

Legislative aspects regarding advertising medicines for human use

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Abstract. Advertising for medicines is any form of information through direct contact, as well as any form of promotion intended to stimulate the prescription, distribution, sale or consumption of medicines.

In order to be of interest to users, advertising for any medicine, regardless of the form in which it is carried out) must be of a high standard and comply with legal provisions and, in addition, must not include anything that could be offensive or deceptive.

Considering the fact that the entire activity of advertising and promotion of medicines must be done responsibly, ethically and to the highest standard, in order to ensure the safe use of medicines, regardless of their mode of release, this article aims to analyze the legislative measures adopted to regulate the advertising of medicinal products for human use.

At the same time, this paper aims to analyze how the National Agency for Medicines and Medical Devices in Romania (ANM DMR), the competent national authority, evaluates and monitors all forms of drug advertising, as well as the role of advertising campaigns that are part of the category medical education.

Keywords. medicinal products for human use, advertising, national legislation, ANM DMR, medical education

1. Introduction

An analysis of drug advertising at the present time must be correlated with the data recorded in the sale of drugs and with the evolution of the advertising market.

The Media Fact Book analysis [1], the only report analyzing the Romanian media and advertising market, estimates a new record net value for the media market in Romania at the end of this year, namely 683 million euros. This development is supported by Digital, where a growth of +9% is estimated, while for Radio, expectations are only +3%, and TV remains at the level of the previous year, but retains its leading position. The only sector for which a decrease (10%) is estimated is Print, where a consolidation of this downward trend is observed, as a result of the increase in production costs and the change in media consumption behaviors.

According to the results of the Pharma & Hospital Report study, Cegedim Customer Information estimates that in the period April 2022 - March 2023, the volume of medicines dispensed to patients in Romania was 712.6 million boxes, increasing by 5.0% compared to the consumption in April 2021 – March 2022. The volume of prescription (Rx) drugs in

pharmacies amounted to 410.1 million boxes (+5.3%) and that of OTC products in pharmacies to 274.0 million boxes (+4.5%)). In the first quarter of 2023, the total volume of medicines dispensed to patients amounted to 185.4 million boxes, 3.8% more than in the first quarter of 2022. The evolution was generated by both the growth of the retail channel (3.5 %) as well as the hospital (11.7%). By segment, the volume growth rate was 6.2% for Pharmacy Rx and -0.2% for over-the-counter products (medicines and nutritional supplements).

2. Theory

Medicines advertising includes any form of information through direct contact (door-to-door system) as well as any form of promotion intended to stimulate the prescription, distribution, sale or consumption of medicines.

Labeling and leaflets and correspondence, even accompanied by materials of a non-promotional nature, necessary to answer a specific question about a particular medicine are not advertised. Also, informative announcements and materials relating to, for example, packaging changes, warnings about side effects that are part of the general precautions for administering the medicine, commercial catalogs and price lists are not subject to advertising, provided that they does not include any promotional statements. Information on human health or disease is also not subject to advertising regulations, provided that there are no references, even indirectly, to medicines.

The National Agency for Medicines and Medical Devices in Romania (ANMMDMR) is the competent authority regarding the evaluation and approval of advertising materials and any other form of advertising for medicines for human use [2].

As all medicines advertising and promotion must be done responsibly, ethically and to the highest standard to ensure the safe use of medicines, regardless of their mode of release, for all medicines advertising activities have been defined norms and standards to regulate this activity [3].

ANMMDMR prohibits advertising for a medicine that does not have a valid marketing authorization in Romania. According to the provisions of art. 823 of Law no. 95/2006, the competent authority takes appropriate and effective measures to monitor medicines advertising. Thus, in the case of medicines that are issued without medical prescription, advertising materials intended for the general public are subject to the prior approval of ANMMDMR. In the case of medicines that are issued with or without medical prescription, the advertising materials intended for persons qualified to prescribe or distribute medicines, are analyzed after dissemination, by survey or as a result of reports.

Natural or legal persons who have a legitimate interest in the prohibition of any advertising that contravenes the legal provisions, may notify ANMMDMR, which must respond to notifications within 60 days.

All information contained in the advertising material for a medicinal product must correspond to the information listed in the summary of product characteristics.

Advertising for a medicinal product must encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties and must not be misleading.

3. Results and discussion

Advertising of medicines for human use is accepted provided that it is in accordance with the legislation in force.

The rules for evaluating and approving advertising for human medicines aim to facilitate the application of legal provisions, by clarifying certain detailed aspects, so that advertising

for any medicine, no matter in what form it is carried out, in order to be of interest to users, should be a high standard and comply with the legal provisions.

The rules regulate the advertising activity of medicines for human use, regardless of whether they are innovative or generic medicines, medicines that are issued on the basis of a medical prescription or OTC medicines. Also, the rules refer to promotional and advertising activities intended not only for doctors, but also for all other health professionals who, in the course of their professional activities, may prescribe, supply, administer a medicine, or encourage the purchase, its distribution or use.

Promotion of medicines includes any activity organized, carried out or sponsored by a pharmaceutical company (or with its authorization) that encourages the prescription, distribution, sale, administration, recommendation or use of drugs, as well as visits by medical representatives accompanied by the handing out of advertising materials, newspaper advertising or magazines, scientific publications, direct advertising by e-mail and other means of electronic communication (sites, web pages, blogs, forums), the use of audiovisual products such as films, video recordings, data storage services.

The rules for evaluating and approving advertising for medicinal products for human use apply not only to the pharmaceutical companies themselves, their subsidiaries or representatives, but also to any other partners (agents, agencies, representatives of the marketing authorization holder) with whom there is a contractual relationship in order to carry out any type of drug advertising. Pharmaceutical companies and their representatives are responsible for complying with the obligations regulated by the rules, even in the case of ceding to third parties promotion, advertising or implementation activities or of their employment, on their behalf, in advertising actions, and the companies pharmaceutical companies must ensure that any third parties to whom they have outsourced their drug advertising activities comply with the legal provisions.

Advertising must be based on the updated evaluation of all relevant evidence and clearly reflect this evidence, encourage the rational use of the medicine, by presenting it objectively, without exaggerating its properties, therapeutic qualities, and must not encourage self-medication or the irrational use of the medicine.

Advertising of medicines must not be misleading, subliminal or misleading by distortion, exaggeration, undue emphasis, omission, or in any other way. According to art. 17 of the Rules, misleading advertising is any form of advertising that, in any way, including through the way of presentation, misleads or may mislead any person to whom it is addressed or who comes into contact with it. To determine the misleading nature of advertising, all its characteristics are taken into account and, in particular, the component elements related to:

- ✓ the characteristics of the medicine (regardless of what they are), the extent to which they correspond to the intended purpose and the results expected as a result of its use;
- ✓ omitting essential information regarding the identification and characterization of the medicine with the aim of misleading the persons to whom the advertisement is addressed;
- ✓ information presented accurately, which may mislead by the general impression created by the fact that it goes against the therapeutic indications. This category may include advertising material that presents images related to driving where the drug shown may affect the ability to drive.

If we refer to comparative advertising (which explicitly or implicitly identifies a product through comparative description), this form of advertising is prohibited for the general public.

Comparative advertising aimed at healthcare professionals is also prohibited if: the comparison is misleading; a competitor's brand name is used (only international common names are allowed); medicines that have different therapeutic indications or different pharmaceutical forms are compared; one or more essential, relevant, verifiable and representative characteristics of some medicines are not objectively compared, which may include price; confusion is created on the market between the advertiser and a competitor or between the different trade marks, international common names or other distinctive signs of the advertiser and those belonging to a competitor; discredits or denigrates the trademark, international common name, other distinctive signs, activities or any other characteristics of a competitor; unfairly takes advantage of the reputation of a trade mark, international common name, distinctive signs of a competitor or any other characteristics of a competitor without having evidence to support the assertions.

No advertising material must promote the use of a medicine outside the therapeutic indications listed in the summary of product characteristics (SPC) approved for that medicine, nor the use of a medicine by certain categories of patients for which there is no indication in the SPC.

When analyzing the advertising of a medicinal product, two aspects are of particular interest: advertising to specialists and advertising to the general public. Advertising to the general public for prescription-only medicines is prohibited, but this prohibition does not apply to vaccination campaigns carried out by the pharmaceutical industry and approved by the Ministry of Health.

Any form of advertising aimed at healthcare professionals must be in accordance with the provisions of the approved SPC of the medicinal product as well as the terms of the marketing authorization (MA), and the promotion of a medicinal product prior to the granting of an MA, as well as the promotion of a medicinal product outside the approved therapeutic indications is prohibited.

Information on some indications of a drug that are not specified in the MA ("offlabel indications") can only be provided in response to a duly documented request from a healthcare professional. However, it is prohibited to use such information in order to promote the drug for unauthorized indications or for its use in conditions other than those listed in the approved SPC. In this case, the holder of the marketing authorization (MAH) ensures that the material provided is informative, non-promotional, clearly stating that the respective information represents "off-label indications".

It is prohibited to leave promotional materials intended for healthcare professionals in places accessible to the general public, such as (but not limited to) pharmacies, waiting rooms of doctors' offices, hospitals and clinics, etc. If the advertising materials are exposed to the general public, it is assumed that the responsibility lies with the pharmaceutical company, which can prove otherwise with documents.

Advertising of prescription medicinal products via the Internet is permitted only if the MAH demonstrates the restriction of access to this information by persons other than healthcare professionals through a valid and verifiable password system. Also, website providers must ensure that the materials published on the website do not contain information that contravenes national and international regulations in force.

If certain websites include links intended for users from other countries, users in Romania must be informed about this. Users in Romania must be able to directly access, for any web page, the information on the medicine (SPC - in the case of sites intended for professionals, or the leaflet - in the case of sites intended for the general public). The web page must specify the category of users to which it is addressed, and any information contained on websites

addressed to health professionals (which constitutes a form of promotion) must comply with the provisions governing the content, format of advertisements, as well as the manner of promotion of medicines.

4. Conclusions

In order to ensure the practice of a truthful, correct, without exaggeration, for the medicines for human use placed on the market in Romania, in accordance with the legal provisions, ANMDMR carries out inspections in units of distribution of medicines for human use (community pharmacies, hospital pharmacies, drug stores, wholesale distributors), in order to verify the advertising or educational materials that they own or provide, as well as in hospitals and medical offices, in order to verify the advertising or educational materials that they own.

Also, ANMDMR carries out inspections at MAH and their representatives in order to verify the advertising or educational materials that they own or provide and in order to verify the training of people who come into contact with health professionals for the purpose of promoting medicines for human use. The competent authority carries out inspections at scientific events (symposiums, conferences, congresses, round tables) attended by health professionals, in the online environment (web pages) as well as at the premises of legal entities that act under contract on behalf of MAH in order to verify the materials advertising or educational that they provide.

Regarding the advertising in the audio-visual field, according to Forbes Romania, in 2022, manufacturers, distributors and pharmaceutical retail chains obtained a TV audience volume for the advertisements ordered at the level of the previous year (decrease of 0.5%). However, the pharmaceutical sector continues to be the biggest investor in TV advertising in Romania. The TV audience volume achieved by the pharmaceutical sector (OTC, dietary supplements and medical devices) represents 28.4% of the total budget delivered by the TV market to advertising clients. In other words, more than a quarter of the TV audience for ads was achieved by drug and dietary supplement brands.

All these data suggest the importance of good evaluation, approval and especially supervision in the field of medicinal products advertising.

The end of this year also brings new information regarding possible legislative changes regarding the advertising of OTC medicines in social media and mobile applications, the draft amendment to Order no. 194 which regulates the advertising of medicines released without medical prescription in social media being prepared for approval, according to a press release from the president of the National Agency of Medicines and Medical Devices in Romania (ANMDMR).

Reference

- [1] Initiative, MediaFactBook România 2023, available at: <http://mediafactbook.ro/MFB2023.pdf>
- [2] Law no. 95/2006 regarding the health reform, republished in the Official Gazette no. 653 of August 28, 2015.
- [3] Order of the Ministry of Health no. 194 of February 23, 2015 regarding the approval of the Norms for the evaluation and approval of advertising for medicinal products for human use, published in the Official Gazette no. 168 of March 11, 2015.