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The new Code of Practice for the Pharmaceutical Industry 2014 comes into force

Farmaindustria publishes the new ethical rules on interaction of the industry with healthcare professionals and patient organisations

The new Code of Practice for the Pharmaceutical Industry came into force on the 1st of January 2014. This Code updates and consolidates in a single text the previous code of interaction with healthcare professionals (October 2010), the code of interaction with patient organisations (January of 2012), their implementation guides, as well as the Rules of procedure for the control bodies of the Pharmaceutical Industry Self-Regulation System (October 2010). Due to its general interest, we will summarize below its main novelties.

Promotion in the digital environment

The new Code recalls that all promotion activities that are performed in the digital environment– including SMS, MMS, web pages, electronic mail, forums, blogs, social networks, chat, platforms, applications or any other type of digital channel– are subject to identical norms and limitations as those which apply in other traditional channels. In this sense, the new text highlights the importance of using valid channels within a context that is basically scientific or professional, and that should be intended exclusively for healthcare professionals authorized to prescribe or dispense medicines. Such professionals should need to identify themselves in order to have access to this information.

Moreover, pharmaceutical companies must have guidelines and rules of conduct for their employees, which shall establish standards for responsible conduct in the digital environment.

Guarantees of Independence

The prohibition of offering gifts to healthcare professionals is maintained, but it does not apply to items of professional use or stationery that (i) are not related with a prescription-only medicine and (ii) have a market price that does not exceed 10 Euro. Regarding informational or educational materials, and items of medical utility, they can be offered as a gift provided that they (i) are relevant to the practice of medicine or pharmacy, (ii) benefit patient care, and (iii) their market price does not exceed 60 Euro. The Code also states that items of medical utility must not alter or modify the routine business practice of the recipient.

Training and control of personnel

Companies must have a written procedure in writing for internal monitoring of compliance with the ethical rules, which must be provided to the Code of Practice Surveillance Unit if such Unit requests it. Moreover, they have to provide adequate training for the personnel involved in the promotion of the products, or in the interaction with healthcare professionals or patient organizations. Finally, it is recommended that the different departments (Marketing-Sales, Medical, Regulatory, Legal, Financial-Administrative) participate and get involved in the committees, policies or internal procedures that the company implements in this area.

Sponsorship and hospitality in scientific and professional meetings

Companies may continue to sponsor or collaborate in events that are exclusively of a scientific and/or professional nature, as long as they comply with the rules of the Code. The main novelty introduced in this field is that a maximum limit of 60 Euro is established per guest for dinners and/or luncheons.

Studies

Pharmaceutical companies must publish detailed information on the clinical trials they perform, in accordance with the current legislation and, moreover, with the *"Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature 2010",* available at http://clinicaltrials.ifpma.org.

Transparency in payments to healthcare professionals and their organisations

The main novelty of the new Code is the obligation that is imposed on companies to document and disclose, on their web pages, all transfers of value –meaning any direct or indirect payment or grant, either in cash or benefits in kind, and regardless of its purpose– whose recipient is a healthcare professional or a health organisation. The only payments excluded from this obligation are those associated with (i) commercial transactions with distributors, pharmacy offices, as well as certain transactions with healthcare organisations, (ii) activities related to products or medicines that are not prescription-only medicines, and (iii) activities not detailed in Appendix I of the Code, such as, the provision of educational materials or of medical utility, samples, dinners or luncheons.

In this manner, as from 2015, companies must disclose within the first 6 months of each year all payments made during the previous year in favour of healthcare professionals as collaboration for their attendance to scientific and/or professionals meetings, or as reward for the provision of legitimate services. Likewise, they will have to publish payments made to healthcare organisations that are made as donations, contributions to organise or attend scientific and/or professional meetings, or fees for services.

Such disclosure shall have to be made on an individual basis for each recipient of any value transfer. However, companies may disclose such information on an aggregate basis, when for legal reasons –such as, for instance, the lack of consent of the holder of personal data– the disclosure cannot be made on an individual basis. In these cases, the number of recipients and the percentage that it represents with regard to all recipients shall have to be published for each category.

On the other hand, the companies' obligation to publish the list of patient organisations with which they collaborate and/or have signed an agreement to provide services, as well as all information related to such collaboration (monetary value, scope and nature, etc.) is maintained. This information must be published within the first 3 months of each year and it must include all the activities and services that were carried out the previous year.

Finally, and in line with the rest of novelties introduced, companies must have a procedure of internal control for monitoring the compliance with the transparency obligations referred to herein.