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SOBRE LA PUBLICIDAD DE LOS MEDICAMENTOS: LEGISLACIÓN

About Advertising of Medicines: Legislation

Carlos del Castillo Rodríguez
Universidad Complutense de Madrid. España.
carlosdelcastillo@farm.ucm.es

Silvia Enríquez Fernández[1]
Universidad Complutense de Madrid. España.
silvienr@ucm.es

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Resumen

La publicidad de los medicamentos está sometida a un régimen especial justificado por los posibles efectos negativos que su práctica puede originar en la sociedad actual y consecuentemente en la salud pública. Las principales normas específicas que regulan el tema objeto de estudio son, entre otros, el *Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios* y el *Real Decreto 1416/1994, de 25 de junio, por el que se regula la publicidad de los medicamentos de uso humano.* En éstas se dispone tanto las características de la publicidad como el control al que estará sometido y las infracciones imponibles en caso de incumplimiento.

Palabras clave: Legislación; publicidad; medicamentos; infracciones; intervención; administración pública.

[1] **Silvia Enríquez Fernández**: Graduada en Farmacia, Universidad Complutense de Madrid; Investigadora doctoral de la Universidad Complutense de Madrid. Departamento de Farmacia Galénica y Tecnología Alimentaria (Historia de la Farmacia y Legislación Farmacéutica). Contacto: silvienr@ucm.es.

Abstract

The publicity of medicines is subject to a special regime which is justified by the importance of negative effects and the risk it may pose to public health. The specific rules governing the subject under consideration are in the Royal Legislative Decree 1/2015 of 24 July approving the consolidated text of the Law on Guarantees and Rational Use of Medicines and Medical Products and in the Royal Decree 1416/1994 of 25 June regulating the advertising of medicines for human use. These normative provide the characteristics of the advertising and the control to which it will be subject and the taxable infringements in case.

Keywords: Legislation; publicity; medicines; control; infringements; intervention; Public administration.

1. ADVERTISING CONCEPT: ADVERTISING OF MEDICINAL PRODUCTS

The general definition of advertising is set out in *Law 34/1988, of 11 November 1988, General Advertising Law.* [2]. Its second article defines advertising as: "any form of communication made by a natural or legal person, public or private, in the exercise of a commercial, industrial, artisanal or professional activity, with the aim of directly or indirectly promoting the contracting of movable or immovable goods, services, rights and obligations".

The only explicit reference to medicines in the aforementioned law is found in Article 5.4, which states that: "narcotic drugs, psychotropic substances and medicines intended for human consumption may only be advertised in the cases, forms and conditions established in the special rules that regulate them". This rule refers us to the specific regulation for the advertising of medicines.

The special regulations on advertising are very extensive, and we can classify them into three groups according to the information they provide us with: according to the means of dissemination, according to the recipients of the advertising, and according to the product. The rules on the advertising of medicinal products fall into the last of these groups[3], i.e. we include medicinal products in advertising legislation on a product basis.

The market for medicinal products is different from that for other products and is therefore subject to a special regime which is justified by the predominance of the protection of consumer interests, as well as the harm it may cause to public health as opposed to the interests of the advertiser[4]. For this reason, there is a specific regulation that aims to ensure that this type of advertising is truthful and informative[5].

[2] BOE no. 274 of 15 November 1988.
[3] *Ibíd.*
[4] Its legal regime is special and particular given its intimate relationship with health protection. There is a great deal of critical literature on this subject. On this subject, see: BOMBILLAR SÁENZ, Francisco Miguel (2010). Intervención administrativa y régimen jurídico del medicamento en la Unión Europea. Doctoral

The first specific regulation published in Spain on the advertising of medicines was the *Order of 10 December 1985, issued by the Ministry of Health and Consumer Affairs, regulating advertising messages referring to medicines and certain health products*[6], which regulated the content of advertising messages of all kinds aimed at the general public and referring to medicines. Subsequently, in 1994, the *Royal Decree 1416/1994 of 25 June 1994 regulating the advertising of medicinal products for human use*[7], was published, which will be dealt with in section III. Likewise, the *Royal Legislative Decree 1/2015 of 24 July 2015, which approves the revised text of the Law on guarantees and rational use of medicines and health products*[8], which will be referred to below, specifically regulates the subject under study.

The legal concept of advertising of medicinal products - regulated in this specific legislation - is the same at national level[9] as in Community law[10], and both define advertising of medicinal products as any form of information, prospecting or inducement designed to promote the prescription, dispensing, sale or consumption of medicinal products. This concept includes advertising of medicinal products to the public, as well as advertising to persons qualified to prescribe or dispense medicinal products, such as sponsorship of promotional meetings; provision of samples; the activities of medical sales representatives; the inducement to prescribe or dispense medicinal products by granting, offering or promising advantages, whether pecuniary or in kind, except where their intrinsic value is minimal; sponsorship of scientific congresses attended by persons qualified to prescribe or dispense medicinal products, and in particular the bearing of travel and subsistence expenses in connection with such congresses.

2. OBJECTIVES

The aim of this article is to carry out an exhaustive study of the legal regime governing advertising of medicinal products and to analyse the actions of the different public administrations in this area.

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[5] Ministry of Health, Consumer Affairs and Social Welfare. 2019. Guidelines for the advertising of medicinal products for human use to the public, cit. p. 5.

[6] BOE (Official State Gazette) No. 302 of 18 December 1985.

[7] BOE no. 180, of 29 July 1994.

[8] BOE no. 177, of 25 July 2015. We will make a specific section on this law.

[9] See article 1.2. BOE no. 180, 29 July 1994. Royal Decree 1416/1994, of 25 June 1994, regulating the advertising of medicinal products for human use.

[10] See Article 86. L 311. 6 November 2001. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

3. LEGISLATION APPLICABLE TO THE ADVERTISING OF MEDICINAL PRODUCTS

3.1. Community legislation

In the European Community legal framework, the directives that refer to or affect the regulation of the advertising of medicinal products are (in chronological order):

- *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*[11], which, as mentioned above, defines the concept of advertising of medicinal products in Article 86. In addition, Articles 87 to 90 define which medicinal products are totally prohibited from being advertised and the requirements that must be met for those that are authorised[12]. In Articles 97 to 100, it makes the marketing authorisation holder responsible for advertising, giving the courts and administrative bodies of the Member States the power to require advertising that complies with the regulations in force.
- *Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising*[13].
- *Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services*[14].

3.2. Regulations at national level

With regard to national regulations affecting the advertising of medicines, we find, in chronological order, the following:

[11] Official Journal of the European Communities. L 311. 6 November 2001.

[12] Refer to articles 87 to 90 of the aforementioned Directive (OJEU 311 of 6 November 2001), which establishes the conditions that the advertising of a medicinal product must contain. In view of their importance, we will stress that the advertising of a medicinal product must promote the rational use of the product, presenting it objectively and without exaggerating its properties. These articles also refer to prohibitions established in the Member States, such as mentioning in advertising to the public therapeutic indications such as tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other tumour diseases, chronic insomnia, diabetes and other metabolic diseases.

[13] OJEC, L 376 of 12 December 2006. The aforementioned directive does not refer to medicinal products specifically, however, it regulates the characteristics of misleading advertising, which is prohibited by Article 87 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. According to the former, misleading advertising is any advertising which in any way, including its presentation, misleads or is likely to mislead the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor.

[14] OJEC, L 75 of 10 March 2010. Vid. Article 10.3 restricting the conditions of promotion and prohibiting the advertising of prescription-only medicines, Article 11.4 b prohibiting programmes from advertising medicines and Article 21 prohibiting the teleshopping of medicines subject to a marketing authorisation within the meaning of Directive 2001/83/EC, as well as the teleshopping of doctor's treatments.

- The Order of 10 December 1985, of the Ministry of Health and Consumer Affairs, which regulates advertising messages referring to medicines and certain health products[15].
- Law 14/1986, of 26 April 1986, General Health Law (LGS, add abbreviation)[16]. Article 27 refers to health advertising, addressing the control of the veracity of commercial advertising and propaganda in the field of health. This article establishes that the public administrations shall control commercial advertising and propaganda to ensure that they comply with truthfulness criteria, within the scope of their competences, in order to limit anything that could be detrimental to health. This article was modified by *Law 33/2011, General Law on Public Health*[17], which maintains the provisions of the LGS, but adds "with special attention to the protection of the health of the most vulnerable population".
- *Law 34/1988, of 11 November 1988, General Law on Advertising,* as mentioned above, refers to the concept of advertising of medicines, and for its regulation it refers to the specific legislation on medicines.
- *Law 3/1991, of 10 January, on Unfair Competition*[18], establishes the prohibition of acts of Disloyal Competition, including unlawful advertising under the terms of the General Advertising Law.
- *Royal Decree 1416/1994 of 25 June 1994, which regulates the advertising of medicinal products for human use*[19].
- Circular 6/95, of the Directorate General for Pharmacy and Medical Devices of the Ministry of Health and Consumer Affairs, clarifications to Royal Decree 1416/1994, of 25 June 1994, regulating the advertising of medicinal products for human use, amended by Circular 7/99, of 27 May 1999, of the Directorate General for Pharmacy and Medical Devices.[20].
- *Royal Decree 1345/2007 of 11 October 2007, which regulates the procedure for the authorisation, registration and conditions of dispensing of industrially manufactured medicinal products for human use*, in article 25, establishes three requirements to be met by medicinal products whose advertising is intended for the public.[21].
- Law 29/2009, of 30 December, which amends the legal regime of Disloyal Competition and advertising to improve the protection of consumers and users[22].
- Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on guarantees and rational use of medicines and health products[23].

[15] BOE No. 302 of 18 December 1985.
[16] BOE no. 102 of 29 April 1986.
[14] BOE no. 240, of 05 October 2011.
[18] BOE no. 10, of 11 January 1991.
[19] BOE no. 180, of 29 July 1994. We will now analyse the specific content of this Royal Decree.
[20] This circular clarifies Royal Decree 1416/94 of 25 June 1994, which regulates the advertising of medicinal products for human use.
[21] Refer to The three requirements set out in the aforementioned article are: 1. That they are not financed by public funds. 2. That their composition and purpose are designed and intended for use without the intervention of a doctor who carries out the diagnosis, prescription or monitoring of the treatment, and that they do not contain psychotropic or narcotic substances in their composition.
[22] BOE no. 315, of 31 December 2009.
[23] BOE no. 177, of 25 July 2015. We will make a specific section on this law.

4. SPECIFIC REGULATION: ROYAL DECREE 1416/1994 OF 25 JUNE 1994, REGULATING THE ADVERTISING OF MEDICINAL PRODUCTS FOR HUMAN USE.

The provisions included in the *Royal Decree 1416/1994 of 25 June 1994, which regulates the advertising of medicinal products for human use*[24], apply to the advertising of industrially manufactured medicinal products for human use.

The principles of this Royal Decree can be summarised in four. Firstly, advertising of a medicinal product that has not obtained the corresponding marketing authorisation is prohibited. Secondly, all elements of the advertising of a medicinal product must comply with the information contained in the product's technical data sheet. Thirdly, advertising must always promote the rational use of the medicinal product by presenting it objectively and without exaggerating its properties. Finally, it prohibits misleading advertising by mentioning article 4 of *Law 34/1988 of 11 November 1988, General Advertising Law, on the prohibition of subliminal advertising.*[25].

The regulation in this law is made by distinguishing between two types of advertising: advertising aimed at the public and advertising aimed at persons authorised to prescribe. Given the importance of both types of advertising, we will see how they are regulated.

4.1. Advertising to the public

Advertising of medicinal products to the general public shall be understood to be that which, having been duly authorised, is addressed to the public for promotional and informative purposes, always promoting the appropriate use of the medicinal product[26]. It must clearly state the advertising nature of the medicinal product, in addition to containing information identifying the medicinal product and the recommendations determined by the Ministry with competence in health to prevent the risks derived from the normal use of the medicinal product.

As regards the information to be included as a minimum in the advertising under consideration, it is the name of the medicinal product[27], the information necessary to promote its rational use and an express invitation to read carefully the instructions contained in the medicinal product.

[24] BOE no. 180, of 29 July 1994.
[25] BOE no. 274 of 15 November 1988. Law 34/1988, of 11 November 1988, General Law on Advertising. Article 4, on subliminal advertising, "for the purposes of this law, subliminal advertising shall be that which, by means of techniques for the production of stimuli of intensities bordering on the thresholds of the senses or similar, can act on the target public without being consciously perceived".
[26] Refer to, article 22. BOE no. 180, 29 July 1994, on the authorisation of advertising aimed at the public.
[27] See, article 5. BOE no. 180, 29 July 1994, must include the name of the medicinal product, as well as the Official Spanish Name or, failing that, the International Nonproprietary Name, or the usual or scientific non-proprietary name when the medicinal product contains a single active ingredient.

It should be noted that advertising of a medicinal product to the public may include only the name of the medicinal product when the sole purpose of the advertising is to recall the name of the medicinal product, provided that the medicinal product is sufficiently well known to the public and has been used in promotional campaigns for at least two years. The advertising message shall include the words: "if in doubt, ask your pharmacist" or a similar expression.

The advertising of a medicinal product to the general public may not include any element which[28]:

a) Attributes to the medical consultation or surgical intervention an unnecessary character, offering a diagnosis or advising a treatment by correspondence.
b) Suggests that its effect is guaranteed, that it has no side effects or that its effects are superior or equal to those of another treatment or medicine.
c) Suggests that the user's health can be improved by it or that the user's health may be affected if it is not used.[29].
d) Suggests or indicates that its use enhances sporting performance.
e) Is directed exclusively or mainly at children.
f) Refers to a recommendation made by health professionals or other persons who may, by virtue of their position or prestige, encourage the use of medicinal products.
g) Compares the medicinal product with a foodstuff, cosmetic or any other consumer product.
h) Suggests that the safety or efficacy of the medicinal product is produced by a natural substance.
i) May encourage a false self-diagnosis, either by a detailed description or representation of the anamnesis.
j) Refers to claims of cure in an abusive, alarming or misleading manner.
k) Uses visual representations of changes in the human body caused by disease, injury, or the action of a medicinal product on the human body.
l) Mention obvious characteristics of the medicinal product, such as that the medicinal product has received health authorisation or any other authorisation.

4.2. Advertising to healthcare professionals

The information that healthcare professionals obtain about medicines is one of the factors that can influence whether they prescribe one medicine or another, which is why it is essential that the advertising of medicines is regulated by law. This type of advertising must contain complete information so that healthcare professionals can judge the therapeutic value of the medicine. To this end, the *Royal Decree 1416/1994 of*

[28] See article 6 on prohibitions. BOE no. 180, 29 July 1994.
[29] This prohibition does not apply to vaccination campaigns regulated in article 9 of this Royal Decree on vaccination campaigns.

25 June 1994, which regulates the advertising of medicinal products for human use[30]*,* establishes the minimum technical-scientific information that advertising must contain: the essential information on the product according to the data contained in the technical data sheet[31], its prescription and dispensing regime and the different presentations of the product, and the dosage and pharmaceutical form.

There are different ways of advertising to healthcare professionals who are authorised to prescribe or dispense medicinal products. One form is the medical visit, whereby a medical visitor goes to health professionals to provide them with technical knowledge about the medicinal product being advertised. This type of advertising requires that the medical representatives receive appropriate training from the laboratory marketing the medicinal product. Each visit shall include the retail price, the conditions of the pharmaceutical presentation financed by the National Health System, if applicable, and, where possible, the estimated cost of the treatment[32]. In addition, at each medical visit, they shall provide the healthcare professional with a technical file on the advertised medicinal product. Finally, they shall notify the scientific service[33] of any information they receive from the health professionals visited.

Another type of advertising aimed at healthcare professionals authorised to prescribe or dispense is the so-called "documentary advertising". This is done through publications such as magazines, bulletins, books and similar (scientific), or incorporated in audiovisual media on optical media, or similar, provided that they are aimed exclusively at persons authorised to prescribe or dispense medicinal products.

Advertising may also be carried out by means of free samples. These shall be made exclusively to persons authorised to prescribe medicinal products, a maximum of ten samples of each medicinal product may be distributed per year and per medical practitioner, and for a maximum period of two years, starting from the date of authorisation of the medicinal product.

Finally, it is worth mentioning two other types of advertising, on the one hand, incentives[34], which are prohibited, and, on the other hand, sponsorship of scientific

[30] See Article 10. BOE no. 180, 29 July 1994.

[31] It must include at least: name of the medicinal product, qualitative and quantitative composition, full clinical particulars, incompatibilities, instructions for use/handling, name and address of the authorisation holder.

[32] See Article 12.3. BOE No 180 of 29 July 1994.

[33] BOE No 180 of 29 July 1994, according to which "the holder of the authorisation for a medicinal product shall have a scientific service within his company responsible for information on the medicinal products he places on the market".

[34] See Article 17, BOE no. 180, 29 July 1994, which states: "It is forbidden to grant, offer or promise to persons authorised to prescribe or dispense medicinal products and in the context of the promotion of medicinal products to such persons, bonuses, pecuniary advantages or advantages in kind, with the exception of those of insignificant value and which are irrelevant to the practice of medicine or pharmacy". Nor may persons authorised to prescribe or dispense medicines accept any of the prohibited inducements provided for in Article 17 of the Royal Decree under study.

meetings. These are permitted, in certain cases, as long as the recipients are clinicians or the organisations with which they are associated.

5. SPECIFIC REGULATION INCLUDED IN THE ROYAL LEGISLATIVE DECREE 1/2015, OF 24 JULY, APPROVING THE REVISED TEXT OF THE LAW ON GUARANTEES AND RATIONAL USE OF MEDICINES AND HEALTH PRODUCTS.

The Royal Legislative Decree 1/2015[35] includes some specifications on the subject under study in this paper, specifically Article 80. In the first section of this article, it establishes the three requirements that must be met in order to advertise a medicinal product, which are also included in the *Royal Decree 1345/2007*[36]. Firstly, only medicines that are not financed by public funds may be advertised. Secondly, medicines that are intended for use without the intervention of a doctor who makes the diagnosis, prescribes or monitors the treatment, even if they require the intervention of a pharmacist. This requirement may be waived in the case of vaccination campaigns approved by the competent health authorities. Thirdly and finally, they do not constitute psychotropic or narcotic substances as defined in international conventions.[37].

It is worth noting Article 80[38], according to which the advertising of medicinal products not subject to medical prescription shall not require prior administrative authorisation. The Ministry of Health, Consumer Affairs and Social Welfare shall establish controls to ensure that advertising to the public for them is evaluated (to be explained in section 6 on control and surveillance of health advertising). This article prohibits premiums, gifts, prizes, contests, competitions, bonuses or similar as methods linked to the promotion or sale of these medicinal products to the public, in any case. The remaining paragraphs of the same article contain specific prohibitions on medicinal products for which advertising to the public is not allowed.

6. CONTROL AND SURVEILLANCE OF ADVERTISING OF MEDICINAL PRODUCTS

Community legislation has established a dual internal and external control system for the promotion of medicinal products. In this respect, on the one hand, as an internal control mechanism, the companies responsible for marketing can rely on a scientific service and thus ensure compliance with the legislation in question. On the other hand,

[35] BOE no. 177 of 25 July 2015.

[36] See, Article 80.1. BOE no. 177, 25 July 2015. An exception not established in the second requirement of Royal Decree 1345/2007 is made, "which by their composition and purpose are designed and intended to be used without the intervention of a doctor who carries out the diagnosis, prescription or monitoring of the treatment". In Royal Legislative Decree 1/2015 this requirement may be exempted when vaccination campaigns approved by the competent health authorities are carried out.

[37] See, Article 80.1. BOE no. 177, 25 July 2015.

[38] See, Article 80.1. BOE no. 177, 25 July 2015. "The advertising of medicinal products not subject to medical prescription shall not require prior administrative authorisation, although the competent health authorities shall carry out the necessary controls to ensure that the advertising content complies with the applicable legal and regulatory standards and that it faithfully complies with the scientific and technical conditions set out in the marketing authorisation".

external control is exercised by both judicial and administrative bodies, without prejudice to the role played by self-regulation in the field of advertising.[39].

6.1. Internal control

There are various means of internal control. For example, in Spain, there is a non-profit association called Asociación para la Autorregulación de la Comunicación Comercial (AUTOCONTROL). This association is made up of advertising agencies, advertisers, professional associations and the media. Its aim is to work for responsible advertising: legal, truthful, loyal and honest[40]. Entre sus servicios encontramos consultas para analizar un proyecto antes de su emisión. Its services include consultations to analyse a project before it is broadcast. In this sense, it resolves, through the Advertising Jury, the complaints that are brought to it in relation to advertising messages aimed at the public on medicines for human use[41].

6.2. External control

In the first place, administrative control is based on article 30 of *Law 14/1986, of 26 April 1986, General Health Law*[42], according to which "all health centres and establishments, as well as promotional and advertising activities, shall be subject to inspection and control by the competent health authorities". Likewise, article 5 of *Law 34/1988, of 11 November 1988, General Law on Advertising*, in its first section, establishes that "the advertising of health materials or products and others subject to technical-health regulations, as well as that of products, goods, activities and services likely to generate health risks (...) may be regulated by their special rules or be subject to the system of prior administrative authorisation. This system may also be established when the protection of constitutionally recognised values and rights so requires". This article gives administrations the ability to control advertising before it is broadcast.

However, mention will be made of the controls that are carried out on advertising of medicines that do not require prior administrative authorisation, which are those that are not subject to medical prescription[43].

These controls are carried out by the Ministry of Health in collaboration with other bodies also involved in this process, such as, for example, the Association for the Self-Regulation of Commercial Communication, which has been mentioned above. Its purpose has been to ensure that the advertising messages that are broadcast comply with each and every one of the conditions imposed by the legal system in this area, without prejudice to the exercise of any administrative powers that may correspond. Its

[39] Á. García Vidal. The promotion of medicines aimed at health professionals. A study from the perspective of Commercial Law. Marcial Pons. Madrid. 2013. 271 pp.
[40] See, website www.autocontrol.es.
[41] See, Ministry of Health, Consumer Affairs and Social Welfare. 2019. Guidelines for the advertising of medicinal products for human use to the public. p. 5.
[42] BOE no. 102 of 29 April 1986.
[43] BOE no. 177 of 25 July 2015, according to which medicines not subject to doctor's prescription do not require prior administrative authorisation.

main objective is to promote self-regulation in the field of advertising of medicinal products for human use to the general public[44].

Secondly, in order to initiate legal action in matters of advertising of medicines, ordinary jurisdiction is used by means of a verbal trial as established in article 249.1.4 of L*aw 1/2000, of 7 January, on Civil Proceedings*[45]. Article 32 of *Law 29/2009, of 30 December, which modifies the legal regime of Disloyal Competition and advertising to improve the protection of consumers and users*[46] regulates the different actions to be taken in cases of illegal advertising: action to cease the unfair conduct or to prohibit its future repetition; action to rectify misleading, incorrect or false information; declaratory action for unfairness; action to remove the effects produced by the unfair conduct; action to prohibit, if the conduct has not yet been put into practice; action for compensation for damages caused by the unfair conduct, if the agent has acted with malice or fault; and, action for unjust enrichment.

Any natural or legal person who is affected and, in general, those who have a subjective right or legitimate interest, associations, professional corporations or those representing economic interests, when the interests of their members are affected, are entitled to bring these actions. The control of advertising of medicinal products is generally carried out in defence of the general, collective or diffuse interests of consumers and users. Therefore, they also have standing to act:[47]:

- The National Consumer Institute and the corresponding bodies or entities of the Autonomous Communities and local corporations competent in consumer and user protection.
- Consumer and user associations.
- Entities of other Member States of the European Community constituted for the protection of the collective interests and diffuse interests of consumers and users that are authorised by their inclusion in the list published for this purpose in the "Official Journal of the European Union".
- The Public Prosecutor's Office.

7. OFFENCES RELATING TO THE ADVERTISING OF MEDICINAL PRODUCTS

The offences in the field of advertising in general, which could be applied in the case of unlawful advertising of medicinal products, are regulated in different rules.

[44] See, Ministry of Health, Consumer Affairs and Social Welfare. 2019. Guidelines for the advertising of medicinal products for human use to the public, p. 5.
[45] See, BOE no. 7 of 8 January 2000. According to the aforementioned article: "claims relating to advertising shall be decided by ordinary trial, regardless of the amount involved, provided that they do not deal exclusively with claims for payment, in which case they shall be processed by the corresponding procedure according to the amount claimed".
[46] BOE no. 315, of 31 December 2009.
[47] See Article 33. BOE no. 315, 31 December 2009.

Article 5 of *Law 34/1988, of 11 November 1988, General Advertising Law*[48], ection six, establishes that failure to comply with the special rules governing the advertising of products, goods, activities and services - including the advertising of medicines - will be considered an infringement for the purposes set out in the *Royal Legislative Decree 1/2007, of 16 November, which approves the revised text of the General Law for the Defence of Consumers and Users and other complementary laws*[49] and in *Law 14/1986, of 26 April, General Health Law*[50]*,* in which they refer to the regulations on special advertising.

With regard to specific infringements on the advertising of medicines, we find in article 111 of the *Royal Legislative Decree 1/2015, of 24 July, which approves the revised text of the Law on guarantees and rational use of medicines and health products*[51]. Infringements are classified as minor, serious and very serious depending on the risk to health, the seriousness of the health and social disruption caused, generalisation of the infringement and recidivism. We will highlight some of them. The fifth section considers it a minor infringement to advertise magistral formulae or officinal preparations. Among the serious infringements, section 27 typifies the conduct consisting of directly or indirectly offering prohibited incentives, gifts or bonuses by anyone with direct or indirect interests in the production, manufacture and marketing of medicinal products. Finally, the general conduct consisting of carrying out promotion, information or advertising of unauthorised medicinal products or without such activities complying with the provisions of this law or the general legislation on advertising is classified as a very serious infringement[52]. For each of the types of infringements, three degrees of infringement are established,[53] and for each of them a range of fines is set.[54].

Finally, it should be noted that the Penal Code refers to the advertising of medicines. On the one hand, it establishes a prison sentence of six months to one year or a fine of 12 to 24 months for advertising of authorised medicinal products which may make false

[48] BOE no. 274 of 15 November 1988.
[49] BBOE no. 287 of 30 November 2007. See Articles 49 to 52, which regulate the infringements, as well as the degrees of infringement and their respective penalties depending on the degree.
[50] BOE no. 102 of 29 April 1986. See Article 35, which typifies health offences.
[51] BOE no. 177 of 25 July 2015.
[52] See, Sánchez Ruiz, M.M. Chapter nine. Algunas cuestiones jurídicas sobre la publicidad de los medicamentos in Cuestiones actuales de la prestación farmacéutica y los medicamentos. Mª Belén García Romero and Mª Del Mar de la Peña Amorós. 2017. ISBN: 978-84-9148-487-5.
[53] See, BOE no. 177, 25 July 2015. Depending on the negligence and intentionality of the offending party, fraud, collusion, failure to comply with prior warnings, turnover of the company, number of people affected, damage caused, profits obtained as a result of the infringement, permanence or transience of the risks and recidivism for committing more than one infringement of the same nature within a year when this has been declared by a final decision.
[54] For minor infringements: minimum grade, up to 6,000 euros, medium grade: from 6,001 to 18,000 euros, maximum grade: from 18,001 to 30,000 euros. For serious infringements, minimum level: from 30,001 to 60,000 euros, medium level: from 60,001 to 78,000 euros, maximum level: from 78,001 to 90,000 euros. For very serious infringements: minimum level: from 90,001 to 300,000 euros, medium level: from 300,001 to 600,000 euros, maximum level: from 600,001 to 1,000,000 euros, which may be exceeded up to five times the value of the products or services that are the object of the infringement.

claims or which state uncertain characteristics[55]. On the other hand, for medicines that are not authorised or are a product harmful to health, it establishes a prison sentence of one to four years, a fine of six to twelve months and special disqualification from profession, trade, industry or commerce for a period of three to six years for producers, distributors or traders[56].

8. CONCLUSION.

Advertising in general terms can influence society's ability to make choices. When it comes to advertising of medicines, it is even more important, as it can cause harm to public health. For this reason, the regulation to which it is subject is of great importance.

Advertising in general is regulated by *Ley 34/1988, de 11 de noviembre, Law 34/1988, of 11 November 1988, General Advertising Law*[57]*.* However, this refers to the specific regulation for legislation on the advertising of medicinal products.

There are various regulations that refer to the advertising of medicinal products, both at Community and national level. In Spain, the main legislation regulating the advertising of medicinal products is the *Royal Decree 1416/1994 of 25 June 1994, which regulates the advertising of medicinal products for human use*[58]*.* There is no doubt that the *Royal Legislative Decree 1/2015, of 24 July, which approves the revised text of the Law on guarantees and rational use of medicines and health products*[59] also makes relevant specifications, specifically in its article 80 on the matter under study.

In order for advertising to be legal and comply with current regulations, there are different methods of control. Furthermore, the advertising of medicines that pose a high risk to health in the event of inappropriate use must have been approved by the authorities.

It is true that the companies responsible for marketing are the ones who must carry out appropriate advertising, but, in order to facilitate this action and in case of doubt, they can turn to associations that ensure responsible advertising (internal controls).

[55] See, Ley Orgánica 15/2003, de 25 de noviembre, por la que se modifica la Ley Orgánica 10/1995, de 23 de noviembre, del Código Penal. BOE no. 283, 26 November 2003. Article 100, which amends Article 282, establishes that "manufacturers or traders who, in their offers or advertising of products or services, make false allegations or state uncertain characteristics about them, in such a way as to cause serious and manifest harm to consumers, shall be punished with imprisonment of six months to one year or a fine of 12 to 24 months, without prejudice to the penalty applicable for the commission of other offences".

[56] See, Organic Law 1/2015, of 30 March, which modifies Organic Law 10/1995, of 23 November, of the Criminal Code. BOE no. 77, of 31 March 2015. Article 190, which adds Article 362 bis to the Criminal Code, according to which "producers, distributors or traders who endanger the health of consumers by manufacturing products whose use is not authorised and is harmful to health, or by trading with them, shall be punished with a prison sentence of one to four years, a fine of six to twelve months and special disqualification for profession, trade, industry or commerce for a period of three to six years".

[57] BOE no. 274 of 15 November 1988.

[58] BOE no. 180, 29 July 1994.

[59] BOE No. 177 of 25 July 2015.

However, there are also controls external to the company, carried out by judicial and administrative bodies.

Lastly, if the advertising does not comply with the regulations in force, the offences laid down for advertising will be different in the case of inappropriate advertising of an authorised medicinal product or, where appropriate, if the medicinal product is not authorised or proves to be harmful.

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AUTHORS

Carlos del Castillo Rodríguez
Degree in Pharmacy, Universidad Complutense of Madrid; Degree in Law, Universidad Nacional de Educación a Distancia; European Doctorate, Università Alma Mater Studiorum di Bologna; Professor. Department of Galenic Pharmacy and Food Technology (History of Pharmacy and Pharmaceutical Legislation).
Contacto: carlosdelcastillo@farm.ucm.es
Orcid ID: https://orcid.org/0000-0003-2247-5966
GoogleScholar: https://scholar.google.es/citations?hl=es&user=b_br7n8AAAAJ

Silvia Enríquez Fernández
Graduate in Pharmacy, Complutense University of Madrid; Doctoral researcher at the Complutense University of Madrid. Department of Galenic Pharmacy and Food Technology (History of Pharmacy and Pharmaceutical Legislation).
Contacto: silvienr@ucm.es.
Orcid ID: https://orcid.org/0000-0002-9868-1312
Google Scholar: https://scholar.google.es/citations?hl=es&user=TeD79asAAAAJ