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Advertising of medical devices on the Internet

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Abstract

Nowadays, Internet is increasingly being used to acquire pharmaceuticals, food supplements and medical devices. Although there is a set of rules established in this regard, they are not sufficient. For this reason, the industry has established a list of ethical standards that complement them, benefiting all sectors that interact in this area.

Key words: Digital economy; advertising; marketing; ethical business; new technologies.

La publicidad de productos sanitarios en Internet

Resumen

En la actualidad, cada vez en mayor medida, se recurre a la Red para adquirir productos farmacéuticos, suplementos alimenticios, y sanitarios. Aunque existe un conjunto de normas establecidas al respecto no son suficientes. Por ello, la industria ha establecido un elenco de normas éticas que las complementan, redundando en beneficio de todos los sectores que en este ámbito interactúan.

Palabras clave: Economía digital; publicidad; marketing; negocios éticos; nuevas tecnologías.

1. INTRODUCTION

One of the most significant competitive tools nowadays is advertising, when economic operators use it to promote the hiring of goods and/or services offered on the market. It should be noticed that advertising not only exposes the character of the products and/or services, but it goes further (Puente Domínguez, 2018). In fact, it has been known from a long time ago that it is configured as a means of transmitting, instilling and enhancing certain values and behaviour patterns estimated as the common base of the collective consciousness (Gallego and De Pablos Heredero, 2016).

Advertising represents a characteristic phenomenon of modern society. Thus, among other aspects, it encourages growth and innovation, drives competitiveness, combats abuses of dominant positions and expands consumer choice (Bello and Villalobos Antúnez, 2014).

To fulfil this important mission, advertising must have a high level of confidence of the latter. To this end, it is necessary to be truthful, legal, honest and loyal. Bad advertising, which does not meet any or all of the above characteristics, even representing a tiny portion compared to the total set, will undermine consumer confidence and finally all advertising in one way or another, will suffer the adverse consequences (Calvo Calvo, 2019).

Therefore, to avoid this and for the benefit of society, it is necessary that advertising is regulated (López Jiménez and Dittmar, 2018.). There are two options applicable to the pharmaceutical sector, which are not mutually exclusive but complementary: legal self-regulation –also known as hetero-regulation- and self-regulation -or discipline or the pharmaceutical industry itself-.

However, not everything is positive, since, precisely, there are problems regarding regulation. While it would be desirable and appropriate to maintain a strict control of all online advertising, the reality shows that, at present, it is not possible. In any case, it will be the own Web which, through self-regulation, determines both a certain increase in the level of responsibility for the pharmaceutical industry and the protection of consumers and / or users.

Control of pharmaceutical advertising content on the Web is a major issue which raises new challenges for Law and, of course, for companies which operate in this environment (López Jiménez, 2013). The way in which this problem has been traditionally addressed, unfortunately, fails on the Web.

This study analyses the virtuality that the phenomenon of self-regulation can play against interactive advertising of medicinal products for human consumption, with the objective to find solutions to the current situation where users can find, in the Web, counterfeit, adulterated, expired or damaged medicines that can compromise seriously their health, without being aware.

2. METHOD

In order to reach those solutions mentioned above, and to be aware of all the research that will be developed, it is necessary first to study the concept and characteristics of the phenomenon of self-regulation. Only then the impact of such an instrument in the particular area of investigation can be understood.

Once that is done, it will be the time to study virtual advertising of medicinal products, in which self-regulation serves as a complementary tool.

3. RESULTS

After analyzing all the literature and Laws regarding self-regulation of Internet advertising, we can reach to the concept of self-regulation and explain its characteristics, including its prerogatives. Once a large enough concept of it has been exposed, the particular role it can play strictly in the advertising scenario will be analyzed.

a) Concept

Self-regulation is the action and the effect of regulating itself. It can be agreed that in a first approach, it must be understood as the ability of a subject to provide standards for himself. Also, this word is used to refer to those principles, standards and techniques that define a

good professional behaviour -called *lex artis*-, or the appropriate behaviour patterns in the daily life of an activity that requires the application of certain technical or ethical knowledge or at least, a certain degree of specialization (López Jiménez, 2014).

The novelty and interest that arises today is due to the effects of some of its features that are outstripping the private orbit, in which, originally, are conceived to achieve a public dimension or, in other words, to become the benchmark that take into account the public authorities.

The advantages of self-regulation, among others, are the following:

- it is voluntary, which greatly facilitates its practical application and enforcement without intervention of the State;
- it is flexible;
- it is specialized: it encourages the development of standards that ensure high levels of correction;
- it is transparent: it prevents the violations in the area regulated, especially if pre-assessment mechanisms exist; the covering of any legal gaps; and easy access. Last but not least important, it is necessary to highlight the advantages of saving time and legal and economic resources for the government, which can lead to the empowerment of these techniques of self-regulation in different models of consumer protection. This is because, besides the additional protection that results in all these

techniques to the consumer and/or user, it can help the legal-public system itself, to get rid of the costs of regulation.

Self-regulation as the formula regulating social relations that occurs in a certain sector has always existed, in one way or another, as any organization, of course, somehow regulates itself (López Jiménez, Monroy Antón and Crichlow, 2017). The phenomenon of self-regulation means the enforcement of a pattern of conduct, ethical principles and standards, which compliance has been previously targeted. Simultaneously, it is also an expression of commitment to social responsibility in a particular sector of industry. We can thus say that the professionalization of business leads to self-regulation (Puente Domínguez, 2019). The pressure regulator of the public authorities, aimed at promoting and even impose, in some cases, self-regulation is one manifestation of the need to increase the degree of professionalization of the companies.

It should be noted also that self-regulation can not be seen as an excuse to exempt the legislature of its obligations, but as a complement to a legislation that, inevitably, will have a very general and ambiguous character.

Advertising self-regulation can be defined as a voluntary system established by the companies in the advertising industry by virtue of which is intended to enable the exercise of advertising activity legally, honestly and responsibly for the benefit of users and consumers, competitors and the advertising market and society in general

(Fernández Martínez and Solé Cuatrecasas, 2015). To do so, adherents to a self-regulation system consciously submit to rules of conduct which observance is entrusted to an independent control.

The phenomenon of cross-border advertising self-regulation represents a manifestation of the progressive development of significant outside-State rules –different from the state laws and international standards (contained largely in international conventions)- not only for the management of commercial relations, but also for the protection of consumers in an environment of international consumer goods trading expansion.

Although drug advertising on the Internet is subject to legal rules, such a system appears not to be sufficient or adequate. In fact, although the hetero-regulation should be a minimum, the truth is that it is not being as effective as it should (Tanganelli, 2017).

Taking into account numerous factors that prevail in the matter, among others, the extraterritoriality of the Network, the astonishing speed of technological changes occurring in the space that is analyzed, and the need to ensure high levels of protection for all types of agents interacting in this space, it is advisable that such legislation is accompanied, but not replaced, by the phenomenon of self-regulation. In any case, it should not go unnoticed that the content of the legislation directly affects the self-regulation.

b) Requirements

The requirements for the existence of a system of self-regulation publicity are: the agreement of the members of the pharmaceutical industry business; the approval, by the encoder body of a reference document (a code of conduct); the existence of a body to verify full and continuous compliance of the articles of the code of conduct on drugs interactive advertising (monitoring body capable of imposing sanctions).

While all these requirements are significant, there are two, as certain authors claim, which have a constitutive character: the reference document -generally, a code of behaviour- and the control body.

Codes of conduct for drugs interactive advertising are documents that include a set of ethical rules of good practice in this area that exceed, in their demands, the current legislation, approved on behalf of the pharmaceutical business industry itself and the rights and interests of the consumer and/or user.

The practical application of the code of conduct can take place both before and after the broadcast of advertising for medicines for human use. When it happens before, in the form of previous consultation (copy advice) or, less frequently, prior opinion, the responsibility belongs to the management body of the self-regulatory organism. The subsequent application of the code of conduct is usually

due to complaints either from competitors, or from consumer associations, consumers or the public administration itself. The inspection body is the body responsible for interpretation by examining the cases submitted for prosecution by the court administrator, alleging a breach of the code. A model example of this kind of body in Spain is the so-called Advertising Jury, which will be discussed later.

For the articles of the codes of conduct not to be worthless, it is essential that the inspection body verifies its compliance in an exemplary manner, to ensure the observance of the rules, imposing penalties when they are broken. Otherwise, this would be mere statements of intent or mere instruments of propaganda without any efficacy (Villalobos Antúnez, 2016).

4. DISCUSSION

Within the wide range of goods that can be purchased over the Internet, drugs occupy a prominent place.

The great success of its sale under this channel is due to its numerous amenities. These include, among others, the following:

- ease of acquisition: both the search for a drug and the subsequent purchase turns out to be a relatively simple process through the Internet. In fact, it would be enough to type in the

computer the trade name or active substance to display a large number of Web sites where it can be bought. In addition, personal emails usually receive on a daily basis spam, with references to Internet pharmacies and individuals who offer such products.

- convenience: the Internet has provided a full accessibility to drugs, so a user can buy them without leaving home. Not surprisingly, the online stores that offer these products are open 24 hours a day, 7 days a week, 365 days a year.

- anonymity: virtual shopping, sometimes, may include some anonymity for the purchaser.

- the possibility of getting drugs that could not be obtained through legal channels, either because they required a prescription or because they are drugs still unapproved in Spain or even because they have been removed or are not licensed in the country. It must be also noticed the possibility that the drug can be purchased without prescription.

- economic reasons: from any of the virtual search engines in the case of countries like Spain, it is easy to contact Internet pharmacies established in Andorra and Gibraltar, from which, incidentally, can be got drugs at prices really competitive. In this regard, drugs that are promoted in this way, increasingly booming, are readily available and cheaper, although in other

cases, it is even stated that they are better than the originals themselves. In short, it refers to properties that can not be real.

Naturally, it is possible that the drugs are legally obtained electronically, meeting all legal requirements. Although such a situation would be the best, the practice shows that not all cases are like that. Indeed, in the Internet, pharmaceutical products sold are counterfeit in a high percentage of cases. Some other times they are adulterated - not containing the active ingredients required or having them in smaller amounts than those indicated- and/or contaminated with substances likely to cause significant damage and, sometimes, death.

In addition, the sale of these drugs is usually performed outside the required prescription and medical follow-up. As if this were not enough, neither manufacturers nor suppliers of these products are monitored by any government agency that guarantees their quality and safety. Finally, both the manufacturing and transportation can be done under conditions that affect their required quality (Gómez-Bezares, Muñoz and Vargas, 2013).

In line with terms discussed, it must be indicated that one of the drawbacks occurring in the whole order of questions is the easiness – and also impunity- with which some companies can bring to market counterfeit medicines. In fact, the World Health Organization determined that up to 62% of medicines sold over the Internet proved to be false (Bélisle-Pipon and Williams-Jones, 2015).

There might also be cases in which marketed drugs are expired or do not include prospectus or, where present, it is incomplete, or in a language other than the patient's usual, and even so-called “miracle products” (Villalobos Antúnez and Ganga-Contreras, 2018).

Therefore, given the inherent risks that these products are likely to cause, it is necessary to submit their promotion to stringent legal requirements so that, as in other areas, they are complemented by self-regulation. In this regard, the resolution of the World Health Organization, of January 23, 1998, on “Advertising, promotion and sale of medical products through the Internet”, urges all Member States to, inter alia, review legislation, regulations, and guidelines to ensure that they are applicable and appropriate to address issues of advertising, promotion and sale of medical products through the Internet.

In other words, both the legal framework and ethical standards, contained in a high percentage of cases in codes of conduct, pursue protect the adequacy and accuracy of the information provided in drug advertising. The functionality of the truth goes beyond being a necessary and fundamental tool to the economic order. It is a right for a party, which does not have enough information, so as to make efficient decisions in an environment where something as important as health is present. In the case of drugs, the requirement of objectivity is crucial to the extent that the advertiser should not deface the real properties or uses from them.

Internet can not be a way to market freely all types of drugs, but it must observe the legal restrictions on products requiring a prescription. In this sense, the Judgement of the Court of Justice of the European Community, December 11, 2003, Case C-322/01, *DocMorris*, determined it was legal the sale online of drugs licensed in the country of destination which needed no prescription. Under the principle of free movement of goods through the territory of the Community, any medicinal product not subject to prescription may circulate.

In Spain, article 2.5 of the law 29/2006 of July 26, on guarantees and rational use of medicines and medical devices, prohibits the sale by mail and telematic procedures of medicines subject to prescription. It is also unlawful widespread publicity within the Community of medicinal products that do not have national and/or community marketing authorization.

Certain pharmaceutical products that are authorized in the country of destination can be marketed through the Internet, provided that the transaction operates with full guarantees of consumer information, especially regarding the product, and, as already said, when the product does not require a prescription. Otherwise it may involve interference with the free movement of goods prevailing in Europe (Czerw and Marek, 2013).

It can not be forgotten that, on Web sites dedicated to the sale of pharmaceuticals, information given in writing, can be read as often as

deemed appropriate, and emails asking certain questions to the pharmacist may be sent. As if this were not enough, occasionally, the opinions of other users about some pharmaceutical products and, where appropriate, the answers given by professionals, can be viewed (Coleman, 2014; De Lange, 2016).

As for the Internet marketing of products that require a prescription, it should be noted that until reliable electronic methods are in place to ensure their holding by the patient, they may not lawfully be bid in the Web. If these requirements were not observed, it could be incurring in a serious offense in accordance with Article 101.b) -number 16- of the Law 29/2006. The penalties for this are set in art. 102.1 of the same rule.

It must be noticed, in this sense, the suggestive work on the control over drugs requiring authorization that the pharmacist develops. In fact, art. 1.5 of Spanish Law 16/1997, of April 25, regulating the services of the pharmacy, determines that the pharmacist has to provide information and monitor drug treatments to patients. E-acquisition of medicines can contribute to the provision of this duty by the pharmacy. Indeed, when the product is purchased through the Internet, the pharmacist has, among other information, the acquirer email, so that he/she can maintain contact with him/her.

Once the legal regulation on the subject has been analyzed, it is time to review the derivative instruments of self-regulation in the field of medicine. These documents come from different sources.

Thus, internationally, in 1988, the World Health Organization as an organization specializing in health, developed the "Ethical Criteria for Medicinal Drug Promotion," intended to serve as a reference for deciding whether the advertising practices are consistent with certain ethical standards (Villalobos Antúnez y Bello, 2014). The above criteria are not binding rules, although it must be said, one of its purposes is to serve as a reference for States to precisely adapt standards in the field as well as for self-regulatory organizations. Although its content is relatively flexible and poorly designed, it incorporates rules on issues addressed in the Spanish and European Community regulations on drug advertising (Villalobos Antúnez, 2018).

As far as Spain is concerned, there are several codes of conduct that must be highlighted, some of which include rules for commercial communications relating to drugs that may be disseminated in various media including the Internet (Coleman, 2014; Mintzes, 2016).

First, it has to be mentioned the Spanish code of good practice in drug promotion and interaction of the pharmaceutical industry to healthcare professionals of October 26, 2010. Such a document of good practice was preceded by several texts which, in turn, different versions were made. Thus, in 1991, the European Federation of Pharmaceutical Industry Associations (EFPIA) endorsed the European Code of Good Practice for the Promotion of Medicines, which was changed a year later. However, new versions of it were approved in 2002, 2005 and 2008.

The control system set up for it consists of three levels that ensure the effective application of the same: the Conduct Surveillance Unit, the Practice Committee of the Pharmaceutical Industry and the Jury of Self-Control of Advertising.

As it was mentioned above, this document is applicable to all methods of promotion, as for example, the press, the activities of drug representatives, sponsorship of scientific congresses and scientific meetings attended by health professionals, and the Internet (Applequist and Ball, 2018).

Second, it has to be mentioned that the Spanish code of good interface practices of the pharmaceutical industry with organizations of patients of June 30, 2008. Again, the enforcement of this paper is attributed to the three bodies set out above, the Conduct Surveillance Unit, the Practice Committee of the Pharmaceutical Industry and the Jury of Self-Control on Advertising.

Third, the code of ethical standards for the promotion and advertising of medicinal products authorized without a prescription not funded by the National Health System and other products for the healthcare of 2007, released by the Self Care Health Association. The articles of such a document of good practice will be applicable to the promotion of the products on which it refers operated in different media such as the Internet.

Finally, from 1999 there is, in Spain, a code of ethical standards of the National Association of Advertising Pharmaceutical Specialties. This, as well as two of the three above-described codes of conduct, is applicable to commercial communications, carried out in different ways -as the Internet- of drugs that do not require authorization as well as to para-pharmacy products.

As shown, the supervisory authority of the various codes of conduct is called the Advertising Jury. It seeks, among other purposes, that the Internet advertising spread by pharmaceutical business by adhering to codes of conduct mentioned, is accurate, legal, honest and responsible. Not surprisingly, it requires the observance of the toughest legal and business practices in the field (Krylova et al., 2018).

The Jury includes in the Spanish association called Self-Control enjoys full independence. The latter was founded in 1995, showing its precedent in Advertising Self-Control S.A., created in 1977. Regarding Self-Control partners, it is noted that among advertisers, agencies and media, it brings together more than 75% of the advertising industry in Spain. Self-Control is the only Spanish private organization that has been incorporated by the European Commission to its European Extra-Judicial Network. The reason is that its extra-judicial body for resolving disputes, the Jury of Advertising, meets the requirements and principles of independence, transparency, adversarial, effectiveness, legality, freedom of choice and right to representation by the consumer, set out in Commission Recommendation 98/257/EC of 30

March, on the principles applicable to bodies responsible for settling disputes out of consumer disputes.

The functions, composition and functioning of the Jury are regulated both in the arts. 44-50 of the Statute of Self-Control, of May 11, 1995 -last amended in April 3, 2006- and in the Regulation of the Advertising Jury, of April 23, 1997, as last reform data on May 10, 2006.

The Jury is formed, under Arts. 44.1 of the Statute of Self-Control and 3 of the Jury Regulation, by a president, six vice-presidents and twenty members of unquestioned impartiality. It must be noted the tone of impartiality that seeks to be highlighted and, therefore, achieved with the word “unquestioned”. It is important to emphasize the need for any member of the jury for not have any relationship with the member companies.

Despite its youth, the advertising self-regulatory system created by Self-Control has become the preferred mechanism for dispute resolution in Spain, above even the courts.

As for the texts that underlie the decisions of the Jury of Advertising, it has to be said clearly that rules are not strictly legal, as if they were, the Jury could be invading the judicial function, according to the article 117 of the Spanish Constitution, which states that it is only the responsibility of judges and courts. Conflict

resolution in interactive advertising of medications, will be based on codes of conduct referred.

5. CONCLUSIONS

The control of content on the Web represents a major issue which raises new challenges for law and, of course, for companies which operate in the Internet. The way this problem has been traditionally addressed, unfortunately, fails on the Web, in fact, States can no longer act alone to face the control of materials flowing through a medium that knows no territorial boundaries.

Therefore, supranational solutions are needed. State regulation should continue boasting an active role in Internet, but together with it, complementary measures are making headway, among which is the corporate self-regulation.

One scenario where this latter phenomenon operates successfully is the interactive advertising of medicines for human use. In fact, under the same have developed codes of conduct that seek to impose the observance of the best practices on that particular matter.

It is not then a trivial matter. Indeed, users can find in the Web, without being aware, counterfeit, adulterated, expired or damaged medicines that can compromise seriously their health. To end with

such practices it is desirable that the pharmaceutical industry itself finds voluntarily quality ethical practices.

One example to highlight is the case of Spain, where business organizations operating in that sector have developed suggestive rules that seek user protection in this area.

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