

2021

Code of Practice for the Pharmaceutical Industry

Sistema^{de}
AUTORREGULACIÓN
farmaindustria

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Code of Practice for the Pharmaceutical Industry 2021

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 National Trade Association of the Spanish-based Pharmaceutical Industry, it gathers most of the R&D based pharmaceutical companies established in our country, representing nearly 100% of prescription medicines 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 this new version of the Code of Practice for the Pharmaceutical Industry, whose latest modification has been ratified by FARMAINDUSTRIA General Assembly in October 2020. The Code is based on:

- Directive 2001/83/EC of the European Parliament and of the Council, dated 6 November 2001, on the Community code relating to medicinal products for human use.
- Royal Decree 1416/1994, of 25 June, regulating the advertising of medicinal products for human use.
- Royal Legislative Decree 1/2015, of 24 July, approving consolidated Law on Guarantees and Rational Use of Medicinal Products and Medical Devices.
- Law 3/1991, of 10 January, on Unfair Competition.
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Code.¹

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices.²
- Spanish Data Protection Agency (SDPA) Legal Department report N° 2016-0172 (REF143318/2016), of April 22nd reproduced in Annex I of the Code.

The Self-Regulation System is based on the following principles and values that must guide the actions of the pharmaceutical industry as a whole, and will serve as a reference and guidance for all matters not specifically covered by the Code:

TRUST: This is the fundamental value on which the reputation and image of the pharmaceutical industry are founded, and which must form the basis of all its actions. Trust which is achieved only by acting with integrity and honesty in improving patient care and quality of life, and respecting the independence of the different stakeholders with whom we interact.

INTEGRITY: Promoting legitimate, honest, balanced and transparent relationships with those we have interacting, avoiding undue influence and properly handling conflicts of interest.

RESPECT: Maintain the independence of Healthcare Professionals and Organisations, with a commitment not to influence the relationship between them and their patients. We are committed to ensuring that the relationship with our stakeholders takes place in an open, responsible and constructive manner with continuous improvement, based on mutual respect. This maintains the independence of the stakeholders in the decision-making process, based on scientific evidence, and while taking account of patients and healthcare system interests.

LEGALITY: The rules of the Code not only respect and are fully aligned with the national and international legislation in force fostering fair competition among pharmaceutical companies, but also providing guidelines and practical recommendations for aspects subject to interpretation.

TRANSPARENCY: Promotes public knowledge of our interactions, in particular with those with whom a conflict of interest could exist.

PREVENTION: The Self-Regulation System must actively monitor compliance and enforcement of the Code, so as to strengthen, reinforce and protect reputation and trust in the pharmaceutical industry.

The 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 pharmaceutical 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 FARMINDUSTRIA members and those companies that have decided to adhere to the Code voluntarily. This Self-Regulation initiative, aligned with the compliance objectives of the pharmaceutical industry 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.

These internal procedures are themselves an integral part of the regulatory compliance programs of the pharmaceutical companies and reinforce the surveillance and control measures of these organisational and management models, resulting in a firm commitment by the companies and their senior

¹ Efpia Code of Practice

² International Federation of Pharmaceutical Manufacturers & Associations Code of Practice

management teams to generate and maintain a global culture of corporate compliance.

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.

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.

Donations and Grants: 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. At times, grants (finalist donations) is the name 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).

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 Regulation (EU) no. 536/2014 of the European Parliament and of the Council, by Royal Decree 1090/2015 and considered in article 14.1 of the Code) and (iii) observational studies with medicinal products (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.³

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 directly or indirectly in the prescription,

³ Article 2 of the Royal Legislative Decree 1/2015, of 24 July, approving consolidated Law 29/2006 on Guarantees and Rational Use of Medicinal Products and Medical Devices.

purchase, supply, dispensation or administration of medicinal products for human use.

For the purpose of this Code veterinarian professionals 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.

Social Media: Social media channels allow for two-way communication based on the Internet, thanks to which individual users or groups can share information, knowledge and opinions. Their key characteristic is, indeed, conversational character generated between the issuer and the receiver of a message, turning all participants in the conversation into issuers and receivers. Social media fosters interaction, in most cases in real time, making it a fully effective media channel.

Scientific-professional Meetings: Any meeting, seminar, congress, conference, symposium, in-person or distance educational course 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 observational studies with medicinal products), organised or sponsored by one or more pharmaceutical companies or under their control (hereinafter, "Meeting(s)").

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 pharmaceutical 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 pharmaceutical 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 pharmaceutical company employees, the Internet, the use of audiovisual materials such as films, 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

In respect of the Code, the following is not considered promotion of prescription-only medicines:

- (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 Healthcare Professional 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 pharmaceutical company, or owner of the trade mark or of the medicines and the firm responsible for editing or the author of the information.

The Code does not cover the commercial operations of pharmaceutical 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.

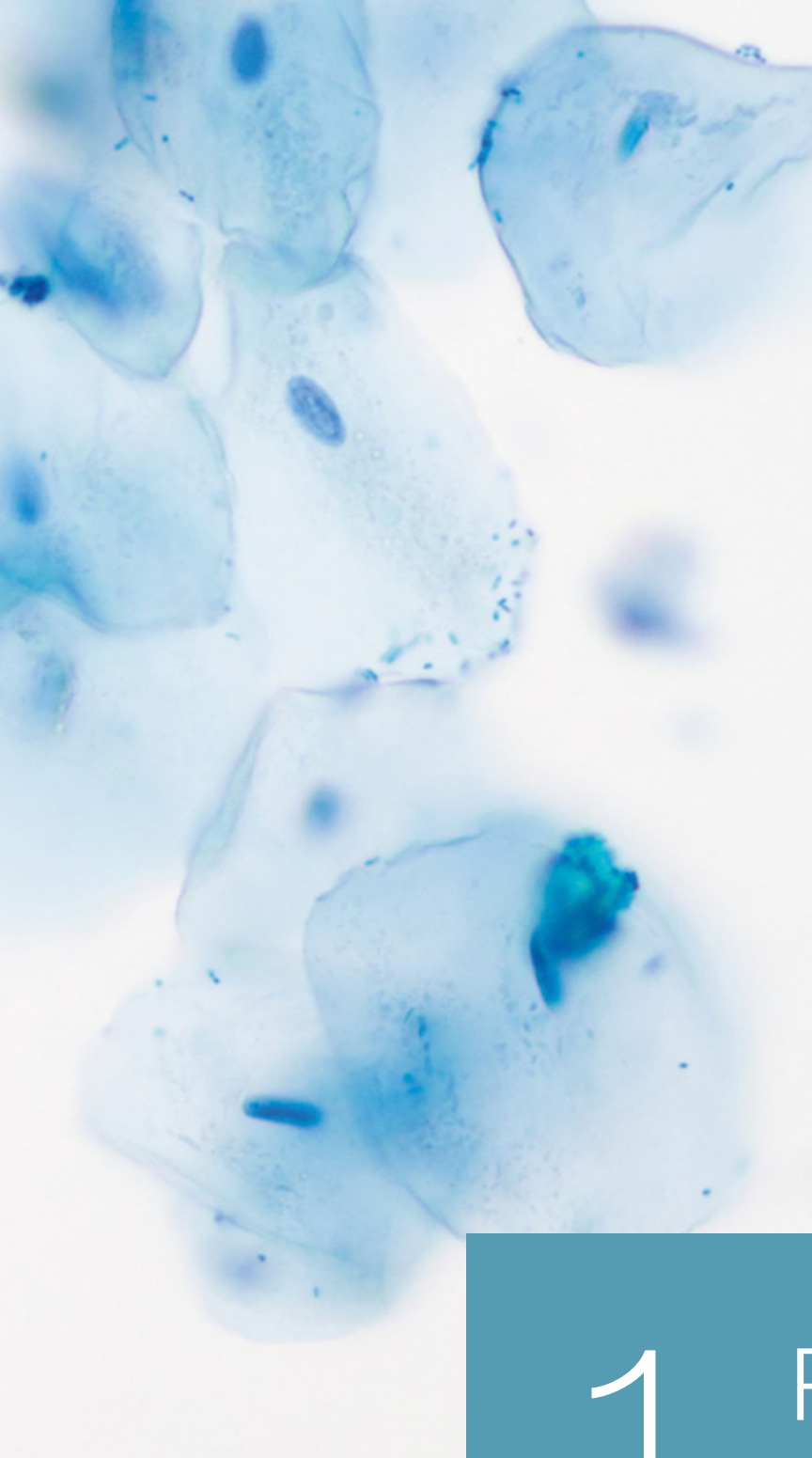
SCOPE OF THE CODE: SUPPLEMENTARY RULES

For clarification purposes, all forms of interaction between pharmaceutical companies and Healthcare Professionals, Healthcare Organisations and Patient Organisations, regardless of origin, scope, nature, purpose, means, support or channel used for its performance are subject to the precepts of this Code.

Annex III to the Code contains a guide the purpose of which is to provide companies with a series of recommendations and practical criteria in their informative activities and as to how they should conduct their relationship with the media.

Other informative activities not considered promotion of prescription-only medicines include:

- The distribution of originals, reprints and/or literal translations of scientific articles and/or abstracts published in scientific sources of established reputation or at congresses, provided that they do not include additional elements such as: (i) printed materials, recordings, electronic links or any other connection with the name of the medicine; (ii) highlighted phrases or paragraphs; (iii) brand names or advertising phrases, or any other advertising material, whether or not connected with the information.
- The distribution of information about a line or different lines of research of the pharmaceutical company, which make mention of the active ingredient and its properties.
- The distribution of educational materials for Healthcare Professionals or patients, the distribution of which is a condition for the marketing authorisation of the medicine, or that have been approved by the competent health authorities.



1

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 pharmaceutical 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 faithful. 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. 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.

INFORMATION ON MEDICINES AND ITS SUBSTANTIATION: SUPPLEMENTARY RULES

3.4. The provisions of this section should be understood as faithfulness to the content of the original source, as established by law and by the Code itself. Tables or graphs included in promotional materials must faithfully reproduce the original source and cite it precisely. Faithful reproduction is to be understood as the replication of the contents of the original source, without exclusions, additions or highlighting that could mislead the recipient or exaggerate the properties of the medicine.

Pharmaceutical companies are reminded that the inclusion of a clear and visible message stating that the material was produced by themselves or is an adaptation does not release them from the obligation to reproduce the information faithfully.

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 meetings in their private field, 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 be recipients of 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 to the general public.

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 be recipients of them must be addressed.

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...”

8. DIGITAL ENVIRONMENT

8.1. Promotion of medicines directed to Healthcare Professionals authorized to be recipients of them disseminated through digital channels must be within a context that is technical, scientific or professional.

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

8.3. There should be a verification system or statement on the Healthcare Professional status of people gaining access or, it should at least 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.

DIGITAL ENVIRONMENT: SUPPLEMENTARY RULES

The companies that are members of FARMAINDUSTRIA or adhere to the Code on an individual basis are committed and obliged to conduct activities - both in promoting medicines and interacting with Healthcare Professionals, Healthcare Organisations or Patient Organisations - respecting and complying with the principles of this Code, regardless of the medium, means of delivery or channel of communication used to perform those activities.

The continuous development of the “Information Society” favours the creation of new media, means of delivery and channels of communication that are available to pharmaceutical companies for promotion of their products and interaction with the different stakeholders (Healthcare Professionals, Patient Organisations, the general public, etc.).

The medium, means of delivery or channel of communication used in any case does not exempt pharmaceutical companies from their obligation to comply with the terms and conditions of the Code. In this regard, companies must refrain from using those methods that, due to their nature, characteristics, technical limitations, conditions of use, etc., do not allow for compliance with the requirements and obligations of the Code to be guaranteed for each type of activity.

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 and third parties acting on their behalf, or under their control, or by virtue of a formal agreement, that establishing 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. Companies' internal guidelines should specify

the legal prohibition against openly sharing or publishing content that could constitute promotion of prescription-only medicines to the general public. The company will also be required to train its employees so as to avoid any inappropriate content, in terms of either style or tone, that its employees might share, link to, publish or comment on through their personal social media profiles, irrespective of whether they are public or private. Inappropriate content could be understood as, for example, comments about competitors' products, off-label promotion, etc.

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

Although there are different types of social media, they may be mainly classified as (i) personal social media (with all aspects focused on the individual), (ii) content social media (with all aspects focused on content), and (iii) mixed social media. There is proliferation of social media platforms intended for specific professional fields.

Pharmaceutical companies will be responsible for understanding and complying with the terms and operating and use conditions of any social media platforms on which they might decide to take part.

To reinforce the above, companies are entirely responsible for the content reproduced during meetings that are organised or mainly sponsored by them. They must therefore adopt appropriate measures to avoid dissemination via social media or any other communication channel, medium or platform, to the extent that such dissemination could directly or indirectly constitute the promotion of prescription-only medicines among the general public. This would require proof of that they have clearly and unequivocally informed to the healthcare professionals and employees attending the meeting. The recommendation in this regard is to include safeguards in the documentation and/or contracts signed with speakers and attendees.

Despite the global nature of social media, the legislation depends on each country, and the Spanish subsidiary will therefore be responsible for the content shared via its social media profile, whether generated by the pharmaceutical company or by a third party, on its behalf, and directly or indirectly controlled or funded on an exclusive or majority

basis, in accordance with the rules of application of the Code defined in article 19.

8.1. 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.

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. The warning referred to in article 8.3. 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 be the recipient of such promotion.

9. SCIENTIFIC DEPARTMENT AND REVIEW OF PROMOTIONAL MATERIAL ON MEDICINES

9.1. Pharmaceutical 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 pharmaceutical 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.

(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.

CHAPTER II

Interaction with Healthcare Professionals and Organisations

10. GUARANTEES OF INDEPENDENCE⁴

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 Euros.

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

GUARANTEES OF INDEPENDENCE: SUPPLEMENTARY RULES

10.1. Prohibition of gifts. 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, pharmaceutical 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.
- 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.

Pharmaceutical 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 pharmaceutical 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.

⁴ Adapted to the new revision of articles 11 and 17 of the EFPIA Code of Practice.

- c) within the framework of **scientific and professional meetings organised by a pharmaceutical 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. Informational or educational materials and items of medical utility. 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 an informational or educational nature is permitted, provided that its market price does not exceed 10 Euro.

In addition, pharmaceutical 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, globes, surgical goggles, tensiometers, 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

The following rules will be applied to all types of meetings that are organised or sponsored by a pharmaceutical company or under its control and to all participants in said meetings, 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 meetings that are exclusively of a scientific-professional nature. Organising or collaborating in

meetings 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 meetings that take place outside of Spain, the maximum threshold established by the National Association of the country where the meeting 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.

At educational activities or scientific-professional meetings conducted in virtual or remote format, no type of hospitality should be offered (social events, travel, accommodation and/or personal/subsistence/pocket expenses). This general principle applies both to meetings organised or mainly sponsored by a pharmaceutical company, and to meetings organised by third parties.

11.2. Hospitality at professional or scientific meetings 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 pharmaceutical 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 meeting, 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 meeting 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 (i) taking place in Spain with Healthcare Professionals regardless their country of professional practice, and (ii) with Healthcare Professionals who conduct their professional activities in Spain, regardless the country where the meeting takes place. In any meeting, the rule established in subsection 11.1 with regard to hospitality limits will apply.

11.8. Meetings 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. Meetings that form part of projects communicated by pharmaceutical companies do not need to be communicated again in accordance with the provisions of articles 16.2 and 35 of the Code ("principle of non-duplication").

11.9. Failure to communicate a meeting 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 meetings that take place outside of Spain (meetings abroad) 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 meeting. This assumption (b) must receive prior authorization from the Code of Practice Surveillance Unit.

In the case of organising or sponsoring meetings abroad, in addition to the Spanish Code, companies must also respect the specific stipulations of the Code of Practice of the country in which the meeting 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 meetings.

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

SCIENTIFIC AND PROFESSIONAL MEETINGS: SUPPLEMENTARY RULES

Regarding organising scientific and professional meetings, a company must not settle for formal compliance with a given criterion in an isolated manner. The behavior of the companies must be guided by two fundamental principles:

1. The quality of the scientific-professional programme must be the main focus of interest of the meeting.
2. The location chosen for holding it must be appropriate for the scientific and educational purpose of the meeting 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 meeting 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 meeting 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 meeting, 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 meeting 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 pharmaceutical company, except in the case of minor costs for travel (taxi, 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 meeting 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 meeting. 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 meeting 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 meetings 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 meetings 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 meetings 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 meetings, regardless of whether or not they are communicated previously to the Code of Practice Surveillance Unit.

Given their inherent characteristics, the communication of educational activities or scientific-professional meetings conducted in virtual or remote format will be voluntary.

Meetings 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 meetings 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. In interrelations conducted in virtual or remote format (including by telephone, videoconference and email), pharmaceutical companies and their employees must also respect and comply with the Code and applicable legislation, including data protection regulations.

12.12. 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 pharmaceutical 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 12.12 with the objective of making it clear that pharmaceutical 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, when requested, with the company's internal procedures that guarantee appropriate training in matters relating to the Code.

12.12. 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 meetings, studies or services (articles 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 meeting 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 pharmaceutical company ensures that the activities have appropriate support and oversight from different perspectives.

The procedures must be formalised in writing and the pharmaceutical 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 pharmaceutical 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.

Pharmaceutical 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. To this end, they may request the collaboration from the Control Bodies of the Code.

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 set by the AEMPS.

The maximum annual number of samples that pharmaceutical companies may distribute within this period will be as established by the legislation in force.

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 psychotropic 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. Pharmaceutical companies must have an appropriate monitoring and accounting system for the samples they distribute.

14. STUDIES

14.1. Clinical Trials

A clinical trial is a clinical study which fulfils any of the following conditions: (1) The trial subject is assigned in advance to a specific therapeutic strategy which does not form part of routine clinical practice. (2) The decision to prescribe the medicine under study is taken together with the decision to recruit the subject for the clinical study. (3) Diagnostic or monitoring procedures are applied to the trial subjects that go beyond routine clinical practice.

A clinical study is any research involving people and intended to: 1. Discover or confirm the clinical, pharmacological or other pharmacodynamic effects of one or more medicines. 2. Identify any adverse reaction to one or more medicines. 3. Study the absorption, distribution, metabolism and excretion of one or more medicines, in order to determine the safety and/or efficacy of those medicines.

Pharmaceutical companies must conduct this type of study in compliance with applicable legislation, after receiving a favorable ruling from the Medical Product Research Ethics Committee (mpREC), 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. Observational studies with Medicinal Products

An observational study with medicinal products is defined as any research that involves the collection of individual data related to the health of individuals, provided that it does not meet any of the conditions required to be considered a clinical trial, and that is carried out for any of the following purposes: (i) to determine the beneficial effects of medicinal products, as well as their modifying factors, including the patients' perspective, and their relationship to the resources used to achieve them, (ii) to identify, characterize or quantify adverse medicine reactions and other risks to patient safety related to their use, including possible risk factors or effect modifiers, as well as to measure the effectiveness of risk management measures, (iii) to obtain information on the patterns of use of medicinal products in the population.

The purpose of observational studies with medicinal products should be to complement the information already known about the medicine without interfering with routine clinical practice.

Pharmaceutical companies should carry out observational studies with medicinal products in compliance with the requirements imposed by the applicable legislation.

Likewise, observational studies not related with medicinal products, research in the field of health, must be approved by a Medical Product Research Ethics Committee and must comply with the applicable regulations.

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 pharmaceutical company's initiative, the initiative of several pharmaceutical 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:

- (i) 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.
- (ii) 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.
- (iii) Aggregate handling of the responses or data obtained.
- (iv) 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, a priori, 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.

If for legal reasons (General Data Protection Regulation) the person participating in the study must be informed of the identity of the pharmaceutical company sponsoring the study (as the data controller), and provided that the participant agrees to be informed of said identity, pharmaceutical companies shall adopt the necessary measures to ensure that such communication is limited to the extent strictly required, and occurs at the end of their participation in the corresponding 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:

- a) Communicate the study prior to its commencement, in accordance with the provisions of Title II Rules of Procedure for the Control Bodies.
- b) Ensure that the study does not modify the physician's prescribing habits or the pharmacist's dispensing habits.
- c) 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.

- d) 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.

- e) Guarantee that the conduction of the study does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer medicines.
- f) Be approved, prior to execution, by the pharmaceutical company's scientific department or by the Compliance Officer stipulated in article 12.12 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. Clinical Trials. 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://www.ifpma.org>⁵

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.

14.3. Market research studies. In compliance with the conditions stipulated in the ESOMAR Code, pharmaceutical 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 pharmaceutical 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, a priori, 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 pharmaceutical 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, pharmaceutical 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 Patient Organisations, 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' or patients' attendance to meetings as stipulated in article 11 and in article 17.8.

⁵ Joint declaration of IFPMA, EFPIA and JPMA.

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 meetings;
- 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 pharmaceutical company's scientific department or by the Compliance Officer stipulated in article 12.12. of the Code.

16.2. When contracting these types of services for a project or activity involves remunerated participation of at least 10 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. If a communicated project includes various meetings, these meetings do not need to be communicated again by the pharmaceutical company under the procedure established in article 33 ("principle of non-duplication").

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 pharmaceutical 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 continue to practice their profession - ensure that these are under the obligation to publicly declare this contract or relationship with the pharmaceutical 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 a meeting in the role of advisor or consultant, the terms and conditions of article 11 apply.

SERVICES PROVIDED BY HEALTHCARE PROFESSIONALS OR HEALTHCARE ORGANISATIONS: SUPPLEMENTARY RULES

It is important that companies evaluate the appearance and content of these types of agreements as a whole. A useful criterion for evaluating compliance with the Code is to ask if the company would like all of the details of the agreement to be widely known publicly.

Companies must be especially careful when they contract a significant number of Healthcare Professionals. In particular, they should not present as services projects that, due to their objectives and characteristics, should be qualified as studies and, therefore, meet the requirements established in article 14.

Annex IV to the Code includes *"Practical guidance and criteria concerning services provided by Healthcare Professionals or by Healthcare Organisations"*.

This guidance establishes, among other aspects, that in order to guarantee in all cases freedom of prescription on the part of Healthcare Professionals, and in order to respect their independent when deciding the most appropriate treatment for each patient, a decision which must be based on the scientific evidence and on the indications authorised for each medicine, pharmaceutical companies must establish annual limits with regard to (i) the total number of Healthcare Professionals with remunerated contracts, and/or (ii) the number of engagements on which the same Healthcare Professional is given a remunerated contract, and/or (iii) the maximum remuneration paid to the same Healthcare Professional for the provision of such services.

16.1. Regarding the conditions detailed in said subsection, pharmaceutical companies must take into account the following:

c) Legitimate Need:

The legitimate need for a particular service will be determined by the existence of objective elements that corroborate and justify the need for it to be performed, taking into account the purpose of the service. The legitimate need must be clearly documented before the service is performed.

As an example:

- If the legitimate need is based on a request for training/updating courses received from a Healthcare Organisation, the recommendation is that the pharmaceutical company should have some document in place in accreditation of this request.
- Legitimate need based on the existence of scientific developments could be justified provided that this refers to new scientific evidence published in the last 4 years.
- The promotion of medicines may constitute a legitimate need justifying the contracting of such services. In these cases, the pharmaceutical company is advised (i) not to generate confusion as regards the nature, character and promotional purpose of the services; (ii) to comply with the requirements of article 16.1, in particular as detailed in subsections (e), (g), (h) and (j); and (iii) to check that there is no legal impediment preventing the hiring of such services.

d) Selection of Healthcare Professionals hired:

Objective criteria must exist in advance for the selection of Healthcare Professionals (for example: expertise, professional record, publications, etc.). The criteria established must be consistent with the purpose, quality, prestige and scientific-professional rigour of the project.

e) Number of Healthcare Professionals hired:

Decisions as to the Project design and the methodology to be followed for its implementation must be essentially based on efficiency and optimisation criteria of the available resources. Aspects such as their nature, scope, objective, type, etc. will determine the maximum number

of remunerated engagements that would be reasonable for each Project.

g) Their hiring does not constitute an inducement to recommend, prescribe, purchase, supply, sale or administer a given medicine:

The hiring of such services cannot and must not in itself constitute a commercial action. As a result, before its arrangement and execution, the pharmaceutical company must evaluate whether aspects such as the purpose, selected methodology, duration, number of collaborators/consultants, location, remuneration, etc. would cause the service in question to be perceived as an undue inducement mechanism.

h) Fair market value of remuneration:

Pharmaceutical companies shall put in place internal procedures and mechanisms to help establish objective remuneration criteria.

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

CHAPTER III

Relationships with Patients Organisations

17. RELATIONSHIPS WITH PATIENT 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 these relationships between the pharmaceutical industry and Patient Organisations are conducted in an ethical and transparent manner, a series of principles at European level were established. Those principles jointly agreed between EFPIA and the Pan-European Patient Organisations, on which the basic rules that should guide pharmaceutical companies are:

- 1. Independence:** The independence of Patient Organisations, in terms of their political judgement, policies and activities, shall be assured.
- 2. Mutual respect:** 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. Non-promotion:** The pharmaceutical industry shall not request, nor shall Patient Organisations undertake, the promotion of a particular prescription-only medicine.
- 4. Transparency:** 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. Multiple sponsorship:** 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. Materials or publications

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. Sponsorships and service contracting

Companies will refrain from requesting to be exclusive collaborator/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 engagement of a Patient Organisation by a pharmaceutical company must not in any way be linked or related to their participation in a promotional act for a medicine;
- h) 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;
- i) 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;
- j) they are approved, prior to contracting, by the pharmaceutical company's Compliance Officer;
- k) 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 pharmaceutical company every time he/she writes or makes public statements regarding any topic related to his/her agreement or to the company. In addition, the recommendation is that contracts should be drawn up in clear, comprehensible language;
- l) each pharmaceutical company will make public the list of Patient Organisations with which they have agreements for the provision of services, in compliance with article 18.7. Furthermore, companies shall promote the transparency of their collaborations on the part of Patient Organisations;
- m) the engagement of patients must be arranged through Patient Organisations;

17.8. Meetings and Hospitality

Meetings 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 meeting, 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 meeting, disregarding whether it is organised by the Patient Organisation or by the pharmaceutical company.

The hospitality provided for meetings 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.). Organising or collaborating in meetings 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 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 meetings that take place outside of Spain, the maximum threshold established by the National Association of the country where the meeting 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.

At meetings conducted in virtual or remote format, no type of hospitality should be offered (social events, accommodation, travel and/or personal/subsistence/pocket expenses). This general principle applies both to meetings organised or mainly sponsored by a pharmaceutical company, and to meetings organised by third parties.

In no case may money be offered to compensate merely for the time spent by patients in attending the meeting.

Companies may not organise or sponsor meetings 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 meeting 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 meetings that take place within Spain.

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

17.9. Prohibition of gifts

Gifts for personal benefit (such as sporting or entertainment tickets, social courtesy gifts) must not be given to patients or representatives of Patient Organisations.

Providing or offering, either directly or indirectly, gifts, monetary or in kind gifts, and/or personal services are also prohibited. For these purposes, personal services are any type of service that confer a personal benefit to the recipient.

RELATIONSHIPS WITH PATIENT ORGANISATIONS: SUPPLEMENTARY RULES

17.2. Scope. 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. Agreements. 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.

17.6. Materials or publications. Irrespective of the format used (printed, digital, etc.), the contents of such materials or publications may be connected with patient health, specific diseases, hygiene-healthcare measures or healthy lifestyles. Such materials must serve to help

patients better understand the course of their diseases and to enhance their quality of life.

To the extent that such materials or publications are intended for patients, their content, text, design and general characteristics must clearly and evidently demonstrate their main goal and purpose: a support tool for people affected by a particular disease. These must be educational and informative materials which will in all cases include visible warning messages standing:

- that their contents must not be interpreted as a potential substitute for a diagnosis performed by a Healthcare Professional, and that in the event of any query regarding their content, the recipient should contact their Healthcare Professional,
- and that the publication is intended to offer explanatory guidance, and that the reader must therefore not undergo treatments or follow advice without first contacting a Healthcare Professional.

The sponsorship of such materials or publications by a company must be explicitly reflected therein.

Pharmaceutical companies will be responsible for fulfilment of the obligations described above, irrespective of the medium, platform or channel of communication used to implement them. To this effect, companies should take into account article 8 of the Code.

CHAPTER IV

Transparency of the pharmaceutical industry's relationships

18. TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY'S RELATIONSHIP

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 on an individual basis

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.

In the case of Healthcare Professionals, in accordance with Directive 95/46/EC article 7f), on the protection of individuals with regard to the processing of personal data and on the free movement of such data, there is a legitimate interest for the companies subject to the Code, recognized by the report issued by the SDPA, of 22 April 2016 (Code Annex I), so that the Healthcare Professionals' consent is not necessary for the disclosure, on an individual basis, the Transfers of Value made to Healthcare

Professionals. In any case, pharmaceutical companies will inform Healthcare Professionals, under Organic Law 3/2018, of 5 December, for Personal Data Protection and Guarantee of Digital Rights, that their data will be disclosed in accordance with the Code.

As far as Healthcare Organizations are concerned, the Transfers of Value made by pharmaceutical companies will be disclosed, in any case, on an individual basis.

Pharmaceutical companies 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.

Transfers of Value (i) associated with activities not detailed in Annex II of the Code, such as, the provision of: materials regulated in article 10 Guarantees of Independence, samples regulated in Article 13 Medical Samples, hospitality associated with dinners or luncheons regulated in Article 11 Scientific and Professional Meetings; (ii) that form part of commercial transactions between pharmaceutical 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

Pharmaceutical 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. Within the first semester of each year, FARMAINDUSTRIA' Board of Directors may establish specific dates for publication. 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 a shorter period is required under applicable national law or regulation.

The information will be disclosed openly on the pharmaceutical company's web page in accordance with the template provided in Annex II. Modification of this template must be approved the FARMAINDUSTRIA Board of Directors.

Following the measures proposed in the report issued by the SDPA, of 22 April 2016 (Code Annex I), pharmaceutical companies must adapt their web sites, with the aim of avoiding further processing of this data in a manner which is not relevant or excessive for the purpose that justifies it. Specifically, companies must applied protocols preventing its indexation through search engines. Likewise, it would be relevant that the website clearly states the purpose of the publication, and that the publication does not grant a general permission for those accessing the website to undertake additional processing of the Healthcare Professionals' data, such as crossing the data with information published in other companies' websites.

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

Transfers of Value shall be disclosed on an individual basis, except for those covered by section 18.5. 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, disclosed on an individual basis, 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.

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 meetings.

Contribution to costs related to meetings, through Healthcare Organisations or third parties, (including sponsorship to Healthcare Professionals to attend meetings), such as:

- (i) Registration fees;
- (ii) Sponsorship agreements with Healthcare Organisations or with third parties appointed by a Healthcare Organisation to manage the meeting; 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 pharmaceutical 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:

Amounts related to any of the categories set forth below:

a) Contribution to costs related to meetings.

Contribution to costs related to meetings, 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 pharmaceutical 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. Non Duplication

Where a Transfer of Value required to be disclosed pursuant to section 18.3 is made to an individual Healthcare Professional indirectly via a Healthcare Organisation, such Transfer of Value shall only be disclosed once. Such disclosure shall be made complying with section 18.1 and 18.3 of this Code.

18.5. 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 meetings 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.

As an exception to the terms set out in the above paragraph, Transfers of Value made to Healthcare Organisations and to Healthcare Professionals related to observational studies with medicinal products that are retrospective nature, which are nonetheless considered as Research and Development, must be published on an individual basis by pharmaceutical companies under the category "provision of services".

18.6. 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

18.7. 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 semester 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 semester of each year including the activities that were carried out the previous year.

TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY RELATIONSHIPS: SUPPLEMENTARY RULES

18.1. Disclosure obligation on an individual basis.

Pharmaceutical companies shall disclose Transfers of Value derived from Market Research Studies only when they know the identity of the Professional or Healthcare Organisation that participates in the study. These will be published as if they were fees for services.

18.2. Form of Disclosure - 18.7. Collaborations.

Pharmaceutical companies will provide the Code of Practice Surveillance Unit with the link to their website where this information is published, as soon as it is available. FARMAINDUSTRIA will provide these links operating as a "gateway" to individual companies websites via the Self-Regulation System website (www.codigofarmaindustria.org).

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 of Practice and especially as they apply to Implementation and Procedural Rules detailed in their Annexes.

19.3. Pursuant to the provisions of the EFPIA Code, 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 Code is 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 Code, 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 Code; 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 Code 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. Code of Practice Surveillance Unit and the 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 submitted by the pharmaceutical companies 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 V).

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 pharmaceutical 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 pharmaceutical 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 pharmaceutical 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. FARMAINDUSTRIA Board of Directors, 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, 18, 21.5 and

22.8 of this Code. In these cases, pharmaceutical 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 pharmaceutical 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 pharmaceutical 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

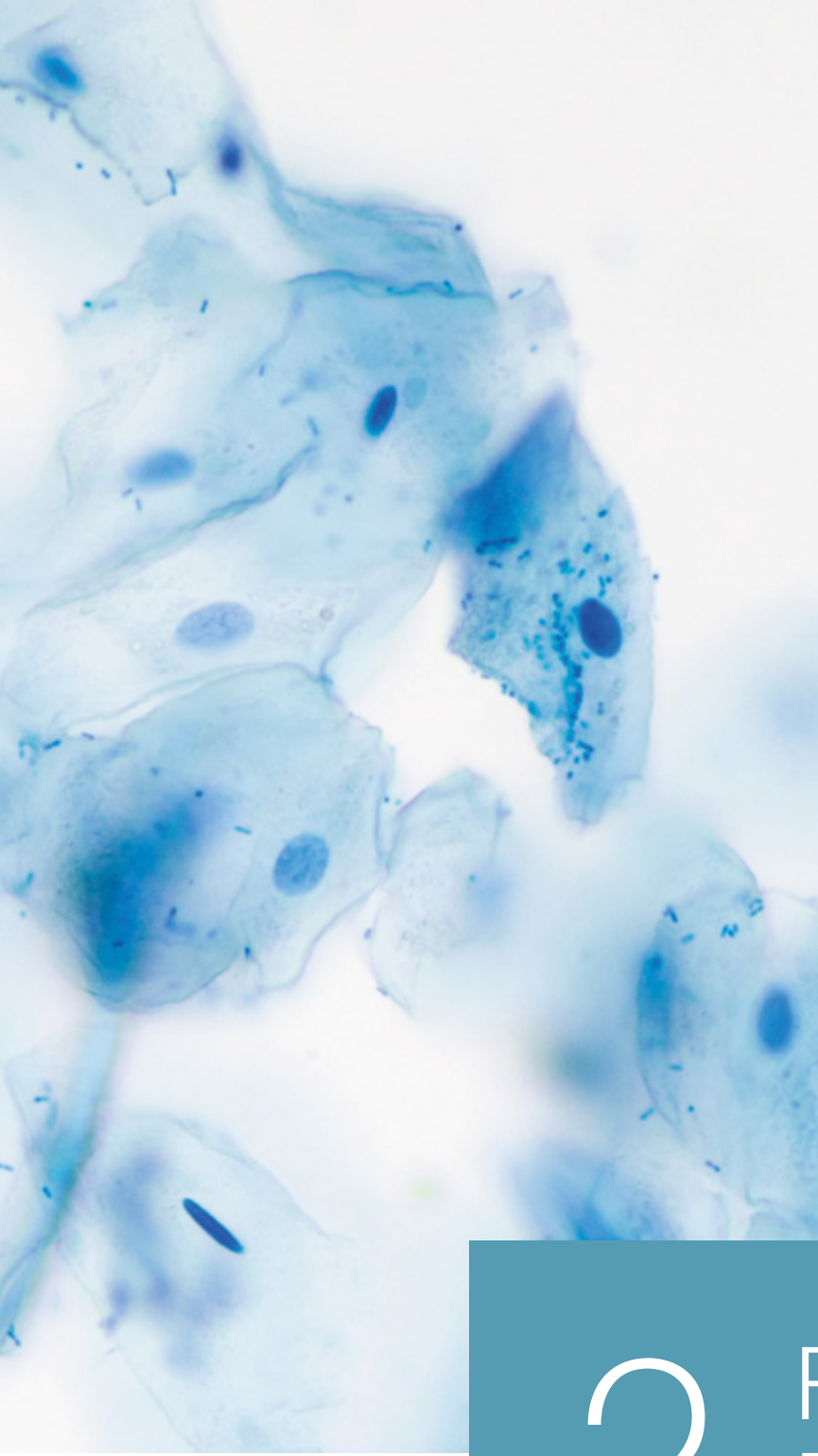
By agreement of the FARMAINDUSTRIA Executive Board, Supplementary Rules to this Code may be created for the purpose of guiding pharmaceutical companies on the appropriate compliance with the rules contained in the Code. Supplementary Rules have the same validity and value as the articles of the Code.

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.



2 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 Board 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. As

an exception, in the event of circumstances or reasons that would justify it, FARMAINDUSTRIA Executive Board may permit the Committee to operate with less than three members.

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 Secretary, 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 pharmaceutical companies to the Code of Practice Surveillance Unit.
- h) To issue circulars, through the Secretary, directed at pharmaceutical 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

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 Surveillance Unit 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 pharmaceutical 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 pharmaceutical companies to provide or exhibit any

information or documentation that is relevant due to being directly or indirectly related to said investigation.

In particular, shall be enabled to establish procedures to monitor the compliance of Transfers of Value disclosure obligations established in article 18. Those procedures shall be approved by FARMAINDUSTRIA Board of Directors.

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.

Pharmaceutical 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 pharmaceutical 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 pharmaceutical companies 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 pharmaceutical companies, forwarding these to the Code of Practice Committee for their reply.
- h) To issue circulars to pharmaceutical companies defining the criteria of the Code of Practice Surveillance Unit with regard to certain activities, meetings 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 pharmaceutical 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.
- b) Name and address of the pharmaceutical 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 pharmaceutical 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.

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.

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.

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 fifteen 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.org). 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 Self-assessment

As an exception, a self-assessment procedure is enabled for those cases in which pharmaceutical companies, as a result of the review and audit processes to which they are subject, detect or learn of activities or practices performed by the pharmaceutical company itself which could be in breach of the Code. The self-assessment procedure will not apply in those cases where a third party or the Code of Practice Surveillance Unit has announced or initiated a complaint procedure against the pharmaceutical company as a result of the same activities or practices.

The self-assessment must be addressed to the Code of Practice Surveillance Unit and must contain at least the following information:

1. Detailed description of the activities/practices which could be in breach of the Code.
2. Documentation, evidence on which the self-assessment is based.
3. Explicit recognition of a possible infringement, on the part of the Legal Representative of the pharmaceutical company.
4. Proposed penalty and corrective measures that the infringing pharmaceutical company would be prepared to accept.

If the self-assessment notice does not contain the required information, the Code of Practice Surveillance Unit will contact the pharmaceutical company to request the missing documents to be submitted within five days.

Once the file is complete, and following an evaluation of the information provided, the Code of Practice Surveillance Unit will issue a report, proposing the classification of the infringement and the measures that in its judgment should

be adopted against the infringing pharmaceutical company. The formal declaration made by the pharmaceutical company will be considered by the Code of Practice Surveillance Unit to be an attenuating circumstance.

The Secretary of the Code of Practice Committee will summon the pharmaceutical company and the Code of Practice Surveillance Unit to the next mediation meeting to continue with the processing of the file in accordance with the procedure set out in article 32.4 of the Code.

32.4. 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 pharmaceutical company, which will include the recognition of the breach by the pharmaceutical company, as well as the corrective measures that are considered necessary based on the severity of the acts and with the objective of 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.

32.5. 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 fifteen 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 own Rules of Procedure. In case of rejection of the request, the file will continue the ordinary process.

33. PROCEDURE FOR COMMUNICATING SCIENTIFIC MEETINGS

The provisions of this article only result of application to article 11 of the Code.

The communication of meetings 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

Pharmaceutical companies must provide prior notification of the holding of any scientific or promotional meeting when the following three circumstances concur:

- that they are organised - directly or indirectly - or sponsored - exclusively or in the majority - by the reporting pharmaceutical company;
- they offer at least one overnight stay; and
- 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 meeting were organised by the pharmaceutical company itself. This communication will not be obligatory for meetings 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 meetings 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 pharmaceutical company.
- b) Nature of the participation: organiser or sponsor.
- c) Title of the meeting.
- 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 meeting.
- 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 meeting (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 pharmaceutical 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 meeting 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 meetings 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 meeting has been authorized.

33.4. Person Responsible

Each pharmaceutical company will designate through their legal representative one or two persons responsible for communicating meetings who will be the intermediary in these matters and who shall be assigned personal passwords for communicating meetings 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 meetings. 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 MARKET RESEARCH 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 be mandatory when all of the following circumstances occur:

- the sponsorship or funding provided by the company represents the majority of the financial resources;
- the company has access, prior to, during or after the study, to the identities of the participating Healthcare Professionals, or has it intervened in the selection beyond defining the participating group in the study protocol;
- the study involves the remunerated participation of at least 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.

The fact that for legal reasons (General Data Protection Regulation) the person participating in the study must be informed of the identity of the pharmaceutical company sponsoring it (responsible for data processing) does not mean that communication of the study would be mandatory.

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) Pharmaceutical company reporting the study.
- b) Name of the sponsor: pharmaceutical 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 pharmaceutical 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 pharmaceutical company executes the study without meeting the corrective measures, the Unit may initiate the corresponding complaint procedure.

34.4. Person Responsible

Each pharmaceutical 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.

If a communicated project includes various meetings, these meetings do not need to be communicated again by the pharmaceutical company under the procedure established in article 33 ("principle of non-duplication").

In any case, such meetings must comply with the terms of article 11 and its supplementary rules.

This communication of these projects will be obligatory when all of the following circumstances occur:

- the sponsorship or funding provided by the company represents the majority of the financial resources;
- the project involves the remunerated participation of at least 10 Healthcare Professionals practicing in Spain;
- the project does not consist 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) Pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical company executes the project without meeting the corrective measures, the Unit may initiate the corresponding complaint procedure.

35.4. Person Responsible

Each pharmaceutical 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

The Code of Practice Surveillance Unit and the pharmaceutical companies may pose queries in accordance with article 20 of the Code according the following procedure:

36.1. Submission

Queries raised by the Code of Practice Surveillance Unit will be directly forwarded to the Code of Practice Committee.

Queries submitted by pharmaceutical companies 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 pharmaceutical 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

Queries raised by the Code of Practice Surveillance Unit will be resolved directly by the Code of Practice Committee.

In case of those submitted by the pharmaceutical companies, 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical company as legal representatives before FARMAINDUSTRIA and as Compliance Officer, and must contain at least the following data.

- a) Name and address of the pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical company or any other company in the Group,
 - (ii) an independent auditor that was providing auditing services to the pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical company 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 pharmaceutical 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.

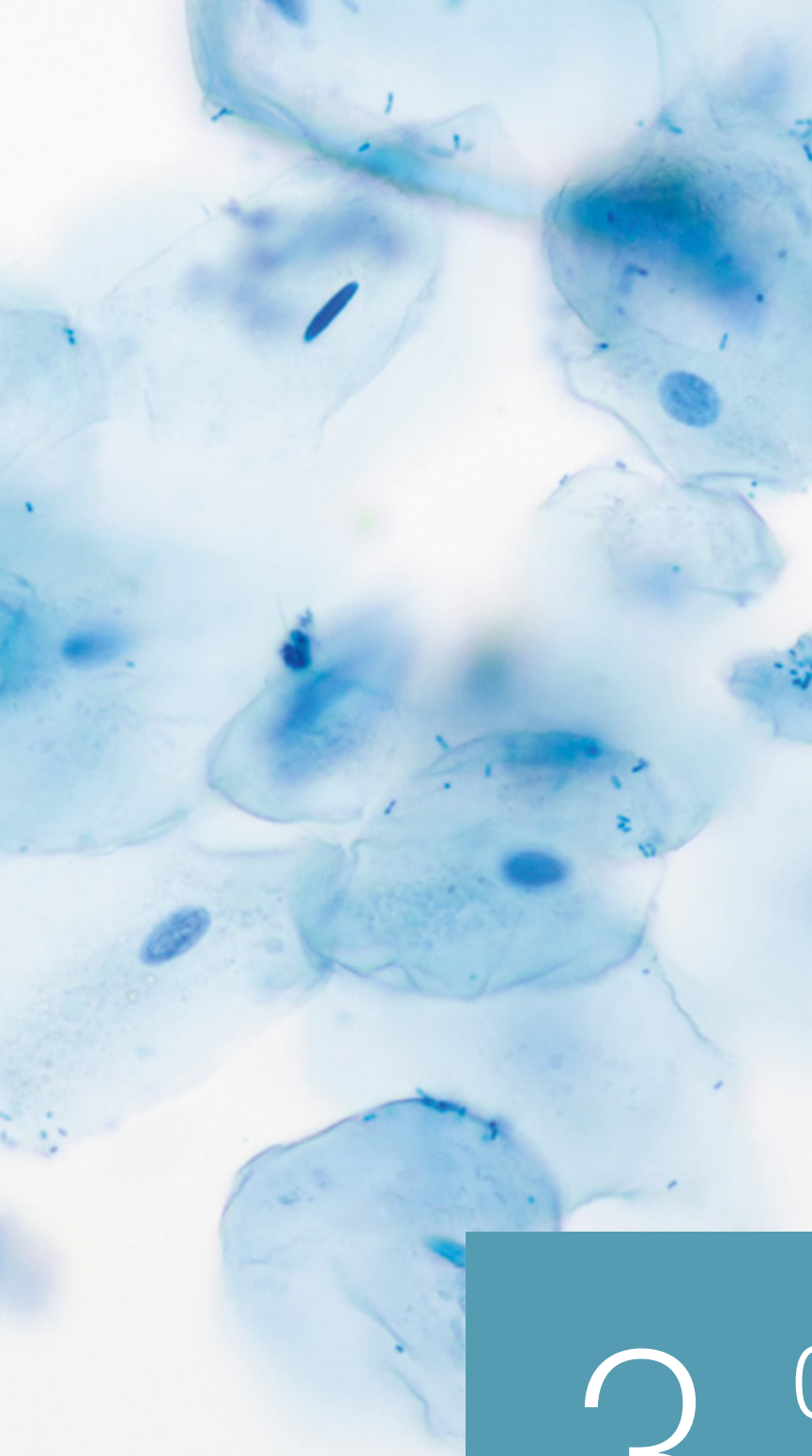
Failure to cooperate with the investigation procedure will have the effects indicated in article 21.6 of the Code and section 37.1 of this article with respect to refusal.

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 pharmaceutical 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 FARMAINDUSTRIA and to the Compliance Officer of the pharmaceutical 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.



3

Coming into Effect
of the Code

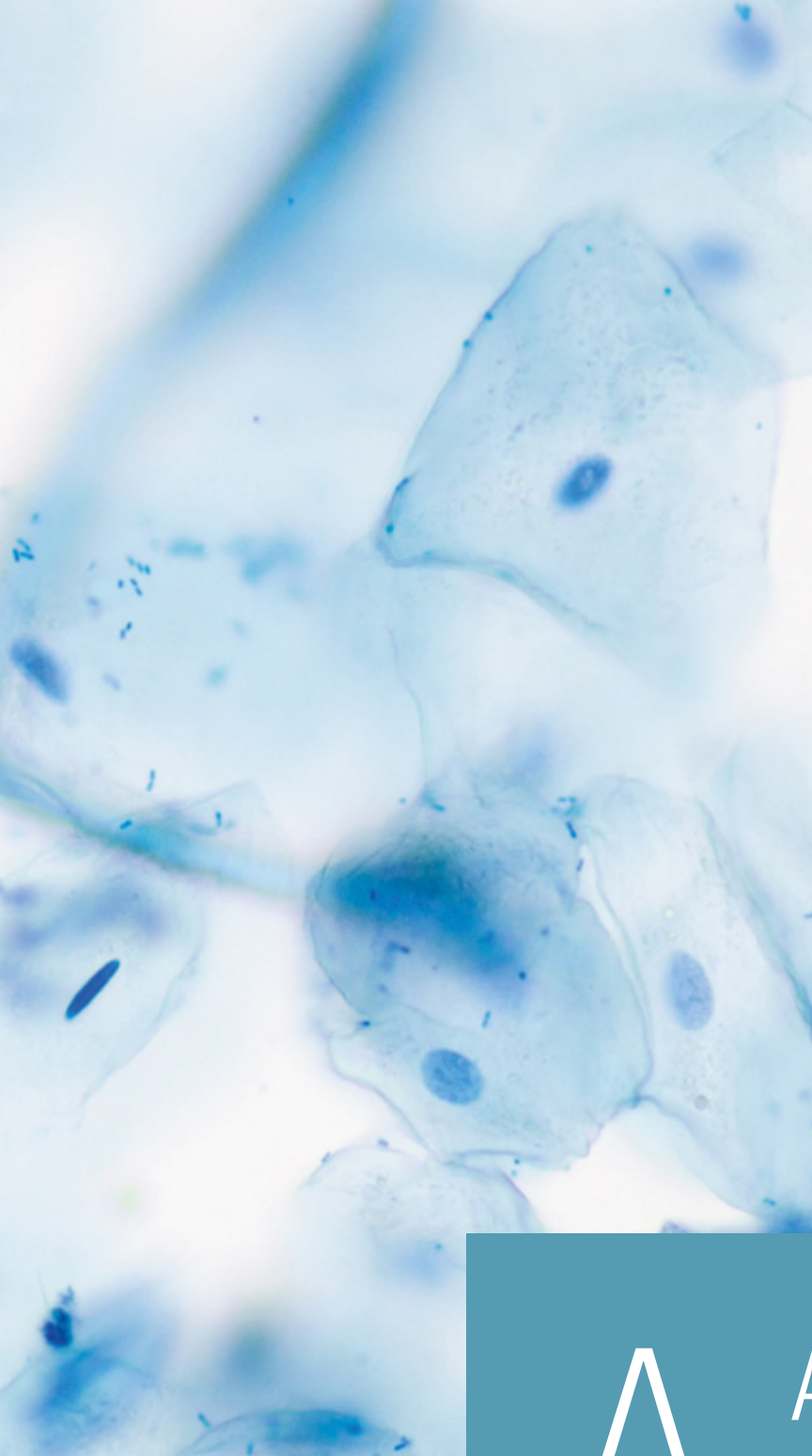
38. COMING INTO EFFECT OF THE CODE

This Code comes into effect on 1st January 2021 and revokes those that were in effect up to this date.

COMING INTO EFFECT OF THE CODE: SUPPLEMENTARY RULES

This Code supersedes and revokes:

The Code of Practice for the Pharmaceutical Industry (October 2016 edition).



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Annex I

Annex I:

Spanish Data Protection Agency Report



The enquiry raises if it is pursuant to Organic Law 15/1999, of 13th December, for Personal Data Protection and its implementing Regulation approved by Royal Decree 1726/2007, of 21st December, that entities belonging to the requesting Association should publish on their web sites and without seeking the prior consent of the parties concerned, individual information related to value transfers carried out by those entities for the benefit of healthcare organisations and professionals, under the terms that shall be introduced in the Code of Practice for the Pharmaceutical Industry with the amendments that are appended to the enquiry.

For this purpose, the enquiry refers to possibly applying to the case the rule of balance of rights and interests laid down by Article 7 (f) of Directive 95/46/EC, under which “Member States shall provide that personal data may be processed only if: (...) (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection under paragraph 1 of Article 1.” In this regard, the enquiry reminds us that the Judgement of the Court of Justice of the European Union of 24th November 2011 has come to recognise the direct effect of the above-mentioned provision of the Directive, which, if applicable to the case, would allow the aforementioned publication to be carried out without the consent of those affected.

As a preliminary matter, and as is clear from the actual text of Article 18 of the Code of Practice for the Pharmaceutical Industry subjected to report, it is necessary to emphasise that this report shall be confined to assessing the appropriateness or inappropriateness of the publication of the transfers of value made to healthcare professionals, whenever regarding organizations pursuant to the the first paragraph of Article 2.2 of the implementing Regulation of Organic Law 15/1999, which confirms that the data protection rules do not apply to legal entities.

Having said this, and focusing on the publication of the transfers of value to individuals and in the application of Article 7 (f) of Directive 95/46/EC, the Judgement of the Court of Justice has expressly declared the direct effect of the aforementioned provision, as indicated in the enquiry. For this reason, this article should be taken directly into account in the application of the regulations on the personal data protection by the Member States, and accordingly by this Spanish Data Protection Agency, because, as pointed out by the Supreme Court in its judgement of 8th February 2012

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“it produces immediate legal effects without the need of national standards for its implementation, and that therefore can be invoked before the administrative and judicial authorities when a transgression is observed”.



As recalled by the Judgement of the Court of Justice of the European Union in its paragraph 38, Article 7 (f) of the Directive “sets out two cumulative conditions that must be fulfilled in order for the processing of personal data to be lawful: firstly, the processing of the personal data must be necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed; and, secondly, such interests must not be overridden by the fundamental rights and freedoms of the data subject , and in connection with the said balancing, paragraph 40 recalls that this “shall depend, in principle, of the individual circumstances of the particular case in question and in the context of which the person or the institution which carries out the balancing must take into account of the significance of the data subject’s rights arising from Articles 7 and 8 of the Charter of Fundamental Rights of the European Union give the interested party”.

For this reason, the Judgement points out in its paragraph 46 that Member States, must, when transposing Directive 95/46, “take care to rely on an interpretation of that directive which allows a fair balance to be struck between the various fundamental rights and freedoms protected by the European Union legal order, therefore, in accordance with paragraph 47 that “there is nothing to preclude Member States, in the exercise of their discretion laid down in Article 5 of Directive 95/46, from establishing guidelines in respect of that balancing.”

Therefore, to determine if the application of the aforementioned provision is appropriate the rule of balancing laid down therein should be applied; that is to say, it shall be necessary to assess whether in the specific case subject to analysis there is a legitimate interest pursued by the data controller or by the third party or third parties to which the data is to be communicated that prevails over the interest or the fundamental rights and freedoms of the person concerned who require protection in accordance with the provisions of Article 1 of the Organic Law 15/1999, according to which “this Organic Law aims to ensure and protect, all that concerning personal data processing, public freedoms and fundamental rights of individuals, and especially of their honour and personal and family privacy” or if, on the contrary, these fundamental rights or interests of the people concerned which relate to the data processing have to override the legitimate interest in which the controller aims to base the personal data processing.

Having said that, it is appropriate to examine whether in this case the publication raised, under the terms indicated in the enquiry and in Article 18 of the Code of Practice for the Pharmaceutical Industry that is attached herein shall be deemed to be covered by the widely quoted Article 7 (f) of Directive 95/46/EC.

Paragraph 3 of Article 18 states that “In each applicable period, companies shall disclose on an individual basis for each clearly identifiable Recipient 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.”

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At the same time, with regard to the professionals, the second sub- paragraph of this article stipulates that the publishing shall relate to the following concepts:



a) Contribution to Costs Related to Events. Contribution to the costs related with 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 related to or made under contracts between laboratories and Healthcare Professionals, from which there is a provision of a service or a value transfer not covered by 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.”

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, a shorter period is required under applicable national law”, according to paragraph 2 of the article, and published within the first six months of the financial year following that in which the transfer of value took place, including it on the company's web page. Transfers of Value related to research and development shall be disclosed only on an aggregate basis, according to paragraph 5 of Article 18.

With regards to the delimitation of legitimate interest invoked by the requesting party, the letter sent to the Agency indicates that “the disclosure of transfers of value on an individual basis pursues, to decrease the perception risk on the influence that the healthcare professional might have received, it promotes a culture of integrity in transactions with healthcare professionals and the confidence of the public and patients in the integrity and independence of the healthcare professional, something essential for generating confidence in such relations and for their proper functioning”. It also indicates that the aim is to “ensure that the pharmaceutical companies comply with the strict limits that are set by both the legislation (national and Community) and the own self-regulation system in the field of promotion of medicines”, avoiding “that interactions of the pharmaceutical industry with the healthcare professionals may constitute an infringement of Directive 2001/83/EC on the Community Code relating to medicinal products for human use and Royal Legislative Decree 1/2015, of 24th July, approving the Consolidated Law on Guarantees and rational use of medicines and medical devices”.

This all means that the aim pursued by the disclosure of the information would be to ensure the adequate knowledge by the general population, and in particular by the patients of a specific health care professional, that the latter's action is not tampered with in any way as a result of the intervention of the laboratories linked to the requesting party and, ultimately reveal the integrity and independence of those professionals to carry out a specific prescription, dispensing and administration of medicines.

In this regard, it should be recalled that Article 4.6 of the Consolidated Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015, of 24th July, in the wording given to it by the final disposition



20.1 of Law 48/2015, of 29th October, establishes in its first two sub-paragraphs that "in order to ensure the independence of decisions related to the prescription, dispensing and administration of medicines in respect of commercial interests, the direct or indirect offer of any type of inducements is prohibited, together with rebates, discounts, premiums or gifts, by those who have direct or indirect interests in the production, manufacture and marketing of medicines to the health professionals involved in the cycle of prescribing and dispensing and administration of medicines or to their relatives and persons with whom they live. This prohibition shall also apply when the offer is made to healthcare professionals that prescribe medical devices".

Equally, Article 78.4 of the Consolidated Law establishes that "the offers of awards, grants and contributions and subsidies to meetings, conferences, study tours and similar acts by any natural or legal person, related to the manufacture, processing, distribution, prescribing and dispensing medicines and healthcare products, shall be made public in a manner to be determined by regulations and shall apply only to activities of a scientific nature when their recipients are healthcare professionals or the entities to which they are associated. The source of financing and the funds obtained from each source must be recorded in the programmes, publications of work and papers of meetings, congresses and similar acts. The same obligation would be applicable to the media through which this work is made public and funds are obtained by or for its publication".

The above standards certainly do not establish a publication system for individual data related to transfers of value, submitting to the detail of the publicity to be given to a later regulatory development. However they do lay down the principle that the companies shall have to make public the information related with transfers of value carried out with the aim expressed in the enquiry, to ensure transparency in their work and the independence of the professionals at the time of prescribing, dispensing or administering medicines.

All this would help to consider that the measure at issue in the enquiry would have as its object that of meeting a legitimate interest, which the trials of suitability and need also indicated in that enquiry could not favourably rule on and that respond to the doctrine emanating from the Constitutional Court and the European Court of Human Rights.

However, to appreciate if the publishing could be based on this legitimate concern without requiring as a result, and unlike as was being carried out until now, the consent of those affected, it is necessary to assess whether this interest has to be regarded as prevalent over the rights and freedoms of health professionals with regard to the information to be published and in particular their right to personal data protection. This would also allow taking into account that in addition to the judgement of suitability and of need, the measure raised would exceed the judgement of strict proportionality mentioned by jurisprudence.

This Agency has been indicating that, in general, the prevalence of legitimate interest could occur in the event that measures are taken that would minimise the impact on those affected as a result of the personal data processing. In any case, and as has been demonstrated, we should not lose sight of the fact that the legitimate interest invoked has been expressly taken into consideration by the legislator:

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In the enquiry raised it is noted that “in any case, these measures would be taken and would be put into practice ensuring respect for the general principles of Organic Law 15/1999 on data processing and comprehensively informing the healthcare professional. Healthcare professionals whose data are to be published would be informed of the adequacy and relevance; the purpose of the data collection and accuracy of the data and the possibility of exercising the rights of access, rectification, cancellation and opposition (ARCO) by the healthcare professionals concerned”.



At the same time, it is relevant to recall that Article 18.3 of the Code of Practice, in the version proposed, anticipates that the publication of the information is carried out in an aggregated manner for the categories referred to in Article 18.3.2, so that only the amount received due to the collaboration in scientific and professional meetings and for the provision of services would be made public, excluding value transfers related to research and development, in accordance with Article 18.5. In this way, only the cumulative data for the categories would be known and not the breakdown of the information from which this amount proceeds from.

Article 4.1 of Law 15/1999 enshrines the principle of proportionality in processing, so that the data that is adequate, relevant and not excessive for the purpose that justifies it. The inclusion of the aggregated amount, without incorporating any breakdown, allows the data object of publication to be the minimum necessary to ensure the objective pursued by this measure, in line with the legal regulations to which reference has been made earlier.

At the same time, the recognition to exercise one's rights makes it possible to take into consideration that in any event the exclusion of the data would be possible if the personal circumstances of the professional were to justify reversal of the rule of balancing that has been analysed through the right of opposition.

Whereas these circumstances would allow to consider that the balancing requested by article 7 f) of Directive 95/46/CE can be secured in favour of the publication, it would be convenient that additional measures were implemented preventing a further processing of data which might deviate from the original purpose, since access to this information might allow those getting to know it to undertake additional processing aimed not as much at the transparency objective linked to the transfers of value, but at the elaboration of profiles of healthcare professionals receiving those transfers.

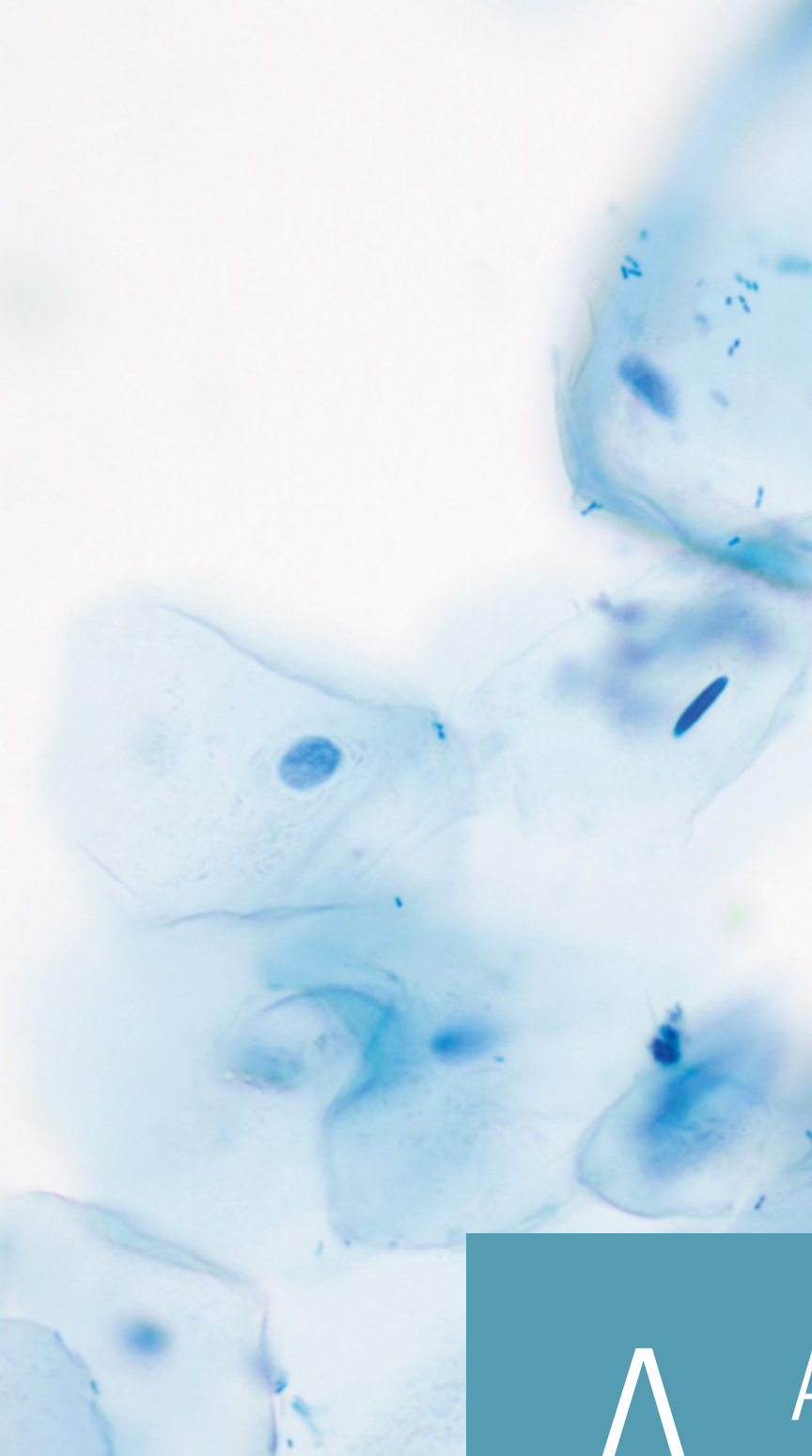
To this effect, it would be convenient that protocols were applied to the website hosting the publication of the data, preventing its indexation through search engines. Likewise, it would be relevant that the website clearly states, in order to guarantee the proportionality of the measure, that the final purpose of the publication is the one indicated in this consultation, and that the publication does not grant a general permission for those accessing the website to undertake additional processing of the healthcare professionals' data, such as crossing the data with information published in other members' websites.

As a consequence, we consider that the publication to which the consultation is referred, and the corresponding amendment of article 18 of the Code of Practice

for the Pharmaceutical Industry is compatible with article 7f) of Directive 95/46/CE, so that the healthcare professionals' consent is not necessary for this publication to be made. In addition, the adoption of measures to guarantee the privacy of the professionals mentioned herein would be convenient, with the aim of avoiding further processing which exceeds the objective justifying this publicity.

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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.



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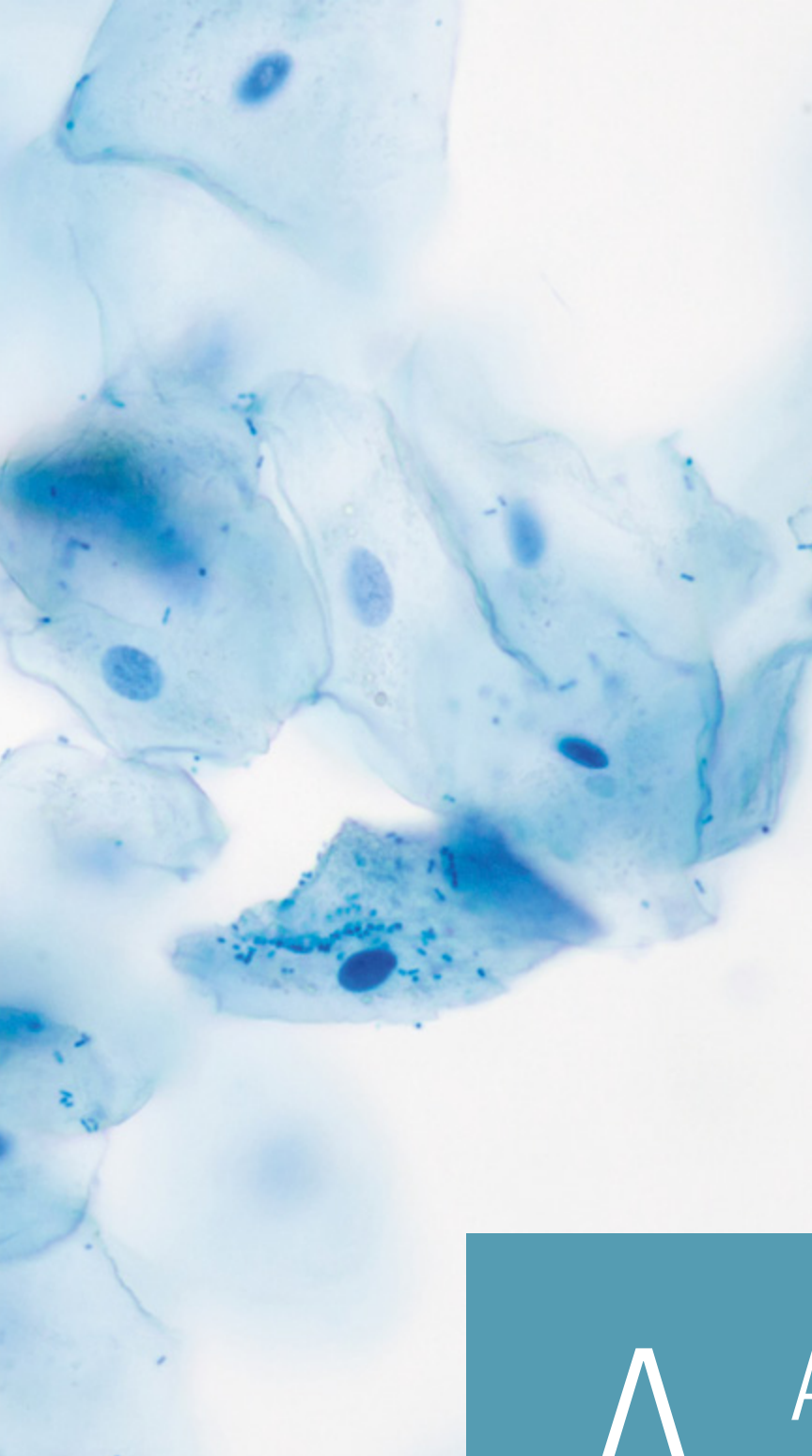
Annex II

Annex II

Disclosure template

	Full Name	Healthcare Professionals (HCPs): city of principal practice Healthcare Organisations (HCOs): city where registered	Country of Principal Practice	Principal Practice Address	DNI / CIF XXX1234X X	Donations (Art.18.3.1.a)
	(Mandatory) (Art. 18.3)	(Mandatory) (Art. 18.3)	(Optional) (Art. 18.3)	(Optional) (Art. 18.3)	(Mandatory) (Art. 18.3)	
Healthcare Professionals (HCPs)	INDIVIDUAL NAMED DISCLOSURE: one line per HCP (i.e. all Transfers of Value during a year for an individual HCP will be summed up. Itemisation should be available for the individual HCP or public authorities'consultation only as appropriate.					
	DR. AAAA					Not applicable
	DR. AAAB					Not applicable
	etc.					Not applicable
	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	
Healthcare Organisations (HCOs)	INDIVIDUAL NAMED DISCLOSURE: one line per HCO (i.e. all Transfers of Value during a year for an individual HCO will be summed up. Itemisation should be available for the individual HCO or public authorities'consultation only as appropriate.					
	HCO 1					Yearly Amount €
	HCO 2					Yearly Amount €
	etc.					Yearly Amount €
Research and Development	AGGREGATE DISCLOSURE					
	Transfers of Value related to Research & Development - Article 18.5					

Contribution to educational and scientific meetings (Art. 18.3.1.b & 18.3.2.a)			Fees for service (Art. 18.3.1.c & 18.3.2.b)		TOTAL
Sponsorship agreements with HCOs/ third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation	
INDIVIDUAL NAMED DISCLOSURE: 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.					
Not applicable	Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Optional
Not applicable	Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Optional
Not applicable	Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Optional
INFORMATION NOT INCLUDED ABOVE: where information cannot be disclosed on an individual basis for legal reasons					
Not applicable	Yearly Aggregated Amount €	Yearly Aggregated Amount €	Yearly Aggregated Amount €	Yearly Aggregated Amount €	Optional
Not applicable	Number of HCPs	Number of HCPs	Number of HCPs	Number of HCPs	Optional
Not applicable	%%		%%		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.					
Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Optional
Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Optional
Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Yearly Amount €	Optional
AGGREGATE DISCLOSURE					
Transfers of Value related to Research & Development - Article 18.5					Yearly Amount €



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Annex III

Annex III

Practical guidance for communication and relations with the media concerning prescription-only medicines

01. INTRODUCTION

The role of pharmaceutical industry is to research, develop, produce and market medicines, whether they are over-the-counter (also known as OTC products or non-prescription medicines) or prescription-only medicines. The activity of a pharmaceutical company therefore includes numerous drug-related processes that are subject to be communicated, from the discovery of a molecule to the final approval of a drug.

In Spain, the pharmaceutical industry is a highly regulated sector, and all its activity is therefore subject to a series of very specific legal conditions, in particular those connected with prescription-only medicines.

There are in fact regulations in force both at the European level, and also national and regional legislation. This regulatory framework to which the sector is subject determines how and when promotional or advertising activities may be conducted for a prescription-only medicine.

Meanwhile, the vast majority of companies based in Spain which market original prescription-only medicines belong to the National Trade Association of the Spanish-based Pharmaceutical Industry, FARMAINDUSTRIA. In 1991, FARMAINDUSTRIA introduced its Code of Practice for the Pharmaceutical Industry in Spain (hereinafter, the Code), a set of standards which are periodically updated and

adopted in order to ensure that the promotion of medicines for human use and the interactions with healthcare professionals and healthcare and patient organizations is conducted in accordance with the strictest ethical principles of professionalism and responsibility.

There is, then, a very specific regulatory and self-regulatory framework for the promotion of prescription-only medicines. This does not extend to information tasks, which in many cases are not only advisable, but also, as will be seen later in this document, necessary. The aim of this guide is to define a practical framework and offer a series of practical guidelines and criteria in the task of providing information about prescription-only medicines, and how to conduct the relationship with the media. In short, the idea is to provide companies with a useful tool that will help them to guarantee, reinforce and distinguish the informative rather than promotional nature of communication activities connected with prescription-only medicines.

What do we understand by communication?

The main challenge faced by Communication departments at the companies belonging to FARMAINDUSTRIA is the lack of definition as to what the concept of communication covers within this field, and the ways in which this should be conducted. This lack of definition to an extent demands constant justification of the activities conducted, both internally and externally, and this need for justification, alongside the lack of specific references, often hampers or even prevents numerous communication activities.

The study of theories in this field and their practical application has facilitated an international consensus in compiling all forms of communication in the form of a field known as Communication Science. There are various disciplines attached to this science, which include in particular journalism and advertising.

Each has its own area of action, and they are therefore studied separately.

These disciplines make use of their own tools in order to conduct the task of communication for which they are conceived, namely information in the case of journalism, and promotion in the case of advertising.

These two quite different disciplines have perfectly defined purposes: to inform on the one hand and to promote on the other.

When the two are combined, since they are complementary, the presence of a promotional interest may compromise the purely informative interest. Hence the importance of properly identifying each of them.

02. LEGISLATION AND SELF-REGULATION REGARDING PROMOTION

As has been seen so far, information and promotion are two different communication activities. The distinction between them is essential, bearing in mind that in the field of prescription-only medicines both the current regulations (international, national and regional) and Self-Regulation affect advertising and promotion.

General regulations

The European Council Directive 84/450/EEC of 10 September 1984 concerning misleading advertising, defines advertising in article 2.1 as:

"'advertising' means the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations".

Spain's General Advertising Act 34/1988, of 11 November 1988, defines advertising in article 2 as:

"Any form of communication conducted in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations".

Royal Decree 1416/1994, of 25 June 1994, on Advertising and Promotion of Medicines, defines the concept of "advertising of medicines" in article 1, Scope of application, subsection 2:

"Any form of information offering, prospecting or incitement intended to promote the prescription, dispensation, sale or consumption of medicines".

By way of clarification, the aforementioned article details in subsection 3 what this concept comprises, establishing that the advertising of medicines comprises:

a) Advertising of medicines addressing the public.

b) Advertising of medicines addressing persons entitled to prescribe or dispense them.

c) Medical visits conducted by medical visitors or information agents of pharmaceutical manufacturers to persons entitled to prescribe or dispense medicines.

d) The distribution of free samples.

e) The sponsorship of promotional meetings attended by persons entitled to prescribe or dispense medicines.

f) The sponsorship of scientific congresses involving persons entitled to prescribe or dispense medicines, and in particular the covering of travel and accommodation costs as a result of such congresses.

g) Incitement to prescribe or dispense medicines through the granting, offering or promise of monetary or in-kind benefits, unless their intrinsic value is minimal.

Subsection 4 below sets out examples of certain activities that would not be subject to said RD 1416/94, as they are not considered to be "advertising of medicines". These are:

a) The labelling of medicinal products and accompanying package leaflets.

b) Correspondence, accompanied where applicable by any non-advertising document required in order to respond to a specific question about a given medicine.

c) Specific information and reference material relating, for example, to pack changes, warnings on adverse reactions in the context of pharmacovigilance, trade catalogues and price lists, provided they include no information on the medicine.

d) Information on human health or diseases, provided there is no reference, even indirect, to a specific medicine.

Regional sectoral regulations

Particular mention should be made in this regard of the initiatives by the Health Department of the Autonomous Government of Catalonia (*Guide for the advertising of medicines for human use*; last update, April 2016), and the Directorate-General for Health of the Autonomous Government of Madrid (Circular 1/2000), the purpose of which is to facilitate the application of legislation on the advertising of medicines for human use, so as to

contribute to and obtain quality advertising, for the benefit of public health interests.

In their interpretation of the provisions of article 1 of RD 1416/94, both regulations specifically include a practice that must not be interpreted as advertising/promotional activity: information.

The Catalan Guide for the advertising of medicines for human use asserts, in its interpretation of RD 1416/94, that the difference between information and advertising lies in the purpose behind the attempt to reach out to the recipient. In this regard it adopts the following approach:

Advertising

when the content offered has the purpose of prescription, dispensation, sale or consumption of a medicine.

Information

the dissemination of new information about a medicine or any material of scientific interest communicated in a manner unconnected with promotional or advertising aspects, through the distribution of original published documentation, without including any type of advertising.

It then goes on explicitly to acknowledge that the following is an example of "information":

Journalistic information of communication professionals in the course of their professional work.

Meanwhile, Circular 1/2000 of the Directorate-General for Health of the Autonomous Region of Madrid acknowledges as "non-advertising information":

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 pharmaceutical company, or owner of the trade mark or of the medicines and the firm responsible for editing or the author of the information. All the foregoing without prejudice to the legislation in force. See also paragraph 19-22 of this Circular, corresponding to "Advertorial Content".

Self-Regulation

As set out in the Code, its scope of application corresponds to 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".

It continues: *"In the field of promotion of medicines for human use, this covers all methods of promotion, including press and direct advertising, activities of pharmaceutical company' employees, the Internet, use of audiovisual material such as films, videos, data storage systems and any others that might arise in the future".*

And the Code specifies that it does not consider promotion of prescription-only medicines:

"Texts written or prepared by journalists as part of their professional work in regular editions, supplements, special issues 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 products launches, press conferences, publications, etc. is presented as a "news item", "interview", "debate", "editorial" or in another similar format, provided that a contractual relationship does not exist between the research pharmaceutical company or owner of the trade mark or medicinal products and the company responsible for publication or the author of the information".

As in the case of national and regional regulations, then, the Code self-regulates communication activity of a promotional nature with reference to a prescription-only medicine, rather than informative communication. As a result, and as already stated, this guide aims to define a practical framework and offer a series of criteria in the task of providing information as to prescription-only medicines and how to conduct the relationship with the media.

03. RIGHT TO INFORM

As with all other legal entities, the law protects the right of pharmaceutical companies to provide all manner of information, including any directly connected with their medicines that are subject to medical prescription.

There are likewise specific rules, such as Royal Legislative Decree 4/2015, approving the recast text of the Securities Market Act applicable to listed companies, which cover the publication of relevant information.

04. PRACTICAL CRITERIA

Having determined the differences between promotion and information, and clarified the right and duty of pharmaceutical companies to inform, this document sets out a series of recommendations, guidelines and practical criteria as to how and when to provide information connected with prescription-only medicines and the relationship between pharmaceutical companies and the media (and media professionals).

Fulfilment of these criteria should help to ensure that communication actions and activities conducted with regard to prescription-only medicines would be considered as informative and not promotional, which should avoid any conflict with the regulation and Self-Regulation of the promotion of medicines.

When to inform

The purpose of information is to disclose a relevant or newsworthy fact. The life-cycle of a prescription-only medicine is subject to numerous events that are significant or subject to be communicated.

The principle of *newsworthiness* establishes that the criteria in order to consider an event newsworthy would include: "novelty; originality, unexpected and previously undisclosed nature; future evolution of events; importance and seriousness; geographical proximity between the event and society; magnitude given the number of people or locations involved; hierarchical status of the figures involved...".¹

According to the regulations in Catalonia and Madrid, the following may be considered newsworthy events:

"information about pharmacotherapy, specific treatments, particular medicines presented as new developments, studies or scientific works or references regarding any medicine, line of research or product launches, press conferences, publications, etc."

There are, then, numerous milestones over the course of the process of research, development and marketing

of a prescription-only medicine that are subject to be presented as information.

These would include:

- Discovery of an innovative molecule.
- Development of a new treatment.
- National and international approvals of a medicine (FDA approval, positive opinion from the EMA, authorisation from the European Commission, etc.).
- Price setting and inclusion within the public funding system.
- New scientific evidence (positive or negative), such as the outcome of a study, that needs to be communicated as a relevant event in accordance with the regulations.
- New indication.
- Loss of patent.
- Adverse effects.
- Product recall...

Any communication actions concerning a prescription-only medicine that does not correspond to a newsworthy event may be interpreted as an activity with promotional or advertising components.

How to inform

The conveyance of information may be performed in two ways: by means of a written or audiovisual platform (informative materials) or verbally (spokespeople).

Informative Materials

Informative materials are tools devised with the aim of disseminating a newsworthy fact. There are various platforms used to develop such informative materials, and technological progress will provide ever more means of providing information.

This document therefore does not aim to list the existing types of informative materials (press releases, announcements, photographic news features, videos, infographics, posts, tweets, etc.), nor the formats or platforms that may be used for this purpose, but rather to

¹ Periodismo, noticia y noticiabilidad (2000). Martini, Stella

offer a series of recommendations and practical guidelines to ensure that the contents are purely informative.

1. First, they must as a prerequisite correspond to one or more newsworthy facts (in this case connected with prescription-only medicines), based on proven scientific data rather than opinions, and at all times including references to the original information on which they are based (if any), in order to allow the journalist to ascertain their veracity.
 2. It must be quite clear which entity, organisation or enterprise is disseminating the information, irrespective of whether this is done directly or through third parties. It would therefore be essential to indicate the contact details of those responsible for the communication, or in default thereof, designated individuals with responsibility, in order to allow journalists to confirm the information.
 3. The trade mark of a medicine has informative value, and so may be cited in any materials produced. In any event, in order to safeguard the informative nature of the material, the recommendation is that pharmaceutical companies should take into account the following measures:
 - a) The trade mark should only be cited if the medicine has a positive opinion from the EMA. Never before, even if the pharmaceutical company has already made a firm proposal to said agency.
 - b) For information prior to the positive opinion from the EMA, only the active ingredient should be used, with the Official Spanish Designation taking priority. If this does not yet exist, then the International Non-proprietary Name (INN) could be used. Lastly, only in those cases where the WHO has not yet granted the compound an INN, use could be made of the pharmaceutical company's own designation or, if preferred, the IUPAC nomenclature².
 - c) If a newsworthy and relevant fact is announced about a medicine in countries outside the European Union that has not yet been authorized in any country of the EU itself, references may be made to the trade name, while specifying that the designation in question has been awarded in the specific country involved.
 - d) To avoid possible misinterpretations as to the purpose of informative material that might be susceptible to be considered promotional, the trade name or active ingredient must be cited in moderation, preferably once or at the most twice, aiming to replace this with generic terms such as medicine, drug, innovation, molecule, etc. and normally avoiding any mention in the headlines. The name of the medicine is not the main news item, except in certain cases, such as a recall, for example.
 4. Informative materials may contain direct or indirect quotations from individuals or organisations, whether internal or external:
 - a) Internal quotations are left up to the company's judgment. If they are used, they must be from duly identified and accredited sources at the pharmaceutical company. Assertions about the medicine must be avoided unless there is scientific basis in support of them, including references to potential benefits for patients, of whatever nature, unless they are proven. The expression of opinions about any aspect of the medicine must be avoided.
 - b) If external sources are drawn on to provide quotations about a prescription-only medicine, these may be scientific or medical bodies (Healthcare Organizations, international or national organisations, universities, hospitals, etc.) or individuals, such as accredited Healthcare Professionals or those from the field of research. The quotation should be based on scientific aspects and be supported by demonstrable clinical or medical data. If the source has any type of contractual relationship with the company, this must be specified and a declaration of interests must be issued and included in the informative material.
- If quotations are used from other external sources comprising other types of body (Patient Organisations, consumer organisations, etc.) or individuals (patients, relatives, carers, etc.), reference must never be made to the medicine covered by the information, and they should instead recount their experience with the disease and how it or its consequences affect them in their daily life. In the case of patients, it should be done through Patient Organisations, while in exceptional and justified cases, individual patients may be used.

2 The IUPAC Nomenclature is a nomenclature system for chemical compounds and for scientific and chemical description in general.

5. Informative material may contain images (photographs, illustrations, graphics, etc.), provided that they would not distort the purely informative objective.

Spokespeople

Spokespeople convey verbal information provided by a company (either directly or through third parties) to a media outlet. This type of activity may be active (through an informative action) or reactive (at the request of the media outlet itself).

1. When an informative action is conducted about a medicine (press conference, involvement at a medical congress, etc.), the company may invite the media to convey information verbally. In such cases, any information that might be provided about a prescription-only medicine may be given by an internal agent at the company (managing director, medical director, etc.) or by an external spokesperson (accredited Healthcare Professional, researcher, etc.). In both cases, the recommendation is to follow the recommendations set out in the subsection on quotations included in the point concerning informative materials in this document:

- a) In the case of an internal spokesperson, assertions about the medicine must be avoided unless there is scientific basis in support of them, including references to potential benefits for patients, of whatever nature, unless they are proven.
- b) For external spokespersons, their references must be based on scientific aspects, and ideally supported by demonstrable clinical or medical data. If the source has any type of contractual relationship with the company, this must be specified during the action, and a declaration of interests issued and included in the informative material.

As in the aforementioned subsection on quotations, if an external spokesperson from some other type of body is used (Patient Organisations, consumer organisations, etc.) or an individual (patient, relative, carer, etc.), reference must never be made to the medicine involved in the information, and they should instead recount their experience with the disease and how it or its consequences affect them in their daily life. Likewise, in the case of patients it should be done through Patient Organizations,

although in exceptional and justified cases, individual patients may be used.

In both cases the data provided by the spokespersons must be supported by the informative materials referring to them, in order to allow the media to corroborate them.

2. Reactive informative actions are those in which the company provides information in response to a request from a media outlet. The offering of information about a prescription-only medicine may be carried out through a very wide range of formulae (interviews, statements, data requests, etc.). In all cases, and even if the offering of information does not go beyond the scope of the article produced by the journalist, the recommendation is to follow the terms set out above: provide proven scientific data without expressing opinions, supported by the informative materials referring to them.

On occasion, the media outlet may also request recommendations from the company as to external statements referring to some aspects connected with the medicine (Healthcare Professionals, patients, etc.). If so, the company may facilitate such contact, by informing the media outlet in question of any relationship that might exist between the pharmaceutical company and those experts.

Which media to provide information to

Fulfilment of the recommendations, guidelines and practical criteria set out above means that to a large extent there is no relevant distinction to be made between general and specialized media outlets, since they could all be susceptible to receive information (whether through informative materials or verbally) concerning a prescription-only medicine. As a result, the media that are to be provided with information would be left to the discretion of the company, in accordance with its individual judgment.

Communication actions combining information and promotion will need to comply with the national and regional regulations in force with reference to the promotion of medicines, as well as the Code of Practice, as the promotional interest will always prevail over the informative interest. As a result, in such cases any communication initiative may only address specialist media outlets for Healthcare Professionals.

Contact with the media:

The relationship between pharmaceutical companies and the media is based on the transmission of information, whether actively or reactively, which accounts for the vast majority of interactions between the two.

However, there are many other forms of collaboration between the two parties, some of which may be provision of a service, usually by a media outlet to the pharmaceutical company.

As set out in previous subsections, this document does not aim to list all types of agreement that a pharmaceutical company might reach with a media outlet, but instead to offer a series of recommendations and practical guidelines for pharmaceutical companies to foster responsible relationships and accurate and rigorous journalism:

1. Collaboration agreements between a company and a media outlet may be of a very diverse nature: from editorial or informative material to advertising or promotional formats.
 - a) Advertising or promotional agreements (whether through advertisements, advertorial, branded content or any other of the existing formulas) will need to comply with the national and regional regulations in force with regard to the promotion of medicines, as well as the Code of Practice.
 - b) Agreements commonly known as editorial agreements must not imply, foster or incite the publication of information in the media outlet in question as to the company's prescription-only medicines.
2. Furthermore there are occasions on which the company invites the media to a press event which includes transport to a venue other than the journalist's place of residence. In such cases the company typically covers the costs of travel, accommodation and meals of the journalists that it invites. To minimise the risk that this could be interpreted as a contractual relationship between the pharmaceutical company responsible for the medicine and the journalist who will potentially be reporting on the event, the recommendation is to adopt the following safeguards:
 - a) The company's Communication Department should handle the invitation of Spanish journalists

to the event, accompanying them during the trip and serving as go-between with the spokespeople.

- b) Informative materials should be adapted into Spanish, taking into account the criteria set out in this document. If the journalist has access to information contained in foreign materials, it should be specified that the materials validated by the company for the Spanish media are those produced ad hoc.
- c) The invitation should explicitly state to the journalist that the funding of the trip does not mean that the media outlet should publish information about the event.

In any case, the journalist (and the media outlet to which they belong) will, in accordance with the relevance of the information received, decide whether or not to publish.
- d) The journalist should be advised that, if they publish information connected with the event, they should clarify that they attended on the invitation of the company and that it financed their trip.
- e) The hospitality offered should always be reasonable and moderate, and be consistent with the terms of article 11 of the Code of Practice.

The value of Communication Departments

Irrespective of whether informative materials and informative actions are produced and developed internally or externally (communication agency), it is the pharmaceutical company which is ultimately responsible for their content. As a result, in accordance with the spirit of this document it is advisable for such activities as far as possible to be developed and overseen by information professionals.

The company's Head of Communication may request medical and scientific supervision of materials in those cases where this is deemed necessary, and in accordance with the criteria established by the company itself.

It is advisable for the Heads of Communication appointed by each company to be information professionals who have the appropriate technical knowledge to decide when an action complies with the requirements to be deemed of informative purpose. As a result, one of this figure's overarching tasks is to ensure that all informative actions and activities do indeed have such informative status.

05. DECALOGUE

1. Pharmaceutical companies are entitled to offer all types of information, including information directly connected with the main object of their activity: medicinal products.

2. The informative activity must correspond to criteria of veracity, honesty and transparency, and be clearly distinguished from promotional initiatives. Information and promotion must not be mixed.

3. Any information actions (whatever the chosen format and channel) about a prescription-only medicine must correspond to a newsworthy event.

4. All information must be based on evidence, not on opinions. It must be complete and must clearly reference the sources on which it is based.

5. The trade mark of a medicine, and the active ingredient, has informative value and may be cited in informative materials, but at all times in a prudent and proportionate manner. This is normally not the main reason for the information.

6. An information action about a prescription-only medicine produced in accordance with the criteria set out may be addressed to any media outlet, whether general interest or specialised.

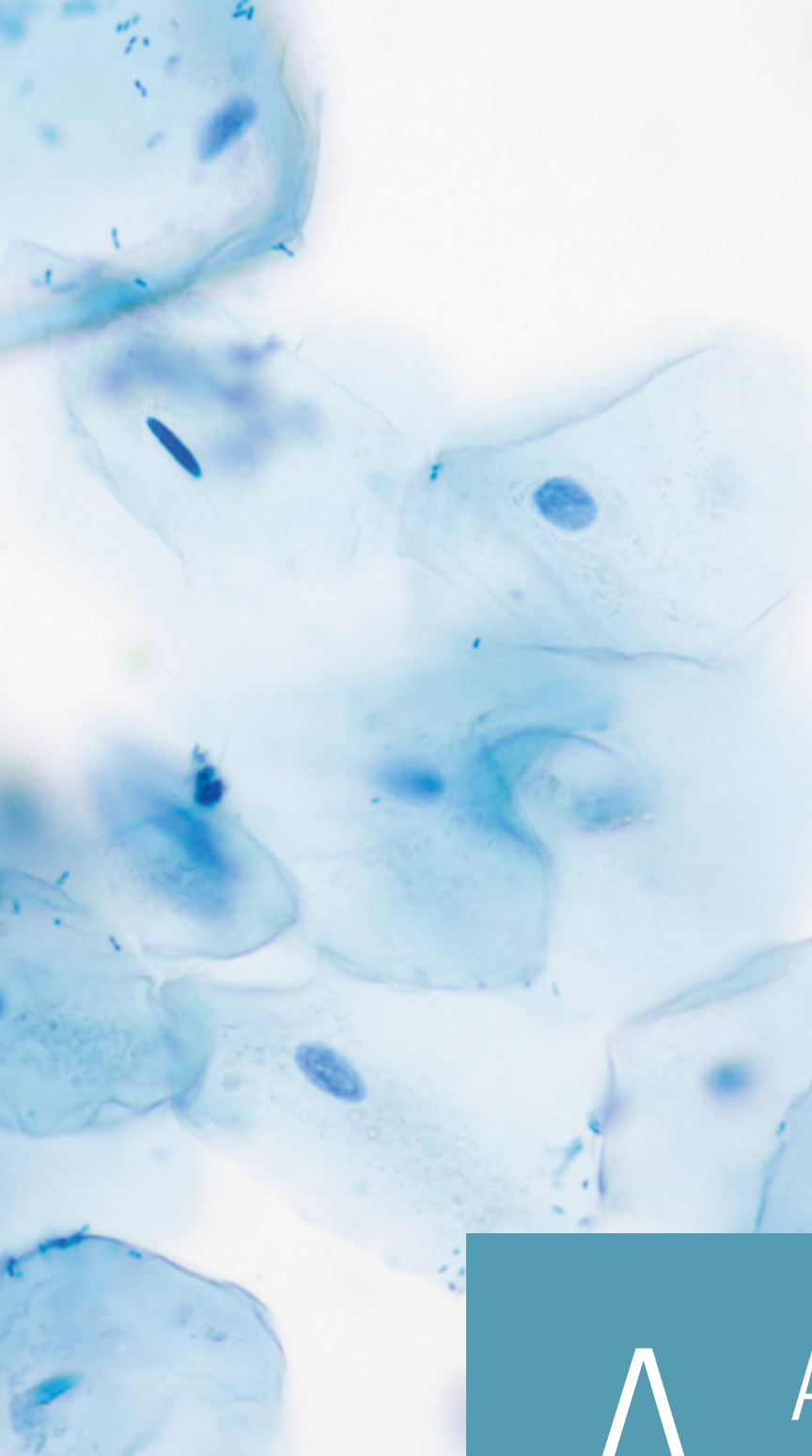
7. If a company invites media representatives to a press event which includes covering the travel, accommodation and meal expenses of the journalists invited, the journalist must be explicitly informed that the funding of the trip does not entail any obligation to publish information.

8. Beyond the transmission of information, there are other forms of equally legitimate collaboration between pharmaceutical company and the media, although no agreement may imply that the media outlet should publish information about prescription-only medicines.

9. Advertising or promotional agreements must comply with the national and regional regulations in force with reference to the promotion of medicines, and the Code of Practice for the Pharmaceutical Industry.

10. The communication actions of a pharmaceutical company must be led by information professionals

belonging to the Communication Departments, with the skills required to distinguish between informative and promotional initiatives.



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Annex IV

Annex IV

Practical guidance and criteria concerning services provided by Healthcare Professionals or by Healthcare Organisations

Healthcare Professionals and Organisations to provide services. In addition, the Code establishes the obligation to communicate such services 10 working days before provision of the service begins.

The unit for the communication of these services will be the Project. For the purposes of this communication, every project will include all services that the company is planning 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.

Communication is mandatory in the case of the services mainly sponsored or financed in by the pharmaceutical company and that involve paid participation of 10 or more Healthcare Professionals.

It should also be recalled that transfers of value made by pharmaceutical companies to Healthcare Professionals and Organisations as a result of the provision of services are subject to the transparency obligations set out in article 18 of the Code.

INTRODUCTION

The interaction between pharmaceutical industry and Healthcare Professionals and Organisations is indispensable. On the one hand, it ensures that Healthcare Professionals refresh and improve their knowledge, while on the other facilitates that biomedical research progress is not interrupted. The exchange of knowledge and clinical experience between Healthcare Professionals and the industry is crucial for research (almost half of R&D investment by the industry in Spain is assigned to collaboration agreements with public and private institutions outside the companies themselves) and for the appropriate use of medicinal products.

These relationships therefore not only serve to keep Spain at the cutting edge of scientific and clinical knowledge, but are also essential so as to maintain the highest level of quality in the healthcare provision received by patients.

In line with the provisions in the EFPIA Code, the FARMAINDUSTRIA Code of Practice for the Pharmaceutical Industry has since 2010 covered the possibility of hiring

PURPOSE

The purpose of this guide is to provide practical guidelines and criteria to assist pharmaceutical companies in complying with the requirements set out in article 16 of the Code.

GENERAL ACTION CRITERIA

Once the execution of these projects has ended, and taking into account their rigorousness, professionalism, quality, etc. and the value that they contribute to the main stakeholders with whom the pharmaceutical industry interacts, the general criterion is to be able to provide public information as to their origin, nature, scope, characteristics and results. In other words, it is desirable and necessary in the origin and underlying purpose of each project that the pharmaceutical company ask itself whether it will be prepared to announce public information as to its details once it has come to an end.

PRACTICAL CRITERIA AND GUIDELINES DEPENDING ON THE TYPE OF SERVICE

By way of example, a list is given of the different formats under which the Code of Practice Surveillance Unit (or 'USD') has over the past nearly 10 years classified those projects that have been communicated by pharmaceutical companies.

Without prejudice to the different typology and classifications of services that may exist, details are given below of a series of practical guidelines and criteria that must be taken into account by pharmaceutical companies, for each of the categories identified by the USD.

(i) CLINICAL CASES:

1. Clinical case competition: an initiative promoting the participation of Healthcare Professionals under specific terms and conditions, with one or more winners being established by means of predefined selection mechanisms. In this type of project, the pharmaceutical company will need to comply with the following requirements:

- Approve sufficiently in advance the publicly available terms and conditions announcing, among other aspects, the organising or sponsoring entities, the conditions for participation, dates, nature, content/topic, minimum number of cases for the competition not to be declared void, value and number of prizes, judging panel appointed to select the winners, etc.
- Prevent these projects from constituting an inducement mechanism. For these purposes, measures will be established as necessary so as to ensure that only the winners of the competition will receive the established economic consideration, in the form of a prize.

2. Clinical case library: In general, this is an initiative aiming to gather together a considerable number of cases so as to make them available to the medical sector with an eminently educational purpose. The sponsoring pharmaceutical company will need to fulfil the following requirements:

- Where necessary, the pharmaceutical company may offer remuneration to a limited number of Healthcare Professionals responsible for reviewing, accepting and selecting the cases that are ultimately published.

- Healthcare Professionals contributing as "case authors" will not receive any type of economic consideration.
- It must be ensured that no confusion is generated with regard to the genuine purpose and nature of the initiative.
- Clear information must be provided in advance as to the minimum requirements imposed for a case to be accepted.
- Information must be given as to the mechanisms or procedures that will be used to disseminate and convey the contents to Healthcare Professionals. This decision will need to be based on criteria of efficiency and optimisation of the available resources.

3. Compilation of clinical cases at the request of a third party: initiative promoted by a third party outside the pharmaceutical company (such as a scientific society), the aim or purpose of which is to publish clinical cases connected with a particular subject or content matter. Irrespective of the format used for execution and dissemination, the pharmaceutical company will need to fulfil the following requirements:

- Limit its collaboration solely to covering the cost of purely logistical aspects, such as editorial and printing expenses, creation and maintenance of the IT platform.
- Explicitly call on the promoter to seek out other additional sponsors (multiple sponsorship), so as to guarantee and underpin the independence of the Project.

(ii) EXPERT MEETINGS/ADVISORY BOARDS

These are advice or consultancy services provided on a distinctly personal basis and which because of their nature require a qualified professional with a high level of knowledge and technical expertise on their professional field. They are typically services involving a small number of professionals acting as experts, with higher levels of remuneration and with planning and contracts established further in advance.

In this regard, the pharmaceutical company must:

- Establish rigorous selection criteria demonstrating, among other aspects, the level of knowledge, experience, qualifications, prestige, etc. of the hired professionals.

- Refrain from basing their selection purely on general selection criteria which would be insufficient to demonstrate the degree of knowledge or qualifications of the professional to be hired (such as geographical location, years of practice, active practice, etc.).

(iii) EDUCACIONAL PROJECTS

These are projects organised or mainly sponsored by a pharmaceutical company, the aim or purpose of which is to disseminate scientific/professional content of use to Healthcare Professionals.

Usually they involve: (a) the preparation of a "slide-kit" presentation approved by the scientific service/medical department of the pharmaceutical company; (b) training for a number of Healthcare Professionals with regard to the content of said presentation; (c) remunerated speaker contracts for those Healthcare Professionals who have previously received such training, so that they disseminate such content to other Healthcare Professionals; and (d) meetings that share methodology, structure and content.

Meetings held within the context of this type of project tend to be given a range of names (workshops, sessions, seminars, courses, etc.), although they all pursue the same shared goal: "train the trainers".

Without prejudice to the fulfilment of any requirements that might be imposed, the pharmaceutical company must adopt the following measures:

- Remunerate only those Healthcare Professionals who actively collaborate in the educational activity (speakers, authors of the educational materials).
- Each meeting must fulfil the speaker/attendee ratio established internally by the pharmaceutical company.
- Have a record or similar detailing, among other aspects, the total number of educational activities undertaken within the context of the Project, number of attendees per activity, evaluation of the educational activity by the attendees (for example, through a quality survey). For educational activities conducted at the request of a Healthcare Organisation, have an evaluation issued by the Healthcare Organisation itself.
- Comply with the hospitality and meetings rules detailed in article 11 of the Code.

(iv) PUBLICATIONS

This refers to remuneration contracts for Healthcare Professionals in order to promote the creation and preparation of scientific materials for subsequent publication. The inclusion and content of such materials must be subject to the independent review processes used by each publication (commonly known as peer review).

The material must, among other aspects, state potential conflicts of interest, and the contribution by the pharmaceutical company, specifying its nature and scope (logistical, medical authorship and/or payments to the authors).

Unless it is the sponsor of a study covered by the publication, the pharmaceutical company is not involved in and does not supervise authorship. If the pharmaceutical company supports or contributes to medical authorship, this will be via an independent specialist.

This type of publication includes a limited number of authors, who have made a significant contribution in the preparation of its contents.

In this type of Project, the pharmaceutical company will need to adopt the following measures:

- Delegate management to an academic or scientific entity which will be responsible for, among other aspects, setting and objectively justifying the number of contributors, and directing the work and outcome.
- Delegate the selection and designation of the contributing Healthcare Professionals to an independent body. Verify that said selection is conducted on the basis of objective criteria.
- Manage and coordinate execution via the medical department.
- Allow the involvement of other sponsors.
- Support this type of project only in the case of independent publications of established reputation.
- Evaluate the outcome of the project, the level of dissemination and acknowledgement achieved.

OTHER PRACTICAL QUESTIONS

In line with the document approved by IFPMA¹ "Note for Guidance on Fees for Services", and in order to ensure that the contracted services are consistent with the terms of article 16 of the Code and its supplementary rules,

The pharmaceutical company must be able to answer "yes" to the following questions:

1. Are all those involved in providing the services (company employees, third parties and consultants) clear on the legitimate need and intended purpose?
2. Has the company evaluated the consultant selection criteria to ensure their suitability and qualifications?
3. Is the intended remuneration for the consultants consistent with objective criteria defined and approved by the pharmaceutical company as the "fair market value"?
4. If there is a connection with an unlicensed/unapproved medicine/indication, is the pharmaceutical company confident that the service (including its design, content, provision, etc.) does not directly or indirectly constitute a promotional activity of that unlicensed/unapproved medicine/indication?
5. Has it been verified whether, if a service is considered to be part of the consultant usual duties, this consultant should not receive any type of remuneration? (For example, a departmental head training their own team.)
6. Are all organisational and logistical aspects connected with provision of the service consistent with the Code (hospitality: site or venue for provision of the service, travel, accommodation, meals and personal/subsistence/pocket expenses, agreed general expenses)?
7. Have measures been adopted to avoid any potential conflict of interest, and to ensure the transparency of the interrelationship/collaboration covered by the service provision agreement?
 - a) Does the agreement require the consultant to obtain the authorisation from their regular employer, or other forms of consent as applicable (such as authorisation from the employer to provide the service during working hours)?
- b) Does the agreement specify the obligation for the consultant to declare their relationship with the pharmaceutical company every time that they write or issue a statement in public about any matter covered by the agreement?
- c) Have measures been adopted to ensure that the presentation (in the case of speakers) or the publication (in the case of consultants), provides clear, visible and transparent information as to the company/companies with which the healthcare professional has entered a contractual agreement for the provision of these services?
8. On an annual basis, are the number of occasions on which a single person has been hired and the total remuneration paid to them reasonable?
 - a) Has the pharmaceutical company adopted measures to ensure that both the frequency with which it hires Healthcare Professionals and the total payments made to them are reasonable? Do these measures prevent the risk of such contracts being perceived as "undue influence"?

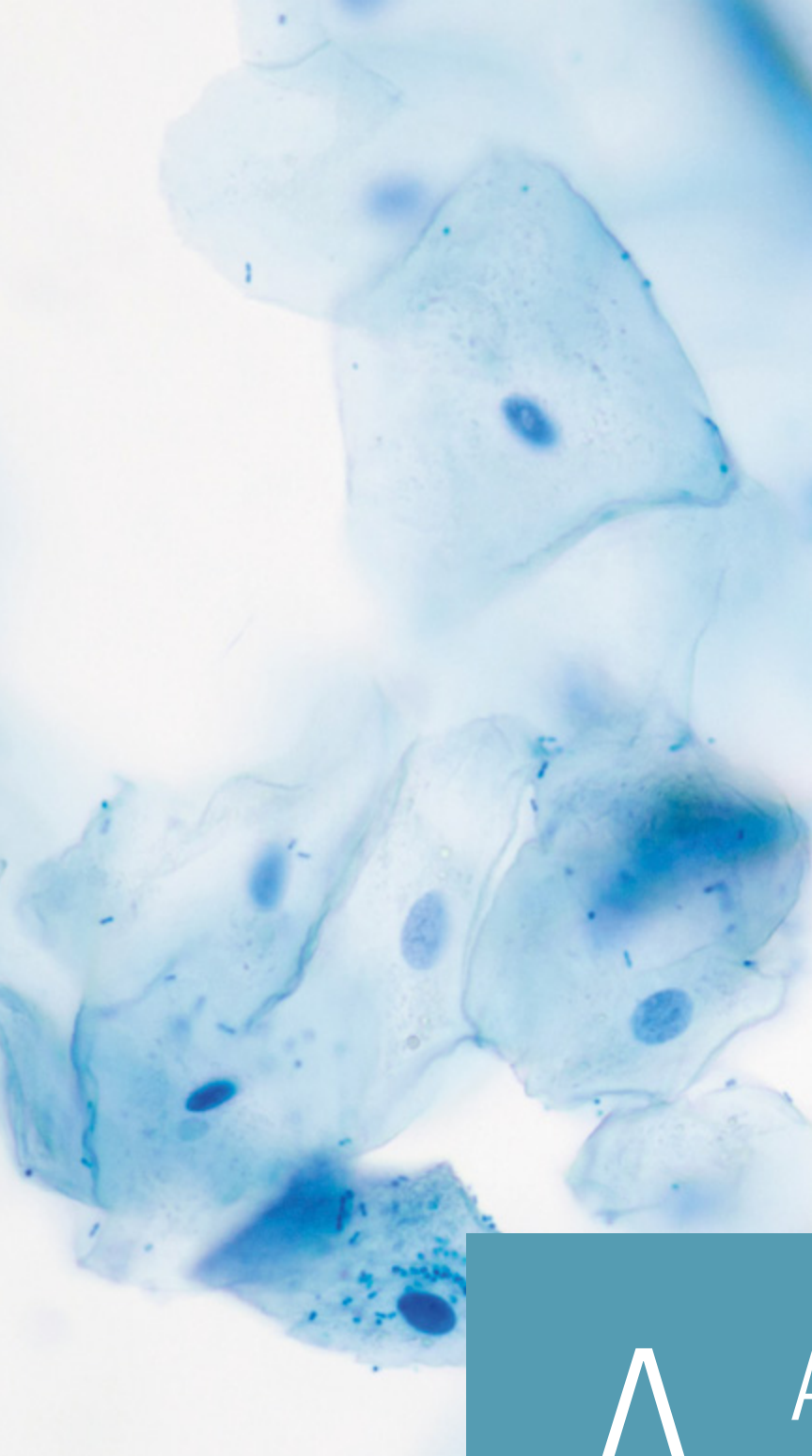
For example, those measures may be: (i) internal procedures establishing limits or CAPS; (ii) inclusion in the agreement a declaration of responsibility under the terms of which the Healthcare Professional hired explicitly states that the total amount received from the pharmaceutical company during the year does not exceed a certain percentage of his/her annual income.
 - b) Have measures been adopted to avoid the recurrent and excessive hiring of the same Healthcare Professionals, when there are others with the same level of expertise, qualifications and availability?
- In the case of "Expert Meetings/Advisory Boards" (a type of service defined above), and without prejudice to compliance with the terms of article 16 of the Code and its supplementary rules, and as detailed throughout this guide, the pharmaceutical company **must be able to answer "yes" to the following questions:**
 9. Is there really an unanswered business matter that the pharmaceutical company needs to resolve and that would justify the contracting of this type of service?

¹ International Federation of Pharmaceutical Manufacturers and Associations: IFPMA Note for Guidance on Fees for Services January 24, 2020

10. Is this type of service ("Expert Meetings/Advisory Boards") the most appropriate way of obtaining the information?
11. Does the pharmaceutical company firmly believe that the only way to satisfy its "legitimate need" is by contracting this type of service?
12. Are the number of experts hired and the number of meetings scheduled strictly necessary and limited to achieve the intended purpose?
13. Do the experts hired have in place all the qualifications, experience and scientific/technical expertise required in order to make a significant contribution to the purpose and the expected outcome of the service?
14. Do the number of experts hired and the designed methodology for provision of the service promote and allow active participation by all of them?
15. Does the structure and design of each meeting prove efficient? Is there enough time for discussion? Is most of the time spent gathering experts feedback and opinions?
16. Before provision of the service begins, are the hired experts provided with clear information and instructions regarding the purpose of the service, the expected advisory role, and the workload to be undertaken?
17. Is the documentation (presentations, articles, etc.) that the pharmaceutical plans to provide to the experts relevant for the established object of their hiring: "consultancy/advise about a specific business question/matter"?
22. How are the outcomes documented? What use will be made of the conclusions/recommendations report?
23. If the pharmaceutical company has contracted such services (expert meetings/advisory boards) during the previous 12 months for the same treatment area/ medicinal product, are there clear reasons justifying a renewed contract?

Additional questions to be taken into account by pharmaceutical companies

18. Does the pharmaceutical company really need to hire this type of "expert meeting/advisory board" service, or could the information be obtained any other way?
19. Are the consultants expected to do prior preparatory work?
20. What criteria were used to select the consultants?
21. If participation or attendance by representatives of the pharmaceutical company is planned at the expert



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Annex V

Annex V

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 pharmaceutical 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. 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. Therefore each new version entirely replaces the previous one.

This document has been approved by FARMAINDUSTRIAS' Board of Directors 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 the Law mentioned and invitations aimed at them shall respect the Code's provisions.

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 pharmaceutical 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. Irrespective of the exclusively corporate/institutional nature or character of such activities, the fact that they are mainly targeted to Healthcare Professionals means that the limits set out in the Code are applicable.

In this sense, such activities would constitute an improper incentive and a form of hospitality contrary to the Code.

5. Are provisions of the Code (including compulsory notification) applicable to market research studies or services carried out by pharmaceutical companies when not directly related to a prescription-only medicine? (For example: a market study to find out what the pharmaceutical 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 pharmaceutical 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.

7. Are originals, reprints and/or literal translations of scientific articles and/or abstracts published in scientific sources of established reputation are considered to be non-promotional scientific information? If so, can they be distributed to Healthcare Professionals even if their content is connected with a medicine or indication pending marketing authorization?

This type of material is considered to be non-promotional scientific information provided if: (i) it has not been manipulated or altered and (ii) it does not additionally include printed or recorded materials or electronic links (or similar), nor the name of medicines, or brands, or advertising slogans, or any other advertising material, whether or not connected with such information.

The distribution of this type of informative material to Healthcare Professionals (including those with contents connected with medicines or indications pending authorization) is permitted provided that the conditions detailed in the above paragraph are respected, guaranteeing the informative and non-promotional character and nature thereof.

ARTICLE 1. MARKETING AUTHORIZATION FOR MEDICINES

8. Can a pharmaceutical 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 pharmaceutical 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.

9. 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 pharmaceutical 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 pharmaceutical company taking place on occasion of a congress or a presentation delivered by a doctor hired by a pharmaceutical 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 pharmaceutical company from informing in a balanced manner about its pipeline on occasion of a scientific congress. It shall then be the pharmaceutical 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

10. What aspects should pharmaceutical companies take into account in terms of information and promotion in the case of new medicines or new indications?

A distinction should be made between information and promotional activities.

Current legislation does not establish limits on the right of pharmaceutical companies to inform about scientific and technical advances, including those that are directly related to new medicines or new indications. In this regard, there are certain activities which, lacking the purpose envisaged in the definition of advertising, are considered by the health authorities themselves to be informative (non-promotional) activities, such as, for example:

- The delivery of the summary of product characteristics or any other type of public information published on the official website of the European Medicines Agency (EMA) or the Spanish Agency of Medicines and Medical Devices (AEMPS in its Spanish acronym).

- The provision of originals, offprints or literal translations of scientific articles or their abstracts published in scientific sources of recognised prestige or at congresses, provided that they are not modified and do not include promotional elements.

With regard to the right of pharmaceutical companies to promote new medicines or new indications, current legislation requires them to have the corresponding marketing authorisation issued by the European Commission, following the opinion of the EMA, in centralised procedures, or by the AEMPS, in other cases.

In addition, Royal Decree 1416/1994 of 25 June 1994, which regulates the advertising of medicinal products for human use, also requires advertising to include the retail price, the reimbursement conditions of the National Health System (SNS in its Spanish acronym), where applicable, and, where possible, the estimated cost of the treatment.

In cases where, following marketing authorisation, a resolution on financing and price is pending in the SNS, the promotion of a new medicine or a new indication does not constitute an infringement of the Code provided that the advertising aimed at persons authorised to prescribe or dispense medicines includes information on this circumstance.

ARTICLE 3. INFORMATION ON MEDICINES AND ITS SUBSTANTATION

11. 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.

Pharmaceutical 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 offprints of scientific articles).

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

ARTICLE 8. DIGITAL ENVIRONMENT

12. What measures must pharmaceutical companies adopt with regard to social media usage and participation by their employees?

Pharmaceutical companies must have in place behavioural standards and guides intended for their employees and third parties acting on their behalf, or under their control, or by virtue of a signed agreement, establishing guidelines for responsible conduct in the digital environment, both when sharing information about or in the name of the pharmaceutical company and when using a medium, platform or channel provided by it.

They must likewise train their employees regarding the characteristics, functionality, recipients, risks, limitations, terms and conditions of the main social media networks which exist, both public and private, so as to prevent and avoid any conduct that could be contrary to the Code (such as promotion of prescription-only medicines to the general public, promotion beyond the technical data sheet - off label-, etc.).

It is important for pharmaceutical companies to remind their employees and third parties acting on their behalf, or under their control, or by virtue of a signed agreement, as to their responsibility as users of social media.

In any event, the internal procedures of the pharmaceutical company must cover the obligation promptly and diligently to correct any irregularity.

13. May the pharmaceutical company, its employees, or third parties acting on its behalf, or under its control or by virtue of a signed agreement, distribute via social media the content reproduced during meetings organised or mainly sponsored by the pharmaceutical company? What about the attendants at such meetings?

The pharmaceutical company will be responsible for all content reproduced during this type of meeting. In this regard, depending on the nature and scope of the content, measures will need to be adopted with regard to the presentation and subsequent dissemination thereof.

In the case of promotional content connected with prescription-only medicines, such measures will need to guarantee that both the presentation and subsequent dissemination thereof are confined solely to Healthcare Professionals entitled to prescribe or dispense this type of product. Open-access social media platforms that do not guarantee the restriction or limitation of the recipients of the content must therefore not be used for presentation and dissemination.

These requirements are applicable both to the pharmaceutical company and to its employees or third parties acting on its behalf, or under its control, or by virtue of a signed agreement. As a result, the signed agreements or contracts must, among other aspects, include a clause under the terms of which the parties explicitly acknowledge that they are familiar with their rights, obligations and responsibilities if they are users of social media.

With regard to the use or dissemination of content from the meeting by the attendees, the pharmaceutical company is likewise advised to adopt some type of measure that would serve to accredit that they have been informed of their rights, obligations and responsibilities, if they are social media users.

By way of example, these measures could include the following: (i) include visible, clear and unequivocal messages as to the limitations on the use of content; (ii) make possible attendance or participation conditional on prior acceptance of the rights, obligations and responsibilities with regard to social media; (iii) commitment to request explicit authorisation from the pharmaceutical company before using or disseminating content from the meeting, etc.

ARTICLE 10. GUARANTEES OF INDEPENDENCE

14. 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.

15. 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.

16. 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.

17. 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.

18. 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).

19. 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.

20. 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.

21. Is it allowed to provide Healthcare Professionals with a box of candy including the name of the pharmaceutical company on the sweets' wrapping contained within a box similar to that of the packaging of a medicine marketed by the pharmaceutical 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.

22. 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 pharmaceutical 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.

23. 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.

24. 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 pharmaceutical company. 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 pharmaceutical companies with distributors, pharmacy offices and Healthcare Organisations are outside the scope of the Code.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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 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.

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

Yes. This amount includes taxes.

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

The Market Price is, according 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.

36. What is the criteria a pharmaceutical 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...).

37. 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.

The Efpia Code bans any collaboration that alters its recipient's routine business practices. As a general rule, it

has to be the Healthcare Professional or his employer the ones that defray or fund this type of collaborations.

As an exception, pharmaceutical companies may defray or fund this type of collaborations if they originate and are carried out due to the execution of a service. In these cases, the contract under which the service is provided shall regulate this type of expenses, and such Transfers of Value shall be published, in compliance with article 18, as "related expenses agreed in the fee for service or consultancy contract".

38. In the case of a pharmaceutical 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.).

39. Can a pharmaceutical 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).

40. 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.

41. 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-informational material of a scientific nature to which end a flash drive is used.

42. 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.

43. 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.

44. What criteria should pharmaceutical 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 n° 32, 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.

45. Would the general reference to a therapeutic area of the pharmaceutical company fall within the concept of corporate/institutional advertising, such as in: “name of the pharmaceutical 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.

46. 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.

47. 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

48. 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 meetings 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.).

49. 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 meeting, 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 meetings 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.

50. 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.

51. 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.).

52. The company's parent company decides to invite a group of researchers to an important scientific meeting 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 meetings, attendance of Spanish professional doctors outside of the European Union may be sponsored provided that provisions of the Code are met.

53. 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 meetings 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 meetings taking place outside of Spain, the maximum threshold established by the National Association of the country where the meeting 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.

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

Although the organisation of meetings corresponds to scientific societies, pharmaceutical companies must always take into account the image that these meetings 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 meeting (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 meetings organised by third parties, the pharmaceutical industry

should not participate or collaborate when these promote attendance of accompanying persons.

55. 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.

56. 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.

Pharmaceutical 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.

Pharmaceutical 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 meeting listing available in FARMAINDUSTRIA's website.

57. What criteria should be taken into account by pharmaceutical 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 pharmaceutical 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 meetings held outside of Spain, notwithstanding that additional criteria may be taken into account, such as security, local criteria of rating and classification, etc.

58. 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.

59. 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 meeting and level of hospitality. Holding a meeting 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 meeting convey an appropriate image of the pharmaceutical industry.

60. 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 meetings outside of Spain?

The particular aspects of each case must always be analysed. A good scale to assess a meeting is to think whether the organising company would be willing to make all of the details of the meeting widely known to the public. Some examples of meetings 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 pharmaceutical company in the location holding the congress; attendance to the meeting 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.

61. Are international meetings 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 pharmaceutical company.

A product presentation is one of the possible scientific meetings foreseen in the Code. The organising of a meeting 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.

62. 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.

63. 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 meeting's complexity so advises. The agency organising the congress or the agency with whom the pharmaceutical 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.

64. 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.

65. 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.).

66. 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.

67. Should a pharmaceutical 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 pharmaceutical 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.

68. 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 pharmaceutical 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.

69. 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 a meeting, this will be considered a full-time meeting, in which case the scientific content of the programme shall be at least 4 hours and 45 minutes long.

There can be half-day meetings (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.

70. Can a foreign entity, linked to or sponsored by a pharmaceutical company based in Spain, invite Healthcare Professionals practicing in Spain to a meeting of a scientific and promotional nature taking place in Spain or abroad?

Yes, provided that the scientific and promotional meeting complies with the Code of Practice for the Pharmaceutical Industry. In such cases, pharmaceutical companies based in Spain, linked to foreign entities that have invited Healthcare Professionals practicing in Spain to a meeting 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.

71. 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).

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

Rest areas, understanding as such those spaces provided in scientific meetings with the aim of allowing, during the holding of the meeting, 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 meeting, must meet the following conditions:

- They shall contribute to professional scientific exchange among meeting 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.

73. Should a pharmaceutical company provide prior notification to the Surveillance Unit of a scientific meeting 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, meetings 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 meeting 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 meeting to be organised by a company or in which participation is foreseen.

74. 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?

1) 4* hotels as a general rule.

2) Possibility of holding the meetings 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 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 meetings organised by a pharmaceutical company taking place both in Spain and abroad, where applicable.

75. 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?

Pharmaceutical 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 nº 63 of Annex V, Queries (Questions-Answers), it is not allowed to make available to the Healthcare Professional the pharmaceutical 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 meetings is forbidden for meetings organised by pharmaceutical companies and, for those meetings 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 nº 54, companies shall not contribute to the presence of accompanying persons.

76. 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 pharmaceutical company? That is to say, should a congress organised by a third party and sponsored by several pharmaceutical 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 a meeting contributing over 50% of the total cost of the meeting.

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 pharmaceutical 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 pharmaceutical company is the majority sponsor, it shall provide prior notification even if the meeting is organised by a third party (scientific societies).

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

77. 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 meeting.

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.).

78. 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 education 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.

79. Is there any case in which meetings organised or sponsored in the majority by a pharmaceutical company – including meetings 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).

80. 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, Inssbruck, 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 meetings 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 meeting 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 meeting 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 meeting. 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 meeting.

81. In the case of meetings 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 meetings 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 a meeting does not justify the payment of fees.

82. Do the rules of article 11 apply to educational activities and scientific-professional meetings conducted on a virtual basis, digital initiatives or multi-channel training activities, such as videoconferences, courses or content available online, via streaming or download, virtual communities, etc.?

Although in-person meetings are the most typical, it is true that the current trend, driven by new technologies and cost-cutting policies, is moving towards remote educational activities in the digital environment. The content of these new activities must be the prevailing factor, and as a result, since they are educational activities, they are subject to the principles of the Code, including the provisions of article 11 "scientific and professional meetings" and article 8 "digital environment".

The definition of "meeting" at the beginning of the Code in fact includes both in-personal and remote educational courses.

At educational activities or scientific-professional meetings conducted in virtual or remote format, no type of hospitality should be offered (social events, travel, accommodation and/or personal/subsistence/pocket expenses). This general principle applies both to meetings organised or mainly sponsored by a pharmaceutical company, and to meetings organised by third parties.

83. How should the hospitality/meal budget be calculated within the context of the company organized/mainly sponsored meeting, in order to ensure that the established limit of €60 (plus VAT) per meal is not exceeded, if the meeting and hospitality take place in a venue which does not have a restaurant service nor the required facilities to offer this?

In this case, in order to calculate the cost per meal then consideration must be given to those expenses directly connected with and imputable to the lunch/meal in question, excluding from said calculation any other more general expenses that the pharmaceutical company would necessarily be required to incur, irrespective of whether any type of hospitality is offered. In this regard, by way of example, consideration must be given to the costs of tableware and waiters or the supplement for the transportation of food, but not the cleaning, security, wardrobe or door staff of the venue.

ARTICLE 15. DONATIONS AND GRANTS

84. 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.

85. 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

86. 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 pharmaceutical 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 pharmaceutical 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.

87. 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 pharmaceutical company for the benefit of a Recipient when the company knows or can identify such Recipient*".

The pharmaceutical company shall in all cases comply with provisions of article 18 of the Code regarding disclosure of such Transfer of Value.

ARTICLE 17. RELATIONSHIP WITH PATIENT ORGANISATIONS

88. May materials or publications targeted at patients and sponsored by a pharmaceutical company include a section concerning treatments? If so, what requirements must be fulfilled?

Materials or publications targeted at patients may be connected with patient health, with specific disease, with hygiene-healthcare measures, or with healthy lifestyles. In short, such materials must serve to help patients better understand the course of their disease and to enhance their quality of life.

Their content, text, design and characteristics in general must clearly demonstrate their main objective and purpose: a support tool for people affected by a particular disease. They will in any event include visible warning messages/disclaimers stating that: (i) their contents must not be construed as a potential substitute for a diagnosis performed by a Healthcare Professional, and that in the event of any query regarding their contents, the recipient should contact their Healthcare Professional, and (ii) that the publication is intended to offer explanatory guidance, and that the recipient must therefore not undergo treatments or follow advice without first contacting a Healthcare Professional.

In the event that this type of educational and/or informative materials include a section concerning treatments, the

recommendation is furthermore to comply with the following requirements:

- Include balanced, accurate and objective information about the available authorised treatments for the disease/pathology in question.
- The reference made to available treatments should be general in nature. For example, in the event that there are authorised medicines they must be referred to as "pharmacological treatment". References to specific medicines, active ingredients, trade marks or similar must not be included.
- Have in place multiple sponsors or collaborators (such as healthcare authorities, pharmaceutical companies, Patient Organisations, scientific societies, companies belonging to other sectors, etc.).
- The content, text, design characteristics of the material must not give rise to doubts as to its intended recipients (patients), and the educational and/or informative nature, character and purpose thereof (non-promotional).
- In the event that such materials or publications are to be distributed at public health centers, their contents should first be shared with the healthcare authorities.

89. May pharmaceutical companies sponsor and collaborate with charitable sporting activities conducted or promoted by Patient Organisations?

One of the aims of the Code is to ensure that the interaction/relationship between pharmaceutical companies and Patient Organisations is conducted in accordance with the strictest ethical principles of professionalism and responsibility.

The need is in this regard to distinguish between Patient Organisation activities intended for patients and their carers and that have a educational and informative nature and purpose (governed by article 17.8 of the Code), and those other activities intended for the general population, with a charitable nature and purpose.

To the extent that the Patient Organisation adopts the necessary measures to maintain and respect this distinction, pharmaceutical companies may collaborate with charitable sporting activities. In any event, the sponsorship or collaboration must be corporate or institutional.

ARTICLE 18. TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY'S RELATIONSHIPS

90. Are observational studies included in the category of Transfers of Value related to Research and Development under article 18?

Observational studies are regulated by article 14.2 of the Code. Likewise, the definition of "Research and Development" includes: activities associated with the design or execution of (i) preclinical studies (as defined by the OECD in "Principles of Good Laboratory Practice"), (ii) clinical trials (as defined in Regulation (EU) No. 536/2014, Royal Decree 1090/2015, and covered by article 14.1 of the Code), and (iii) observational studies with medicinal products (covered by article 14.2 of the Code).

As an exception to the terms set out in the above paragraph, Transfers of Value made to Healthcare Organisations and to Healthcare Professionals connected with observational studies with medicinal products of a retrospective nature, which are nonetheless considered Research and Development, must be published individually by pharmaceutical companies under the category "provision of services".

91. 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.

92. Regarding Healthcare Organisations, what information should be included in the Disclosure Template (Annex II) in the column "registration fees" of the category "contribution to educational and scientific meetings"?

Those Transfers of Value made by the pharmaceutical 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 pharmaceutical company neither selects nor has the possibility of knowing which Healthcare Professionals are finally benefitting from its collaboration.

For the purpose of disclosing those Transfers of Value, the pharmaceutical company should bear in mind what is stated in article 18 of the Code (“general principle establishing that information must be disclosed on an individual basis, identifying the Healthcare Professional”), and in question n° 126.

93. When it is the parent pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 Healthcare Professional or Healthcare Organisations, 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 pharmaceutical company make payments in the same country to the same Healthcare Professional, these payments shall be disclosed in one website; and not separately, arguing that there are different entities of the pharmaceutical company involved.

94. Should Transfers of Value made within the framework of a market research study, where the pharmaceutical 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 pharmaceutical company shall disclose the Transfers of Value under the category “fees for service” on an individual basis complying with article 18 of the Code.

95. 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 pharmaceutical company and Healthcare Professionals.

The pharmaceutical company shall provide information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.6 of the Code.

96. 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 complying with article 18 of the Code.

97. 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 meeting.

98. What information should be disclosed in a meeting organised by a third party when the pharmaceutical company covers 100% of costs such as room rental, hostesses, audiovisuals, etc., and where all Healthcare Professional participants are from such location, there being no Transfers of Value related to accommodation or travel?

The pharmaceutical 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 Healthcare Organisations or third parties appointed by Healthcare Organisations to manage a meeting”).

In a situation such as the one described in the question, no Transfers of Value would be disclosed regarding attendees on an individual basis.

99. What information should be disclosed regarding attendees in an educational meeting organised by a pharmaceutical 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 pharmaceutical 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 pharmaceutical 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, audiovisuals, catering, hostesses, etc.).

100. Should Transfers of Value made through intermediaries be disclosed on an individual basis by pharmaceutical companies?

Transfers of Value shall be disclosed on an individual basis complying with article 18 of the Code.

In the agreements with third parties that are to act on behalf of a pharmaceutical company or on its representation it shall be guaranteed that these disclosure obligations are met. In this sense, it is recommended to pharmaceutical companies that in their agreements with these third entities the measures and provisions guaranteeing compliance with this obligation and with the obligations detailed in questions nº 116 and nº 117 herein. In this regard, pharmaceutical 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.)”.

101. How should a Transfer of Value be disclosed on an individual basis when the fees of a Healthcare Professional for provision of a service are paid to an entity or a legal person (for example: limited company, hospital foundation or scientific society), under Healthcare Organisation or under Healthcare Professional?

The Code of Practice for the Pharmaceutical Industry establishes, as a general principle, the obligation to disclose on an individual basis all the Transfers of Value made, either directly or indirectly through third parties, to Healthcare Professionals. Thus, in accordance with that principle, section 18.1 of the Code establishes that to the maximum extent legally possible and provided that it can be made accurately and consistently, pharmaceutical companies shall disclose this information on an individual basis, identifying the Healthcare Professional (instead of the Healthcare Organisation).

The hiring of Healthcare Professionals for the provision of services is regulated by article 16 of the Code. Said article,

* Legal person: organization or natural person group to whom the law grants independent status differentiated from the one of each of its members or components. Legal persons are usually classified as corporations (societies or associations, depending on having profit or non-profit purposes) foundations, or legal persons subject to public or private law.

in its section 16.1 requires, among others, the compliance of several conditions, “b) the existence of a written contract prior to providing these services”.

An easy and useful criteria for a pharmaceutical company, in order to decide to whom the Transfer of Value should be allocated, and therefore in whose name should be disclosed, is to publish the name of the natural or legal person who signs the contract. In this regard:

- (i) If the pharmaceutical company signs the contract for the provision of services with a natural person acting individually, in its own name and rights, the invoice should be issued in the name of the natural person (including a NIF number).
- (ii) In case a legal person (*) provides the service, the invoice should be issued in the name of the legal person (including a CIF number).

In the methodological note stipulated in article 18.6 of the Code, the pharmaceutical company shall provide information with regard to the treatment of this Transfers of Value.

In any case, in order to comply with the general principle detailed in the first paragraph, it is the responsibility of each pharmaceutical company to previously verify, using the mechanisms it considers appropriate: (i) the characteristics, structure, bylaws, goals and corporate purposes, etc. of each Healthcare Organisation with whom plans to contract, and (ii) if, according to their scope and nature, it is deemed appropriate to contract those services with a legal person (instead of a natural person). In particular, if the service contracted (and the corresponding Transfer of Value) is directly attributable to a certain natural person (Healthcare Professional), the pharmaceutical company shall disclose and assign said Transfer of Value, on an individual basis, which is made to that Healthcare Professional.

102. Sometimes Healthcare Professionals–without intermediation/participation of a Healthcare Organisation – directly request pharmaceutical companies’ sponsorship or collaboration with educational and scientific meetings organised by those Healthcare Professionals individually. Can pharmaceutical companies collaborate/sponsor such activities? If the answer is “yes”, how would Transfers of Value related to such collaboration/sponsorship be disclosed?

Pharmaceutical companies shall not sponsor nor collaborate, directly or indirectly, with educational and scientific meetings organised individually by Healthcare Professionals.

103. Should the amounts disclosed in “Annex II Disclosure Template” be in gross or net?

In compliance with provisions of section 18.6 of the Code, each pharmaceutical 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.

104. The Disclosure Template (“Annex II of the Code”) includes ID/CIF, as fields of mandatory filling. It additionally shows a specific format to follow when filling that field, hiding the first three and last two digits. Should pharmaceutical companies apply the same format when filling this field? Does this procedure implies the use of algorithms for data encryption?

For each Transfer of Value, pharmaceutical companies shall be able to identify the Recipient. For this purpose, in Spain the use of ID/CIF number, as appropriate, was agreed as the unique identifier element.

Using the NIF number (for natural persons) or the CIF number (for legal persons) is more appropriate.

In order to avoid an inappropriate use of this information, pharmaceutical companies decided to publish this identification number partially. Hiding does not mean encrypting; therefore the use of algorithms is not needed.

Each pharmaceutical company shall decide the digits to hide, from a maximum of 5 to a minimum 3.

105. 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 pharmaceutical companies member of FARMAINDUSTRIA and the pharmaceutical 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 pharmaceutical 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.

106. If a pharmaceutical 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 pharmaceutical company shall disclose the Transfers of Value derived from its collaboration for their attendance to the congress on an individual basis complying with article 18 of the Code.

If the identity of the Healthcare Professionals is unknown and the conditions detailed in question nº126 are met, the pharmaceutical company shall disclose the Transfers of Value derived from its collaboration under the category “sponsorship agreements with Healthcare Organisations or third parties appointed by Healthcare Organisations to manage a meeting”.

107. Article 18.6 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.

108. 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 pharmaceutical 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.

109. 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?

Pharmaceutical 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 pharmaceutical company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.6 of the Code.

110. 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.

111. There are sponsorship agreements with Healthcare Organisations that are not directly related to the category of the Disclosure Template (Annex II): 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 pharmaceutical 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 pharmaceutical companies under the category contribution to educational and scientific meetings in

section: "sponsorship agreements with Healthcare Organisations or third parties appointed by Healthcare Organisations to manage a meeting".

At any rate, the pharmaceutical company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.6 of the Code.

112. Are Transfers of Value derived from medicine assessment studies regarded as falling within the definition of Research and Development?

Pharmaceutical 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 pharmaceutical company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.6 of the Code.

113. 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.

114. 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 pharmaceutical company must be in possession of the itemisation of the Transfers of Value included in this category.

115. Should Transfers of Value made by pharmaceutical 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: Transfers of Value made to a technical secretariat hired for the management of an educational activity”.

Yes. These should be regarded as “indirect” Transfers of Value to Healthcare Organisations. In compliance with provisions of article 18.3 of the Code, pharmaceutical companies shall disclose them, in all cases, on an individual basis.

116. What information shall pharmaceutical companies provide to Healthcare Professionals, whose data are to be published, in order to comply with the Organic Law 3/2018, of 5th December, for Personal Data Protection and Guarantee of Digital Rights?

Before carrying out any activity or practice that implies a Transfer of Value to Healthcare Professionals, the pharmaceutical company should inform those Healthcare Professionals, that their data will be published in accordance with the transparency obligations and following the rules, stated in article 18 of the Code, in an expressly, accurately, and unequivocally manner.

When informing those Healthcare Professionals whose data will be disclosed, pharmaceutical companies should expressly mention that its publication is based on the following principles:

- Appropriateness and relevance: the data to be published are the minimum and strictly needed for the purposes for which they have been collected.
- Purpose-oriented character: the use of that data is exclusively limited to comply with the Code transparency purposes and obligations.
- Accuracy: when collected, the information was accurate and responds to a truthful situation.

Standard provisions are available for pharmaceutical companies, in order to help them to comply with the obligation to inform Healthcare Professionals.

Moreover, the information provided should include the possibility of exercising the data protection rights as established in articles 15 and following of Regulation 2016/679, of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with

regard to the processing of personal data and on the free movement of such data.

117. How are data protection rights exercised by Healthcare Professionals?

Healthcare Professionals may freely exercise their data protection rights as detailed in articles 15 to 22 of the General Data Protection Regulation. Briefly, these rights include: Access (find the data you have the pharmaceutical company and which are to be published), Rectification (correct mistakes materials), Suppression (block data processing in accordance with the provisions of the Law), Limitation (to challenge the processing of data as it is considered excessive for the purposes pursued), Portability (to request an electronic copy of personal data), and Opposition (to object to the processing of personal data).

In reference to the Opposition right, it should be noted that, as stated in Spanish Data Protection Agency (AEPD) Report, of 22 April (Annex I of the Code), if a Healthcare Professional exercising this right justifies to the pharmaceutical company the existence of serious and legitimate grounds relating to a specific personal situation determining that, the reversal of the rule of balancing should apply, not prevailing the transparency legitimate interest that covers its publication, the company shall exclude that Healthcare Professional data and disclose it, exceptionally, on an aggregate basis.

118. Are travel agencies, technical secretaries, service providers, covered by Healthcare Organization definition?

The Code defines Healthcare Organisation as: “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”. Notwithstanding the above mentioned definition, it seems reasonable to consider Healthcare Organizations as those entities that mainly have, corporate purposes, aims and activities, among others, the provision of healthcare assistance, healthcare research, continuous medical education, etc. Where there is any doubt, pharmaceutical companies are recommended to review the bylaws of those entities which they interact with.

Sometimes Healthcare Organizations and pharmaceutical companies, hire third entities (service providers), for carrying out and manage their activities. The mere fact of providing those services does not automatically turns into or grants those entities the status of Healthcare Organizations. In these cases, pharmaceutical companies are recommended to request those entities, to identify the Healthcare Organization to which they provide their services (for example through invoices, contracts, collaboration or sponsorship agreements, etc), as Transfers of Value will be allocated, in any case, to those Healthcare Organizations.

119. A group of physicians, with the collaboration of an entity specialized in meetings organization and management, acting as “technical secretary”, organized a scientific-professional meeting. Could pharmaceutical companies collaborate/sponsor that meeting? Will the answer be different, if that meeting counts with a continuing medical education credit recognition certificate?

Pharmaceutical companies could only collaborate or sponsor with that meeting, if a Healthcare Organization in charge of its organization or management exists. Transfers of Value made, directly or indirectly, for such collaboration or sponsorship will be disclosed, on an individual basis, to the Healthcare Organization.

Pharmaceutical companies' collaboration or sponsorship, with these kinds of activities depends, in any case, on the existence of a Healthcare Organization.

Finally, pharmaceutical companies are recommended to review the Code's definition of Healthcare Organization, including also the previous question related with third entities/providers, and question nº102 of Annex V of the Code.

120. How should pharmaceutical companies disclose those Transfers of Value made through subsidiaries, foundations, or group companies?

Previously, it is appropriate to clarify that, pharmaceutical companies including their subsidiaries, foundations, and any other legal entity that belongs to the Group of Companies, are expressly excluded from Healthcare Organization definition.

Pharmaceutical companies could decide to which entity they assign the Transfers of Value made to those Healthcare Professionals or Healthcare Organizations, practicing or with a registered office in Spain. Each entity will individually publish that information using the Disclosure Template (Annex II of the Code).

In any case, and regardless its publication in the name of different legal entities, the pharmaceutical company must guarantee that, the information related to the Transfers of Value made to those Healthcare Professionals or Healthcare Organizations, practicing or with registered office in Spain, is accessible through one single website.

121. The pharmaceutical company's OTC division, supports a Healthcare Professional attendance to a scientific meeting, paying for his/her registration fee, travel and accommodation. Shall the pharmaceutical company disclose that Transfers of Value?

Section 18.1 of the Code establishes that Transfers of Value related to products or medicines that are not prescription-only medicines, do not fall within the scope of the disclosure obligation described herein.

In any case, each pharmaceutical company should assess if a Transfer of Value, although is formally paid by a non-prescription medicines business unit/division, could in any manner be linked with prescription-only medicines and if it, hence considers, that disclosures applies.

Nevertheless it is important, not to use this mechanism or procedure; as a way to avoid transparency obligations, and also that a pharmaceutical company, when deciding if disclosure applies, takes into consideration the Healthcare Professional receiving the Transfer of Value.

At any rate, the pharmaceutical company shall provide detailed information regarding treatment of this kind of Transfers of Value in the methodological note described in article 18.6 of the Code.

122. Should in kind Transfers of Value, that do not “a priori” imply a direct cost for a pharmaceutical company, be disclosed? For example: collaborations based on pharmaceutical company assignation of resources or employees to provide a service, for a Healthcare Professional or Healthcare Organization, benefit?

In principle these collaborations should be disclosed. In the methodological note, each pharmaceutical company shall explain those collaborations, and also the criteria used to determine their value.

123. Should Transfers of Value, derived from the collaboration agreements between pharmaceutical companies and governmental public institutions or healthcare providers, be disclosed?

Pharmaceutical companies must disclose the Transfers of Value derived from collaboration agreements with any kind of “healthcare entities or institutions”, regardless if those have healthcare assistance nature or character.

In this regard, the criteria stated in question nº 113 Annex V of the Code, should be considered.

124. The information to be disclosed under the “scientific and professional meetings” category, according to the Disclosure Template (Annex II of the Code), exclusively applies to meetings organized by third parties?

No, it applies for both, meetings organized by third parties and also for meetings organized or mainly sponsored by one pharmaceutical company.

Under such a category, and broken down accordingly to each corresponding item (collaboration/sponsorship agreements, registration fees, travel & accommodation), pharmaceutical companies must disclose the Transfers of Value related with meetings.

The Code defines meeting as: *“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 observational studies with medicinal products) organised or sponsored by a pharmaceutical company or under its control”.*

125. For hiring a commercial stand, at a national scientific society congress (10.000€), the pharmaceutical company receives 10 individual registrations, free of charge. According to the published congress official dossier price list, the registration fee per person costs 300€.

Is there any practical guidance or criteria that pharmaceutical companies could follow, when disclosing these “special benefits or free of charge Transfers of Value”, obtained from their collaboration or sponsorship with the Healthcare Organization meeting?

As a general practical criterion, pharmaceutical companies should bear in mind that the “free for charge” concept does not exist. Hence it is recommended to calculate the value of the benefit received, in order to be able to subtract that amount, from the pharmaceutical company global collaboration in that activity.

Having said that, two scenarios could exist:

Scenario 1: the pharmaceutical company does not know the identity of those Healthcare Professionals benefiting from those free for charge registration and the conditions set forth in query nº 126 are met:

Assign to the name of the Healthcare Organization it will disclose the following information: 7.000€ under “Sponsorship agreements with Healthcare Organisations or third parties appointed by Healthcare Organisations to manage a meeting” concept and 3.000€ under “Registration fees” concept.

Assign to the name of the Healthcare Professional, no information shall be disclosed.

Scenario 2: the pharmaceutical company knows the identity of those Healthcare Professionals benefitting from those free for charge registration:

Assign to the name of the Healthcare Organization it will disclose the following information: 7.000€ under “Sponsorship agreements with Healthcare Organisations or third parties appointed by Healthcare Organisations to manage a meeting” concept. Assign to the name of each Healthcare Professional it will disclose, on an individual basis, 300€ under “Registration fees” concept.

In the methodological note, detailed in article 18.6 of the Code, the pharmaceutical company shall provide more information with regard to this kind of Transfers of Value registration.

126. Is there any circumstance in which collaboration provided by a pharmaceutical company to Healthcare Organisations for

attendance by Healthcare Professionals at scientific-professional meetings does not need to be published individually, identifying the Healthcare Professional?

Prior to any possible collaboration, each pharmaceutical company will be responsible for verifying that the meeting and all elements connected with it are consistent with the Code of Practice for the Pharmaceutical Industry and comply with the requirements set out regarding "Scientific and professional meetings" (article 11, supplementary rules, queries, circulars, etc.).

The Code of Practice for the Pharmaceutical Industry establishes as a general principle the obligation to publish individually all Transfers of Value made directly or through third parties to Healthcare Professionals. As a result, and in accordance with this principle, article 18.1 of the Code establishes that to the extent legally possible, and so long as they can be provided accurately and consistently, pharmaceutical companies will need to publish Transfers of Value made to Healthcare Organisations on an individual basis, identifying the Healthcare Professional (rather than the Healthcare Organisation).

With regard to the circumstance raised in the consultation, the understanding is that it would not be possible to provide such information accurately and consistently if the identity of the Healthcare Professionals benefiting from the collaboration with the pharmaceutical company cannot be ascertained before, during or after the meeting is held.

In order for this circumstance genuinely to exist, in the collaboration provided by a pharmaceutical company to Healthcare Organisations for attendance by Healthcare Professionals at scientific-professional meetings, all the following conditions must be fulfilled:

- (i) The meeting must have various sponsors (at least 2) not belonging to the same Corporate Group, and as a result no individual link may be established between the sponsoring pharmaceutical company and the Healthcare Professional. In any event, sponsorship by each pharmaceutical company (including companies belonging to their group) must not represent a majority.
- (ii) Pharmaceutical companies wishing to collaborate with Healthcare Organisations offering the possibility of sponsoring Healthcare Professional educational support plans, on the terms defined in this consultation, will first need to ascertain that at least two months prior

to the starting date thereof the following information is publicly available:

- Total approximate budget to be assigned to the training support plan, and the number of beneficiaries.
- Minimum number of sponsors required, at least two.
- Conditions for sponsorship. Maximum limit on participation by one single sponsor, which must be no greater than 50%.
- Public and objective procedure detailing:
 - a) Requirements and deadlines to request and obtain training/educational support.
 - b) Type, scope, concepts and amount of the support offered.
 - c) Assignment criteria, separate and independent from the sponsors.
 - d) Commitment and obligation to publish the beneficiaries within two months of the end of each activity, and to keep this information publicly available for a minimum period of 3 years.
 - e) Commitment and obligation to identify the sponsors of the support plan.
- Declaration of the party responsible for the training/educational support plan, with a commitment to comply with the terms of this consultation.

- (iii) Pharmaceutical companies must include in the sponsorship agreement with the Healthcare Organisation all the safeguards needed to comply with the aforementioned conditions, and to guarantee that the collaboration provided is assigned to activities consistent with the Code of Practice.

If all the conditions detailed above are fulfilled, the collaboration provided by the pharmaceutical company in accordance with the terms of article 18.3.1(b) will be published in the name of the Healthcare Organisation.

Pharmaceutical companies will be responsible for verifying compliance with the terms of this consultation. In the event of a breach or non-compliance regarding any of the conditions detailed above by the Healthcare Organisation concerned,

pharmaceutical companies must, without prejudice to the measures adopted to rectify said situation:

- explicitly call on the Healthcare Organisation to comply with the obligations assumed, and
- report this situation to the Code of Practice Surveillance Unit.

The Unit will report any incident derived from compliance and application of this consultation to the Governing Bodies of FARMAINDUSTRIA, in order for them to adopt any measures they might deem appropriate, as applicable.

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