may arise in the future.

In addition, the Code covers all forms of interaction between pharmaceutical companies with Healthcare Professionals and with Healthcare Organisations, including the sponsorship of scientific conferences and meetings of a professional or scientific nature that are attended by Healthcare Professionals, the provision of samples and hospitality, and those derived from research agreements (clinical trials, studies) or other types of agreements (collaboration, consultation, etc.). It also covers all forms of relationships between pharmaceutical companies and Patient Organisations.

The Code does not cover:

i) The labeling of medicinal products and package leaflets.

ii) Correspondence, accompanied, where applicable, by any document of a non-promotional nature (for example, scientific articles) that is needed to respond to a specific question about a specific medicine, but only if it refers to the question that is the subject of inquiry and is accurate and not misleading.

iii) Specific information and relevant documents related to, for example, changes in packaging, adverse reaction warnings in the framework of pharmacovigilance, sales catalogues and price
lists, provided no information on the medicine is included. It also does not cover information on certain medicines that the physician can provide to the patient that, due to the complexity of dosage, route of administration, etc., require the provision of additional information, and only if this information is intended to improve adherence to treatment.

iv) Information on human health or diseases in individuals provided there is no reference, even indirect, to specific medicinal products.

v) Corporate advertising from pharmaceutical companies, except as stated in article 10.

vi) Provision of promotional materials on medicines that can be advertised to the general public, except as stated in article 10.

vii) Texts written and produced by journalists in their professional work in regular editions, supplements, extraordinary numbers or editions, etc., of newspapers, magazines, television or radio programmes, etc., in which information about drug therapies, specific treatments or “new” medicines, scientific studies or papers or references to a specific medicine, lines of research or product launchings, press conferences, publications, etc. is presented as a news item, an interview, a debate, an editorial or another similar format, provided that a contractual relationship does not exist between the research company, or owner of the trade mark or of the medicines and the firm responsible for editing or the author of the information.

viii) Commercial transactions by the companies with distributors, pharmacy offices and Healthcare Organisations.

The purpose of this Code is not to halt the interchange of medical and scientific information during a product’s development phase, nor is it to limit the interaction between pharmaceutical companies and Healthcare Professionals or Organisations and Patient Organisations, but rather to establish rules of procedure that the entire pharmaceutical industry commits to follow.

Companies must comply with the spirit and wording of the Code, maintaining the same behavioural standards in their relationships with the different stakeholders with whom they interact.

<table>
<thead>
<tr>
<th>SCOPE OF THE CODE: SUPPLEMENTARY RULES</th>
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<tbody>
<tr>
<td>For clarification purposes, all forms of interaction between pharmaceutical companies and Healthcare Professionals, Healthcare Organisations and Patient Organisations, regardless of origin, scope, nature or purpose, are subject to the precepts of this Code.</td>
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Title I
Provisions of the Code
CHAPTER I

Promotion of Prescription-Only Medicines

1. MARKETING AUTHORIZATION FOR MEDICINES

1.1. A medicine cannot be promoted prior to the granting of the marketing authorization allowing its commercialisation. This prohibition also covers medicines that, while authorized in another country, have not obtained commercialisation authorization in Spain. This precept, however, does not place a limit on the right of the scientific community to be fully informed of medical and scientific progress, nor does it restrict the complete and appropriate exchange of scientific information related to medicines or medicinal products, included among which is the appropriate and objective disclosure of research findings in scientific media and scientific congresses.

1.2. All parts of the advertising of a medicinal product must be consistent with the information contained in the applicable summary of product characteristics and with the approved indications.

2. INFORMATION ON MEDICINES TO BE MADE AVAILABLE

2.1. All printed promotional material must include the following information clearly and legibly:

a) Essential information consistent with the data contained in the current summary of product characteristics, specifying the date on which it was prepared or last reviewed.

b) The medicine’s prescribing and dispensing conditions.

c) The different presentations of the medicine, where applicable, and the dosage and/or pharmaceutical form.

d) The public sale Price, the conditions for reimbursement by the National Health System, where applicable, and, whenever feasible, the estimated cost of treatment.

2.2. In audiovisual materials such as videos, films and the like, as well as in interactive systems, the information may be provided:

a) In a document made available to all persons to whom the material is shown or sent.

b) Included in the recording or interactive system. In this case, the information will be included as technically possible and adapted to the chosen medium, but in a manner that guarantees rapid and comprehensible access to the current summary of product characteristics. In this regard, if the information is included in an interactive system, the instructions for accessing the information must be clearly visible.

2.3. In accordance with national legislation, the advertising may, by derogation of the stipulations of paragraph 2.1, include only the name of the medicine, whenever the advertisement is intended only as a reminder and the medicine has been authorized for at least two years. In this case, the name of the medicinal product must be included and, when this is a brand name or a fantasy name and the product only contains a single drug substance, it must be accompanied by the Spanish Official Name or, if it does not have one, the International Non-Proprietary Name. The product logo and name and the company logo may also be included, but no other information.

2.4. Any printed information or documentation that pharmaceutical companies provide to the physician to be handed over to the patient on medicines that, due to the complexity of dosage, route of administration, etc., require the provision of additional information, as long as it is intended to improve treatment compliance, will not be considered a promotional material.
3. INFORMATION ON MEDICINES AND ITS SUBSTANTIATION

3.1. Information on medicines must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion on the therapeutic value of the medicine concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not lead to confusion through distortion, undue emphasis, omission or any other way.

3.2. All graphic material, including illustrations, graphs and tables, must conform to the content and spirit of the Code. The graphs and tables must be presented in a manner that offers a clear, fair and balanced view of the topics covered and they must not be included unless they are relevant to the affirmations or comparisons being made.

Particular care must be taken to ensure that all artwork included in the promotion is not misleading with regard to the nature of a medicine (for example, whether it is appropriate for use in children) or with regard to a claim or comparison (for example, by using incomplete or statistically irrelevant information or unusual scales).

3.3. The information and statements on side effects must reflect the available evidence. It must not be stated that a product has no side effects, toxic hazards or risks of addiction or dependency.

3.4. In order to avoid adaptations that may introduce biases and cause confusion in the presentation of data, when the promotional material refers to published studies, the latter must be cited in a precise manner. In the case of tables or graphs, their reproduction must be literal. In accordance with the rules on publishing data, the reference to the published work must be included.

In this regard, and as an example, when efficacy, safety or other properties of different active ingredients are compared for the purposes of advertising, information such as the level of statistical significance of the results cannot be omitted, nor can the results of different studies or clinical trials be included in the same table or graph unless the source is a meta-analysis. Also, statistics, conclusions or any other data from different studies conducted with different methodologies cannot be mixed or compared unless they are derived from systematic reviews or meta-analysis in which the homogeneity criteria are expressed.

3.5. No exaggerated or general statements may be made, or statements that presume that a medicinal product, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

3.6. The term “new” cannot be used to describe a medicine or presentation that has been widely available, or any indication that has been the subject of widely available promotion, for more than two years in Spain.

3.7. The brands or brand names of medicines from other companies can only be cited when unequivocally indicating in a clear and visible manner that they are the property of their marketer.

3.8. Comparative advertising must respect the norms of fair competition in all cases. It cannot be denigrating and comparisons must be based on comparable and relevant extremes. In all cases, and especially in comparative advertising, care must be taken to ensure that the sources that serve as a basis for the statements are valid and immediately accessible to the competitor.

3.9. Any information, claim or comparison included in the promotional material must be substantiated. This substantiation (or justification) must be provided at the request of physicians and other Healthcare Professionals who are authorized to prescribe or dispense medicines. In particular, any comparison that is made between different medicines must be scientifically verified. The statements related to the indications approved in the current summary of product characteristics do not need to be substantiated.

4. ACCEPTABILITY OF PROMOTIONAL MATERIAL

4.1. Any promotional activity or material must respect the special nature of the medicine and the professional level of the recipients without causing any type of offence or decrease in confidence in the pharmaceutical industry.
4.2. The promotional material must not imitate the products, slogans, presentation or general designs adopted by other companies in a way that may lead to error, be misleading or confusing.

4.3. Postcards, any other type of open mail, envelopes or packaging must not contain anything that could be confused with advertising directed to the public.

4.4. All material related to medicines and their uses which is sponsored by a pharmaceutical company must clearly indicate the sponsor.

5. TRANSPARENCY IN PROMOTION OF MEDICINES

5.1. No promotional activity or material may hide its true objective or nature.

5.2. When a company directly or indirectly finances, participates in or organises the publication of promotional material in newspapers or magazines, it must clearly indicate that said material is not presented as an independent editorial and the sponsoring company must appear in a visible location.

5.3. Any material related to medicines and their uses, whether of a promotional nature or not, that is sponsored by a company must clearly indicate that it has been sponsored by that company.

5.4. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a Healthcare Professional.

6. USE OF QUOTATIONS

6.1. Quotations from medical and scientific literature or from personal communications must exactly reflect the opinion of the author.

6.2. Quotations related to medicines collected from public broadcasts, such as radio and television, and those collected at private Events, must not be used without the formal consent of the speaker, lecturer or orator author of the quotations.

7. DISTRIBUTION OF PROMOTIONAL MATERIAL FOR MEDICINES

7.1. Promotional material related to prescription-only medicines must be distributed or provided exclusively to those Healthcare Professionals that are authorized to prescribe or dispense them.

Unless authorized by the competent health authority (for example, vaccine campaigns), no promotion of medicines that can only be dispensed through facultative prescription may be carried out.

7.2. Mailing lists for sending promotional material must be kept up-to-date periodically. Requests to be removed from promotional mailing lists from Healthcare Professionals authorized to prescribe or dispense medicines must be complied with.

7.3. All promotional activities must be performed in compliance with personal data protection applicable legislation.

7.4. At international conferences and meetings organised by third parties that are attended by a large number of professionals from other countries, professionals attending the conference can be informed about a medicine that is not authorized in Spain or an indication not authorized in Spain provided that:

(i) the information created or provided is written in English or in some of the languages corresponding to the country where it is authorized, and

(ii) the item or advertising material indicates or states, at least in Spanish, with clearly visible highlighted letters in a constant, lasting and legible way, some text or warning of the following type: “this medicine is not marketed in Spain or the following countries ...” or “only authorized in ...” or “not authorized in Spain for the following indication...”.

These texts are the non-official translation of the Spanish version of the texts approved by Farmaindustria General Assembly. The Spanish versions shall always prevail.
8. DIGITAL ENVIRONMENT

8.1. Promotion of medicines directed to Healthcare Professionals authorized to prescribe or dispense medicines disseminated through the Internet must be within a context that is basically technical, scientific or professional.

8.2. In addition, measures should be taken to ensure that this promotion is only disseminated to these professional groups.

8.3. It must include, in a clearly legible, highlighted manner, a warning stating that the information on the web page is intended exclusively for the Healthcare Professional authorized to prescribe or dispense medicines; specialised training is therefore required for the correct interpretation of the information.

In all cases, pharmaceutical companies are responsible for the content disclosed through the media, means of delivery or channels of communication that directly or indirectly control or finance exclusively or in the majority. Therefore, usage and style guidelines must be implemented that establish rules of conduct and consequences derived from non-compliance, as well as a procedure for monitoring the content to which they provide access, host, temporarily copy or link. This procedure must address the obligation to correct any irregularity quickly.

In addition, pharmaceutical companies must possess guidelines and rules of conduct for their employees that establish standards for responsible conduct in the digital environment, both for when sharing information about or in the name of the company as well as when using a medium, means of delivery or channel provided by the company.

The above includes but is not limited to SMS, MMS, web pages, electronic mail, forums, blogs, social networks, chat, platforms, applications or any other type of digital channel, means of delivery or medium.

8.4. In this regard, pharmaceutical companies must take into account the rules established by the competent health authorities for “valid means of delivery”. In general, this refers to means of delivery that are used as a mechanism of information or promotion, whether it be written, audiovisual or of another nature, that meets the following conditions: (i) the majority or practical entirety of its content must be scientific or professional and (ii) it is directed exclusively to persons authorized to prescribe or dispense medicines.

In all cases, pharmaceutical companies are responsible for the content disclosed through the media, means of delivery or channels of communication that directly or indirectly control or finance exclusively or in the majority. Therefore, usage and style guidelines must be implemented that establish rules of conduct and consequences derived from non-compliance, as well as a procedure for monitoring the content to which they provide access, host, temporarily copy or link. This procedure must address the obligation to correct any irregularity quickly.

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8.2. Pharmaceutical companies must refrain from making any promotional content on prescription-only medicines directly or indirectly available to the general public through the use of links, comments, markers or any other practice that involves it being repeated, copied or resent.

8.3. This warning must appear in a clear and prominent way before accessing the information, as well as on the pages, mobile applications or similar outlets in which the information appears. Individuals who access the content must declare their status as a Healthcare Professional who is authorized to prescribe or dispense medicines.
9. SCIENTIFIC DEPARTMENT AND REVIEW OF PROMOTIONAL MATERIAL ON MEDICINES

9.1. Companies must have a scientific department to compile and collate all information, whether received from their employees or any other source, related to the medicines which they market and inform about it.

9.2. The promotional material must not be disclosed without the final version, which has not undergone any subsequent modifications, being reviewed and controlled by the company’s scientific department. The scientific department must guarantee that it has examined the final version of the material and that, in its opinion, it complies with applicable advertising rules and with this Code, that it is within the bounds of the marketing authorization and, in particular, of the information that appears on the summary of product characteristics or authorized prospectus, and that it is an honest and faithful presentation of the data of the medicine.

CHAPTER II
Interaction with Healthcare Professionals and Organisations

10. GUARANTEES OF INDEPENDENCE

10.1. Prohibition of Gifts
In order to avoid incentivizing the prescription, dispensing or administration of prescription-only medicines, the direct or indirect offering or provision of any type of incentive, prize or gift (in cash or in kind) to Healthcare Professionals is prohibited.

The above prohibition does not apply to the direct or indirect offering or provision of stationery or items for the practice of medicine or pharmacy that meet the following conditions: (i) is not related to a prescription-only medicine and (ii) the market price does not exceed 10 Euro.

10.2. Informational or Educational Materials and Items of Medical Utility

10.2.1. The direct or indirect provision of informational or educational materials to Healthcare Professionals will be permitted provided that they meet the following three conditions:

(i) Inexpensive. In this regard, the material is considered to be inexpensive when the market price does not exceed 60 Euro.

(ii) Materials directly relevant to the practice of medicine or pharmacy.

(iii) Materials that directly benefit patient care.

Provision of this type of materials shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

10.2.2. Items of medical utility aimed directly at the education of Healthcare Professionals and patient care can be directly or indirectly provided to Healthcare Professionals if they are inexpensive (their market price does not exceed 60 Euro) and do not offset routine business practices of the recipient.

GUARANTEES OF INDEPENDENCE: SUPPLEMENTARY RULES

10.1 In application of the principle of coherence and in order to avoid it being interpreted as an offering or provision of gifts related to prescription-only medicines, companies:

a) within the framework of medical visits mainly related to prescription-only medicines, shall refrain from the offering or provision of stationery or items for the practice of medicine or pharmacy.

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4 Adapted to the new revision of articles 9 and 17 of the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.
b) within the framework of **scientific and professional meetings organised by a third party**, where promotion mainly pertains to prescription-only medicines, shall refrain from the offering or provision of stationery or items for the practice of medicine or pharmacy. Companies shall not offer or provide stationery or items for the practice of medicine or pharmacy in the exhibition stands.

Pens or pads included in the congress bag shall not include any kind of promotional element or reference, that is to say, they shall not include corporate/institutional advertising or product advertising.

Each company shall be responsible for individually assessing the scope and nature of each scientific and professional meeting, including the activities/practices it plans to carry out within its framework, in order to determine whether such meeting is mainly related to prescription-only medicines.

c) within the framework of **scientific and professional meetings organised by a company**, only pens and pads may be offered or provided; provided that they are not related to a prescription-only medicine and their market price does not exceed 10 Euro (tax included).

10.2. The provision of materials to Healthcare Professionals, including but not limited to those detailed below, is permitted provided they meet the requirements indicated in articles 10.2.1 and 10.2.2 (*):

- Printed materials used to promote or provide information on medical practice and medicines. The contents of these materials must meet the requirements indicated in articles 2 through 7 (inclusive) of the Code.

- Reprints, supplements from scientific articles.

- Educational materials provided to the Healthcare Professional for use with patients.

(*) As an exception, the provision of flash drives that contain scientific-professional content of an informational or educational nature is permitted, provided that its market price does not exceed 10 Euro.

In addition, companies must take into account:

a) In those materials aimed at patients, guarantee that these do not include elements that directly or indirectly relate to prescription-only medicines (for example: colours, logos, brand, active ingredient, claims/promotional sentences, etc.).

b) In those materials aimed at Healthcare Professionals (different from those used to promote their products), refrain from including elements directly or indirectly related to prescription-only medicines, unless such materials meet the conditions established by the competent health authorities for “valid means of delivery”.

c) Regardless of their market price, refrain from directly or indirectly offering or providing to Healthcare Professionals items or articles necessary or essential to their professional practice, as such activity/practice offsets routine business practices, especially taking into account the individual and exclusive use of many of them. The Healthcare Professional or the organization where he provides his service are the ones that have to provide the resources and means necessary for the carrying out of his professional activity. Consequently, regardless of its market price and even if they could be considered medical utility items, stethoscopes, phonendoscopes, pulsioximeters, medical coats, medical clogs, surgical caps, gloves, surgical goggles, tensimeters, masks, gauzes, bandages, dressings, etc. shall not be provided.

d) In all cases, the direct or indirect offering or provision to Healthcare Professionals of informational or educational materials and items of medical utility whose market price exceeds 60 Euros shall constitute a breach of the Code.

e) The offering or provision to Healthcare Organisations of items or materials not permitted mentioned in the above (c) and (d) sections shall constitute a breach of the Code when they involve an indirect offering or provision to Healthcare Professionals.

f) These requirements shall apply regardless of the means of delivery used to directly or indirectly offer or provide the informational or educational materials and items of medical utility (for example: on a physical medium – printed materials-, or on a digital medium – mobile apps-, etc...).
11. SCIENTIFIC AND PROFESSIONAL MEETINGS\(^5\)

The following rules will be applied to all types of Events that are organised or sponsored by a pharmaceutical company or under its control and to all participants in said Events, be they Healthcare Professionals or any other persons who, in exercising their professions, may perform or influence the activities of prescribing, purchasing, distributing, dispensing or administering a medicine.

11.1. Pharmaceutical companies may organise or collaborate in Events that are exclusively of a scientific-professional nature. Organising or collaborating in Events that contain elements of entertainment or entertainment activities or are of a recreational nature is prohibited. The welcome cocktail, working luncheons and gala dinners that normally occur within official programs at scientific conferences and meetings are not included in this prohibition provided they are reasonable and moderate and do not include additional elements (cultural, leisure or entertainment, etc.). In all cases, a maximum cost of 60 Euro (including taxes) per guest applies for any form of hospitality associated with meals. Payment for a meal that costs more than the maximum threshold mentioned above will be considered a breach of the Code. For Events that take place outside of Spain, the maximum threshold established by the National Association of the country where the Event occurs will apply. Therefore, for hospitality offered outside of Spain involving meals, the general rule provided for in article 19.4 ("If there is a conflict between rules of the different applicable codes for a given activity, the most strict or restrictive rule will apply") will not be applicable.

Payment to Healthcare Professionals for any form of hospitality that takes place at the margins of a scientific-professional context is considered to be an activity/practice that is a breach of the Code.

11.2. Hospitality at professional or scientific Events must always be reasonable and the cost must not exceed the cost the Recipients would be willing to pay in the same circumstances. The concept of hospitality includes the real costs of travel, registration and accommodation that are paid by the company. These costs must be moderate and not exaggerated and will be applied to the days in which the scientific meeting is planned. In this regard, hospitality may not be extended beyond what is reasonable for conducting the Event, nor may it include sponsorship or organisation of entertainment activities (sports, leisure activities, etc.). Hospitality must always be accessory to the primary object of the meeting. The scientific objectives must constitute the primary focus in the organisation of these meetings. Hospitality offered by a pharmaceutical company must be limited to including strictly necessary logistical means, in all cases reasonable and moderate, that allow the Healthcare Professional to attend the Event and not any other expenses.

11.3. Hospitality may not be extended to persons other than Healthcare Professionals.

11.4. Payments must not be made to physicians or groups of physicians, either directly or indirectly, to rent rooms for meetings unless it is duly accredited that the payments are for meetings of a scientific or professional nature.

11.5. When meetings, conferences, symposia and similar Events are sponsored by pharmaceutical companies, this fact will appear on all documents related to the meeting in addition to any type of essay, paper or document that is published in relation to them.

11.6. Payment of reasonable honoraria and reimbursement of personal expenses, including travel, is acceptable to moderators and speakers at these meetings, conferences, symposia and similar Events of a professional or scientific nature.

11.7. Pharmaceutical companies established in Spain that belong to business groups with headquarters or subsidiaries or, in general, associated companies located in foreign countries will be responsible for compliance with this Code by these affiliated companies for all activities related to promotion or interaction with Healthcare Professionals who conduct their professional activities in Spain, whether they are invited to a foreign country or to other Events that take place within Spain.

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\(^5\) Adapted to the new wording of article 10 of the EFPIA HCP Code.
11.8. Meetings and Events of a scientific or promotional nature, organised or sponsored by pharmaceutical companies, must be previously communicated in accordance with the stipulations of Title II, Rules of Procedure of the Control Bodies.

11.9. Failure to communicate a meeting or Event of a scientific and promotional nature, when its communication is obligatory, will constitute a breach of this Code.

11.10. Companies may not organise or sponsor Events that take place outside of Spain (international Events) unless it makes more sense from a logistical standpoint, because:

a) the majority of invited participants are from a foreign country; or because

b) a resource or relevant expertise is located in a foreign country and it is the object or subject matter of the Event. This assumption (b) must receive prior authorization from the Code of Practice Surveillance Unit.

In the case of organising or sponsoring International Events, in addition to the Spanish Code, companies must also respect the specific stipulations of the Code of Practice of the country in which the Event will take place, as established in article 19.4.

11.11. Companies must comply with the criteria found in the applicable codes with regard to selecting and sponsoring Healthcare Professionals to attend Events.

11.12. In no case may money be offered to compensate merely for the time spent by Healthcare Professionals in attending the Event.

2. The location chosen for holding the Event must be appropriate and the levels of hospitality reasonable.

These two criteria are easily summed up in one statement: Ask yourself if, as the company organising the meeting, you would like all of the details of the meeting to be widely known publicly in, for example, the media. If the answer is yes, the meeting is surely in line with the provisions of the Code.

11.1. – 11.2. Besides being moderate and secondary to the main purpose of the meeting, hospitality offered within the framework of congresses and scientific meetings should avoid situations that could result in an inappropriate image for the pharmaceutical industry.

In this regard, the company must ensure that the location where the scientific meeting takes place conveys a suitable image. Therefore, locations which are solely touristic or associated solely or primarily with leisure, recreational or sporting activities should be avoided. The locations where the activities take place should be selected by taking into account ease of travel for the participants, costs, and the suitability and appearance of the location.

Travel times to the location where the Event takes place will be adjusted to the duration of the scientific meeting. Therefore, planning the trip will depend on the scientific programme, avoiding modification of the plan before or after the Event takes place in consideration of activities different from the meeting itself (cultural or recreational).

In this regard, hospitality may only be extended to the day after or before the Event, in accordance with efficient travel planning. Physicians may extend their stay in the destination location whenever the additional costs of accommodation, travel and subsistence incurred by said extension are charged to the physician and does not involve any change to the initial program for the majority of participants.

The companies will be directly responsible for paying the necessary expenses (registrations, airline or train tickets, hotels, meals, etc.) for the participation of the Healthcare Professionals in courses, conferences and scientific meetings, and may use intermediary agencies if the complexity of the Event justifies their use. No monetary reimbursement can be made to the Healthcare Professional for expenses incurred to suppliers that should have been paid directly by the company, except in the case of minor costs for travel (taxis, mileage, etc.) with appropriate justification of said expenses.
The provision of travel grants in cash or similar to Healthcare Personnel invited to conferences or meetings are not considered acceptable.

The scientific content at conferences and meetings must take up the majority of the duration of the Event with a minimum of 60% of each working day.

In case of doubt, an 8-hour working day will be calculated. Excluded from this is time needed for travel, which must be the most direct travel possible.

As a summary of this section, it is important that companies value the appearance and content of the Event. A useful criterion for evaluating compliance with the Code is to ask whether the company would like all of the details of the organisation of the Event to be widely known publicly.

11.3. If Healthcare Professionals who are authorized to administer medicines participate in conferences and scientific meetings, the same rules on hospitality that apply to Healthcare Professionals authorized to prescribe or dispense medicines will apply.

The presence of accompanying persons at Events organised by the industry should not be allowed, even when they pay their own expenses, as this can damage the image of the pharmaceutical industry. The pharmaceutical industry should not participate or collaborate in Events organized by third parties if these parties promote the attendance of accompanying persons.

11.6. With regard to the payment of fees, market prices and number of hours worked or the service actually provided must be taken into account. Any remuneration for services rendered (papers, presentations, etc.) by Healthcare Professionals shall be made directly by the pharmaceutical company and documented by means of a contract and an original invoice that the pharmaceutical company must register in its files for possible inspection. Except in justified cases, no agreements will be made to make payments to Healthcare Professionals through third parties.

11.8 – 11.9. The communication of Events is intended to facilitate the monitoring work of the Code of Practice Surveillance Unit. In no case should this be understood as implying authorization. The companies continue to be solely responsible for compliance with the Code in these Events, regardless of whether or not they are communicated previously to the Code of Practice Surveillance Unit.

Events where prior communication is not obligatory will still be subject to the Code in all cases.

11.10. – 11.11. For the purposes of this article, scientific and professional Events may be organised or sponsored in the Principality of Andorra under the same conditions that apply to any part of Spain.

12. PHARMACEUTICAL COMPANY PERSONNEL

12.1. Pharmaceutical company personnel that interact with Healthcare Professionals in the course of their work must be appropriately prepared, by or in the name of the company in which they are employed, with sufficient scientific knowledge to present information on the company’s medicines in an accurate and responsible manner.

12.2. They must conduct their work in a responsible manner, respecting current legislation and ethical rules, as well as the provisions of this Code.

12.3. No inducement or subterfuge may be used to gain an interview. No amount of money may be offered or paid in order to gain an interview.

12.4. Employees must ensure that the frequency, time and duration of visits to Healthcare Professionals, administrative staff and health authorities or similar, as well as the manner in which they are performed, do not cause any inconvenience.

12.5. When coordinating and conducting interviews, reasonable measures must be taken at all times to ensure that they do not lead to confusion about the identity of the employee or the company he/she represents.

12.6. Any information received from the professionals visited that is relevant to the use of medicines must be reported to the pharmaceutical company’s scientific department, especially indicating any side-effects reported by the professionals visited.
12.7. At each visit, the current summary of product characteristics for each medicine presented must be provided or made available to the person visited, if requested, accompanied by information on the different pharmaceutical forms and dosage, its prescribing and dispensing conditions, information on price, the conditions of reimbursement by the National Health System, where applicable, and whenever possible, the estimated cost of treatment.

12.8. Companies must adopt effective methods and monitor that pharmaceutical company personnel involved in the preparation, approval or provision of promotional material, or information intended for Healthcare Professionals, are informed and comply at all times with the provisions of this Code and the rules applicable to advertising and promotion of medicines.

In addition, they must adopt effective measures and monitor that the interactions of their employees with Healthcare Professionals and Patient Organisations comply with the provisions of this Code and applicable rules at all times.

12.9. Pharmaceutical company personnel that interact with Healthcare Professionals in the course of their work must have sufficient training to disclose the characteristics of medicines. Each company is responsible for periodically ensuring (through tests, additional training, teamwork, etc.) that their personnel’s training is appropriate.

12.10. The same rules will apply to pharmaceutical company personnel who interact with pharmacy offices in the course of their work, respecting both current legislation on this matter as well as ethical rules and provisions of this Code in the area they work.

12.11. Each company should appoint at least one employee or manager with sufficient qualifications who will be responsible for internal oversight of compliance with the Code. Supplementary Rules will explain the basic principles and mechanisms of internal monitoring that all companies must respect. In all cases, the existence of persons responsible for internal supervision does not exempt the company’s senior officers from responsibility.

**PHARMACEUTICAL COMPANY PERSONNEL: SUPPLEMENTARY RULES**

Below, the Supplementary Rules develops articles 12.8 and 12.11 with the objective of making it clear that companies must have an appropriate internal system for monitoring compliance with the Code. In this regard, it does not intend to impose any model, as it must respect different corporate cultures and existing working procedures. Instead, it simply ensures that the procedures exist in writing and they fulfill the purposes for which they were conceived.

12.8. In order to verify their compliance, pharmaceutical companies must provide the Code of Practice Surveillance Unit with the company’s internal procedures that guarantee appropriate training in matters relating to the Code.

12.11. Companies must have internal monitoring procedures that are appropriate for verifying that their activities are in compliance with the Code.

The role of the Compliance Officer or the person responsible for communicating Events, studies or services (art. 33.4, 34.4 and 35.4 of the Code) is understood in a broad sense and may be a single person, several persons or a Committee that jointly decides how activities are to be performed and that compliance with the Code is internally verified. As such, the Compliance Officer may or may not be the same as other figures anticipated in the Code, such as the scientific department responsible for reviewing the materials (art. 9 of the Code) or the person responsible for Events communication (art. 33.4 of the Code).

It is convenient for committees, policies or internal procedures to incorporate the participation of different departments (Marketing-Sales, Medical, Records, Legal, Financial-Administrative) in such a way that the company ensures that the activities have appropriate support and oversight from different perspectives.

The procedures must be formalised in writing and the company must provide a copy of these to the Code of Practice Surveillance Unit, if requested in the course of their oversight work, as well as the name(s) of the Compliance Officer(s). The information provided to the Code of Practice Surveillance Unit will be considered confidential and may only be used for the purposes for which it was submitted.
The procedures must, at the least, address approval of promotional materials and organisation and/or funding or sponsoring of conferences, scientific meetings, provision of samples, conduction of studies, formalisation of agreements with third parties and Healthcare Professionals, as well as training of company personnel. The procedures must also provide appropriate means for ensuring that subcontractors and providers used to perform activities are aware of and respect the rules of the Code and that they commit to cooperate with the Code of Practice Surveillance Unit.

Companies will include modules or programs of information and updates of the Code in their internal communication and training plans, especially in those directed toward personnel involved in promoting medicines and those who interact with Healthcare Professionals and/or Patient Organisations.

13. MEDICAL SAMPLES

13.1. In accordance with national law, a limited number of free samples may be supplied to Healthcare Professionals who are authorized to prescribe medicines so that they can become familiar with new medicines, provided that such provision is in response to a request from them.

13.2. Samples may be provided for a maximum of two years from the date the medicine obtained the marketing authorization.

13.3. A sample of a medicine must not be larger than the smallest presentation of the medicine available in the national market.

13.4. Each sample must bear the statement “free medical sample – not for sale”, and the coupon must be crossed out or removed. Each provision of samples must be accompanied by a copy of the current summary of product characteristics, together with updated information on the price, reimbursement conditions of the National Health System, where applicable, and whenever possible, the estimated cost of treatment.

13.5. The provision of samples that contain psychoactive or narcotic substances as defined in international treaties is prohibited, as is the provision of samples of medicines that can lead to dependence or create public health problems due to their inappropriate use, and other medicines so determined by competent health authorities.

13.6. Samples distributed by pharmaceutical company personnel will be provided directly to Healthcare Professionals authorized to prescribe medicines who have requested them, or to individuals authorized to receive them on their behalf.

13.7. When distributing samples in hospitals, the requirements and procedures of the hospital in question must be respected.

13.8. Companies must have an appropriate monitoring and accounting system for the samples they distribute.

14. STUDIES

14.1. Clinical Trials
A clinical trial is any research conducted on humans to determine or confirm clinical, pharmacological and/or other pharmacodynamic effects, and/or detect side effects, and/or study the absorption, distribution, metabolism and excretion of one or more medicines under study for the purpose of determining their safety and/or efficacy.

Pharmaceutical companies must conduct this type of study in compliance with applicable legislation, after receiving a favorable ruling from the Clinical Research Ethics Committee, the agreement of each of the Centers where the research will be conducted and authorization from the Spanish Agency of Medicines and Medical Devices (AEMPS in its Spanish acronym).

14.2. Post-Authorization Studies
Post-authorization studies are any clinical or epidemiological study conducted during the commercialization of a medicine according to the conditions authorized on its summary of product characteristics, or under normal usage conditions, in which the medicine or medicines of interest are the fundamental exposure factor being investigated. These types of studies may be conducted as clinical trials (art. 14.1) or as observational studies.
An observational study is a study in which medicines are prescribed in the usual manner in accordance with the conditions established in the marketing authorization. Assigning a patient to a specific therapeutic strategy will not be decided ahead of time by the study protocol, but instead it will be determined by routine medical practice and the decision to prescribe a given medicine will be clearly separated from the decision to include the patient in the study. No intervention will be applied to any patient, be it diagnostic or monitoring, that is not a part of routine clinical practice and epidemiological methods will be used for analysis of the data collected.

Post-authorization studies of an observational nature will be those epidemiological studies that meet the conditions of being post-authorization and observational. These studies must be conducted in compliance with the requirements of applicable legislation, including the presentation of documentation to the AEMPS for registration and classification, presentation to a Clinical Research Ethics Committee for evaluation, etc. These studies must in no case be conducted as a procedure for promoting a product or for the purpose of influencing prescribing habits.

Legislation also contemplates conducting observational studies that are not post-authorization (Non-PAS). These are observational studies in which the primary exposure factor under investigation is not a medicine, as is the case, for example, in disease prevalence or incidence studies. These observational studies must also be conducted in compliance with the requirements of applicable legislation.

### 14.3. Market Research Studies

Market research (including social and opinion research) consists of the systematic compilation and interpretation of information on individuals and organisations using statistical and analytical methods and social science techniques that are applied in order to obtain new perceptions or to provide elements that support decision-making.

In these studies, the identities of the interviewees are not revealed to the user of the information without their expressed consent, nor are interviewees contacted for sales activities that result from the information they provide.

Notwithstanding applicable legislation, there is a general ethical framework within which market research must be conducted, as shown in the ICC/ESOMAR International Code for the Practice of Social and Market Research from the European Society of Marketing and Opinion Research (ESOMAR). In the specific case of the pharmaceutical industry, the self-regulation framework on this material consists of the European Pharmaceutical Market Research Association (EphMRA) Code of Conduct.

This regulation does not presume to replace the EphMRA Code, but instead establishes certain mechanisms that guarantee the appropriate execution of these studies in the application of this Code. The EphMRA Code will be of subsidiary application for the appropriate interpretation of this Code.

All market research studies are subject to this article if they are conducted at a company’s initiative, the initiative of several companies that share business strategies for a product or when a pharmaceutical company hands the study to a third party (research institute, scientific society, etc.) that has undertaken the work at its own initiative.

Market research studies must meet the following requirements:

1. **Blinding of the identity of the persons participating in the study.** The pharmaceutical company will not have the ability to learn before, during or after the study, the identity of the individuals participating in the study.

2. **Anonymous nature of the information collected.** The pharmaceutical company will not have the ability to associate the data or opinions obtained with the names of the participants.

3. **Aggregate handling of the responses or data obtained.**

4. **Proportionality between the universe and the sample.** Quantitative market research studies pursue a level that is representative of the universe. When calculating sample size, if parameters other than those generally used in market research studies (simple random sample, 5% margin of error, 95% confidence level and 50% level of heterogeneity),
the prior approval of the Code of Practice Surveillance Unit will be necessary.

v) The individual who participates in the study does not know and does not have the opportunity to link the study with the pharmaceutical company or with a specific product. Therefore, the pharmaceutical company’s sales network cannot play any role in developing and conducting the study.

vi) The results of the study and the data obtained will not be published or used in promotional materials.

Any exception to these requirements must receive prior approval of the Code of Practice Surveillance Unit. In particular, the requirements of i, ii and v are included in the Supplementary Rules for market research studies associated with a product.

In addition, in order to guarantee that the marketing research studies do not represent an inducement to prescribe, or may contain an incentive that is prohibited under the Code, pharmaceutical companies undertake to:

i) Communicate the study prior to its commencement, in accordance with the provisions of Title II Rules of Procedure for the Control Bodies.

ii) Ensure that the study does not modify the physician’s prescribing habits or the pharmacist’s dispensing habits.

iii) To have a written protocol that clearly establishes the objectives, methodology, anticipated results and use.

In this regard, written agreements will be formalised with the professionals and/or entities with whom the studies will be conducted on the one hand and the company sponsoring the study on the other, specifying the nature of the services to be rendered, the conditions for participation and remuneration to the professionals, etc.

iv) Remuneration to participating professionals must follow market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed. In addition, it must be appropriately formalised.

Remuneration must be monetary. In exceptional cases and with the prior authorization of the Code of Practice Surveillance Unit, remuneration may be provided in kind.

v) Guarantee that the conduction of the study does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer medicines.

vi) Be approved, prior to execution, by the company’s scientific department or by the Compliance Officer stipulated in article 12.11 of the Code.

These requirements will be applicable regardless of the methodologies, sources or techniques applied to implement them, for example: survey method, observation, experimental designs, ethnographic techniques, expert groups, qualitative techniques, etc.

Failure to communicate studies referred to in this article 14.3 that are required to be reported will constitute a violation of this Code.

14.4. Any other type of activity, practice or initiative that collects information not considered in the previous sections or in article 16 of the Code that involves direct or indirect remuneration of Healthcare Professionals will qualify as a promotional action and, as such, will be subject to the provisions of this Code, particularly as stipulated in article 10 (Guarantees of Independence).

STUDIES: SUPPLEMENTARY RULES

14.1. Pharmaceutical companies must provide detailed information on clinical trials in accordance with current legislation and the stipulations of the “Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature 2010”, available at http://clinicaltrials.ifpma.org.6

The Spanish Agency of Medicines and Medical Devices (AEMPS) has developed and launched the Spanish Clinical Studies Registry (REec), which can be consulted at https://reec.aemps.es. This site offers information on clinical research on medicines with marketing authorization being conducted in Spain.
14.2. Post-authorization studies may be conducted for the following purposes:

- To determine the efficacy of the drugs, meaning their beneficial effects under routine clinical practice conditions, as well as modifiable factors such as therapeutic non-compliance, polypharmacy, disease severity, presence of comorbidities, special groups (elderly, children, etc.), genetic factors or lifestyle-related factors.

- To identify and quantify the side effects of the medicine, especially those that were not known prior to marketing authorization, and to identify possible risk factors or effect modifiers (demographic characteristics, concomitant medication, genetic factors, etc.).

- To obtain new information on medicine usage patterns (dosage, treatment duration, appropriate use).

- To evaluate the efficiency of medicines, meaning the relationship between the health outcomes and resources used through the use of pharmacoeconomic analysis.

- To learn the effects of medicines from a patient’s perspective (quality of life, satisfaction with treatments received, etc.).

14.3. In compliance with the conditions stipulated in the ESOMAR Code, companies may only access the identity of participants for the purpose of supervising and controlling the quality of the study. For this purpose, access to this data will be temporary while quality control activities are being conducted and no record of data from participants may remain in the possession of the company.

There are market research studies that have the objective of learning the opinion of Healthcare Professionals on a specific medicine, to study interest in a product based on its strong or weak points, or, for example, to analyse materials that will be used to provide information about the product’s characteristics, etc. In these cases, the Healthcare Professional who participates knows, or may know, the pharmaceutical company that is developing said study and, in addition, when the aim is to test the content, comprehension, design, ease of presentation or interest in the materials used by companies to promote their medicines, personnel from the company’s marketing or sales departments may also be involved.

Because of their nature, market research studies on a product will only be remunerated when strictly necessary and must be conducted on very small sample sizes. When in doubt, companies must take the ruling of the Code of Practice Surveillance Unit on this matter into account.

Regardless of the study being undertaken, when remuneration is provided, this must be of an ancillary nature. Therefore, not only should market criteria and the time used, the work performed and the responsibilities assumed by the professional be taken into account, it should also be proportional to the aims of the study.

The purpose of communicating studies is to facilitate the monitoring work of the Code of Practice Surveillance Unit. In no case should this be understood as implying authorization. The companies continue to be solely responsible for compliance with the Code in these studies, regardless of whether or not they are communicated previously to the Code of Practice Surveillance Unit.

15. DONATIONS AND GRANTS

Donations, grants or benefits in kind to institutions, organisations, associations or foundations made up of Healthcare Professionals and/or those that provide social or humanitarian healthcare services, research, teaching or education, that are not considered in any other article of this Code are only permitted if:

i) they are conducted for the purpose of collaborating with healthcare, research, teaching/training or social or humanitarian care;

ii) they are formalised in writing with the company retaining a copy of these documents; and

iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer medicines.

Donations or grants to individual Healthcare Professionals is not permitted except when collaborating with or sponsoring Healthcare Professionals’ attendance to Events and meetings as stipulated in article 11.
16. SERVICES PROVIDED BY HEALTHCARE PROFESSIONALS OR HEALTHCARE ORGANISATIONS

16.1. Contracting Healthcare Professionals on an individual or group basis is permitted for providing advice or counseling services such as communications at meetings as a speaker or moderator, educational activities, expert meetings, etc., where such participation involves payment of remuneration and/or expenses for travel and subsistence.

Agreements with individual Healthcare Professionals, and/or with entities in which these concur (institutions, foundations, scientific societies, organisations of professional associations, etc.), that cover the legitimate provision of these types of services must meet the following conditions:

a) they are contracted for the purpose of collaborating with healthcare, research, teaching/training or the organisation of professional or scientific Events;

b) the existence prior to providing these services of a written contract that specifies, at the least, the nature of the services to be provided and, in compliance with letter (h) below, the criteria that form a basis for calculating the remuneration for their provision;

c) they clearly identify, prior to requesting these types of services and signing any type of agreement with the possible consultants, the legitimate need for these services;

d) the criteria used to select the consultants are directly related to the identified need and the person responsible for their selection has the necessary expertise to evaluate if the Healthcare Professionals meet these requirements;

e) the number of Healthcare Professionals contracted does not exceed the number that would be reasonably necessary to achieve the planned objective;

f) the contracting company must maintain documentary support of the services provided by the consultants and employ these services for the planned use;

g) contracting Healthcare Professionals to provide these types of services does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a given medicine;

h) remuneration to participating professionals must follow market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed. In addition, it must be appropriately formalised;

i) remuneration must be monetary. In exceptional cases and with the prior authorization of the Unit, remuneration may be provided in kind;

j) they are approved, prior to contracting, by the company’s scientific department or by the Compliance Officer stipulated in article 12.11 of the Code.

16.2. When contracting these types of services for a project or activity involves remunerated participation of at least 20 Healthcare Professionals, they must be communicated by the pharmaceutical companies that organise or sponsor the majority of the project or activity prior to its commencement, in accordance with the stipulations of Title II Rules of Procedure for the Control Bodies.

Failure to report these services will constitute a breach of this Code.

16.3. In these contracts, it is recommended that the pharmaceutical companies include a clause in which the Healthcare Professional commits to declare that he/she provides services or consultation to the company every time he/she writes or makes public statements regarding any topic related to their agreement or to the company.

In addition, it is recommended that those pharmaceutical companies that employ Healthcare Professionals on a part-time basis – meaning they con-
continue to practice their profession – ensure that these are under the obligation to publicly declare this contract or relationship with the company any time they write or make public statements regarding any topic related to said contract or to the company.

The stipulations of this section are applicable at all times and in spite of the fact that the Code expressly excludes corporate advertising from pharmaceutical companies from its scope.

16.4. When a Healthcare Professional participates in an Event in the role of advisor or consultant, the terms and conditions of article 11 apply.

CHAPTER III

Relationships with Patients Organisations

17. RELATIONSHIPS WITH PATIENTS ORGANISATIONS

17.1. The pharmaceutical industry recognises that it has many interests in common with Patient Organisations that advocate for and/or support the needs of patients and/or caregivers.

In order to ensure that the relationships between the pharmaceutical industry and Patient Organisations are conducted in an ethical and transparent manner, EFPIA adopted the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

The principles, agreed jointly between EFPIA and the Pan-European Patient Organisations, on which this Code is based are:

1. The independence of Patient Organisations, in terms of their political judgement, policies and activities, shall be assured.

2. All partnerships between Patient Organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value.

3. The pharmaceutical industry shall not request, nor shall Patient Organisations undertake, the promotion of a particular prescription-only medicine.

4. The objectives and scope of any partnership shall be transparent. Financial and nonfinancial support provided by the pharmaceutical industry shall always be clearly acknowledged.

5. The pharmaceutical industry welcomes broad funding of Patient Organisations from multiple sources.

Compliance with these principles ensures the respect and commitment of the pharmaceutical industry, both with the Patient Organisations – which are...
necessarily called on to become groups with greater social and institutional recognition – as well as with the rational use of medicines.

In light of the need to establish a collection of rules that govern the relationships between the pharmaceutical industry and Patient Organisations, since 2008 Farmaindustria has adopted the EFPIA rules at all times, the contents of which are explained below.

17.2. Scope
It covers all forms of relationships between pharmaceutical companies and Patient Organisations. The objective is not to prohibit or limit the relationship between pharmaceutical companies and Patient Organisations, but instead to establish rules of conduct that the entire pharmaceutical industry undertakes to comply with.

17.3. Promotion of Medicines
European and national laws are applicable as is this Code (article 7.1), which prohibits promotion of prescription-only medicines directed to the general public (except with the prior authorization of the competent health authority, where applicable, for example, during vaccination campaigns).

17.4. Agreements
Collaboration between pharmaceutical companies and Patient Organisations must be documented in writing, describing at least: the activities to be carried out, the level and sources of funding, the purpose of said funding, relevant indirect support (e.g. services provided free of charge by public relations agencies) and any other type of non-financial collaboration that is relevant.

Pharmaceutical companies will establish a procedure for approving these types of collaborations prior to conducting them.

17.5. Registered Logos and Materials
The use of any logo, brand, identifying mark, registered material, etc., that is property of a Patient Organisation will require prior consent. Any pharmaceutical company that requests said authorization must clearly indicate the specific purpose and manner in which said material will be used.

17.6. When pharmaceutical companies sponsor a material or publication from a Patient Organisation, they will not intend to influence the content in favor of the company’s own commercial interests. This does not prevent the possibility of correcting eventual inaccuracies or material errors.

17.7. Companies will refrain from requesting to be exclusive sponsors of a Patient Organisation or any of their principal activities.

Agreements with Patient Organisations for providing any type of service to a pharmaceutical company will only be permitted if said services are provided for the purpose of collaborating with healthcare and/or research.

Contracting of Patient Organisations is permitted for providing advisory or consultation services such as communications at meetings as a speaker or moderator, expert meetings, etc. The agreements that cover the legitimate provision of services of this type must meet the following conditions:

a) the existence prior to providing these services of a written contract that specifies, at the least, the nature of the services to be provided and, in compliance with letter (g) below, the criteria that form the basis for calculating the remuneration for their provision;

b) clear identification, prior to requesting these types of services and signing any type of agreement, of the legitimate need for these services;

c) the criteria used to select the consultants are directly related to the identified need and the person responsible for their selection has the necessary expertise to evaluate whether the chosen consultants meet these requirements;

d) the number of consultants contracted does not exceed the number that would be reasonably necessary to achieve the planned objective;

e) the contracting company must maintain documentary support of the services provided by the consultants and employ these services for the planned use;
f) the contracting of Patient Organisations for the provision of these types of services does not constitute an inducement to recommend a specific medicine;


g) the remuneration for providing these services must follow market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed. In addition, it must be appropriately formalised;


h) the remuneration must be monetary. In exceptional cases and with the prior authorization of the Code of Practice Surveillance Unit, the remuneration may be provided in kind;


i) they are approved, prior to contracting, by the pharmaceutical company’s Compliance Officer;


j) in these contracts, it is recommended that the pharmaceutical companies include a clause in which the Patient Organisation commits to declare that he/she provides services or consultation to the company every time he/she writes or makes public statements regarding any topic related to his/her agreement or to the company;


k) each company will make public the list of Patient Organisations with which they have agreements for the provision of services, in compliance with article 18.8.


17.8. Events directly or indirectly sponsored or organised by a company must be held at a location that is appropriate in relation to the primary purpose of the event, avoiding sites that are known for their entertainment facilities or those that are extravagant or inappropriate.


Any form of hospitality provided by the pharmaceutical industry to Patient Organisations and their members will be reasonable and of a nature that is secondary to the purpose of the event, disregarding whether it is organised by the Patient Organisation or by the company.


The hospitality provided for events will be limited to travel, accommodation and subsistence expenses and registration fees. Companies may only defray or finance these expenses through the Patient Organisation and never directly to individual patients. Hospitality will only be extended to attendees. However, for health reasons (for example, disability), they may defray expenses for travel, accommodation, subsistence and registration of accompanying persons who attend in the role of caregivers.


Hospitality will not include the sponsorship or organisation of recreational and/or entertainment activities (cultural, sports, etc.).


Companies may not organise or sponsor events that take place outside of Spain unless:


a) the majority of invited participants are from a foreign country; or


b) a resource or relevant expertise that is the primary object of the event is located in a foreign country.


This assumption (b) must receive the prior authorization of the Code of Practice Surveillance Unit.


Pharmaceutical companies incorporated in Spain that belong to business groups with headquarters or subsidiaries or, in general, associated companies located in foreign countries will be responsible for compliance with this Code by these affiliated companies for all activities related to promotion or interaction with Patient Organisations that perform their activities in Spain, whether they are invited to a foreign country or to other events that take place within Spain.


In general, the standards of hospitality established in article 11 of the Code must not be exceeded.


RELATIONSHIPS WITH PATIENT ORGANISATIONS: SUPPLEMENTARY RULES


17.2. Activities conducted, organised or sponsored by a pharmaceutical company, or under its control – subsidiaries, foundations, associations, institutes, agencies, third-party providers, etc., from which direct or indirect collaboration, support and/or compensation to Patient Organisations will be considered forms of relationships subject to the precepts of this Code.
17.4. When support provided by the company to the Patient Organisation is economic, or of any other type (in kind, etc.), and is significant, a written agreement must be formalised clearly establishing the nature and scope of the collaboration.

The following model can be used in its entirety or adapted in an appropriate manner, with the key points of a written agreement:

- Title of the activity.
- Names of the entities (pharmaceutical company, Patient Organisation and, where applicable, collaborating third parties included by mutual agreement between the parties).
- Type of activity. Specify whether the agreement refers to grants or donations of a general nature for activities, specific meetings, sponsorships, brochures, campaign information, training programs, etc.
- Objectives.
- Role to be played by each of the parties of the agreement.
- Duration of the agreement.
- Financial support provided (in Euro).
- Description of any other type of significant non-financial support (example: resources made available for free, free educational courses, etc.).
- The parties agree to conduct this collaboration publicly and transparently.
- Signatories.
- Date.

CHAPTER IV

Transparency of the Pharmaceutical Industry’s Relationships

18. TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY’S RELATIONSHIPS

Interaction with Healthcare Professionals and Organisations

Healthcare Professionals provide expert knowledge and an independent point of view derived from their clinical and professional experience and they share it with the pharmaceutical industry and other Healthcare Professionals in order to promote improvement in patient care. These services are fundamentally important to the industry and help to design and give form to the activities that the industry performs.

In order to increase confidence in the pharmaceutical industry, the industry has decided to publicly disclose the nature and level of said relationships.

18.1. Disclosure Obligation

Companies subject to the Code as established in articles 19.1 and 19.3 must document and disclose payments and Transfers of Value detailed in this article (hereinafter “Transfers of Value”) that they make, either directly or indirectly, to or for the benefit of the Recipients.

Laboratories must disclose this information on an individual basis, identifying the Healthcare Professional (instead of the Healthcare Organisation) whenever legally possible and whenever this can be provided with precision and consistency.

Payments or Transfers of Value (i) associated with activities not detailed in Appendix 1 of the Code, such as, the provision of: materials regulated in article 10 Guarantees of Independence, samples regulated in Article 13, hospitality associated with dinners or luncheons regulated in Article 11 Scientific and Professional Meetings; (ii) that form part of commercial transactions between companies...
and distributors, pharmacy offices and Healthcare Organisations and (iii) those related to products or medicines that are not prescription-only medicines; do not fall within the scope of the disclosure obligation described herein.

18.2. Form of Disclosure

Companies must have a specific internal procedure that guarantees compliance with the obligations of transparency indicated in article 18.

Within the established disclosure period — within 6 months after the end of the relevant reporting period — pharmaceutical companies will disclose the information on each reporting period on an annual basis. Reporting period is defined as a full calendar year. The year 2015 is the first reporting period to be published.

The information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable national law or regulation, or (ii) the Recipient consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked, and this revocation was legally binding for the company.

The information will be disclosed openly on the company’s web page in accordance with the template provided in Annex I. Modification of this template must be approved the Farmaindustria Board of Governors.

In order to reinforce compliance with the transparency obligations, companies will provide the information to the Code of Practice Surveillance Unit on an annual basis.

Disclosure shall be made pursuant to the national code of the country where the Recipient carries out their professional activity or has its legal address. If a company is not resident or does not have a subsidiary or an affiliate in that country, the company shall disclose such Transfers of Value in a manner consistent with the national code to which it is subject.

Disclosure shall be made in Spanish. In addition, companies are encouraged to make disclosures in English.

Companies shall document all Transfers of Value required to be disclosed pursuant to this article and maintain the relevant records of the disclosures made under this Code for a minimum period of 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable national laws or regulations.

18.3. Individual Disclosure

Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. The companies shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each reporting period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value must be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

In accordance with applicable personal data protection legislation in Spain, the individual disclosure of payments or Transfer of Values made to Healthcare Professionals requires their prior express consent. Pharmaceutical companies must be able to prove both the request of the consent and also its procurement or not. For those cases where the Healthcare Professional denies his consent, section 18.4 of the Code will apply.

Personal data protection legislation in Spain applies exclusively to individuals. For this reason, pharmaceutical companies must disclose the payments or Transfers of Values made to Healthcare Organisations on an individual basis.

18.3.1. Transfers of Value to Healthcare Organisations

Amounts related to any of the categories set forth below:

a) Donations. Donations and grants to Healthcare Organisations that support healthcare, including donations and grants (either in cash or benefits in kind) to institutions, organisations or associations that are comprised of Healthcare Professionals and/or that provide social or humanitarian healthcare services, research services, teaching or education (governed by article 15 of the Code).
b) Contribution to Costs Related to Events.
Contribution to costs related to Events, through Healthcare Organisations or third parties, (including sponsorship to Healthcare Professionals to attend Events), such as:

i) registration fees;

ii) sponsorship agreements with Healthcare Organisations or with third parties appointed by a Healthcare Organisation to manage the Event; and

iii) travel and accommodation (governed by article 11 of the Code).

c) Fees for Service. Transfers of Value resulting from or related to contracts between companies and institutions, organisations or associations of Healthcare Professionals under which such institutions, organisations or associations provide any type of services to a company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

18.3.2. Transfers of Value to Healthcare Professionals

a) Contribution to Costs Related to Events. Contribution to costs related to Events, such as:

(i) registration fees; and

(ii) travel and accommodation (governed by article 11 of the Code).

b) Fees for Service. Transfers of Value resulting from or related to contracts between companies and Healthcare Professionals under which such Healthcare Professionals provide any type of services to a company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

18.4. Aggregate Disclosure
For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 18.3., cannot be disclosed on an individual basis for legal reasons, companies shall disclose the amounts attributable to such Transfers of Value in each reporting period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

18.5. Non Duplication
Where a Transfer of Value required to be disclosed pursuant to section 18.3 or 18.4 is made to an individual Healthcare Professional indirectly via a Healthcare Organisation, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual Healthcare Professional named basis pursuant to section 18.1 and 18.3 of this Code.

18.6. Research and Development Transfers of Value
Research and Development Transfers of Value in each reporting period shall be disclosed by each company on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

18.7. Methodology
Each company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category. The note shall describe the recognition methodologies applied and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.
Relationships with Patient Organisations

18.8. Collaborations. Each company must make publicly available a list of those Patient Organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs. For significant nonfinancial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the Patient Organisation receives. This information may be provided on a national or European level and should be updated at least once a year.

This information must be published during the first quarter of each year including the activities that were carried out the previous year.

Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

Services. Each company must make publicly available a list of Patient Organisations that it has engaged to provide contracted services. This should include a description of the nature of the services that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies must publish annually the total amount paid to each Patient Organisation for the provision of these services annually.

This information must be published during the first quarter of each year including the activities that were carried out the previous year.

CHAPTER V
Rules of Application, Monitoring, Breaches and Sanctions

19. RULES OF APPLICATION

19.1. Companies member of Farmaindustria or adhered to the Code commit to abide by and respect the principles outlined in this Code.

Companies member of Farmaindustria or adhered to the Code who, in addition, belong to other associations whose aims or objectives coincide with any of the aims indicated in the Farmaindustria bylaws will be obliged to apply, as a priority, the stipulations of this Code with respect to other self-regulation systems that may be applicable, notwithstanding the stipulations in section 19.4.

In the case of Groups of Companies, companies belonging to these who are member of Farmaindustria or adhered to the Code on an individual basis will be responsible for possible breaches of the Code committed by companies or their Group that are not member of Farmaindustria and are not adhered to the Code.

In addition, companies member of Farmaindustria or adhered to the Code on an individual basis will be liable for possible breaches of the Code committed by third parties acting on their behalf or representation, or under their control, or by virtue of a written agreement (for example, external sales networks, market research companies, travel agencies, advertising agencies, etc.).

Companies adhered to the Code that are not member of Farmaindustria must contribute to the operating costs and application of the self-regulation system, through a financial contribution, in at least the same proportion as companies member of Farmaindustria.

19.2. In addition, in its role as national association member of EFPIA, Farmaindustria submits to the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Pa-
tient Organisations and the EFPIA Disclosure Code (hereinafter, EFPIA Codes), and especially as they apply to Implementation and Procedural Rules detailed in their Annexes.

19.3. Pursuant to the provisions of the EFPIA Codes, the member companies of said Federation must comply with the applicable codes in the different countries where they operate, and ensure that their respective affiliate companies are compliant.

EFPIA member companies must comply with the codes and the rules that are applicable. In conformity with the stipulations contained in the bylaws of said Federation, the EFPIA member companies must: (i) in the countries where they operate – directly or through an affiliate – in which the EFPIA Codes are applicable, belong to the member association, or (ii) agree in writing for each member association – or their affiliate – to be subject to the code of said association (including the applicable sanctions that may be imposed by them).

19.4. As established in the EFPIA Codes, the codes applicable to promotion and interactions with Healthcare Professionals or Patient Organisations (hereinafter, the “activities”) that take place in Europe (meaning, those countries in which the codes of the EFPIA member associations apply) are the following:

a) (i) in the case of an activity conducted, sponsored or organised by a company or under its control, sited in Europe, the code of the national association where the company is sited; (ii) if the activity is performed by a company not sited in Europe, the EFPIA Codes; and

b) the code of the national association of the country in which the activity is conducted.

If there is a conflict between rules of the different applicable codes for a given activity, the most strict or restrictive rule will prevail.

The term “company” used in the EFPIA Codes refers to any legal entity, be it the parent company or headquarters, controlling company, marketing company, subsidiary or any other type of legal status that organises or sponsors promotional activities in Europe. The term “Europe” refers to those countries in which the codes of EFPIA member associations apply.

20. QUERIES

20.1. Companies subject to the Code provisions in accordance with articles 19.1 and 19.3 may submit queries on the application of the Code for a given activity or request clarification of a more general nature in relation to the Code. Queries related to the content of specific promotional material are excluded.

20.2. Queries must be addressed to the Code of Practice Surveillance Unit according to the procedure established for this purpose in Title II Rules of Procedure for the Control Bodies and must be resolved by the Code of Practice Committee. Queries will be binding for the Code of Practice Surveillance Unit and the Code of Practice Committee.

20.3. Neither the queries nor the result may be mentioned in promotional activities or in the interactions with Healthcare Professionals or Patient Organisations.

20.4. Queries of general interest to the sector as a whole may be published at the discretion of the Executive Board in the form of questions and answers, respecting the anonymity of the company that made the query (Annex II).

21. MONITORING OF COMPLIANCE WITH THE CODE

21.1. Monitoring of compliance with the rules established in this Code is the responsibility of the Code of Practice Surveillance Unit, the Code of Practice Committee for the Pharmaceutical Industry in Spain (hereinafter, the Code of Practice Committee) and the Jury of the Association for Self-Regulation of Commercial Communications (hereinafter, the Jury).

21.2. In this regard, the companies subject to the provisions of the Code as indicated in articles 19.1 and 19.3, notwithstanding the request for cessation that may be issued to the company that is presumably in breach, commits to register their eventual complaints against the practices of other companies subject to the provisions of the Code, as a first step prior to resorting to the Courts of Justice or Health Authorities, to the Code of Practice Committee, as well as to obey and immediately comply with the mediation agreements reached and the content of the resolutions of the Jury.
Companies that initiate a claim in compliance with the provisions in the Code guarantee that said claim has not been resolved, nor is it being processed in legal proceedings or in an administrative procedure.

21.3. Both the complainant and the respondent companies agree to maintain the confidentiality of the complaint procedure and its resolution, refraining from disclosing any information on the procedure, until the resolution of the dispute has not been published, where applicable.

21.4. For the effective application of this Code and the processing and resolution of any complaint that is filed against the activities of the companies subject to the provisions of the Code as defined in articles 19.1 and 19.3, the Code of Practice Surveillance Unit, the Code of Practice Committee and the Jury must be subject to the provisions stated in their respective Rules of Procedure.

21.5. Failure to cooperate with the Control Bodies by a company that is subject to the provisions of the Code as established in articles 19.1 and 19.3 will constitute a breach as defined in article 22.

21.6. Unjustified refusal or lack of cooperation with the investigative procedure regulated in article 37 of Title II Rules of Procedure for the Control Bodies, by a company that is subject to the provisions of the Code as established in articles 19.1 and 19.3, will constitute a severe or very severe breach according to the stipulations in article 22.

22. BREACHES AND SANCTIONS

22.1. Breaches will be classified as minor, severe and very severe, according to the following criteria:

a) Magnitude of the breach and, in particular, its possible risk to patient health.

b) Repercussion on the medical or scientific profession, or on society in general of the act that generates the breach.

c) Unfair competition.

d) Generalisation of the breach.

e) Recidivism.

f) Damage to the image of the pharmaceutical industry.

Once the breach has been classified as minor, severe or very severe according to the above criteria, aggravating factors may be involved that will be taken into account by the Jury when imposing the corresponding sanctions according to the scale in section 2 of this article. Accumulation of aggravating factors may modify the initial classification of “minor” to “severe” or “severe” to “very severe”. These aggravating factors are as follows:

i) Degree of intentionality.

ii) Non-compliance with prior warnings.

iii) Concurrence of several breaches in the same act or activity.

iv) Financial benefit for the company derived from the breach.

Additionally, for qualifying and determining the pecuniary sanction, the Jury may take into account the estimated total cost of the infringing activity.

22.2. In light of the criteria indicated above, the Jury and the Executive Board of Farmaindustria, where applicable, in accordance with the stipulations of section 3 of this article, may impose the following pecuniary sanctions:

a) Minor breaches: From 6,000 to 120,000 Euro.

b) Severe breaches: From 120,001 to 240,000 Euro.

c) Very severe breaches: From 240,001 to 360,000 Euro.

In the case of breaches categorised in articles 11.9, 14.3 and 16.2, the first two times they occur, they will be subject to a warning by the Code of Practice Surveillance Unit and, in the Event of a third successive breach within a period of less than one year, the applicable sanctions will be 1,000 Euro for each obligatory communicating activity that has not been
reported in due time and appropriate form to the Code of Practice Surveillance Unit.

In complaints presented by the Code of Practice Surveillance Unit, the Jury, in addition to pecuniary sanctions, may impose on the infringing company the corrective or rectifying measures proposed by the Unit in the mediation meeting, according to the severity of the acts and always with the objective of repairing the damage caused and preventing its recurrence in the future.

In cases in which the Jury detects the existence of a breach and the affected company has acted in good faith in accordance with a query as stipulated in article 20 of the Code made by the company itself, provided the facts and the terms of the query are identical, the Jury will request that the company cease this conduct but will not impose any other sanction.

22.3. FARMAINDUSTRIA will collect those contributions agreed during the mediation phase and execute the sanctions imposed by the Jury. The amount obtained from pecuniary sanctions will be used to constitute a special fund in FARMAINDUSTRIA that will be set aside for promoting the rational use of medicines. In addition, the FARMAINDUSTRIA Executive Board, as proposed by the Code of Practice Committee or the Code of Practice Surveillance Unit, will impose and execute the sanctions for non-compliance as stipulated in articles 11.9, 14.3, 16.2, 21.5 and 22.8 of this Code. In these cases, companies that are directly affected by the matter analysed shall abstain from participating in the deliberations and agreements of the Executive Board.

22.4. In cases of severe or very severe breaches, or when the contents of a resolution issued by the Jury are not honored, the Code of Practice Committee and the Code of Practice Surveillance Unit – in cases in which the latter acts as a complainant – may propose to the Governing Council that FARMAINDUSTRIA proceed with issuing a complaint against the offending company to the competent health authorities and/or propose that the Executive Board of the Association expel the company from the association, following the procedure outlined in the Association bylaws. If the company is expelled for this reason, readmission cannot be considered for a period of at least one year.

22.5. Readmission of the company to the Association will only occur after this period has elapsed if the company expressly commits not to carry out practices prohibited by the Code and after all fees that would have applied during the expulsion period have been paid.

22.6. In all cases, in the resolution adopted by the Jury, a determination will be made as to which party or parties are responsible for the administrative costs incurred in processing the complaint to AUTOCONTROL. All of the fees accrued by AUTOCONTROL for processing the procedure, as well as the monetary costs of expert support, where applicable, as determined by the Jury — by ruling or at the request of the party — will be the responsibility of the party that has had all its claims rejected. If the ruling were partial, each party will pay its own costs and half the administrative costs mentioned above.

22.7. In the Event of repeated complaints that are clearly unfounded, the Jury may impose a pecuniary sanction as it sees fit. This sanction will be in proportion to the supposed severity of the alleged acts.

22.8. Repeated and unfounded reporting of presumed breaches to the Code of Practice Surveillance Unit may also be subject to sanctions by the Executive Board, at the proposal of the Code of Practice Surveillance Unit.

23. SUPPLEMENTARY RULES

By agreement of the FARMAINDUSTRIA Executive Board, Supplementary Rules to this Code may be created for the purpose of guiding companies on the appropriate compliance with the rules contained in the Code. Supplementary Rules have the same validity and value as the articles of the Code.

In addition, the Executive Board may authorize the signing of agreements to collaborate with other entities or organisations for better implementation of the self-regulation system.
24. PUBLICATION AND COLLECTION OF RESOLUTIONS

24.1. The Jury may agree to disclose or report the resolutions that it adopts through the means it considers appropriate.

24.2. Based on the criteria of the Farmaindustria Executive Board, a complete compilation of all of the resolutions adopted in the course of its work, as well as summaries of the materials and mediation agreements reached will be published periodically.
Title II
Rules of Procedure for the Control Bodies
Introduction

The Code of Practice Committee of the Pharmaceutical Industry in Spain (hereinafter, the “Code of Practice Committee”), the Code of Practice Surveillance Unit and the Jury of the Association for Self-Regulation of Commercial Communications (hereinafter, the “Jury”) are the bodies responsible for ensuring the effective application of the Code of Practice for the Pharmaceutical Industry (hereinafter, the “Code”).

CHAPTER I

The Code of Practice Committee of the Pharmaceutical Industry in Spain

25. STRUCTURE AND FUNCTIONS

25.1 Structure

The Code of Practice Committee will be designated by the Farmaindustria Executive Body at the recommendation of the Governing Council. The duration of the position will be three renewable years from the date of appointment. Members who cease their functions prior to the expiration date of their post will be substituted for the time remaining to complete their mandate.

The Code of Practice Committee shall be comprised by:

a) A minimum of three members, all of whom will be technical-professional individuals of recognised prestige.

b) A Secretary designated among the persons assigned to the Farmaindustria Legal Department who will assist the members and be entitled to express his/her opinions but not to vote.

25.2. Operation

The Code of Practice Committee will have a quorum in the presence of at least three members and the Secretary. Decisions will be taken by majority agreement of the members.

The Committee may request the opinion and assistance of experts in any field. The experts that are consulted and who perform advisory tasks may be invited to attend the Code of Practice Committee meeting, but they will not have the right to vote.

The administrative organisation will correspond to the Secretariaship, which will be located in Farmaindustria under the responsibility of the Secretary. Relations with EFPIA provided for in the Rules of the Federation for application of the Code will correspond to the Secretary.

The actions of this Code of Practice Committee will be submitted in periodic reports and, in all cases, an annual report to the General Management who, based on his/her considerations, will transfer the report to the Governing Council and the Executive Board.

The Code of Practice Committee undertakes to maintain the confidentiality of its actions, avoiding the disclosure of any information on the complaint procedure and its resolution.

25.3. Functions

The Code of Practice Committee will have the following functions:

a) To monitor the application of the Code.

b) To provide advice, guidance and training in relation to the Code.

c) To process complaints received due to breaches of the Code.

d) To mediate between the parties involved in a complaint by seeking conciliation of the disputes concerning matters subject to the Code.

e) To transfer to the Jury all complaints received from the Secretary, except when prior conciliation has been achieved.

f) To monitor the efficacy and prompt execution of the resolutions issued by the Jury.
g) To issue rulings of a technical or ethical nature on the diverse questions that may be solicited by Farmaindustria within the scope of their actions and to resolve queries presented by the companies to the Code of Practice Surveillance Unit.

h) To issue circulars, through the Secretaryship, directed at companies informing about matters that, in accordance with the Code, correspond to the Code of Practice Committee.

i) Any other applicable functions by virtue of the Code.

26. MEETINGS

The Code of Practice Committee will meet, whenever necessary, in an ordinary meeting after a summons from the Secretary, with at least 48 hours notice, indicating the agenda. In special emergency cases, the Code of Practice Committee may meet in an extraordinary session, in which case the notice period indicated above may not apply, but there must be good cause.

The Director of the Code of Practice Surveillance Unit may attend the Code of Practice Committee meetings, having the right to speak but no voting rights.

Minutes of the meeting must be taken and signed by the Secretary of the Code of Practice Committee and the members.

27. AUTHORITIES

The Code of Practice Committee, notwithstanding the authorities that correspond to the Code of Practice Surveillance Unit, may have inspecting authorities to confirm the acts that have been reported and the presumed breaches of the Code, either directly or through the Code of Practice Surveillance Unit.

The Code of Practice Committee may request copies of any documentation or evidence it considers relevant from the pharmaceutical companies, including copies of communications submitted to the competent health authorities. In addition, the Code of Practice Committee may request a copy of the manuals used by employees that interact with Healthcare Professionals.

CHAPTER II

The Code of Practice Surveillance Unit of the Pharmaceutical Industry in Spain

28. STRUCTURE, ORGANISATION, OPERATION PRINCIPLES AND AUTHORITIES

28.1. Structure and Organisation

The Code of Practice Surveillance Unit will be headed by a Director, designated by the Farmaindustria Executive Board at the request of the Governing Council and with the approval of the Code of Practice Committee. The duration of the post will be three years, whereby the appointment may be renewed indefinitely for successive periods of equal duration.

In order to perform his/her functions, the Code of Practice Surveillance Unit Director will, at all times, have the personnel and material means necessary to perform his/her functions according to the judgment of the Farmaindustria Governing Bodies.

The Code of Practice Surveillance Unit may be called to inform the Code of Practice Committee and, in all cases, shall be responsible for its activities before the Board of Governors.

The Code of Practice Committee will function in collaboration with the Code of Practice Committee and will have the support and advice of the Farmaindustria Legal Department, being able to propose to the Code of Practice Committee the opinion and assistance of experts in any field whenever they deem it necessary.

The Code of Practice Surveillance Unit will draw up a quarterly report on its actions, which must be presented to the Code of Practice Committee and Farmaindustria General Management, who will transmit the report, with his/her considerations, to the Board of Governors and the Executive Board.
28.2. Operation Principles

a) Confidentiality: The Code of Practice Surveillance Unit will maintain the confidentiality of its actions, avoiding the disclosure of any information on the processing of complaints and its resolutions, until these have not been issued or until their publication has been agreed to.

b) Veracity: All actions carried out by the Code of Practice Surveillance Unit in the clarification of facts will have the presumption of veracity.

c) Impartiality: The Code of Practice Surveillance Unit will act under the principle of impartiality and with clear objectivity in defense of the rules contained in the Code.

d) Independence: The Code of Practice Surveillance Unit will be independent of party interests and will remain autonomous for performing its work.

e) Agility: The Code of Practice Surveillance Unit will use the most appropriate means to guarantee maximum agility in the execution of its procedures with the objective of being effective in its preventative and supervisory work.

28.3. Scope of Action

The Code of Practice Surveillance Unit may act anywhere within the national territory and in foreign countries when the activities under investigation are conducted by a company subject to the application rules of the Code.

28.4. Functions and Authorities

As the body responsible for the active monitoring of compliance with the Code, the Code of Practice Surveillance Unit may exercise the following functions and authority, among others:

a) To collaborate with the Code of Practice Committee and the Jury with the aim of promoting effective application of the rules contained in the Code, either on its own or at the request of any person with a legitimate interest.

b) To provide advice, guidance and training in relation to the Code.

c) To implement the measures necessary to investigate compliance with the Code of a given activity, requiring companies to provide or exhibit any information or documentation that is relevant due to being directly or indirectly related to said investigation.

Some of the documentation, including but not limited to, that is subject to this requirement: procedure manuals, internal control documentation, and copy of the agreements with third parties that may lead directly or indirectly to activities that fall within the scope of the Code.

Companies will adopt the measures necessary to facilitate providing or exhibiting said documentation.

Within this same investigation, and only in the case that the information or documentation supplied by the company was insufficient or incomplete according to the judgment of the Director of the Code of Practice Surveillance Unit, said Unit may request in writing that an investigations procedure be undertaken according to the terms stipulated in article 37 of the Code.

d) To manage the prior communication procedure of scientific meetings, studies and services stipulated in articles 11.8, 14.3 and 16.2 of the Code and, based on its criteria, collect additional information before or after they are carried out. In addition, the Unit may appear on site in order to obtain more information when conferences and scientific meetings take place, whenever there are rational reasons or evidence of a breach.

e) To draw up warnings of a preventative nature to laboratories when, in activities to be conducted, and according to information in their possession, there is a risk of breach of the Code.

f) To initiate complaint procedures before the Code of Practice Committee if supervisory actions lead to the discovery of a Code breach; to propose corrective measures in mediation agreements, which may include a monetary contribution to the fund created by Farmaindustria set aside for the rational use of medicines.

g) To issue rulings of a technical or ethical nature on the questions submitted by Farmaindustria within the scope of their actions and report regarding queries on the Code presented by companies, forwarding these to the Code of Practice Committee for their reply.
h) To issue circulars to companies defining the criteria of the Code of Practice Surveillance Unit with regard to certain activities, Events or any other aspect or information related to compliance with the Code by the companies.

i) To verify, through the means it deems appropriate and proportional, compliance with the resolutions of the Jury and the mediation agreements by the infringing companies.

j) To notify to the competent healthcare authorities those practices which, being conducted by companies not subject to the provisions of the Code, may result in violations of applicable legislation.

k) To provide a certificate that allows for accreditation of compliance with the precepts of the Code for a given activity, according to the procedure approved by the Farmaindustria Executive Board.

l) Any other applicable functions by virtue of the Code.

28.5. Reporting of Possible or Presumed Breaches

Any person or legal entity that has a legitimate interest in action being taken with regard to a specific activity within the scope of application of the Code, may report a possible breach to the Code of Practice Surveillance Unit. The Code of Practice Surveillance Unit is obliged to keep the identity of the informant confidential.

Reporting of possible or presumed breaches to the Code of Practice Surveillance Unit must be formalised in writing to the Director, who will maintain a register of all communications received.

The communications must contain, at a minimum, the following data:

a) Name and address of the informant and, where applicable, personal data of the representative, who must certify the power of attorney.

b) Name and address of the company that is the possible or presumed violator.

c) A detailed explanation of the facts that constitute the possible or presumed breach being reported.

d) The evidences, documents or means of proof that the informant possesses.

The Code of Practice Surveillance Unit will evaluate the facts reported, and may carry out any investigations or means of evidence it deems appropriate in order to initiate proceedings against the presumed offending company, where applicable.

If the written communication does not contain any of the required information or if the Code of Practice Surveillance Unit does not perceive the existence of a breach, the Unit Director may close the file without any further process, reporting this decision to the informant. The Director of the Unit may also close the file if the presumed breach involves a given piece of promotional material or if, after evaluation, the Director determines that the informant has sufficient evidence to present the complaint on his/her own without the need for intervention by the Unit.

CHAPTER III

The Jury of Autocontrol

29. THE JURY

The Governing Bodies of Farmaindustria have agreed, under the terms specified in the relevant agreement, that control of compliance and interpretation of the Code of Practice for the Pharmaceutical Industry shall be the responsibility of the Jury of the Association for Self-Regulation of Commercial Communications, which is governed by its own Rules of Procedure.

30. NOTIFICATIONS AND EXECUTION OF RESOLUTIONS OF THE JURY

The resolutions of the Jury are reported immediately to the parties for their compliance. Simultaneously, the Jury will communicate these resolutions to the Code of Practice Committee, who will transfer them to the Farmaindustria Governing Bodies in order to be executed and, where applicable, proceed to collection of pecuniary sanctions imposed by the Jury.
CHAPTER IV
Procedures

31. GENERAL RULES

31.1 Deadlines
The deadlines indicated in days are understood to refer to business days and will be counted from the day after notification of the act to which it applies.

Non-working days, excluded from calculation, are considered to be Saturdays, Sundays and legal holidays in the municipality where the interested party has the professional address or where the Body’s headquarters are located, as well as those determined by the Secretary of the Code of Practice Committee whenever appropriately motivated exceptional circumstances arise. The month of August shall be considered a non-working month to all effects.

The Secretary of the Code of Practice Committee and, where applicable, the Director of the Code of Practice Surveillance Unit, may also grant an extension of the established time periods that does not exceed half the period, if appropriately motivated exceptional circumstances arise.

31.2. Notifications
Notifications will be made by any means that allows for confirmation of reception by the interested party or its representative, as well as the date, identity and contents of the act being notified. Confirmation of the notification provided will be incorporated into the file.

32. COMPLAINT PROCEDURE

32.1. Commencement
The procedure will commence by a complaint from any person who has a legitimate interest in action being taken with regard to a specific activity, or by a complaint from the Code of Practice Surveillance Unit.

32.2. Complaints
Complaints made to the Code of Practice Committee will be directed to the Secretary of the Code of Practice Committee, preferably by electronic mail to secretariacomision@codigo.farmaindustria.es whenever the size of the file and the nature of the acts being reported allow for the use of this medium.

A registry book with all complaints received will be maintained.

The complaints must contain, at a minimum, the following data:

a) Name and address of the complainant and, where applicable, personal data of the representative, who must certify the power of attorney. In the case of complaints made by the Unit, it is sufficient that this appears as the complainant.

b) Name and address of the defendant.

c) A detailed explanation of the facts constituting the presumed breach of the Code that is being reported and the appropriate request for this to be investigated.

d) Documents, evidence on which the complaint is based and, where applicable, an original copy of the promotional materials that are the source of dispute.

In addition, the complainant may also propose any other means of evidence to certify the activities denounced, which shall be used if deemed necessary by the Code of Practice Committee.

If the written complaint is missing any required information, the Secretary of the Code of Practice Committee will address a communication to the interested complainant requesting provision of the information, within a period of three days, in order to complete the file.

If the time elapses without the interested party providing the information, the file will be closed, with no other processing, and this will be communicated to the complainant.

Complaints received through EFPIA will follow the same procedure.

Complaints will only be processed if:
a) They relate to promotional materials that have been carried out in the previous twelve months.

b) They relate to activities that were carried out within the previous 3 years.

c) They do not relate to complaints related to a promotional activity that has been resolved or is undergoing a legal process or administrative procedure.

Letters a) and b) do not apply when they concern a presumed ongoing breach, construed as the realization of a plurality of actions or omissions that breach the same or similar precepts of the Code, in execution of a preconceived plan or taking advantage of an identical or similar occasion.

Once the file has been completed, the Secretary will inform the defendant, which can make any allegations it deems convenient within five days of receiving the complaint. Written allegations should preferably be presented by electronic means.

Afterward, the Secretary will transfer a copy of the file with a succinct informative note to the members of the Code of Practice Committee so that the matter can be discussed at the next scheduled meeting. The order of issues will be determined by the Secretary of the Code of Practice Committee, according to the timetable for meetings that will be periodically published by circular in the FARMAINDUSTRIA self-regulation system web (www.codigofarmaindustria.es). If the matter is considered urgent because of its importance, then the Secretary, after a verbal consultation with the members, will call an extraordinary meeting. The Secretary of the Code of Practice Committee will formally convene the parties, with a minimum of two working days notice, to a mediation hearing before the Code of Practice Committee.

32.3. Mediation
If the Code of Practice Committee succeeds in assisting the parties in reaching an amicable agreement, the complaint will be resolved without the need to be transferred to the Jury. The mediation agreement reached will be signed by the parties. If an agreement were not possible, the Secretary of the Code of Practice Committee will transfer the file to the Jury within a maximum period of two days. In addition, the Secretary, in coordination with the Code of Practice Committee and the complainant, may transfer the file to the Jury if it appears that the defendant is delaying the mediation process unnecessarily.

In order to facilitate achieving an amicable agreement, the complainant may propose the terms under which an amicable agreement can be reached to the accused company, which will include the recognition of the breach by the company, as well as the corrective measures that are considered necessary based on the severity of the acts and with the objective or repairing the damage caused and preventing recurrence in the future. The mediation agreements will be published monthly on the FARMAINDUSTRIA website, except when the Code of Practice Committee considers it necessary to maintain the confidentiality of the agreement.

In the same way as the resolutions by the Jury, the parties must immediately comply with the agreement reached.

32.4. Direct Resolution by the Jury
When there are reasons for urgency, direct resolution of complaints by the Jury may be requested. Once the complaint has been admitted for processing, in accordance with the stipulations of section 32.2, the Secretary of the Code of Practice Committee may transfer the complaint to the defendant so that the allegations he/she feels are appropriate can be presented within the five days following receipt of the complaint. Once the file is complete, it will be transferred to the Code of Practice Committee so that said request can be resolved within a maximum of 2 days. If appropriate, it will be sent immediately to the Jury, which will act according to its owns Rules of Procedure. In case of rejection of the request, the file will continue the ordinary process.

33. PROCEDURE FOR COMMUNICATING EVENTS AND SCIENTIFIC MEETINGS
The provisions of this article only result of application to article 11 of the Code.

The communication of meetings and Events of a scientific and promotional nature that are subject to mandatory communication in accordance with the provisions of article 11.8 of the Code must be notified according to the following conditions:
33.1. Conditions
Companies must provide prior notification of the holding of any scientific or promotional meeting or Event when the following three circumstances concur:

a) that they are organised – directly or indirectly – or sponsored – exclusively or in the majority – by the reporting company;

b) they include at least one overnight stay; and

c) they involve the participation of at least 20 Healthcare Professionals practicing in Spain.

Nevertheless, when a company organises the attendance of a group of more than 20 Healthcare Professionals who practice in Spain to a conference or meeting organised by a third party (scientific societies, professional organisations, etc.), it must be communicated as if the Event were organised by the company itself. This communication will not be obligatory for Events that have been reviewed by the Code of Practice Surveillance Unit. To this end, the Unit will provide a system through which the list of Events organised by third parties, both at national and international levels, that have been reviewed by the Unit can be consulted.

33.2. Deadlines
The communication shall be addressed to the Code of Practice Surveillance Unit at least 10 working days before its beginning.

33.3. Information to be Provided
The communication must contain the following data:

a) Name and address of the company.

b) Nature of the participation: organiser or sponsor.

c) Title of the meeting or Event.

d) Healthcare Professionals to whom it is directed (specialty and place of residence – local/regional, national or international scope).

e) Number of Healthcare Professionals Invited.

f) Approximate number of participants at the Event.

g) Location and dates (if held at a hotel, name and rating and number of overnight stays).

h) Scientific programme, with an indication of the number of hours.

i) Social programme and parallel activities.

j) Other entities involved in the organisation and sponsorship of the Event (scientific societies, professional organisations, foundations, etc.).

A procedure will be put in place to present these communications through electronic media to ensure the agility of the process, its efficacy and the confidentiality of data.

The Code of Practice Surveillance Unit must confirm receipt of the communications to the respective companies, at the same time may also request additional information or corrective measures for compliance with the Code, if necessary. In the latter case, if the company holds the Event without meeting the corrective measures, the Unit may initiate the corresponding complaint procedure.

The Unit will have five working days from receipt of the report to make any pronouncements on international Events that, according to the stipulations of article 11.10 (b) of the Code, require previous authorization. The absence of such a pronouncement within the stipulated time period will imply that the Event has been authorized.

33.4. Person Responsible
Each company will designate through their legal representative one or two persons responsible for communicating Events who will be the intermediary in these matters and who shall be assigned personal passwords for communicating Events via the Internet/electronic mail. This will also be the person who will contact the Code of Practice Surveillance Unit for any clarifications on the reported Events. The Code of Practice Surveillance Unit will maintain a database in which all reports received will be collected. This will be kept strictly confidential. This database must comply with current regulations on the protection of personal data.
34. PROCEDURE FOR COMMUNICATING STUDIES

The provisions of this article only result of application to those studies regulated in article 14.3 of the Code the communication of which is obligatory.

34.1. Conditions
Companies must provide prior notification of the carrying out, financing or sponsoring of the studies mentioned in article 14.3. Such communication shall not be mandatory when any of the following circumstances occur:

- the sponsorship or funding provided by the company does not represent the majority of the financial resources; or
- the company does not have access, prior to, during or after the study, to the identities of the participating Healthcare Professionals, nor has it intervened in the selection beyond defining the participating group in the study protocol; or
- the study involves the remunerated participation of less than 20 Healthcare Professionals practicing in Spain. The subdivision of a study into smaller units when such units share the same focus, objectives and methods is not permitted.

34.2. Deadlines
The communication shall be addressed to the Code of Practice Surveillance Unit at least ten working days before the beginning of the study or exceptional access to the identity of the participants for reasons of quality control.

34.3. Information to be Provided
The communication must contain at least the following data:

a) Company reporting the study.

b) Name of the sponsor: company, scientific society, healthcare institution, other.

c) Title of the study.

d) Objective of the study.

e) Methodology being applied.

f) Planned times of execution.

g) Approximate number of Healthcare Professionals participating in the study.

h) Specialty to which the Healthcare Professionals belong.

i) Geographical scope of the study (international, national, regional, local).

j) Planned remuneration of the participating Healthcare Professionals.

k) Other individuals or legal entities involved in the execution or sponsorship of the study (scientific societies, healthcare institutions, third-party service providers, etc.).

l) In the case of exceptional access to the identity of the participants for reasons of quality control, position in the company of the persons with said access.

A procedure will be put in place to present these communications through electronic media that ensure the agility of the process, its efficacy and the confidentiality of data.

The Code of Practice Surveillance Unit must confirm receipt of the communications to the respective companies, it may at the same time also request additional information or corrective measures for compliance with the Code, if necessary. In the latter case, if the company executes the study without meeting the corrective measures, the Unit may initiate the corresponding complaint procedure.

34.4. Person Responsible
Each company will designate through their legal representative one or two persons responsible for communicating studies who will be the intermediary in these matters and who shall be assigned personal passwords for communicating studies via the Internet/electronic mail. This will also be the person who will contact the Code of Practice Surveillance Unit for any clarifications on the reported studies. The Code of Practice Surveillance Unit will maintain a database in which all reports received will be collected. This will be kept strictly confidential. This database must comply with current regulations on the protection of personal data.
35. PROCEDURE FOR COMMUNICATING SERVICES PROVIDED BY HEALTHCARE PROFESSIONALS OR HEALTHCARE ORGANISATIONS

The provisions of this article only result of application to those services regulated in article 16 of the Code the communication of which is obligatory.

35.1. Conditions
Prior to initiation, companies must report on the implementation, funding or sponsorship of projects that require contracting services provided by Healthcare Professionals or Healthcare Organisations, in accordance with article 16.2 of the Code.

The communication unit for these services will be the project. For the purposes of this communication, each project will include all of the services that the company plans to contract with Healthcare Professionals or Healthcare Organisations, within the timeframe of one year and throughout Spain, that share the same approach, objectives and methods.

This communication of these projects will not be obligatory when any of the following circumstances occur:

• the sponsorship or funding provided by the company does not represent the majority of the financial resources; or

• the project involves the remunerated participation of less than 20 Healthcare Professionals practicing in Spain; or

• the project consists of a clinical trial or study stipulated in sections 1 or 2 of article 14 of the Code.

35.2. Deadlines
The communication shall be addressed to the Code of Practice Surveillance Unit at least ten working days before its beginning.

35.3. Information to be Provided
The communication must contain at least the following data:

a) Company reporting the project.

b) Title of the project.

c) Objective of the project.

d) Methodology being applied.

e) Planned times of execution.

f) Approximate number of Healthcare Professionals participating in the project.

g) Specialty to which the Healthcare Professionals belong.

h) Geographical scope of the project (international, national, regional, local).

i) Planned remuneration of the participating Healthcare Professionals.

j) Other individuals or legal entities involved in the execution or sponsorship of the project (scientific societies, healthcare institutions, third-party service providers, etc.).

Together with the above data, the communicating company must provide a report with the following points to the Code of Practice Surveillance Unit:

i) justification for the need to contract these types of services;

ii) criteria used to select the contracted Healthcare Professionals, which must be consistent with the objectives of the project;

iii) criteria used to calculate the remuneration for the provision of services;

iv) documentation for ensuring effective provision of the service (project deliverables);

v) copy of the contract or signed contracts (anonymised if necessary) or the contract template, if available.

A procedure will be put in place to present these communications through electronic media that ensure the agility of the process, its efficacy and the confidentiality of data.
The Code of Practice Surveillance Unit must confirm receipt of the communications to the respective companies, at the same time it may also request additional information or corrective measures for compliance with the Code, if necessary. In the latter case, if the company executes the project without meeting the corrective measures, the Unit may initiate the corresponding complaint procedure.

35.4. Person Responsible

Each company will designate through their legal representative one or two persons responsible for communicating services provided by Healthcare Professionals or Healthcare Organisations who will be the intermediary in these matters and who shall be assigned personal passwords for communicating services via the Internet/electronic mail. This will also be the person who will contact the Code of Practice Surveillance Unit for any clarifications on the reported projects. The Code of Practice Surveillance Unit will maintain a database in which all reports received will be collected. This will be kept strictly confidential. This database must comply with current regulations on the protection of personal data.

36. QUERIES PROCEDURE

Companies may pose queries in accordance with article 20 of the Code according the following procedure:

36.1. Submission

Queries shall be addressed in writing to the Director of the Code of Practice Surveillance Unit, who will maintain a registry of the queries received.

Queries will be vacated in the first scheduled meeting of the Code of Practice Committee, provided they are received at least fifteen working days prior to the meeting, in accordance with the dates that will be announced as they are set. If received within a shorter time period, the query may be transferred for resolution in a later meeting.

The queries must contain, at least, the following data:

a) Name and address of the company posing the query and, given its binding nature, the personal data of the representative, who must certify the power of attorney.

b) Wording of the query, expressed clearly, simply and specifying, if possible, the applicable provisions of the Code.

No queries will be processed if they deal with a promotional activity that is under consideration by the Control Bodies. The processing of the query will be suspended until the resolution of said issue.

36.2. Reply

Once a query is admitted for processing, the Director of the Code of Practice Unit will transfer the query together with a reply proposal to the Secretary of the Code of Practice Committee, who, with his/her considerations, will transfer it to the members of the Code of Practice Committee so that they can vacate it at the corresponding meeting. The result of the query will be sent to the company that requested it.

Queries that have not been published in accordance with the provisions of article 20.4 of the Code will not have any effect toward third parties.

In addition, queries resolved after filing of a complaint cannot be added to the complaint, except under duly justified circumstances and if the Code of Practice Committee, in coordination with the Secretary, deem its contribution.

37. INVESTIGATION PROCEDURE

37.1. Form of Initiation

The procedure will begin with a letter signed by the Director of the Code of Practice Surveillance Unit. This written notice may be submitted in those cases in which the company – having been required in accordance with article 28.4 section (c) – does not provide the Unit with the requested information or documentation, or if said information or documentation is insufficient or incomplete in the judgment of the Unit.

This written notification must be addressed to the representatives designated by the company as legal representatives before Farmaindustria and as Compliance Officer, and must contain at least the following data:

a) Name and address of the company, personal data of the representatives to whom it is directed and date.
b) Explicit request to open the investigation procedure.

c) Brief description of the reasons why the investigation procedure is being initiated. Summary of the presumed activity/practice that is in breach of the terms and provisions of the Code.

Within a period of ten working days from receipt of the request, the company’s legal representative before Farmaindustria must report in writing to the Unit regarding their acceptance or rejection of the investigation procedure, including their reasons. Failure to reply within the prescribed period will be understood to be an unjustified rejection of the investigation procedure.

In case of accepting the investigation procedure, the company must also indicate in its document:

a) Its willingness to collaborate in good faith with the activities considered necessary to conduct the investigation procedure.

b) The entity responsible for conducting the investigation, being able to select between:

i) an individual or legal entity that does not have any relationship with the company or any other company in the Group,

ii) an independent auditor that was providing auditing services to the company on the date that the investigation procedure was initiated, or,

iii) the Code of Practice Surveillance Unit.

For cases (i) and (ii), this must be an entity of recognised prestige that is accepted by the Unit. In the Event that an agreement is not reached, the Unit will propose a list of entities from which the company must choose one, within a maximum period of 5 working days from the date of receipt. The costs associated with conducting the investigation procedure by an entity other than the Unit will be assumed, in all cases, by the company.

c) Its submission to the outcome.

Unjustified refusal to submit to the investigation procedure will prompt the Unit to initiate a complaint procedure before the Code of Practice Committee, both to sanction the refusal to collaborate as stipulated in article 21.6 of the Code, as well as the activity that is the object of the investigation.

37.2. Report: Submission, Scope and Content

From the moment of receipt in writing of the acceptance to conduct the investigation procedure, the entity designated to conduct the investigation will have one month to:

i) collect whatever information and documentation can be found in relation to the activity/practice that led to the investigation procedure being initiated, and

ii) provide the Unit (unless this was the entity designated to conduct it) and the company’s legal representative with a written report.

The Unit may agree to extend the time period.

Failure to submit the report, or its submission outside of the timeframe – when an entity other than the Unit is responsible for conducting it – will have the effects described in the provisions of section 37.1 concerning the refusal to submit to the investigation procedure.

The report must contain at least the following:

a) A statement of the author of the report as to the veracity of its contents, objectivity in its drafting and the conclusions issued.

b) A detailed description of the investigation work performed, the means employed and the level of collaboration from the company.

c) The company’s internal procedures that would be applicable to an activity/practice such as that which led to the initiation of the investigation procedure. These procedures must include, at least, the areas and persons at the laboratory responsible for supervising its application and compliance, the internal control mechanisms (checklist, sign-off sheets, etc.), the reporting and archiving system, etc.

d) A list of the documentation examined for the purpose of issuing the report, as well as information...
that, having been requested, was not provided or exhibited by the company. Together with the list, originals or copies of the documents submitted must be provided.

e) Recommendations or proposals for improvement, where applicable.

f) Expressed written authorization to allow the Unit to use the report for any actions it deems appropriate because of their relation to the investigation procedure, including the provisions of section 37.4.

g) The conclusions of the report.

37.3. Collaboration Commitment

The companies subject to the provisions of the Code, as provided in articles 19.1 and 19.3 of the Code, commit to collaborate with the entity in charge of conducting the investigation procedure, providing to this end all information and documentation that said entity requires as useful or necessary for the conduct of its investigative work.

Failure to cooperate with the investigation procedure will have the effects indicated in article 21.6 of the Code and section 37.1 of this article with respect to refusal.

37.4. End of the Procedure

The Unit will have thirty days from receipt of the report or finalisation of its drafting, for analysis and review of its contents, holding those meetings it deems appropriate with the persons in charge of the company or with the entity put in charge, where applicable, for drawing up of the report.

Once the deadline has passed, the Unit will have five days to submit a report addressed to the legal representative before FARMÁNDUSTRIA and to the Compliance Officer of the company, indicating:

- The finalisation and closure of the investigation procedure.

- The measures to be taken by the Unit in light of the investigation procedure:

  (i) closing of the matter, or

  (ii) transfer of the recommendations the Unit deems appropriate and closing of the matter, or

  (iii) initiation of a complaint procedure before the Code of Practice Committee.
Title III
Coming Into Effect of the Code
38. COMING INTO EFFECT OF THE CODE

This Code comes into effect on 1 January 2014 and revokes those that were in effect up to this date. The Code of Practice Surveillance Unit is authorized to establish, by circular, adaptation periods for the practical application of the novelties introduced in article 10 of the Code, which must in no case extend beyond 30 June 2014.

COMING INTO EFFECT OF THE CODE: SUPPLEMENTARY RULES

This Code supersedes and revokes:

The Spanish Code of Practice for the Promotion of Medicines and Interaction between the Pharmaceutical Industry and Healthcare Professionals (October 2010).


Spanish Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (January 2012).


Rules of Procedure for the Control Bodies of the Pharmaceutical Industry Self-Regulation System (October 2010).
Annex 1
## Annex I
### Disclosure Template

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Healthcare Professionals (HCPs): city of principal practice</th>
<th>Country of Principal Practice</th>
<th>Principal Practice Address</th>
<th>DNI / CIF XXX1234XX</th>
<th>Donations (Art. 18.3.1.a)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory</strong> (Art. 18.3)</td>
<td>(Mandatory) (Art. 18.3)</td>
<td>(Optional) (Art. 18.3)</td>
<td>(Optional) (Art. 18.3)</td>
<td>(Mandatory) (Art. 18.3)</td>
<td></td>
</tr>
<tr>
<td><strong>INDIVIDUAL NAMED DISCLOSURE:</strong> one line per HCP (i.e. all Transfers of Value during a year for an individual HCP will be summed up. Itemisation should be available for the individual HCP or public authorities' consultation only as appropriate.**</td>
<td>DR. AAAA</td>
<td>HealthCare Professionals (HCOs): city where registered</td>
<td>DR. AAAB</td>
<td>etc.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### INFORMATION NOT INCLUDED ABOVE: where information cannot be disclosed on an individual basis for legal reasons.

- Aggregate amount attributable to Transfers of Value to HCPs – Article 18.4: Not applicable
- Number of HCPs disclosed at aggregate level – Article 18.4: Not applicable
- % of total Transfers of Value to HCPs – Article 18.4: Not applicable

**INDIVIDUAL NAMED DISCLOSURE:** one line per HCO (i.e. all Transfers of Value during a year for an individual HCO will be summed up. Itemisation should be available for the individual HCO or public authorities' consultation only as appropriate.

<table>
<thead>
<tr>
<th>Healthcare Organisations (HCOs)</th>
<th>Yearly Amount €</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCO 1</td>
<td>Yearly Amount €</td>
</tr>
<tr>
<td>HCO 2</td>
<td>Yearly Amount €</td>
</tr>
<tr>
<td>etc.</td>
<td>Yearly Amount €</td>
</tr>
</tbody>
</table>

### AGGREGATE DISCLOSURE

**Transfers of Value related to Research & Development – Article 18.6**
## Contribution to educational and scientific meetings (Art. 18.3.1.b & 18.3.2.a)

<table>
<thead>
<tr>
<th>Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event</th>
<th>Registration Fees</th>
<th>Travel &amp; Accomodation</th>
<th>Fees</th>
<th>Related expenses agreed in the fee for service or consultancy contract, including travel &amp; accomodation</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Yearly Amount €</td>
<td>Yearly Amount €</td>
<td>Yearly Amount €</td>
<td>Yearly Amount €</td>
<td>Optional</td>
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### INFORMATION NOT INCLUDED ABOVE:
where information cannot be disclosed on an individual basis for legal reasons.

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## Fees for service (Art. 18.3.1.c & 18.3.2.b)

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### AGGREGATE DISCLOSURE

**Transfers of Value related to Research & Development – Article 18.6**

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Annex II
Annex II
Queries (questions and answers) on the interpretation of the Code of Practice

The aim of these general interest queries, presented in the form of questions and answers, is to clarify several points related to the interpretation of specific issues regarding application of the Code of Practice for the Pharmaceutical Industry by gathering the interpretation of the Surveillance Unit and the Code of Practice Committee.

As such, the aim of these queries is to detail and clarify the self-regulation provisions that establish the framework within which industry’s activities should be carried out, guiding and easing compliance of companies with such regulations, always taking into account that, in case of dispute, the interpretation of self-regulation provisions ultimately pertains to the self-regulation Jury (Autocontrol).

This Queries document has been enriched since its first edition (January 2004) to clarify, with a mainly practical approach, the doubts that have had a greater impact in the addressees of the Code since then up until the current version (June 2014). This document gathers a very ample casuistry that may be object of modification in order to adapt it and update it to each moment’s reality.

This document was approved by the Board of Directors and the General Assembly of Farmaindustria in its June 2014 meeting under the provisions of article 20.4 of the Code.

DEFINITIONS

1. When defining Market Price, does the Code refer to gross or net value (both for gifts and informational/educational materials or items of medical utility)?

The Code defines Market Price as the amount a private party should generally have to pay in order to acquire a unit of a good, product, material, article or similar in Spain. To this effect, such concept should be interpreted as including all applicable taxes.

SCOPE OF THE CODE

2. Within the context of educational meetings or courses endorsed by scientific societies dealing with general aspects of certain pathologies and of interest due to their programme, could persons not authorized to prescribe or dispense medicines, but relevantly linked to the handling of these diseases, be invited or have their attendance sponsored in case of a prior request? For example: psychiatric disorders – psychologists (belonging to multidisciplinary psychiatric treatment teams); muscular disorders – physiotherapists; diabetes – educators; in general – nurses or others.

The invitation to persons not authorized to prescribe or dispense medicines that are considered Healthcare Professionals by the Law 44/2003 of 21 November on the Organisation of Health Professions is permitted, provided that the same criteria that apply to Healthcare Professionals authorized to prescribe or dispense medicines in compliance with provisions of the Code of Practice are applied.

Paragraph 3 of art. 6 of the above law establishes that those in possession of an official degree of specialist in Health Sciences for psychologists are also Healthcare Professionals of licentiate level.

In the same way, art. 7 of the Law recognises that physiotherapists and nurses are Healthcare Professionals of graduate level.

Consequently, psychologists, physiotherapists and nurses are Healthcare Professionals according to
3. Would the following promotional practice be compliant with the Code’s provisions? When prescribing a non-reimbursed medicine, a doctor hands out to the patient its mandatory medical receipt together with an informational material detailing the product’s administration and a coupon to be filled out by the patient in case the medicine does not have the expected results after its first administration. In exchange for its delivery in the pharmacy where the product was acquired, the price paid when picking up the product would be returned. The company, in turn, when receiving the filled out coupon from the pharmacy would refund the product’s cost.

No. This kind of promotional practices cannot be carried out due to the very own nature of medicines. It must be taken into account that the therapeutic or adverse side effects of medicines may not appear after the first administration and that marketing authorization of medicines is granted by the regulatory organisms (AEMPS in Spain) and, consequently, any information about them must be made following the legally established procedures (summary of product characteristics or leaflet).

4. Owing to its 50th anniversary, could a pharmaceutical company invite a group of Healthcare Professionals to an activity of an exclusively corporate/institutional nature in, for example, a (i) golf tournament, (ii) classical music concert or sports event, (iii) banquet?

No, entertainment activities are not appropriate in the context of an interaction between the pharmaceutical industry and Healthcare Professionals.

Institutional events may include a hospitality section, which shall respect the limits defined in the Code of Practice for the Pharmaceutical Industry.

5. Are provisions of the Code (including compulsory notification) applicable to market research studies or services carried out by companies when not directly related to a prescription-only medicine? (For example: a market study to find out what the company’s image is among doctors, or hiring of a Healthcare Professional to participate as a speaker in a corporate/institutional activity?)

Yes, the Code of Practice includes all aspects of the interaction between Healthcare Professionals and the pharmaceutical industry.

6. The scope of the Code excludes the commercial transactions of companies with distributors and pharmacy offices. Does this mean we can keep carrying out direct marketing campaigns with pharmacy offices and, if so, is it only if no medicine is mentioned or also if it’s related to a medicine?

The concept “direct marketing” allows for different interpretations. In all cases the activities related to the promotion of prescription-only medicines or interactions with Healthcare Professionals are within the scope of the Code. Commercial transactions (discounts and commercial conditions legally provided) are outside the scope of the Code.

ARTICLE 1. MARKETING AUTHORIZATION FOR MEDICINES

7. Can a company inform Healthcare Professionals attending a congress taking place in Spain about molecules undergoing research (not yet in possession of marketing authorization) through abstracts elaborated by this same company within posters located on the walls of the company’s stand at the congress?

Informative panels about pipelines may only contain information that has been published in indexed scientific journals or approved by the appropriate scientific committee for their presentation in the congress of a scientific society.

8. In case of a communication in a scientific meeting regarding data of products in clinical development (not authorized) or of a new indication in development, what are the limits that may differentiate scientific communication from promotion?; is it acceptable to communicate scientific data of a product not yet authorized in the context of a scientific congress when delivered by a Healthcare Professional;
is it any different if this professional is a company employee (doctor)?; is it any different if the data is communicated in a satellite symposium sponsored by the company?

Legislation and authorities have developed several criteria and examples to distinguish between information and promotion of medicines and provisions of Title I of the Code are to be applied when dealing with promotion of prescription-only medicines. The data communicated or presented in the official part of a congress (oral communication, poster, abstract) under the supervision of the prestigious organising scientific society constitutes information and not promotion, provided it is delivered in a complete form, with no modifications or additions to maintain that condition. A satellite symposium of a company taking place on occasion of a congress or a presentation delivered by a doctor hired by a company are, in principle, promotional activities, unless proven that the messages/contents delivered are purely informative both in their form and content, with no bias or modification.

The above does not prevent a company from informing in a balanced manner about its pipeline on occasion of a scientific congress. It shall then be the company’s responsibility to justify that the tone and scientific basis are appropriate, guaranteeing that these messages cannot be perceived as promotion of a non authorized prescription-only medicine or indication.

ARTICLE 2. INFORMATION ON MEDICINES TO BE MADE AVAILABLE

9. Can physicians be informed about approval of a new product once marketing authorization has been granted, even if the decision of the Ministry of Health, Social Services and Equality on reimbursement and price is still pending? And when a new indication is approved for a product already marketed, but the price and reimbursement conditions for the new indication are pending?

The approval of a new medicinal product and the content of the corresponding summary of product characteristics are public information which, in the case of a centralized procedure, are published in the web page of the European Medicines Agency (EMA), and whose dissemination is, according to the law, the responsibility of the authorization holder. The Spanish Agency of Medicines and Medical Devices also publishes in the Internet the summaries of product characteristics.

On the other hand, the law establishes that once a medicinal product is authorized and registered, the State shall decide, before the product is marketed, whether it is included in the pharmaceutical benefits of the Social Security and, if so, the maximum price will be fixed. The regulations also require that any promotional material (printed, digital or electronic, etc.) must include, among other things, the selling price to the public, the reimbursement conditions under the National Health System, if applicable, and, when feasible, an estimation of the cost of treatment.

Thus, mere transmission to Healthcare Professionals of the summary of product characteristics, with no other type of commercial claim, message or explanation of a promotional nature is not considered a breach of the Code. However, in such cases a clear warning must be present indicating that the product is not yet available in the market due to a pending administrative decision on reimbursement and price.

For a new indication, an express warning that the new indication is not reimbursed until the appropriate administrative decision is made should be added, and it should also be stated that the price may be reviewed if and when the new indication obtains its reimbursement conditions.

ARTICLE 3. INFORMATION ON MEDICINES AND ITS SUBSTANTATION

10. In the case of posters that have been published/accepted and presented in the context of a scientific society congress:

1. Can they be used as the only literature reference to back a statement in a promotional material if they are available at the congress website? Does their potential use depend solely on
whether or not they are published in an indexed journal?

2. The posters which are published in an indexed journal don’t usually appear in full, but as a summary. In this situation, do we have to use exclusively the information in the journals?

3. Could we consider posters to be informative material (like an abstract), so they can be distributed as such (without adding anything) outside the congress in the context of medical visits? Does it still depend on whether they are published in an indexed journal?

This query stems from a main premise: the existence of a scientific material – a poster, in this case – whose contents, design and characteristics have previously been validated by a scientific society, authorizing its publication and communication.

1. Provided that this is a published material, thus, accessible, we do not see a problem in its being used as bibliographic reference to sustain the claims of a promotional material.

Companies may use those materials published in renowned technical and scientific bibliographic sources that select essays with methodological quality and whose reading allows the professionals to gather clarifying or complementary information necessary to draw their own conclusions as to the therapeutic value of the medicine.

Prior to their use, pharmaceutical companies must ensure that the above requirements are met, without prejudice to the physical medium used for publication of the poster: congress poster book, renowned indexed scientific journal, official website of a congress or scientific society, etc.

2. Figures, tables, etc. in the poster shall be reproduced literally, that is, exactly as published. Additionally, they shall include a clear reference that allows them to be known or found.

3. Posters produced by Healthcare Professionals in the exercise of their professional work that are published in renowned scientific sources, provided they do not include printed, recorded, electronically linked nor in any other way the name of medicines, brands, claims nor any other promotional material, related or not to this information, may be considered informative materials (like abstracts, originals or off-prints of scientific articles).

Their distribution shall depend on their compliance with the provisions mentioned in the previous paragraph and those in section 1.

ARTICLE 10. GUARANTEES OF INDEPENDENCE

11. According to the Code, could an electronic device be offered to a Healthcare Professional on occasion of the Christmas season?

Direct or indirect provision of laptops, tablets, mobile phones, notebooks, mp3 mp4 mp5 players, e-books, cameras, etc. is unacceptable, as they are portable electronic devices susceptible of personal use, besides a professional one. In this sense, their provision to Healthcare Organisations would also be prohibited. Special dates, such as Christmas, do not justify their provision.

Provision of this kind of devices is a breach of Article 10.1 of the Code.

12. According to the Code, could a pharmaceutical company provide physicians with gift vouchers?

No. Under the provisions of article 10.1 gift vouchers are considered a banned incentive.

13. According to the Code, could a company invite a doctor to the premiere of a children’s film?

No. Such practice is considered a gift banned by article 10.1 of the Code.

14. A pharmaceutical company decides to give a group of Healthcare Professionals food products as a gift. Would it be in breach of the Code?

Yes. Article 10.1 of the Code prohibits provision of gifts of this nature.
15. Would a company infringe the Code if it decides to give a 450 Euro scientific book to a doctor as a gift?

Yes. Article 10.2 of the Code states that the provision of educational or informational materials shall be permitted provided that they meet the following three conditions:

(i) Inexpensive. In this regard, a material shall be considered inexpensive when its market price does not exceed 60 Euro.

(ii) Materials directly related to the exercise of medicine or pharmacy.

(iii) Materials that directly benefit patient care.

Consequently, provision of a scientific book with a market price of 450 Euro is an infringement of the Code, as it surpasses the established limit for these materials (60 Euro).

16. A pharmaceutical company decides to invite a group of urologists to spend the weekend in London and, as it coincides with the company’s anniversary, it decides to give the doctors a Rioja wine bottle as a gift. Would this be permitted under the Code?

No, unless the organisation of a scientific meeting in London were duly justified (article 11.10) and in compliance with the rest of the Code’s provisions regarding hospitality and content of such meetings. As for the provision of wine, it would not be acceptable, as article 10.1 bans the provision of gifts.

The only materials that may be provided are stationery or items for the practice of medicine or pharmacy that meet the following conditions: (i) unrelated to any prescription-only medicines and (ii) whose market price does not exceed 10 Euro.

17. What should be the objective criteria to calculate the value of the materials mentioned in article 10? Should it be the unit cost of the provider’s bill or the market price?

The criteria will be the material’s market price, this meaning the amount a person should pay (tax included) in order to acquire a unit of such product in Spain.

18. Is it allowed to provide Healthcare Professionals with a box of candy including the name of the company on the sweets’ wrapping contained within a box similar to that of the packaging of a medicine marketed by the company, clearly indicating that the content is candy and not medicines?

The item used as a promotional aid must be related to the practice of medicine or pharmacy and in no case create a potential risk of its being confused with the promoted medicine, even if aimed exclusively at Healthcare Professionals. In this particular case, the package of a medicine containing candy cannot be considered a valid support for the promotion of medicines for human use, even if indicating that the contents are candy.

Additionally, article 10.1 bans the provision of gifts as a general rule.

19. Is it allowed to provide Healthcare Professionals with a stethoscope, taking into account that:

- The stethoscope’s value is lower than that of some magnetic, electronic or similar books or materials that may be directly provided to the Healthcare Professional, as their market price is below 60 Euro.

- It cannot be used for the private benefit of the professional, but only for the benefit of the patient and the improvement of professional practice.

The provision of items that are necessary or indispensable for the Healthcare Professional to carry out his practice may be interpreted as an activity/practice offsetting routine business practices of the recipient, especially taking into account the exclusive and individual use of many of them. The Healthcare Professional himself or his employer should be the one to provide the resources and materials necessary for the carrying out of his professional activity. Consequently, even though they are medical utility items, the provision of stethoscopes, fonendoscopes, pulsioximeters, medical coats, medical clogs, surgeon caps, gloves, goggles, tensiometers, masks, gauzes, bandages, dressings, etc. is not permitted.

As for the provision of magnetic, electronic or similar books or materials, may we remind companies that their provision is permitted if three conditions apply, that they are inexpensive (their market price does not
surpass 60 Euro), related to the practice of medicine or pharmacy and that directly benefit patient care.

**20. Can a pharmaceutical company offer to pay a medical association/society’s membership fees for a specific time period to Healthcare Professionals? Could this be considered similar to the payment of subscriptions to scientific journals?**

Activities carried out by scientific associations or societies are mainly of a scientific content, but they also hold many other activities that may be of a socio-cultural nature and, thus, should not be sponsored by pharmaceutical companies.

Therefore, registration expenses or membership fees of scientific societies should not be paid to Healthcare Professionals. Also, it should be taken into account that the pharmaceutical industry already collaborates with the different scientific societies by sponsoring their multiple scientific activities.

Finally, payment of a subscription to a scientific journal and payment of a society or association’s membership fees cannot be compared, as they are different things.

**21. According to the Code, can a pharmacy obtain special advantages from a supplier of products/services benefitting from an agreement between a pharmaceutical company and that supplier? The pharmaceutical company would not intervene in the management, financing or delivery of the services to the pharmacy nor would have a legal identity linked to the laboratory. Could the advantages be extended to suppliers of products/services not linked to practice in the pharmacy?**

No. Despite there being no direct link between the pharmaceutical company and the pharmacy, it must be taken into account that the pharmaceutical company would be indirectly extending, as if it were one of its subsidiaries, the commercial advantages obtained from third party suppliers of products/services – by virtue of the agreements made with these – to independent companies/entities, as are pharmacies.

In general terms, this practice would in our view represent an inducement to dispensation which is not permitted under article 10.1 of the Code.

In any case, commercial transactions of companies with distributors, pharmacy offices and Healthcare Organisations are outside the scope of the Code.

**22. Could a company distribute bags within the context of a congress to Healthcare Professionals for the carrying of collected materials and articles?**

Article 10.1 of the Code bans as a general rule provision of gifts.

The above prohibition does not apply to the direct or indirect offering or provision of stationery or items for the practice of medicine or pharmacy that meet the following conditions: (i) unrelated to any prescription-only medicines and (ii) whose market price does not exceed 10 Euro.

**23. Would a promotional material, aimed at the medical and/or pharmaceutical sector, consisting in a (low quality) plastic coffee pot with a real Market Value of 12.20 Euro per unit be acceptable under the Code due to its being considered an inexpensive gift that may fit within the so called “items for the professional practice or stationery” because its end use would be none other than the physician’s office and the pharmacist’s back office?**

Article 10.1 of the Code bans as a general rule provision of gifts.

The above prohibition does not apply to the direct or indirect offering or provision of stationery or items for the practice of medicine or pharmacy that meet the following conditions: (i) unrelated to any prescription-only medicines and (ii) whose market price does not exceed 10 Euro.

A coffee pot is not considered (i) professional practice item, (ii) stationery, (iii) informational or educational material, or (iv) item of medical utility, so under no circumstance may it be offered or provided.

Gifts to Healthcare Professionals, disregarding their economic value, must in all cases preserve the dignity of the medical act.
24. Under article 10 of the Code and its Supplementary Rules, would it be acceptable to provide Healthcare Professionals with a small transparent self-closing plastic bag with a capacity of not more than one litre, containing a series of empty bottles with a capacity of up to 100 ml., which included either the product logotype or the company logotype? The bag would be distributed at congresses to physicians who regularly travel by airplane on account of their scientific activity, in compliance with the regulations governing liquids and gels in hand baggage at airports, so that they may carry, if they so wish, alcohol, povidone iodine, oxygenated water or any other liquid that they may consider necessary on their trips.

It being a gift unrelated to the practice of medicine or pharmacy, it should not be provided.

25. Can a pharmaceutical company distribute to Healthcare Professionals through its medical visit sales representatives works of a medical-scientific content, disregarding their value and the format in which they are presented; CD, DVD, CD-ROM, etc.?

They must comply with established legal requirements and conditions detailed in article 10.2 of the Code and its supplementary rules, that establish that their Market Price shall not exceed 60 Euro, they should be directly relevant to the practice of medicine or pharmacy and benefit patient care.

In any case, provisions of this kind of materials must not constitute an inducement for the recommendation, purchase, supply, sale or administration of medicines.

26. Can a pharmaceutical company assign an electronic book (e-book) to a healthcare institution as IT support (to upload scientific articles and books) allowing its use in the clinical services rendered by the center and the training of its professionals?

Due to their nature, characteristics and purpose, these kind of devices (e-book, tablet, portable video player, portable audio player MP3 MP4 or MP5, etc.) are devised and designed for an exclusive and individual use. Additionally, their technical characteristics make them presently known as devices associated more to leisure or personal entertainment than to professional use. Due to all of the above, disregarding whether they are assigned to a healthcare institution, their provision is not permitted.

27. Is there any exceptional case that allows provision of items of medical utility aimed at Healthcare Professional’s education and patient care of a value over 60 Euro?

No, items of medical utility aimed at the education of Healthcare Professionals and patient care may be provided as long as they are inexpensive (Market Value does not exceed 60 Euro) and do not offset its recipient’s routine business practices.

28. Can informational or educational materials and items of medical utility that may be provided, due to their complying with the conditions foreseen in article 10.2 of the Code, include the trade name or brand of a prescription-only medicine?

No. In general terms the adding of trade names or brands of a prescription-only medicine in informational or educational materials and items of medical utility that comply with conditions foreseen in article 10.2 is not permitted, unless conditions are met for them to be considered by the pertinent healthcare authorities in matters of medicine advertising a valid support.

29. Does the 60 Euro limit refer to the total of the material provided (educational, informational and articles of medical utility) or to each of the individual materials?

The 60 Euro (tax included) limit applies to the unit value of each material.

30. Would it be permitted to provide Healthcare Professionals with medical utility items used in patient care with a value below 60 Euro, for example, a pulsioximeter, a spirometer, etc. (between 30 and 50 Euro)?

No. The provision of items that are necessary or indispensable for the Healthcare Professional to carry out his practice may be interpreted as an activity/practice offsetting routine business practices of the recipient, especially taking into account the exclusive and individual use of many of them. The Healthcare Professional himself or his employer should be the one providing the resources and materials necessary for the carrying out of his profes-
sional activity. Consequently, even though they are medical utility items, the provision of stethoscopes, fonendoscopes, pulsoximeters, medical coats, medical clogs, surgeon caps, gloves, goggles, tensiometers, masks, gauzes, bandages, dressings, etc. is not permitted.

31. Should the 60 Euro threshold established for the provision of educational materials be interpreted as including taxes?

Yes. This amount includes taxes.

32. When providing reprints or offprints, what price should be taken into account? The one paid by the company when acquiring it or the one the Healthcare Professional would pay if buying it directly?

The Market Price is, according to the Code’s Definitions, the amount a private party should generally have to pay in order to acquire a unit of a good, product, material, article or similar in Spain. It should not exceed 60 Euro including taxes.

33. What is the criteria a company should follow with regard to its own publications, which are not publicly available and, thus, have no retail price?

Each copy should not exceed 60 Euro (tax included) taking into account the real total cost of its publication (including, but not limited to copyright, layouts, revisions, printings...).

34. What would be the treatment for the sponsorship of translations, medical writing, journal publication fees and editing of posters?

Firstly, it should be determined whether this kind of collaborations is compliant with the Code’s provisions.

35. In the case of a company hiring a Healthcare Professional as a speaker to deliver a presentation in a congress, could expenses other than the fees for service be paid for, such as translation of slides or poster editing?

Any expense to be defrayed, resulting or related to the work to be carried out by the Healthcare Professional, may be included in the contract. In this way, along with the fees, expenses resulting from such collaboration may be covered (travel, accommodation, translation, materials, etc.).

36. Can a company provide Healthcare Professionals with pens or stationery including the name or trademark of a prescription-only medicine as brand reminders, if their Market Price does not exceed 10 Euro?

No. Brand reminders in the form of pens or stationery including the name or trademark of a prescription-only medicine, regardless of their Market Price, are not permitted. (See article 10.1 Prohibition of Gifts).

37. Article 10.1 allows as an exception the provision of stationery, provided that it is not related to a prescription-only medicine and its Market Price does not exceed 10 Euro. Can it include any element (images, branding, logotypes, colours, claims, etc.) used in the promotional materials?

No. These articles cannot include any element, image or colour related to the prescription-only medicine.

38. Is provision to Healthcare Professionals of a flash drive whose Market Price does not exceed 10 Euro permitted? Can it include the trade name or brand of a prescription-only medicine visibly on the outside?

As an exception, article 10.2 allows for the provision of flash drives, provided that they include informational or educational contents of a scientific-professional nature and their Market Price does not exceed 10 Euro. These materials cannot include the trade name or brand of a prescription-only medicine visibly on the outside, although they may include the corporate identification.

The final goal is not to provide a gift to the Healthcare Professional, but a digital copy of an educational-infor-
39. Is there any exception to the 60 Euro threshold applicable to the provision of educational/informational materials? The price of some of these materials usually exceeds the above figure.

There is no exception regarding the 60 Euro threshold applicable to the provision of informational or educational materials.

40. Would a company be in breach of the Code if it decides to give a doctor a 100 Euro scientific book?

Yes. The provision of educational-informational materials of any kind (including subscriptions to books and scientific journals) whose Market Price exceeds 60 Euro (tax included) is not permitted.

41. What criteria should companies follow regarding yearly subscriptions to scientific journals? When using the yearly calculation it is easy to exceed the 60 Euro threshold, whereas, when apportioned monthly, the subscription price would be lower.

In line with the guidance of query nr. 29, the 60 Euro threshold (tax included) applies to the value of each unit of an item. In this case, the item would be the “yearly subscription”, which means that if its cost exceeds such limit, its provision would not be permitted.

42. Would the general reference to a therapeutic area of the company fall within the concept of corporate/institutional advertising, such as in: “name of the company” + “oncology”, “respiratory”, “dermatology”, “diabetes”, “cardiology”, etc.? Could gifts including references to such corporate areas and/or to dedicated websites be provided?

No. Reference to corporate areas, business lines or the like, exceeds the concept of corporate/institutional advertising. Consequently, provision of gifts including references of this type would be against provisions of article 10 of the Code.

43. Would it be permitted to include logotypes of prescription-only medicines in the materials mentioned in sections 10.2.1 and 10.2.2 (educational materials and items of medical utility that directly benefit patient care)?

No. As a general rule, inclusion of trade names or brands of a prescription-only medicine in educational or informational materials and items of medical utility that comply with conditions foreseen in article 10.2 is not permitted, unless conditions are met for them to be considered by the pertinent healthcare authorities in matters of medicine advertising a valid support.

For those materials aimed at the patient directly, no element directly or indirectly related to prescription-only medicines may be included.

44. Is it possible to collaborate with Healthcare Organisations through the provision of educational and informational materials or items of medical utility?

This type of collaborations with Healthcare Organisations is permitted, provided that they do not entail an indirect contribution to a Healthcare Professional (in which case the thresholds stated in article 10.2 would apply) and that the terms and conditions of the Code are met.

ARTICLE 11. SCIENTIFIC AND PROFESSIONAL MEETINGS

45. According to the Code, could a pharmaceutical company organise a scientific meeting in Cairo, where the physicians will also be able to take advantage of the location to visit the pyramids at Giza after a three hour working day?

No. The organisation of Events outside of Spain when participants are solely or mainly Spanish physicians is considered unacceptable unless there is a justified reason (article 11.10), which is not provided in the question. Furthermore, this would be a breach of the Code, since scientific aims must constitute the main focus in the organisation of these meetings (the scientific content must represent at least 60% of the working day, and 3 hours only represent 37%) and, also, hospitality cannot include sponsorship or organisation of entertainment activities (sport, leisure, etc.).

46. According to the Code, would it be acceptable to allow the return trip of a physician take place two days after the ending date of the meeting? What rules should apply to accompanying persons?
Hospitality may only be extended to the day before or after the Event, in accordance with an efficient planning of travel. Physicians may extend their stay in the location, provided that additional costs of accommodation, travel and upkeep resulting from such extension are paid for by themselves and do not cause a modification on the initial programme of most of the participants.

In the Events organised or sponsored by industry, presence of accompanying persons should not be permitted, even if paying for their own expenses, as this may damage the image of the pharmaceutical industry.

47. According to the Code, would it be permitted to hold a scientific meeting in March in Sierra Nevada with a daily 7 hour sessions programme?

This is not permitted, because, as a general rule, locations that may convey an inappropriate image (as is the case of locations linked to sporting or leisure activities during peak season) must be avoided, even when the duration of the scientific programme does comply with the Code.

48. A pharmaceutical company invites a group of 90 physicians to a scientific meeting in Barcelona followed by attendance to a football match. Would it be breaching provisions of the Code?

Yes. Hospitality offered by a pharmaceutical company can under no circumstances include the sponsorship or organising of entertainment events (sporting, leisure, etc.).

49. The company’s parent company decides to invite a group of researchers to an important scientific Event in San Francisco to which doctors of different countries are to attend in order to learn the latest data of the American Cancer Society. Would the company be breaching the Code?

No. As an exception, in the case of international official congresses or independent international Events, attendance of Spanish professional doctors outside of the European Union may be sponsored provided that provisions of the Code are met.

50. According to the Code, could a pharmaceutical company invite a group of doctors to dine at a restaurant offering a price per guest of 100 Euro?

No. According to the contents of the Code, hospitality within a scientific context shall always be moderate and this type of gatherings would damage the image of the pharmaceutical industry. A lunch/dinner of this kind and price does not fall within what may be considered as a regular working lunch/dinner in the carrying out of promotional activities.

For those Events taking place in Spain, the Code establishes a maximum threshold of 60 Euro (tax included) per guest for any form of hospitality associated with meals. For Events taking place outside of Spain, the maximum threshold established by the National Association of the country where the Event occurs will apply.

In all cases, the payment of any form of hospitality to Healthcare Professionals taking place outside of a scientific-professional context is considered a practice contrary to the Code.

51. What are the criteria for sponsoring meetings or Events organised by scientific societies?

Although the organisation of Events corresponds to scientific societies, companies must always take into account the image that these Events transmit as well as the Code provisions. In this way, industry shall not sponsor meetings where the scientific-professional nature does not prevail or that do not respect the criteria required for the meetings organised by industry itself. It is permitted to sponsor or finance logistical elements necessary to carry out the Event (rooms, meals, materials, etc.) and, in general, anything that may be considered as reasonable and moderate hospitality in the sense of the Code. In the Events organised by third parties, the pharmaceutical industry should not participate or collaborate when these promote attendance of accompanying persons.

52. Is it possible to sponsor attendance of Spanish doctors to a meeting in an EU country, outside of Spain, that has speakers and is organised by scientific or medical societies from both countries?

It is possible, provided that the scientific programme is appropriate and doctors from both countries attend; with the aim of boosting scientific exchange. In all cases, the basic criteria that have to be taken into account in each circumstance are mainly: the scientific-professional content of the meeting and the appropriateness of the location, together with an adequate and reasonable hospitality level.
53. Can educational courses be sponsored or provided to doctors in Spain on clinical topics or professional abilities, such as: IT courses; how to make presentations in public; how to produce slides; how to perform clinical studies; how to prepare a poster; biostatistics course; health management course; scientific presentations in English; how to write an article for publication in scientific journals, etc.?

Educational activities must contribute positively to the training of the Healthcare Professional and to the development of abilities that benefit his healthcare activity, even if these have a more general scope and content.

Companies must, in all cases, adopt all measures necessary to avoid that their collaboration in educational activities and initiatives constitute an inducement to the recommendation, prescription, purchase, supply, sale or administration of medicines.

Companies, prior to making a decision about the appropriateness of collaborating or not in this type of educational activities shall, among other aspects, assess the following internally:

- The prestige, rigour, seriousness, duration, cost and contents of the activity, as well as the usefulness it represents to the continued medical education of the Healthcare Professional, it being advisable that it belong to a programme with a credit recognition system.

- Its compliance with the Code and current legislation.

Collaboration of pharmaceutical companies in the educational activities dealt with in this query is not subject to the communication procedure described in article 33 of Title II of the Code, Rules of Procedure for the Control Bodies.

Also, these educational activities shall not be object of publication in the third-party Event listing available in Farmaindustria’s website.

54. What criteria should be taken into account by companies regarding hotel use?

The typology and characteristics of hotels that pharmaceutical companies may use to accommodate Healthcare Professionals are issues widely regulated in the Code.

As a general rule, 4* hotels are considered the appropriate standard for the holding of scientific-professional meetings.

Notwithstanding the above, a 5* hotel may be exceptionally used if all of the following circumstances are met: (i) venue hotel or there were no availability in the venue hotel, (ii) business non-ostentatious hotel in developed metropolitan area, and (iii) participation of at least 200 Healthcare Professionals.

Finally, there is a hotel typology whose use will in no case be justified. This includes: (i) regardless of their official category: sports resort hotels (with golf course, etc.), theme park hotels, winery hotels, and (ii) 5* grand luxury hotels. Within these establishments companies shall not: install commercial stands, use their rooms or installations to carry out any kind of activity (symposia, conferences, seminars, meals, etc.), nor accommodate Healthcare Professionals.

For those establishments having more than one official rating, the company shall take into account whichever category is the highest.

The same philosophy shall apply to Events held outside of Spain, notwithstanding that additional criteria may be taken into account, such as security, local criteria of rating and classification, etc.

55. What would the practical recommendation be to define the hotel and/or location of a meeting?

Criteria such as number of participants and their origin, availability of other hotels in the meeting location that conform to the appropriate conditions to hold the meeting, ease of travel or connection, distances, costs, participants’ convenience regarding logistical aspects, etc. may be used.

56. Would it be appropriate to hold a scientific meeting in a location that is well-known as a tourist destination, such as the Canary Islands, when, due to other reasons, and together with an appropriate scientific programme, it is advised the meeting take place in that Autonomous Community?

We must insist upon the necessity of preparing a good scientific programme, assessing as a whole the Event and level of hospitality. Holding an Event in the Canary
Islands does not constitute a problem in itself, provided that the selection of the location is accounted for and that all other aspects of the Event convey an appropriate image of the pharmaceutical industry.

57. How to reconcile the scientific nature of an action, the involvement of local participants and the consideration of tourist destination of that city? Can you pose some examples of justified cases where it is considered acceptable to organise Events outside of Spain?

The particular aspects of each case must always be analysed. A good scale to assess an Event is to think whether the organising company would be willing to make all of the details of the Event widely known to the public. Some examples of Events that could take place outside of Spain would be: a visit to a scientific center or institution in the country holding the congress; the presence of a production plant or a research or development center of the organising company in the location holding the congress; attendance to the Event of doctors from different countries; bilateral meetings or cooperation agreements among institutions of two or more countries and, in general, whenever there are justified causes for the holding of the congress outside of Spain.

58. Are international Events organised by a company compliant with the Code? As in, for example, a new product presentation in an international destination, where doctors of several countries participate and to which Spanish doctors attend, invited by the company.

A product presentation is one of the possible scientific meetings foreseen in the Code. The organising of an Event such as the one described in the question seems reasonable if the product is authorized in Spain and most of the attendees are not Spanish.

59. Is it acceptable to provide a specific amount of money in advance as a travel grant for attendance to a congress in order to cover part of the costs of the Healthcare Professional, such as, for example, registration, hotel, etc., which consists in a money transfer or a personal cheque with the corresponding congress attendance travel grant invoice issued by the doctor?

Provision of a cash advance to a Healthcare Professional is not acceptable, not even if documented by a receipt or similar. All payments must be performed by directly covering the expenses. The existence of an invoice issued by the Healthcare Professional implies that a professional service has been rendered, service that must be duly indicated in the invoice. Mere attendance to a congress, symposium or scientific or professional meeting is not a professional service.

60. Can payments in the form of travel grants be made directly to travel agencies appointed by the doctor or the congress organiser to manage travel arrangements, hotels, tickets, registration, etc.?

As a general rule, payments must be made directly to the provider; it being possible to use intermediary agencies when the Event’s complexity so advises. The agency organising the congress or the agency with whom the company usually works are the acceptable intermediary agencies. In all cases, the pharmaceutical company shall be responsible of ensuring that the agency respects the Code’s provisions, safeguarding that the funds are indeed used for the purposes intended. Under no circumstance is it acceptable to make payments to travel agencies appointed by the doctor.

61. Should that be the case, must these contributions correspond to a given service (plane, hotel) or can they be partial amounts of the total cost of the trip the doctor is to make and that could eventually be covered by several companies?

That the contributions be of a given service is always preferred. Although, if this were not possible, it is permitted that some costs be partially sponsored by several companies. An original invoice from the provider shall be required, including a precise indication of the service or concept paid for.

62. What is the supporting documentation required from travel agencies regarding the company’s contributions to congress attendance?

The original invoice; although the company must know the names of the Healthcare Professionals attending the congress, as well as the sponsored concept (plane ticket, registration, accommodation, etc.).

63. In the time calculation of a work day (8 hours), what consideration does time dedicated to lunch have?
Lunch shall not be considered time dedicated to scientific content. The 60% proportion established in the Supplementary Rules of article 11 shall be observed in all cases.

64. Should a company notify the meetings (national or international) it organises as a result of the planning, information and coordination activities of the multicentric clinical trials it promotes, when these involve medical researchers hired for those trials, who also receive fees from the company for their research activities?

The Code covers all forms of interaction between pharmaceutical companies and Healthcare Professionals or any other person who, in exercising their profession, may perform or participate in the prescription, purchase, supply, dispensation or administration of medicinal products for human use. Its terms and conditions thus apply to this kind of meetings.

Thereby, in compliance with article 33.1 of Title II of the Code, Rules of Procedure for the Control Bodies, prior notification shall be mandatory for those meeting the conditions foreseen in said article; that is to say, that they are organised – directly or indirectly – or sponsored – exclusively or in the majority – by the company, involve the participation of at least 20 Healthcare Professionals practicing in Spain and include at least one overnight stay.

65. Does the ban on the provision of travel grants in cash to Healthcare Professionals invited to congresses and meetings involve a ban on travel vouchers or bonuses issued by third parties, in so far as, directly or indirectly, they may be exchanged for cash or used by third persons or employees in other dates or for other destinations or ends?

A travel voucher or bonus that, once given to the Healthcare Professional, can be used without the company’s knowledge for purposes different from that of attendance to the meeting or congress for which it was issued, does not guarantee the appropriate use of the funds and, in this sense, is comparable to a travel grant in cash. Its use is, consequently, not acceptable.

66. Can activities of a short duration (for example, an hour and a half) with a scientific or professional content, followed by a cocktail or dinner, be organized, even if they do not take up 60% of a work day?

In general, when two overnight stays are included in an Event, this will be considered a full-time Event, in which case the scientific content of the programme shall be at least 4 hours and 45 minutes long.

There can be half-day Events (those including only one overnight stay for out of town attendees), in which case the scientific content shall be of at least 2 hours and 20 minutes.

Finally, talks or conferences of a shorter duration may be organised, provided that the hospitality level is reasonable and no overnight stay is offered.

67. Can a foreign entity, linked to or sponsored by a company based in Spain, invite Healthcare Professionals practiced in Spain to an Event of a scientific and promotional nature taking place in Spain or abroad?

Yes, provided that the scientific and promotional Event complies with the Code of Practice for the Pharmaceutical Industry. In such cases, companies based in Spain, linked to foreign entities that have invited Healthcare Professionals practicing in Spain to an Event of a scientific and promotional nature, shall provide prior notification of such activities to the Surveillance Unit when these meet the conditions for compulsory notification stated in article 33.1 of Title II of the Code, Rules of Procedure for the Control Bodies.

68. Can a foreign pharmaceutical company invite, within the context of an international congress taking place in San Francisco, a group of Healthcare Professionals including doctors practicing in Spain to an excursion to the Grand Canyon in Colorado?

The pharmaceutical company inviting a doctor to that excursion would be in breach of the Code and, consequently, according to article 11.7, responsibility of such breach would fall upon the linked company based in Spain (for example, one that belongs to the same business group).

69. What conditions must “rest areas” meet according to provisions of the Code?

Rest areas, understanding as such those spaces provided in scientific Events or meetings with the aim of allowing, during the holding of the Event, attending
Healthcare Professionals to make use of an area near the rooms where the meeting is being held and where refreshments are served during the Event, must meet the following conditions:

- They shall contribute to professional scientific exchange among Event attendees.

- They shall be aimed solely at Healthcare Professionals, not allowing entrance of non-participants, such as accompanying persons.

- The hospitality offered shall be moderate; not moderate meaning services such as massages, etc. or offering of refreshments exceeding the usual ones in a meeting (alcoholic beverages, excessive appetizers). In short, companies must endeavor to avoid elements that may damage the image of the pharmaceutical industry.

- They shall not be used to carry out promotional activities related to medicines. As an exception, corporate/institutional advertising is allowed.

70. Should a company provide prior notification to the Surveillance Unit of a scientific Event if:

- It has a duration of a work day (starting early in the morning and ending in the evening), there are at least 20 professionals participating, none of them staying overnight, but there are also, for example, 8-10 speakers, who will be staying overnight the day prior to the meeting?

In compliance with art. 33.1 of Title II of the Code, Rules of Procedure for the Control Bodies, Events directly organised by pharmaceutical companies shall be subject to compulsory prior notification whenever at least 20 Healthcare Professionals practicing in Spain are participating and an overnight stay is included. Consequently, in compliance with provisions of the Code, the Event shall be notified whenever attendees are offered an overnight stay.

In any case, it is recommended to make voluntary prior notifications of any kind of Event to be organised by a company or in which participation is foreseen.

71. Are the following selection criteria for appropriate venues to hold promotional meetings organised by pharmaceutical companies in compliance with the Code of Practice for the Pharmaceutical Industry?

- 4* hotels as a general rule.

- Possibility of holding the meetings or Events anywhere in Spain, except for the following seasonal limits:
  - Avoid towns in the coast during July and August.
  - Avoid mountain areas related to skiing during December, January, February and March.

  1. - A 4* hotel is indeed the appropriate standard for the holding of scientific-professional meetings.

  2. - Locations chosen to hold scientific meetings or Events shall portray an image that does not damage the pharmaceutical industry. In this sense, towns in the coast that are mainly touristic shall be avoided in peak season (second fortnight of June, July, August and first fortnight of September), as well as mountain locations related to skiing while ski resorts are open.

These same criteria shall apply to Events organised by a pharmaceutical company taking place both in Spain and abroad, where applicable.

72. Could a pharmaceutical company make available to Healthcare Professionals its travel agencies so that they may benefit from their economic conditions in the hiring of services for the attendance of accompanying persons, even though the cost of the accompanying person would be covered by the Healthcare Professional?

Companies must manage directly the travel arrangements of those Healthcare Professionals they sponsor with the aim of ensuring that the money they provide is spent for the intended purposes. Consequently, in compliance with art. 11 of the Code, the Supplementary Rules implementing it and the reply to query nr. 61 of Annex II, Queries (Questions-Answers), it is not allowed to make available to the Healthcare Professional the company’s travel agencies so that he may organise attendance of others to the congress.

It is recalled that presence of accompanying persons in scientific Events or meetings is forbidden for Events organised by pharmaceutical companies and, for those Events organised by a third party, the pharmaceutical industry shall not participate or collaborate if these promote attendance of accompanying persons.
In any case, in compliance with the Supplementary Rules of art. 11.3 of the Code and the response to query nr. 52, companies shall not contribute to the presence of accompanying persons.

73. What does it mean to be a majority sponsor? Does the status of majority sponsor include sponsorship of congresses organised by a third party (scientific societies, professional organisations, etc.) and sponsored by a company? That is to say, should a congress organised by a third party and sponsored by several companies be notified when being a majority sponsor?

Firstly, the dictionary of the Royal Spanish Academy defines “sponsor” (2nd meaning) as: “said of a person or entity: that sponsors an activity, often for advertising purposes”.

Secondly, according to the same source and 2nd meaning, the concept of majority refers to something that constitutes the majority.

Thus, a majority sponsor is one sponsoring an Event contributing over 50% of the total cost of the Event.

Continuing with the above definition of sponsor, sponsorship covers any activity of financing or support, regardless of, on the one hand, who the organiser is and, on the other hand, whether several companies are sponsoring it together.

Consequently, and in compliance with art. 33.1 of Title II of the Code, Rules of Procedure for the Control Bodies, if the company is the majority sponsor, it shall provide prior notification even if the Event is organised by a third party (scientific societies).

In any case, it is recommended to make voluntary notifications of any kind of Event to be organised by a company or in which participation is foreseen.

74. In the context of an international congress lasting 4 days, is it possible to take doctors to a theatre to see a play?

As relevant information, be it pointed out that such activity is not part of the official programme of the congress organisation, nor does it interfere or take place at the same time as the scientific programme and it would be the only cultural activity to be carried out by the pharmaceutical company for its own guests and during the projected trip. The cultural activity would not prevail over the scientific, which would still be the main focus of the Event.

Pharmaceutical companies sponsoring the attendance of Healthcare Professionals practicing in Spain to international congresses organised by a third party with Healthcare Professional participants from different countries shall endeavour to ensure that hospitality offered is that of the congress official programme, provided this is reasonable and moderate. Situations that may constitute an inappropriate image for the pharmaceutical industry shall thus be avoided, in compliance with the Supplementary Rules. Consequently, offering invitations other than those of the organiser may damage the image of the pharmaceutical industry and breach provisions of the Code.

Secondly, invitation to spectacles, whatever their nature, aimed at Healthcare Professionals also constitutes an incentive in kind and, consequently, is not allowed in compliance with art. 10.1 of the Code of Practice.

Hospitality shall not include sponsorship or organisation of entertainment activities (sporting, leisure, etc.).

75. Is it possible to offer hospitality, as pictured in art. 11.3 of the Code, to biologists-geneticists, taking into account that they are part of multidisciplinary work groups, carrying out a role of indication and follow up of specific protocols or therapeutic guides as well as management of pre-treatment information to the patient, but that do not prescribe directly?

The Code defines Healthcare Professionals as “any member of the medical, dental, pharmaceutical, nursing or podiatric profession, any other person legally considered as such, or any other person who, in exercising their profession, may perform or participate in the prescription, purchase, supply, dispensation or administration of medicinal products for human use.”

As a consequence, continued educations of different professionals is justified, within a context where the professional exercise is carried out in an interdisciplinary manner, with professionals from several disciplines agreeing on objectives and participating in the decision making process. Consequently, it is legitimate to offer hospitality within scientific congresses to biologists-geneticists, provided it is reasonable and compliant with provisions of the Code.
76. Is there any case in which Events organised or sponsored in the majority by a pharmaceutical company – including Events organised by companies belonging to its group or entities under its control - may be held in a 5* Grand Luxury hotel?

No. A 4* hotel is considered the appropriate standard for the holding of scientific-professional meetings. 5* hotels may only be used as an exception when all the following conditions are met: venue hotel or there were no availability in the venue hotel, business non-ostentatious hotel in developed metropolitan area, and participation of at least 200 Healthcare Professionals. Under no circumstance will use of 5* G.L. hotels be permitted. This ban is not limited to lodging, but also includes the use of installations (meeting rooms, use of restaurants and other services).

77. According to the Code, would it be permitted to organise or participate in a scientific meeting (whose daily scientific sessions programme complied with provisions of the Code) held in:

- a location that, due to its characteristics – mountain area -, its situation – within a ski resort or less than 50 kilometers away from a ski resort -, its being related to the practice of this sport, etc. (for example: Jaca, Vielha, Andorra, Davos, Saariselkä, Innsbruck, etc.), and

- during the time period when the installations for the practice of such sport are open (in general, from December to March, both included).

No. The scientific objective and character of the Events must constitute the main focus for its organisation, prevailing over any social or cultural aspect, which shall result, in all cases, secondary and accessory.

In this sense, the choosing during Winter locations clearly related to the practice of a sport such as ski may in itself result in the scientific objective and character of the Event taking second place, the possibility to practice such sport becoming its main attraction, conveying thus an inappropriate image of the pharmaceutical industry.

It is important to assess the appearance and contents of the Event as a whole. There is no doubt that elements such as location, dates, ease of access for participants, etc., help assess the appearance of the Event. An unfortunate decision regarding any of them, which may create doubts about its intended scientific objective, would prevent potential participation of pharmaceutical companies in the Event.

78. In the case of Events of a short duration (for example, an hour and a half), followed by a cocktail or dinner, to which a group of 10 or 15 Healthcare Professionals is invited for a new product presentation or to discuss aspects related to a product, being the intention also to obtain feedback from such professionals on the product and other aspects related to it:

Can attending Healthcare Professionals be paid amounts ranging from 300 to 600 Euro for their participation in this activity?

If the answer to the above question is “yes”, can this activity be carried out in different areas or regions of Spain, inviting 10 to 15 professionals from each of the areas?

In compliance with article 11.6 of the Code, the execution of payment to Healthcare Professionals participating in scientific Events is only permitted when these are acting as speakers or moderators.

In any case, contracting of these services will be subject to provisions of article 16 of the Code.

The mere participation or attendance to an Event does not justify the payment of fees.

79. Are provisions of article 11 applicable to digital or multi-channel scientific and professional educational activities and initiatives such as videoconferences, courses or contents, both online and streaming or by download, virtual communities, etc.?

Although face-to-face meetings and Events are the most common, it is true that the present trend, fostered by new technologies and saving policies, aims toward distance learning activities in a digital environment. The content of these new activities is the principle that should govern them and, thus, they being educational activities, they are subject to provisions of the Code, article 11 “Scientific and Professional Meetings” and article 8 “Digital Environment”, among others. In fact, the definition of “Event” at the beginning of the Code includes in-person or distance educational courses.
ARTICLE 15. DONATIONS AND GRANTS

80. Would the offering or provision, “via donation”, of portable electronic devices susceptible of personal use, besides a professional one, to Healthcare Professionals and Healthcare Organisations be compliant with the Code?

No. A practice/activity of this kind would be in breach of the Code, disregarding whether the offering or provision is to a Healthcare Professional or a Healthcare Organisation.

Let it be reminded that article 10 establishes conditions applicable to the materials and items susceptible of being offered or provided.

81. According to the Code, is it possible for a pharmaceutical company to pay a provider for the upkeep of equipment (X-ray, tomograph, etc.) of a hospital?

Payment for services that are not included within a collaboration agreement for a specific objective between the company and the Healthcare Organisation would not fall inside the scope of interactions permitted by the Code, due to which it could be considered an inducement and, consequently, unacceptable.

At any rate, the concept of Healthcare Organisation in this context is based on the existence of an interest of a more general nature, different from the private interest of the Healthcare Professional.

ARTICLE 16. SERVICES PROVIDED BY HEALTHCARE PROFESSIONALS OR HEALTHCARE ORGANISATIONS

82. According to the Code of Practice, could a pharmaceutical company grant a prize in cash or sponsor, in collaboration with a scientific society, the granting of a prize in cash to Healthcare Professionals in recognition for the preparation and presentation of a poster, research paper, etc.?

A company may organise and sponsor calls for awards and grants. Taking into account the potential risk of perception of a possible conflict of interest, it is recommended to take measures such as the following, with the aim of guaranteeing that they do not constitute nor are perceived as an inducement to the recommendation, prescription, purchase, supply, sale or administration of medicines:

- Establishment of a framework partnership agreement with an independent scientific or academic organisation.
- Submission of the public call for the award or grant, publicly identifying the sponsorship of the company and indicating the bases and criteria for the award or grant.
- Within the published bases, guarantee independence from the pharmaceutical company of the award or grant through the establishment of:
  • A jury selected by the independent scientific or academic organisation.
  • Participation of the company in the jury as an attendee with no right to vote, in order to validate the follow-up of the agreed upon bases.
  • Public release of the result.
- The concession of awards and grants shall follow the provisions of article 18 of the Code regarding publication of Transfers of Value.

83. Is it possible to make the payment of speaker fees and hospitality costs through a third party when it is the parent company of a multinational company the one sponsoring the participation of a Spanish doctor as a speaker in an international congress or a congress taking place in Spain? Or can the parent company in this case make a direct payment to the Spanish Healthcare Professional for the service provided?

Yes. The Code defines “Transfers of Value” as: any direct or indirect Transfers of Value, whether in cash, in kind or otherwise, regardless of its purpose. Direct Transfers of Value are those made directly by a company for the benefit of a Recipient. Indirect Transfers of value are those made by a third party (provider, agent, partner or affiliate – including foundations -) acting on behalf of a company for the benefit of a Recipient when the company knows or can identify such Recipient.

The company shall in all cases comply with provisions of article 18 of the Code regarding disclosure of such Transfer of Value.
ARTICLE 18. TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY’S RELATIONSHIPS

84. Are observational studies included within the Transfers of Value related to Research and Development category of article 18?

Yes. Observational studies are regulated by article 14.2 of the Code. Also, the definition of “Research and Development” includes: activities related to the planning or conduct of (i) non-clinical studies (as defined by the OECD “Principles of Good Laboratory Practices”), (ii) clinical trials (as defined by Directive 2001/20/EC and considered in article 14.1 of the Code) and (iii) post-authorization studies (considered in article 14.2 of the Code).

85. Is it understood that medical insurance is included within the subcategory “travel and accommodation” of contribution to educational and scientific meetings for the purposes of article 18?

Yes. Medical insurance is included within the total cost related to travel and accommodation.

86. Regarding Healthcare Organisations, what information should be included in the Disclosure Template (Annex I) in the column “registration fees” of the category “contribution to educational and scientific meetings”?

Those Transfers of Value made by the company upon request of a Healthcare Organisation for “registration fees” to defray registration of those Healthcare Professionals selected by the Healthcare Organisation (“grant holders”).

In these cases, the company neither selects nor has the possibility of knowing which Healthcare Professionals are finally benefitting from its collaboration.

87. When it is the parent company the one that sponsors participation of a Healthcare Professional practicing in Spain to a congress in a different country, who should disclose the Transfers of Value related to such collaboration?

Each company shall decide how to organise disclosure of the information, at a central level or at a local level. However, information will have to be publicly available in the country where the Recipient mainly carries out his professional activity.

If the company does not operate or have an affiliate in the country where the Recipient mainly carries out his practice, the company shall disclose the information of such Transfers of Value in compliance with provisions of the local Code of the country where the Recipient mainly carries out his practice.

If the company has several separate legal entities in the same country, it shall choose the most appropriate legal entity to disclose the information. All Transfers of Value made to the same Recipient shall be published in “one place” – disclosure in the country where the Recipient mainly carries out his professional activity shall enclose all Transfers of Value made to the same HCP/HCO, disregarding where they have taken place (both in and out of the country where the Recipient mainly carries out his professional activity).

Regardless of the decision made regarding publication (in the website of the parent company or the affiliate), disclosure shall be carried out in compliance with the local Code of the country where the Recipient mainly carries out his practice and in compliance with local regulations applicable in that country.

In those cases where different entities of a company make payments in the same country to the same HCP, these payments shall be disclosed in one website; and not separately, arguing that there are different entities of the company involved.

88. Should Transfers of Value made within the framework of a market research study, where the company does not have access to the identity of the participating Healthcare Professionals, be disclosed?

The Code does not require disclosure of those Transfers of Value where identity of the Healthcare Professionals is unknown.

One of the basic characteristics included in the definition of market research studies and in the Codes of Practice regulating them worldwide is the right of participants not to make their identities known.

In those market research studies where it exceptionally has access to the identities of participating Healthcare...
Professionals, the company shall disclose the Transfers of Value under the category “fees for service” on an individual basis (provided that prior express consent of the Healthcare Professional has been granted) or on an aggregate basis (in the absence of such prior express consent).

89. What happens to those Transfers of Value related to corporate social responsibility projects? For example: sending doctors to carry out humanitarian work, which involves the existence of related costs of travel and accommodation.

This kind of collaborations shall be carried out and formalised through an organisation in all cases, never individually.

The Code is applicable because this is a form of relationship between the company and Healthcare Professionals.

The company shall provide information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.7 of the Code.

90. Are costs associated to the transfer airport-hotel-airport, by taxi or public transport, considered travel costs? Should they be disclosed?

Yes. They shall be disclosed under the relevant category; depending on whether they are related to “contribution to educational and scientific meetings” (travel and accommodation) or to “fees for service” (related expenses agreed in the fee for service or consultancy contract, including travel and accommodation); on an individual basis (provided prior express consent of the Healthcare Professional is granted) or on an aggregate basis (in absence of such prior express consent).

91. Should general costs of organising a meeting, such as room, hostesses, etc., be divided upon the number of participants and be disclosed?

No. These are general expenditures made by the company for the organisation of the Event.

92. What information should be disclosed in a meeting organised by a third party when the company covers 100% of costs such as room rental, hostesses, AV, etc., and where all Healthcare Professional participants are from such location, there being no Transfers of Value related to accommodation or travel?

The company shall only disclose under the category “contribution to educational and scientific meetings” the Transfers of Value made to the Healthcare Organisation in charge of organising the meeting (in the column “sponsorship agreements with HCOs/third parties appointed by HCOs to manage an Event”).

In a situation such as the one described in the question, no Transfers of Value would be disclosed regarding attendees on an individual basis.

93. What information should be disclosed regarding attendees in an educational meeting organised by a company where there are no travel and accommodation expenses (for example: “webinar”, “teleconference”)?

No Transfer of Value need be disclosed regarding attendees, as there is no registration fee (it being a meeting organised by the company) nor Transfers of Value related to accommodation or travel of attendees (it being held in such a way it avoids the necessity of such expenses).

The company would not be forced to disclose the Transfers of Value related to logistical expenses stemming from organising a meeting of this type (room rental, AV, catering, hostesses, etc.).

94. Should Transfers of Value made through intermediaries be disclosed on an individual basis by companies? Would their disclosure need, besides the prior express consent of the Healthcare Professional benefitting from them, the prior express consent of the intermediary?

Transfers of Value shall be disclosed on an individual basis, their publication on an aggregate basis being permitted only as an exception.

In the agreements with third parties that are to act on behalf of a company or on its representation it shall be guaranteed that these disclosure obligations are met. In this sense, it is recommended to companies that in their agreements with these third entities the measures and provisions guaranteeing compliance with this obligation are included. In this regard, companies shall take into account article 19.1 of the Code, which states:
“In addition, companies member of Farmaindustria or adhered to the Code on an individual basis will be liable for possible breaches of the Code committed by third parties acting on their behalf or representation, or under their control, or by virtue of a written agreement (for example, external sales networks, market research companies, travel agencies, advertising agencies, etc.).”

The Code establishes that disclosure of Transfers of Value be made on an individual basis taking into account their Recipient. When companies make these Transfers of Value through third intermediaries, acting on their behalf and representation, they shall sign all applicable agreements with such entities. Each agreement will be specific, based on the nature/scope of the collaboration between the company and the third entities.

In principle, consent of Recipients (Healthcare Professionals) shall be obtained by the owner of the file that is to publish/disclose this data, that is to say, the company.

Section 18.1 of the Code establishes that to the maximum extent legally possible and provided that it can be made accurately and consistently, companies shall disclose this information on an individual basis, identifying the Healthcare Professional (instead of the Healthcare Organisation).

If the Transfer of Value is made through a Healthcare Organisation, it shall be disclosed under the Healthcare Organisation’s name on an individual basis, unless the Healthcare Professional has previously granted his express consent for disclosure, in which case it shall be disclosed on an individual basis under the Healthcare Professional’s name.

If the Transfer of Value is made to an entity or legal person other than a Healthcare Organisation, the company shall disclose it under the name of the Healthcare Professional, on an individual basis (if prior express consent of the Healthcare Professional has been granted) or on an aggregate basis (in absence of such prior express consent).

96. Sometimes Healthcare Professionals – without intermediation/participation of a Healthcare Organisation – directly request companies’ sponsorship or collaboration with educational and scientific meetings organised by those Healthcare Professionals individually. Can companies collaborate/sponsor such activities? If the answer is “yes”, how would Transfers of Value related to such collaboration/sponsorship be disclosed?

Companies shall not sponsor nor collaborate, directly or indirectly, with educational and scientific meetings organised individually by Healthcare Professionals.

97. Should the amounts disclosed in “Annex I Disclosure Template” be in gross or net?

In compliance with provisions of section 18.7 of the Code, each company shall publish a document describing the methodology used, explaining with simple language the information provided and the way in which it has been obtained and classified.

Said document shall inform whether disclosed amounts are gross or net.

98. What criteria should the company follow if the prior express consent provided by a Healthcare Professional does not allow disclosure on an individual basis of all Transfers of Value made by the company to that Healthcare Professional?

The company shall comply at all times with applicable regulations regarding personal data protection in Spain.

In compliance with provisions of articles 5 and 6 of the Organic Law 15/1999, of December 13th, on Personal Data Protection, Healthcare Professionals must grant their express consent freely and voluntarily for disclosure of their data on an individual basis and information related to the Transfers of Value, being able to choose not to provide it, in which case, the tacit consent derived from the preexisting contractual relationship shall operate, allowing the company to publish it on an aggregate basis.

The consent shall be express and obtained in written form for each collaboration individually or, on the contrary, it can be agreed to obtain a general consent for all the collaborations between the company and the Healthcare Professional. Consent can be revoked at any time.
Taking into account that within a year there can be several collaborations between the company and a single Healthcare Professional, it is recommended to companies that, to the extent possible, they expressly request the Healthcare Professional to provide his general consent for all collaborations.

If the consent provided by the Healthcare Professional is partial (that is to say, that it does not allow publication on an individual basis of all Transfers of Value made), the company shall disclose all Transfers of Value made to that Healthcare Professional on an aggregate basis, as consent must be provided unambiguously.

99. Companies must disclose the payments and Transfers of Value made directly or indirectly to Healthcare Professionals identifying, when possible, the Healthcare Professional. When will this not be possible? Only when the Healthcare Professional does not grant his consent or can there be other cases?

The company shall comply at all times with applicable regulations regarding personal data protection in Spain.

In compliance with provisions of articles 5 and 6 of the Organic Law 15/1999 of 13 December on Personal Data Protection, Healthcare Professionals must grant their express consent freely and voluntarily for disclosure of their data on an individual basis and information related to the Transfers of Value, being able to choose not to provide it, in which case, the tacit consent derived from the preexisting contractual relationship shall operate, allowing the company to publish it on an aggregate basis.

The consent shall be express, and obtained in written form for each collaboration individually or, on the contrary, it can be agreed to obtain a general consent for all the collaborations between the company and the Healthcare Professional. Consent can be revoked at any time.

Companies shall not publish on an individual basis the information related to the Transfers of Value made to the Healthcare Professionals that do not expressly authorize their disclosure.

For the purpose of guaranteeing compliance with applicable regulations regarding personal data protection and the transparency provisions established in article 18 of the Code, the company shall have in place an internal procedure that guarantees all legal regulations to obtain the express consent of the Healthcare Professionals with whom it interacts have been complied with.

The company must be able to prove at any time whether the Healthcare Professionals with whom it interacts granted their express consent for the publication of their data and their Transfers of Value on an individual basis.

100. Under the usual confidentiality clauses included in contracts, would it be possible to avoid complying with the new transparency provisions established in the Code, avoiding in particular application of the provision that demands disclosure of the Transfers of Value?

In view of the query posed, it is deemed necessary to point out that the Code is binding and of compulsory compliance both for the companies member of FARMAINDUSTRIA and the companies that have adhered to the Code.

Consequently, the existence of confidentiality clauses in a contract does in no case exempt from compliance with the informational and transparency provisions imposed by the Code.

Furthermore, it would be advisable that, for those contracts of companies subject to the Code signed after the entry into force of these new transparency obligations, all cautions and measures necessary to ensure and ease compliance with those obligations are adopted. In other words, inclusion of clauses or pacts contrary to compliance with provisions of the Code in such contracts shall be avoided. In this sense, inclusion of confidentiality clauses in contracts signed by pharmaceutical companies subject to the Code after the entry into force of the new transparency provisions – among them, disclosure of the Transfers of Value – and that are contrary to compliance with such provisions, may even be eventually regarded as a breach of the Code, as they would constitute a medium to shelter or encourage a potential breach.

101. The Disclosure Template (Annex I) provides for a publication on an individual basis of the Transfers of Value made to Healthcare Organisations. Taking into account that these are entities or legal persons, are there any legal reasons that may prevent their disclosure on an individual basis?

Article 3 letter a) of the Organic Law 15/1999 of 13 December on Personal Data Protection defines "personal
data” as: any information related to identified or identifiable natural persons.

Consequently, in order to disclose on an individual basis the data and information regarding Transfers of Value to Healthcare Organisations, the company will not need to obtain prior express consent from them. Given the absence of legal reasons in Spain to prevent it, companies subject to the Code shall disclose on an individual basis the Transfers of Value made to Healthcare Organisations.

In addition, the statements of query nr. 100 will also be applicable.

In any case, it is recommended to companies that before disclosure they inform the Healthcare Organisation of the data that is to be disclosed.

102. If a company sponsors attendance of 100 Healthcare Professionals to a congress of a Healthcare Organisation, how should such Transfers of Value be disclosed, as payments to the Healthcare Organisation or as payments to each Healthcare Professional? How should these payments made through third parties be managed (technical secretariats, Healthcare Organisations despite the beneficiary being the Healthcare Professional, etc.)?

If the identity of the Healthcare Professionals is known, the company shall disclose the Transfers of Value derived from its collaboration for their attendance to the congress on an individual basis (if prior express consent has been obtained from the Healthcare Professional) or on an aggregate basis (in absence of such prior express consent).

If the identity of the Healthcare Professionals is unknown, the company shall disclose the Transfers of Value derived from its collaboration under the category “sponsorship agreements with HCOs/third parties appointed by HCOs to manage an Event”.

103. Article 18.7 of the Code establishes that each company shall publish a document describing the methodology used and explaining the information provided and the way in which this information has been obtained and classified. Where will this document be published?

This information shall be contained within the company’s own proceedings and the description of the methodology will be published in the same place where the Disclosure Template is made public.

104. If a Spanish Healthcare Professional is living temporarily in a non-European country and receives a fee or another Transfer of Value from the US parent company, is it necessary to collect and disclose it in the report of the Spanish affiliate?

It would not be necessary, given that such Healthcare Professional does not mainly exercise his professional practice in Spain.

Without prejudice to the location where the Transfer of Value takes place, disclosure of such information shall be made in the country where the Recipient mainly carries out his practice or has his registered office and complying with the local Code applicable in such country.

The Code demands Transfers of Value are disclosed where he mainly carries out his profession or has his registered office because this is the way of guaranteeing that interested third parties (patients, stakeholders) may easily find the information. The professional address of the Healthcare Professional or the registered office of the Healthcare Organisation has to be used as a reference when determining the country in which to disclose the information.

Example:

- A Spanish company collaborating with the participation of a US expert in an advisory board meeting taking place in Argentina would not be forced to disclose the information related to such Transfer of Value. However, disclosure of such information may be compulsory in compliance with other jurisdictions.

105. Would Non-Governmental Organisations, “NGOs”, to which sometimes medicines are donated for humanitarian projects, fall within the concept of Healthcare Organisations? What value should be applied to donated medicines? Company’s selling price, company’s selling price + VAT, cost for the company?

Companies themselves shall determine, on a case by case basis, whether a specific NGO would fall within the concept of Healthcare Organisation provided in the Code, taking into account aspects such as its characteristics, members, statutes, goals and corporate purpose, etc.
As for the nature of the donation, accounting principles applicable in general to this type of collaborations or aids shall be taken into account.

At any rate, the company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.7 of the Code.

106. Is it possible to provide or register Healthcare Professionals to educational courses on scientific subjects? If so, in what section would these educational costs be disclosed according to article 18?

It is possible. This would be disclosed under the category “contribution to educational and scientific meetings”, in the “registration fees” section.

107. There are sponsorship agreements with Healthcare Organisations that are not directly related to the category of the Disclosure Template (Annex I): contribution to educational and scientific meetings, such as sponsorship of the Healthcare Organisations’ website, where, in exchange for a price, the institutional logotype of the sponsoring company is included. In which section of the Template should Transfers of Value related to such sponsorships be disclosed?

This type of collaborations/sponsorships is not regarded as contributions to educational and scientific meetings.

Notwithstanding the above, due to the inherent educational nature of Healthcare Organisations’ websites, we understand that Transfers of Value related to this type of collaborations/sponsorships should be disclosed by companies under the category contribution to educational and scientific meetings in section: “sponsorship agreements with HCOs/third parties appointed by HCOs to manage an Event”.

At any rate, the company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.7 of the Code.

108. Are Transfers of Value derived from medicine assessment studies regarded as falling within the definition of Research and Development?

Companies themselves shall determine, on a case by case basis, whether the Transfers of Value derived from medicine assessment studies would fall within the definition of Research and Development provided in the Code.

At any rate, the company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.7 of the Code.

109. Are the Health Councils of the autonomous communities included in the definition of “Healthcare Organisations”?

Yes, due to the competences they have been assigned by applicable regulations.

110. Will Transfers of Value included in the aggregated category for R&D be detailed? (Fees, clinical research meetings, collaborations with studies driven by researchers or cooperative groups, CROs).

Just as specified in the Disclosure Template, the Transfers of Value related to Research and Development will be published on an aggregate basis.

However, the company must be in possession of the itemisation of the Transfers of Value included in this category.

111. Should payments or Transfers of Value made by companies to third entities that – not falling within the definition of Healthcare Organisations – organise, manage, etc., on behalf of or representing a Healthcare Organisation, activities described in article 18.3.1 of the Code be disclosed? “For example: payments or Transfers of Value made to a technical secretariat hired for the management of an educational activity”.

Yes. These should be regarded as “indirect” payments or Transfers of Value to Healthcare Organisations. In compliance with provisions of article 18.3 of the Code, companies shall disclose them, in all cases, on an individual basis.