Industry News:

Changes brought by the draft Order for the approval of the Norms for the evaluation and approval of advertising to medicinal products for human use

Overview

The draft Order for the approval of the Norms for evaluating and approving the advertising of medicinal products was published on January 11, 2015 on the website of the Ministry of Health (hereinafter the "Norms"). The Norms have not been published and thus, changes might appear in the final version.

The Norms bring a number of important changes regulating the activity of advertising medicinal products for human use and the activities of promotion and publicity. Also, the Norms regulate the procedure for the declaration of sponsorship activities and other expenses incurred for doctors, nurses, professional organizations, patient organizations and any other organizations working in the health industry.

The main purpose of the Norms is to regulate the activity of advertising medicinal products for human use and the activities of promotion and publicity. Also, the Norms contribute to the development of adequate and effective mechanisms for monitoring the advertising of medicinal products for human use, resulting in their rational use.

The main changes brought by the Norms are the following:

- Supplementing the provisions of **Law no. 95/2006** on healthcare (which contains general provisions regarding advertising in health domain) and of **Law no. 158/2008** regarding misleading and comparative advertising, with specific provisions as regards the advertising of medicinal products for human use. The regulations contained in the Norms are included in the health policy;
- The Norms provide a definition of the notion of misleading advertising, listing the characteristics that allow its correct identification;
- The Norms introduce the concept of comparative advertising, meaning any type of publicity which explicitly or implicitly identifies a competing product and/or a comparative description. As per the provisions of the Norms, comparative advertising to the general public is forbidden;
- The Norms introduce the notions of internet advertising and advertising in medical events;
- Unlike the current regulation, which prohibits the advertising of a medicinal product which does not have a marketing authorization valid in Romania, according to the new provisions the advertising for this case is forbidden only when addressed to the general public;
- Under the new regulation, the marketing authorization holder ("DAPP") is obliged to submit to the National Agency for Medicines and Medical Devices ("ANMDM") for approval all advertising to the general public / patients and to put them on market only after obtaining the endorsement of the authority;

- According to the Norms, the producers, holders of marketing authorizations or their representatives in Romania, wholesale distributors and retail of medical products, devices and supplies are required to declare to ANMDM all sponsorship activities, and any other expenses incurred by doctors, nurses, professional organizations, patient organizations and any other organizations that worked in health domain. If case of sponsorship activities, such obligation should be observed by beneficiaries also;
- The Norms contain standard forms for declaring sponsorship activities for both sponsor and recipient, and also a form for declaring other expenses;
- The information contained in the declaration forms will be published in the first quarter of the year for the previous one, on the websites of ANMDM, of the entity performing the sponsorship and of their beneficiaries;
- Unlike the current regulation, the Norms expressly regulate the maximum value (150 RON including VAT before customization) of promotional items to be provided or offered to health care professionals. Moreover, the Norms provide clear conditions regarding the engraving on the promotional items.

Should you have any questions, please do not hesitate to contact us:

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