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The new Farmaindustria Code 2021

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1. Introduction

On 1 January 2021 the new version of the Pharmaceutical Industry Code of Best Practices (the "**new Code**" or the "**Code**", available via this link) has come into force. It was approved in October 2020 by Farmaindustria's General Assembly.

The main purpose of this revision was to incorporate the amendments that were made to the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in June 2019 ("**EFPIA Code**"). However, as will be analysed below, this revision has had a wider reach and new requirements and recommendations have been introduced, largely as a result of the many years of experience that the control bodies have of reviewing those activities that are subject to the provisions of the Code. Some of these incorporations are recommendations that were already being applied (for example, this is the case of the rules regarding relations with the media), but some others are new and are going to have a significant impact on the organisation and decision-making of pharma companies, especially regarding engagement of healthcare professionals and organisations for the provision of services and the execution of some very common projects. The Code also includes a significant change in relation with the possibility of benefiting from reduced penalties if the companies spontaneously acknowledge their liability for breach of the Code.

Since 1 January 2021 the Code is fully in force. No transitional periods have been established -unlike on previous occasions and even though EFPIA allowed for a transitional period due to the COVID-19 crisis. Therefore, the new obligations and recommendations already apply. We discuss below the most significant.

2. General matters

2.1. REFERENCE TO GENERAL PRINCIPLES AND VALUES

One of the main modifications to the new Code is the inclusion of a new section dedicated to the general principles of conduct of pharmaceutical companies, as a series of values that govern the conduct of the industry as a whole.

Other self-regulation Codes establish more generic rules of conduct. By contrast, in its previous versions the Code had always followed a particular method: instead of setting out general deontological rules, it listed what is permitted and what is not with great level of detail. Without intending to deviate from this approach, the new version of the Code incorporates for the first time six main principles or values, which, quoting the Code, "*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.*"

Therefore, these new general principles have to serve as reference and guideline both for interpreting the Code and for applying it to conduct not expressly contemplated in it, but which may contravene its underlying values. Thus, these principles will probably be applied by the supervisory bodies in a way similar to the general good faith provision established in the Unfair Competition Law.

These principles and values, which are fundamental pillars of Farmaindustria's Self-Regulation System, can be summarised as follows:

(i) **TRUST**: to act with integrity, honesty and independence. According to the Code, these are the fundamental values on which the reputation and image of the pharmaceutical industry are founded, form the basis of its actions, and they are achieved only by acting in accordance with them improving patient care and quality of life, and respecting the independence of the different stakeholders.

(ii) **INTEGRITY**: relationships must be legitimate, honest, balanced and transparent, avoiding undue influence and handling conflicts of interest adequately.

(iii) **RESPECT**: relationships with stakeholders (healthcare professionals and organisations) must be transparent, consistent and based on mutual respect.

(iv) **LEGALITY**: according to the Code, its rules are aligned with the applicable laws, fostering fair competition, and should serve as a guide in matters subject to interpretation.

(v) **TRANSPARENCY**: the Code promotes public knowledge of the industry's interactions, especially with those with whom there may be a conflict of interest.

(vi) **PREVENTION**: the Self-Regulation System must actively ensure compliance with the Code, so as to strengthen, reinforce and protect reputation and trust in the pharmaceutical industry.

2.2. DEFINITIONS AND TERMS

The Code has introduced some new terminology. "Events" are now referred to as "scientific-professional meetings" (or simply "meetings"). The Code also defines terms "grant" (as in a "finalist donation" [*donación finalista*]) and "social media", which will be relevant when establishing the rules regarding the conduct of pharmaceutical companies in the digital environment, as referred to below.

3. Differences between information and advertising. Relations with the media

One of the new Code's aims is to provide clarity on the scope of the concept of "information" (as opposed to "promotion" or "advertising"), and to provide guidance on what type of activities are deemed as purely informative and, therefore, are not subject to the rules governing the promotion of medicines (particularly those included in the Code). From a formal perspective, the Code stipulates that certain activities do not constitute (or at least for "its purposes") promotion and are therefore excluded from its scope of application. However, such activities will only be excluded if they meet certain requirements that are, in some instances, described by the Code in great detail. From a practical point of view, far from limiting its scope of application, the Code actually extends it: it regulates how information can be, or should be, provided so that the boundary between information and advertising is not crossed.

Firstly, and aligned with the previous interpretation of the supervisory bodies, the Code expressly establishes (in a new Supplementary Rule included in the section Scope of the Code) that - as long as

the respective requirements are complied with- the following activities will not be considered to be promotional:

(i) The distribution of **originals, reprints and/or literal translations of scientific articles and/or abstracts** published in reputable scientific sources 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, regardless of whether or not it is related to the information.

(ii) The distribution of **information about a line or different lines of research** of the pharmaceutical company, which mentions the active ingredient and its properties.

(iii) The distribution of **educational materials for healthcare professionals or patients**, which is a condition for the marketing authorisation of the medicine, or that have been approved by the competent health authorities.

It is noteworthy that the distribution of information about research on active ingredients has been broadly excluded from the concept of advertising; it is even possible to identify the active ingredient and its properties without entering into the concept of promotion. This is not mechanical, however; even if the Code does not expressly mention them, pharmaceutical companies must take into account other limitations in order to ensure that such information is not considered to be of a promotional nature.

In this regard, the criteria introduced by the New Code, although specifically referring to the publications made in the media, can be used as general guidelines to differentiate information from advertising. These guidelines are included in the "***Practical guidance for communication and relations with the media concerning prescription-only medicines***" (the "**Guide**"). This Guide was already being applied by the control bodies, in essentially the same terms, but had not been incorporated into the Code; it is now added as Annex III.

In addition to the guidelines for distinguishing between advertising and information, the Guide includes specific and detailed standards on "**When to inform**", "**How to inform**", "**To which media to provide the information**" and on how to establish "**Contact with the media**". Thus, through the Guide specific guiding principles for publications of an informative nature are included in the Code. If these principles

are not adhered to, the publication might be deemed to be of promotional nature and this would constitute a breach of the Code (because, as a minimum, formal obligations would not be being observed).

In any case, the **premise is that pharmaceutical companies have a right to provide information about prescription medicines**. The parameters for doing this are summarised in a Decalogue. We highlight the following:

(i) respecting the principle of **newsworthiness** to determine the facts that would be allowed to be publicised for information purposes, for being considered "news" (for example, the different milestones in the regulatory procedure of the medicine) or because their communication is mandatory (for instance, by listed companies);

(ii) the possibility of mentioning -at all times in a prudent manner and subject to certain limitations- not only the active ingredient but also the **trademark** of the medicine; the Code states that the trademark of a medicine has informative value;

(iii) the possibility of including the information of prescription medicines -even if identified as such- **both in scientific media as well as in media that is addressed to the general public**; and

(iv) in line with the principle of **separation**, the rule that information actions must be led by the communication departments of pharmaceutical companies (and, therefore, not by the commercial or marketing departments).

4. Digital and social media

4.1. NEW RULES FOR A DIGITAL ENVIRONMENT

Former versions of the Code already stipulated that pharmaceutical companies must comply with the provisions and principles of the Code regardless of the medium, means of delivery or channel of communication used to perform the activities subject to the Code, which, logically, included any type of digital channel or medium. In order to give full effect to this rule, the new Code reinforces the obligations of pharmaceutical companies in the digital environment, taking into account the increasing impact that digital communication channels and social media have on the transmission of information, encouraging

real-time interaction and the constant distribution of content to multiple recipients. The Code incorporates EFPIA's non-binding recommendations in this area, with some adaptations.

The Code presumes that pharmaceutical companies are responsible for the content included in the media or channels of communication that they, exclusively or mainly, control or finance. In other words, the Code establishes that any publication in such media or channels of communication may be attributable to the company, even if it was not made by the company or its authorised representatives, but by its employees -on their own initiative- or healthcare professionals with whom they collaborate. In addition, and as explained below, companies must not only take measures in regard to the media and social media that they control and manage but must also train their employees and collaborators on how to use their **own private social media.** The changes introduced by the new Code in this area require pharmaceutical companies to take measures to prevent inappropriate publications so that they cannot be held accountable for them. In particular:

(i) **Access by healthcare professionals to websites that contain promotional information about medicines**. In relation to the promotion, through digital media, of medicines directed exclusively at healthcare professionals, Article 8.3 of the former code stated that it should "*include, in a clearly legible, highlighted manner, a warning stating that the information on the web page is intended exclusively for the Healthcare Professional (…)*". The new Code explains that it would be preferable to include "*a verification system or statement on the Healthcare Professional status of people gaining access"* but still allows the use of the warning -"*at least*"-
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(ii) **Compliance and rules of conduct**. Pharmaceutical companies must have guidelines and rules of conduct addressed not only to their employees, but also to "*third parties acting on their behalf, or under their control, or by virtue of a formal agreement*". These guidelines must establish standards for responsible conduct in the digital environment, both for when sharing information about or in the name of the company as well as when using a medium or communication channel provided by the company. According to the new Code, these guidelines must specify "*the legal prohibition against openly sharing or publishing content that could constitute promotion of prescription-only medicines to the general public*". In addition, the internal rules of conduct of the company must "*address the obligation to correct any irregularity quickly*".

(iii) **Training**. Pharmaceutical companies must also train their employees regarding "*characteristics, functionality, recipients, risks, limitations, terms and conditions of the main social media networks which exist, both public and private*" to prevent any conduct that may be in breach of the Code and to avoid their employees sharing, linking to, publishing or commenting on their personal social media profiles (public or private) "*inappropriate content, in terms of either style or tone*" (comments about competitors' products, off-label promotion, etc.).

(iv) **Content distributed during meetings**. Pharmaceutical companies are entirely responsible for the content reproduced during the scientific-professional meetings. To guarantee that the presentation and subsequent dissemination of such content is limited to healthcare professionals:

a. open-access social media platforms cannot be used;

b. employees and participants (e.g. speakers) must expressly acknowledge in their agreements with the company their rights, obligations and responsibilities in relation to social media.

c. to avoid the inappropriate disclosure of the content of the meeting, the company must be in a position to prove that that it has informed all those attending of their responsibilities in relation to their conduct on social networks. By way of example: (i) include clear warnings on the limitations applicable to the use of the content distributed during the meeting; (ii) request as a requirement to be able to attend or participate in the meeting the prior acceptance of the rights, obligations and responsibilities regarding social networks; or (iii) undertaking to request the company's authorisation before using or distributing the content of the meeting.

5. Engaging healthcare professionals to provide services. New guide and rules of conduct

5.1. INTRODUCTION

Engaging healthcare professionals to provide services to pharmaceutical companies is the most exhaustively covered area in the new Code. Unlike the matters analysed above, the changes to this chapter do not generally arise from the requirements or recommendations of the EFPIA Code. Some criteria regarding such engagements developed by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) have been incorporated, but the general impression is that Farmaindustria has introduced the **experience acquired** by the Code's supervisory bodies, which are already well versed in the subject matter. In fact, since 2010 the Code has required associated companies to notify the Code's supervisory bodies (currently, the Surveillance Unit) of those projects and activities in which the services of 20 or more health professionals are engaged. The experience gained through analysing such communications has served as a basis for the Surveillance Unit to propose introducing in the Code new guidelines and criteria on the matter, which is one of the most sensitive areas, both because of its economic and compliance implications (in particular, anti-corruption compliance). To date, this area has not been subject to any interpretation guidelines or publications regarding the experience gained from its application: neither the questions and answers, nor the (former) development guides have comprehensively dealt with this matter, nor are there any decisions by the Self-regulating Jury (*Jurado de Autocontrol*) on the application of these rules.

This situation has been resolved with a regulation that goes the opposite way, since it is, as we will see, very complete and case-based and goes beyond the scope of the rules on engaging services by regulating in depth how a variety of diverse projects (such as educational projects, clinical cases and publications) should be carried out.

The modifications have been structured in two ways:

- on the one hand, a "*Practical guide and criteria concerning services provided by healthcare professionals or organisations*" (the "**Guide for the engagement of services**") has been approved as Annex IV to the Code.

- on the other hand, the Supplementary Rules of Article 16 have been developed to introduce some provisions (with language specific to their mandatory nature - "*must*") that are also included in the Guide for the engagement of services as mere recommendations.

Perhaps the modification that, due to its horizontal nature, will affect day-to-day business most is the provision that requires companies to establish **annual limits** on (i) the total number of health professionals hired; (ii) the number of times the same health professional is hired; or (iii) the maximum remuneration paid to the same healthcare professional for the provision of the services. The limits refer, logically, to services for which healthcare professionals are paid. In addition, the Code requires companies to design internal mechanisms and procedures to help establish **objective criteria for remuneration**. All these rules are specific to the Code; they do not arise from the recommendations of EFPIA or IFPMA.

The Code does not provide any specific guidance on what is a reasonable limit – on contracts and on fees –; therefore each company must set its own limits.

In this regard, the Code states that "*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***".* For the first time, the Code introduces a general principle that governs contracting so that it is not considered a mechanism for channelling illegitimate payments: companies should engage healthcare professionals in a rational manner, being cost-conscious and efficient (as with other service providers).

Finally, the Surveillance Unit is given greater control as it must now be given more ample notice of projects involving 10 or more health professionals (instead of 20 as previously). Exceptionally, projects carried out exclusively online are not subject to such prior notice.

However, the Guide does not only provide guidelines (or obligations) regarding the engagement of services. It also regulates specific activities and introduces conduct criteria that have little to do with the engagement of services. For example, it introduces rules applicable to several types of **clinical cases**, **educational projects** or **publications**. Some of these rules seem to be aimed at preventing the indirect promotion of medicines through such projects rather than establishing the legal framework on how healthcare professionals that participate in the referred activities should be engaged. For instance, in the case of publications, it is not sufficient to submit them to peer review: other sponsors must be allowed to

participate, they must be managed by the medical department and the decision on selecting the participating healthcare professionals must be delegated to an independent entity. Something similar occurs with projects for clinical cases, although the specific requirements vary depending on the type of clinical case. In relation to the educational projects, the most striking point is the rule that obliges companies to establish their own **speaker-attendee ratio**; this is something that some companies were already doing to avoid the need or appropriateness of these educational projects, and thus of hiring professionals for them, being challenged .

When the Guide refers to projects (such as educational projects or publications) that are "sponsored" by the industry, or with which it "collaborates" or provides "support", it would have been useful to clarify whether such sponsorships or collaborations are subject to Article 15 of the Code, which regulates donations and grants. Even though the support consists of facilitating the engagement of healthcare professionals or paying their fees for a specific project, if it indeed entails "support" or collaboration with the own activities of a third party (and in particular of a health organisation) , this collaboration would constitute an in-kind donation or grant and be subject to Article 15 of the Code. Therefore, the "support" or collaboration must, among other requirements, be formalised in writing, and be disclosed to the public as a donation and not (or not only) as a provision of services.

Finally, the Guide for the engagement of services incorporates the content of IFPMA's new "*Note for Guidance on Fees for Services*" dated February 2020. It provides clear examples of signs that could result in the need (and thus legitimacy) of contracting healthcare professionals for the provision of services being questioned. Almost as would occur in a cross-examination, the company is asked very case-specific questions to which it should be able to give a fully satisfactory answer. The focus is placed on all matters related to the organisation of advisory boards, which seem to be the main concern (at least within IFPMA). However, conceptually and in application of the principles of the Code, all the issues that arise apply to any provision of services, regardless of their nature and objective.

6. Relationship with patients and patient organisations

Article 17 of the Code and its Supplementary Rules set out the rules applicable to the relationships of pharmaceutical companies with patient organisations; rules that are based on the principles agreed between EFPIA and pan-European patient organisations. The main changes introduced by the Code are the following:

(i) **Materials for patients**: according to the Questions and Answers, and similarly to what is set forth in relation to publications, these materials must necessarily have a variety of sponsors or collaborators. It would seem that, if this is not the case, their informative and non-promotional nature could be questioned, especially if they make a reference (which in any case has to be a general reference) to treatments. There is also an obligation to include a message informing the patient that the material is for information purposes only and does not substitute a medical appointment or advice, and to clearly state that the material has been sponsored by the industry.

(ii) **Engagement of services**: among other changes, it is established that the contracting of patients to provide services must necessarily be channelled through patient organisations, and not on an individual basis. In any event, it cannot be linked to participation in promotional activities for medicines.

(iii) **Meetings, hospitality and gifts**: as a general rule, the limitations applicable for scientific-professional meetings with health professionals are extended to relationships with patient organisations.

(iv) **Sponsorship of charitable activities**: corporate sponsorship of these activities is expressly permitted.

The new Code does not include a provision regarding Patient Support Programs (PSPs), which are very common in some therapeutic areas and have raised many regulatory questions. Although their analysis exceeds the scope of this document, the new Royal Decree regulating observational studies (Royal

Decree 957/2020 of 3 November regulating observational studies with medicines for human use) approved a few weeks after the modification of the Code, should be taken into account.

7. "Self-Assessment"

The main change in "*Title II - Rules of Procedure for the control bodies*" (together with a much-demanded extension of certain deadlines) is the authorisation of an exceptional procedure, for those cases in which pharmaceutical companies, through their internal review and audit processes, identify practices that may infringe the Code. The procedure, called "***self-assessment***", could be inspired by the leniency systems of the antitrust law, although with substantial differences.

The "self-assessment" procedure basically consists in a company incriminating itself before the Surveillance Unit and, as a consequence, benefiting from a reduced penalty. Companies cannot use this procedure if a complaint from a third party or from the Unit has already been filed. Moreover, the company must (i) provide a detailed description of the activities or practices that infringe the Code, including evidence; (ii) acknowledge the infringement; and (iii) formulate a proposal for sanctions and corrective measures. The Surveillance Unit will issue a report proposing the qualification of the infringement (including consideration of possible mitigation) and the measures to be adopted. The procedure follows the standard route, namely, a mediation meeting before the Code of Practice Committee and, if no agreement is reached, a referral to the Self-Regulating Jury (*Jurado de Autocontrol*).

Including the possibility of following this "self-assessment" procedure, which is very common in other jurisdictions, marks a significant move forward in the Code. Although probably in the interest of prudence it has been introduced with a minimalistic approach, since it does not provide for exemption from liability, only its mitigation. The Code does not state that the information provided by the pharmaceutical company and/or the corresponding ruling or mediation agreement will be confidential, an aspect that is likely to be key for companies.

8. Other matters

8.1. TRANSPARENCY REGARDING POST-AUTHORISATION STUDIES

The new Code establishes that transfers of value made to healthcare organisations and to healthcare professionals regarding retrospective post-authorisation studies must be published **individually** by pharmaceutical companies under the category "provision of services", even though they fall under the category of research and development. Therefore, these activities can no longer be published in an aggregated matter with value transfers related to research and development.

8.2. SURVEILLANCE UNIT CONSULTATIONS

The Surveillance Unit has the power to submit binding consultations to the Code of Practice Committee regarding the interpretation of the Code. Only pharmaceutical companies had this power before.

8.3. HOSPITALITY IN VIRTUAL MEETINGS

The Code expressly mentions that offering any kind of hospitality for attending online meetings is prohibited.

8.4. DEADLINES

The deadline to submit complaints to the Code of Practice Committee is extended from 5 to 15 days and the possibility of requesting extensions has been removed. Moreover, the deadline to publish collaborations with patient organisations has been extended to the first half of each year.

8.5. TABLES AND GRAPHS

In relation to promotional material, the only relevant change is a Supplementary Rule regarding the use of tables and graphs that clarifies the concept of "*faithfulness to the content of the original source*". Tables and graphs may only be reproduced literally without omissions, additions or highlights, even if a caveat is included stating that the company has produced or adapted the material.

9. Final thoughts

There is no new material regulation on promotion in the new Code. Although some very specific rules (or rather clarifications) have been introduced, the promotion of medicines is not a matter of concern in this review; the rules on promotion are clear and well known, and the matters that could be subject to interpretation have, after many years of work, been clarified in successive versions of the Code or by decisions issued by the Self-regulating Jury (*Jurado de Autocontrol*).

The focus is, or rather continues to be, on transfers of value and in particular those regarding engagements to provide services. To some extent, the Code urges companies to constantly question the appropriateness of each hiring and each payment, not only individually, but in aggregate and in comparison with all other payments the company makes. As we have seen, this is a universal concern, which is also reflected in the IPFMA standards, although further steps have been taken in Spain for the first time in terms of limits on engaging or paying for services. The specific limits need to be set by each company itself, so the company's decision-makers will have to agree on parameters that are reasonable for all and can be justified internally and externally, which seems to be no easy task.

The new Code's attempt to regulate informative non-promotional activities is also noteworthy. On the one hand, it has taken a flexible approach on certain issues, which to date have not always been uncontentious. This is the case, for instance, of the possibility of identifying in messages circulated by the company concerning its prescription medicines not only an active ingredient, but also a medicine's brand name, and not only in scientific media but also in media that is addressed to the general public. On the other hand, the new Code aims to avoid the neutrality or objectivity of certain materials such as publications or materials directed to patients from raising concerns, so it excludes (or discourages) a single company from sponsoring such publications or materials.

For the future, it will certainly be interesting to follow up on how the new "self-assessment" procedure is being used and how the supervisory bodies are applying it.

The Code has not addressed a number of other issues that are under discussion in the industry, perhaps due to a lack of consensus. The main one is the strict approach of equating unauthorised medicines and

medicines that have already been authorised but which await a resolution on financing and price, in relation to prohibiting their promotion.

Finally, although this point is of lesser significance, it does not remove the explanations and clarifications (especially in the Q&A section) on issues that were perhaps unclear at one time, but which now – after almost three decades since the Code's first publication – would not seem to be entirely necessary.

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