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New version of the Code of Practice for the Pharmaceutical Industry of Farmaindustria

The new version of the Code of Practice has come into force on 1 January 2021

Principles and values

Since its first version, the Code of Practice has been based on a number of principles implicit in its provisions. The new version has the virtue of detailing them explicitly, in a format similar to the one used in the EFPIA Code.

The 6 principles and values that must govern the activity of the pharmaceutical industry, and which will also serve to assess matters that are not specifically covered by the Code are: Trust, Integrity, Independence of Healthcare Professionals (HCP) and Healthcare Organizations (HCO), Legality, Transparency and Prevention, implying that the self-regulation system must actively ensure compliance and enforcement of the Code, in order to reinforce and protect the reputation and trust in the pharmaceutical industry.

Social media and digital environment

Regarding social media, the most relevant developments are:

Access control. Companies may use a HCP status verification system in order to have access to promotional materials, but the option of having only a warning and a declaration system is maintained.

Internal guidelines and training. The Guidelines on responsible action in the digital environment must also apply to third parties acting on behalf of the company or under its control or pursuant to an agreement, and the company will be responsible for these actions. The company must also train its employees in order to avoid them posting inappropriate content on their personal social media profiles, such as comments on competitors' products or off-label promotion.

Publication of contents of meetings. Companies must clearly and unequivocally inform HCP and employees attending meetings organized or sponsored mostly by the company, that they must not post any promotional content regarding these meetings on social media. It is also recommended to include safeguards in the agreements signed with speakers and attendees.

Tables and graphs

Tables or graphs from studies included in promotional materials must be a "faithful" reproduction, without the need for them to be a "literal" reproduction. However, the Code clarifies that "faithful" reproduction should be understood as one that replicates the content from the original source, without exclusions, additions or highlights that may mislead or exaggerate the properties of any medicinal product. In addition, the Code clarifies that including a warning message saying that the table or graph is an adaptation does not exempt the company from the obligation of reproducing the information faithfully.

Meetings, services and communication

The application of the **principle of territoriality** in relation to scientific and promotional meetings is regulated in greater detail in this new version. Pharmaceutical companies established in Spain will be responsible for the compliance with the

Code by the companies in their same group, regarding any activities they may carry out in Spain involving any HCP and also regarding activities carried out in any country and involving any HCP who conduct their professional activities in Spain. In both cases, the quantitative limits on hospitality of the Code shall apply.

The principle of non-duplication is introduced: when several scientific or promotional meetings are held in relation to a project, it will be sufficient to communicate the first of these meetings prior to their holding. This principle also applies to the contracting of services provided by HCP and HCO for these projects.

As regards **communications**, two new developments stand out: in case of projects where remunerated professionals are hired, pharmaceutical companies must notify them if at least 10 HCP are being hired (instead of 20). On the other hand, the communication will be voluntary in case of training activities or scientific meetings that are carried out **virtually**.

Virtual events

The offering of any hospitality in any virtual event (including training activities or scientific professional meetings) is prohibited.

Patients and patient organisations

Services provided by patient organisations (PO). The hiring of PO must not be linked to their participation in a promotional event for a medicinal product; and the hiring of patients must be carried out through the PO.

In terms of **hospitality**, the same limits applicable to meetings with HCO apply to PO, but in meetings outside Spain the maximum threshold established by the National Association of the country where the meeting is being held will apply. Offering money to compensate patients for the time spent in attending the meeting is prohibited.

Patient materials. New supplementary rules are introduced, according to which these materials or publications must:

- Serve patients to better understand the development of their disease and to improve their quality of life.
- Explicitly mention if they have been sponsored by a company.
- Clearly and visibly demonstrate that their main purpose is to be a support tool for patients affected by a particular disease.
- Be educational and informative, including in a visible way a warning stating that these are guidance and informative materials that cannot be interpreted as a substitute for the diagnosis or the advice of an HCP.

It is also established that the provisions related to the digital environment shall apply to patient materials, regardless of the medium, platform, or channel.

Prohibition of gifts. Gifts or presents for the personal benefit of patients or PO representatives are prohibited.

Transparency

The new version of the Code states that, in addition to other information to be published, transfers of Value made to HCO and to HCP related to post-authorization studies of a retrospective nature must be published individually under the category "provision of services".

On the other hand, the obligation to inform on the PO with which companies are collaborating must be done during the first half of each year (instead of the first quarter as previously foreseen). Companies must provide the Code of Practice Surveillance Unit (USD) with the link to their website where this information is published, and these links will be posted by Farmaindustria on its website.

USD Queries

The USD can submit binding queries to be answered by the Code of Practice Committee regarding the compatibility of any activity with the Code or to request for general clarifications.

Procedures

Deadlines. In general, the possibility of extending deadlines is eliminated. Moreover, in the complaint procedure, the period for the defendant to submit allegations is extended from 5 to 15 days.

Self-assessment. A new procedure called self-assessment (which perhaps should be called self -incrimination) is enabled, whereby companies can report to the USD their own activities that may be infringing the Code, after which the USD will issue a report proposing the qualification of the infringement and the measures to be adopted.

Guidance for relations with the media

This guidance sets out a series of recommendations on how to provide information on prescription medicinal products and on interactions with both generalist and specialized media. We highlight the following:

- The information must respond to a newsworthy event, for example the discovery of innovative molecules or the approval of a medicinal product.

- If the brand and the active ingredient are named, this should be done in a prudent and proportionate manner, no more than twice, and they should not be mentioned in the headline.

- Where there is a contractual relationship between the company and the media, a declaration of interest must be issued and included in the informative material.

- If journalists are invited to an event where travel, accommodation and other expenses are covered, they must be informed that there is no obligation to publish anything in return.

- Signing agreements for the publication of information on prescription-only medicinal products is forbidden.

- The company's communications departments must be trained so that they are able to distinguish between informative and promotional initiatives.

Guidelines on services provided by HCPs or HCOs

This guideline has a binding nature and establishes as a general criterion that, after the of each "project", the company should be able to make a public disclosure of its origin, nature, scope, characteristics, and results.

The projects are classified into 4 categories (by way of example and without prejudice to the existence of other types of projects): Clinical Cases, Advisory Boards, Educational Projects and Publications.

With respect to advisory boards, rigorous and specific selection criteria should be established to prove the qualifications of the participants.

Regarding educational projects, it is noted that they generally involve the preparation of a presentation previously approved by the scientific service/medical department of the pharmaceutical company; the training of several HCPs with respect to the content of such presentation; remunerated speaker contracts for HCPs, and the holding of meetings that share methodology, structure, and content. In these cases, the company must:

- Remunerate exclusively those HCPs who actively collaborate in the educational activity, such as speakers and authors of the materials.

- Ensure compliance with the speaker-attendee ratio that the company establishes internally for each meeting.

- Hold records detailing the total number of educational activities for each project, number of attendees per activity, evaluation of the educational activity by the attendees and, if the activity is carried out at the request of an HCO, have an evaluation issued by the HCO itself.

- Comply with the Code`s hospitality and meetings standards.

Regarding **publications,** in case an HCP is paid to promote the development of scientific materials to be published after a peer review, the material must contain information on potential conflicts of interest, and it must state the contribution by the company specifying its nature and scope. In addition, in these projects, the company must:

- Delegate the management of the project to an academic or scientific entity which will objectively set and justify the number of HCPs, will select them, direct the work and outcome.

- Ensure that the company's medical department manages and coordinates the execution of the project.

- Allow that other companies or institutions participate as sponsors if they wish to do so.

- Ensure that the publications are independent and have a well-established reputation.

- Evaluate the outcome of the project, the level of dissemination and acknowledgement achieved.

In addition to the types of projects discussed above, this guideline sets out a series of questions (23 in total) that companies must be able to answer affirmatively in order to ensure that they comply with the Code. These questions are set up in line with IFPMA' "Note for Guidance on Fees for Services".

It should also be noted that the new version of the Code includes examples to consider when assessing whether projects that involve hiring a HCO or a HCP to provide any service comply with the principles of legitimate need, selection of HCP, maximum number of HCP hired, and remuneration.