Importance of the Regulation of Pharmaceutical Marketing

Karla Zarceño, Vivian Carballo, Zulma Pérez
Promotion and Advertising Unit
National Directorate of Medicines
revistadnm@medicamentos.gob.sv

Regulatory Approach

Received:
October 24, 2023

Accepted:
January 29, 2024

Published:
July 01, 2024

Abstract

In recent years, the world of the pharmaceutical industry has been evolving, as well as the way of advertising its products. That is why, in El Salvador since 2012, through the Promotion and Advertising Unit (UPP) of the National Directorate of Medicines, the issue of "Pharmaceutical Marketing" is treated with great importance, considering that one of its main objectives is to authorize, before its dissemination, all types of advertising of pharmaceutical products. In addition, to regulate by means of monitoring, surveillance and inspection, the advertising that is already exposed to the population.

The purpose of this is to guarantee that the message issued by the industry to the final consumer promotes the rational use of drugs, as well as the prevention of their abuse, through precise and objective communication based on the therapeutic indications previously approved by the regulatory authority.

Key words:
Pharmaceutical industry, pharmaceutical products, marketing, strategies, pharmaceutical advertising, commercialization.

Introduction

In the past, the regulation of advertising in the pharmaceutical industry was not carried out with as much emphasis as it is today. In El Salvador, since 2012, thanks to the creation of the National Directorate of Medicines and the application of the Law of Medicines and its General Regulations, the advertising of pharmaceutical products is more precisely regulated and the one in charge of this important function is the Promotion and Advertising Unit.

The main commitment by regulating the advertising of pharmaceutical products is to safeguard the health of consumers and to ensure that the advertising is truthful and in accordance with the therapeutic indications previously approved. Nowadays, the regulation of such advertising is based on three main axes, which are: avoiding the abuse of credibility and good faith of individuals, promoting the rational use of pharmaceutical products and the decoding of the advertising message.

Importance of Pharmaceutical Marketing Regulation

The importance of its regulation is because the contribution made by the pharmaceutical industry to society is legitimate and valuable, but it should be noted that part of this model is that they also pursue a commercial purpose, to position their products and their business model. And like any business, it also needs marketing and communication strategies to increase profits and position its brand. The higher the sales volume of pharmaceutical products, the higher your revenues will be, and to increase sales, one of the key factors is a good advertising campaign. It is precisely this factor that drives the innovation of strategies that support economic

profits and, on occasions, limits factors relevant to public health, and the business model must balance product sales and advertising, as this can lead to the irrational use of pharmaceutical products.

Pharmaceutical advertising regulation plays a vital role between industry and consumer decisions. It is responsible for guiding and managing the interactions between both groups to ensure that marketing practices contribute to better results in people's decision making when purchasing a product. In this sense, it does not seek to limit the industry in the use of strategies to reach consumers, but rather to guide, so that this approach is based on guidelines and principles in which an adequate and rational use of pharmaceutical products is encouraged.

In our daily life, unconsciously, people have become consumers of pharmaceutical advertisements, for example, when someone goes for a walk, they can see advertisements of these products on billboards. When surfing the Internet, through pop-up notifications or web banners, information about pharmaceutical products can also be seen. Many of these buttons even redirect people directly to catalogs with more options. This without leaving behind the radio, which is a medium widely used by the industry to broadcast radio spots, jingles or interviews focused on marketing their pharmaceutical products.

Being so exposed to the constant bombardment of advertising, the need for pre and post pharmaceutical marketing regulation becomes vital.

Regulation of Pharmaceutical Marketing in El Salvador

In El Salvador, since 2012, there is the National Directorate of Medicines (DNM), a regulatory entity that, within its functions, is responsible for qualifying all types of advertising of pharmaceutical products through the Promotion and Advertising Unit (DNM, 2022; DNM, 2023).

The advertising of all products must be offered to the public as a means of prevention and cure of diseases, promotion or restoration of health, avoiding that such advertising implies omission, exaggeration, inaccuracy or that may induce the consumer to deceive, error or confusion about the origin of the product, the components or ingredients, the benefits or implications of its case, avoiding that such advertising abuses the good faith and credibility of the people.

The Medicines Law (LM) defines advertising as follows: "Advertising of pharmaceutical specialties and products shall be understood as that which is made by any form or means of dissemination, such as: printed advertising, broadcast, tele-cast, drawn, painted, projected or disseminated by means of internet, audio system, fixed or itinerant, as well as the free distribution of samples." Advertising of pharmaceutical products is classified into two groups contained in articles 60, 61 and 62 of the LM of El Salvador (LM, 2012).

The regulation of pharmaceutical marketing in the country is based on three main axes:

Avoid abuse of people's credibility and good faith

According to the Ethical Aspects for Pharmaceutical Advertising in El Salvador (DNM, 2012), good faith refers to the fact that all promotion and advertising of pharmaceutical products should never constitute a means to abuse the good faith of the consumer or encourage the irrational use of medicines.

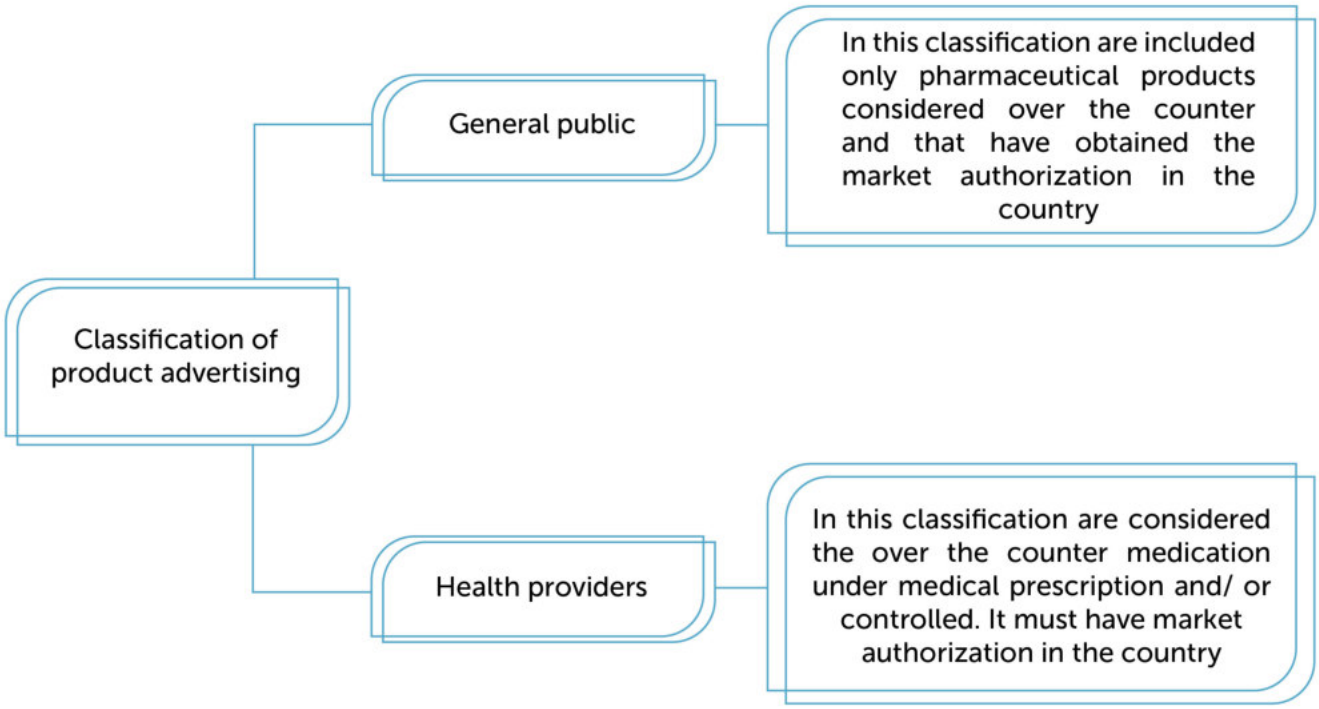
In marketing, there is a commercial tendency to create advertising campaigns with definitive solutions that can reach the limit of miraculous situations that put an end to the consumer's needs. However, in the pharmaceutical industry, a pharmaceutical product cannot be advertised under a strategy that exaggerates or exalts its goodness, making it look like the best, unique or perfect. This, besides generating unfair competition, would provoke a behavior in the consumer to buy it, consume it and even recommend it because of the language used in advertising.

The Promotion and Advertising Unit is in charge of making sure that all advertisements and publicity materials that appear daily in the different media are reliable, that they do not abuse the good faith of the people, that they do not exaggerate the benefits of the product for commercial purposes, that the information placed in each material is accurate and precise with the prescription of the drug being advertised, that therapeutic properties not approved by the registration area are not added, that it is disclosed in the most understandable way (language and choice of appropriate words), and that it is indicated that it is a drug that is being advertised, (that the pharmaceutical product does not appear to be a beverage, food or snack). In addition, publications should always contain an explicit call to read the indications of the product and to consult a doctor or pharmacist in case of any doubt.

To promote the rational use of pharmaceuticals

Drug advertising promotes the protection of citizens' health through its rational use, so when a pharmaceutical product is authorized for marketing, it is accompanied by approved product information. This information details the use or uses for which the drug was approved (its indication), its dosage and administration, precautions and warnings, as well as information on contraindications, adverse effects and interactions with other drugs.
For the manufacturer's advertising to be consistent with the approved product information, it must adhere to the approved indications and conditions of use. For example, if a drug has been approved only for epilepsy, the manufacturer cannot advertise it for bipolar disorder or depression.
Advertisements of pharmaceutical products can promote rational use when the information is objective and unbiased. That is why, before an advertisement of pharmaceutical products is publicly available, a medical and technical analysis, as presented in Figure 1, is carried out in accordance with the provisions of the pharmaceutical legislation in force.

Figure 1. Advertising classification



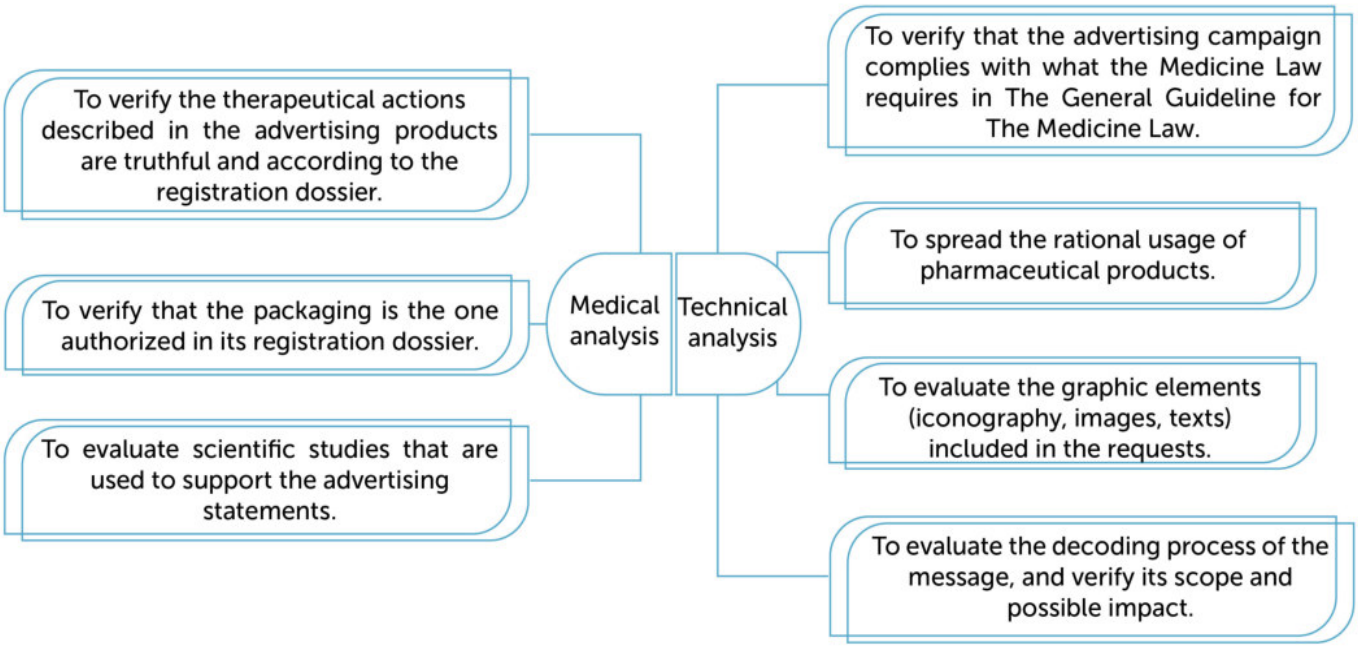
Source: self made

These and more details are contained in Articles 73 of the General Regulations of the Medicines Act (2012) and in the Medicines Act (2012) Article 60.

Decoding the advertising message

The decoding of the advertising message refers to the analysis that the Promotion and Advertising Unit performs in each of the advertising projects, before their dissemination, to issue an analysis based on technical criteria and to ensure that the advertising reaches the consumer in a clear, concise and true manner, see Figure 2.

Figure 2. Advertising analysis



Source: self made

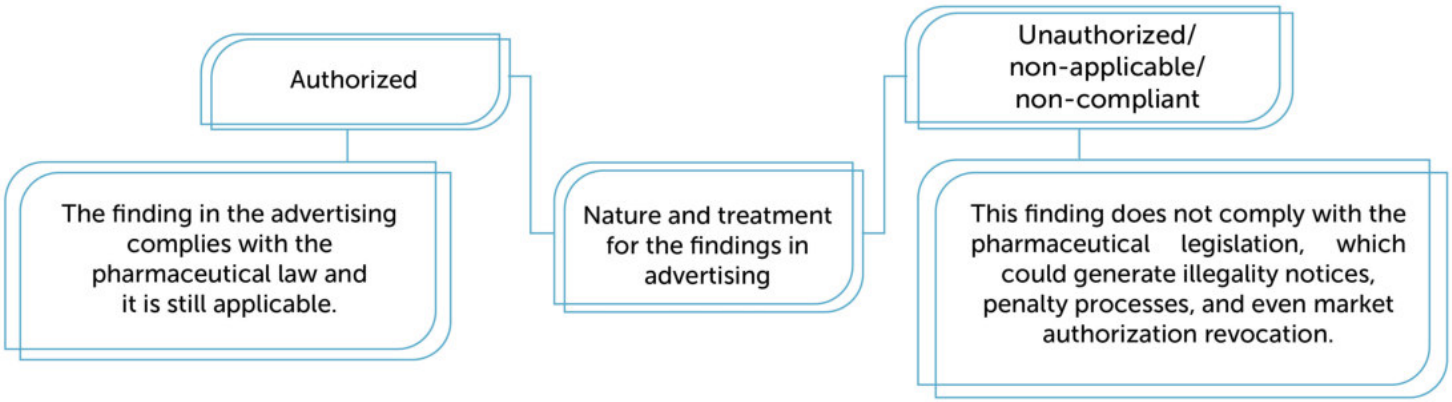
For this analysis it is necessary to critically and accurately evaluate both the advertising message and the graphic or audiovisual elements that accompany it. These elements must be coherent with each other and must have the purpose of transmitting truthful and accurate content so that the consumer can make correct decisions about the pharmaceutical products to be consumed and avoid their abuse. Advertising messages should not implicitly contain invitations to consume alcohol and use narcotics, nor should it be implied through advertising that the use of the pharmaceutical product will prevent future illnesses because of the consumption of these substances.

Pharmaceutical Advertising Surveillance

Constant monitoring is another tool that enables the regulation of pharmaceutical marketing. The team in charge of this task compiles various findings through different media. Subsequently, an analysis is made, and it is corroborated if the finding in question has current authorization, if it does not have authorization or if it complies with what has been authorized.

The inspections of advertising at the point of sale are another form of monitoring, these are carried out by DNM inspectors, accompanied by personnel from the Promotion and Advertising Unit. In this work, findings are also collected and subsequently processed according to their nature, as shown in Figure 3.

Figure 3. Treatment of findings



Source: self made

This is why surveillance through monitoring and inspections also play a fundamental role in the regulation of pharmaceutical marketing. It becomes the main tool to check whether the pharmaceutical industry is carrying out its advertising strategies in accordance with the provisions of the Medicines Law and its General Regulations.

Conclusion

Considering the analyzed aspects, it can be concluded that the advertising of pharmaceutical products has a direct influence on consumers and even plays a very important role in decision-making. Therefore, it is vital to previously authorize the message to be conveyed through an advertising campaign to ensure that the purchase decision is made consciously and accurately and not only by advertising influence.

Thus, by conducting an analysis prior to advertising campaigns, monitoring the media and constantly monitoring points of sale, it can be ensured that campaigns are based on verifiable facts, that they seek the rational use of the product and, above all, that they do not use strategies that mislead or confuse the consumer's perception in any way.

Bibliographic references

1. Dirección Nacional de Medicamentos (30 de enero 2023). Guía para la calificación y autorización de publicidad de productos farmacéuticos en televisión, radio, internet, prensa escrita, vallas publicitarias, carteles y similares. https://www.medicamentos.gob.sv/?wpdmpro=guia-para-la-calificacion-y-autorizacion-de-publicidad-de-productos-farmaceuticos-en-television-radio-internet-prensa-escrita-vallas-publicitarias-carteles-y-similares
2. Dirección Nacional de Medicamentos (3 de enero 2012). Aspectos éticos para la publicidad farmacéutica en El Salvador. https://www.medicamentos.gob.sv/?wpdmpro=aspectos-eticos-para-la-publicidad-farmaceutica-en-el-salvador-2
3. Dirección Nacional de Medicamentos (5 de octubre 2022). Guía para la calificación y autorización de promoción de productos farmacéuticos. https://www.medicamentos.gob.sv/?wpdmpro=guia-para-el-tramite-de-autorizacion-de-promocion-de-productos-farmaceuticos.
4. Decreto 1008 de 2012. Por medio del cual decreta la Ley de Medicamentos. 2 de marzo de 2012 (El Salvador).