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ADVERTISING OF MEDICINES FOR HUMAN USE. PERSPECTIVES FROM EUROPEAN COURT OF JUSTICE

R.D. APAN

Rodica Diana APAN

Dimitrie Cantemir Christian University of Bucharest

Cluj-Napoca Faculty of Law

E-mail: avocat.apan@gmail.com

ORCID: 0000-0002-5730-1774

Abstract

The present study aims, in the reflection of a decision given by the European Court of Justice to analyze the way to (re) establish the protection of persons in online sales of medicines, both against excessive consumption of medicines generated by advertising, self-medication and the harmful effects of long-term medication not adapted to the person's health. This method is found in the French Consumer Code and is a real connection between the requirements of the pharmacist profession and the requirements of public health protection. Given that a similar protection measure is not included in our legislation, the French regulation would be a good model for a proposal of lege ferenda in the matter.

During the Conference "Public safety and the need for high social capital", panel VII, "Protection of human capital in the field of the right to health and social care" was organized, and this study aims to raise the protection of human capital, through rules and jurisprudence which gives efficiency to the concept of "public health". Or, the protection of the population through regulations regarding the distribution of medicines is part of this broad concept.

Keywords: advertising, drugs, pharmacy, online sales, drug abuse

INTRODUCTION

Medical-pharmaceutical services are those services provided by individuals and legal entities, organized in various ways, to exercise their professions in this field. Attracting and retaining customers is one of the challenges of professionals practicing the medical-pharmaceutical professions. (Apan, R.D., Fodor E.,M., 2018) This objective, although it is pursued in both the medical and pharmaceutical professions, is observed with priority in the "pharma" area, in the activity of selling medicines.

The drug is defined in art. 699 of Law 95 of 2006¹, corroborated with the provisions of art. 4, point 10 of the Order of the Ministry of Health no. 194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicines for human use², as:

- a) any substance or combination of substances presented as having properties for treating or preventing disease in humans; or
- b) any substance or combination of substances which may be used or administered in humans, either for the restoration, correction or modification of physiological functions by the exercise of a pharmacological, immunological or metabolic action, or for the establishment of a medical diagnosis.

The advertising of the drug, as it is defined above, as a recipient of the general public, seems a utopia, but has become a stark reality in recent years.

The present study aims that, in the reflection of the decisions given by the European Court of Justice to (re) establish the balance in the consumption of medicines, crushed by the online publicity that attracts the abuse of medicines, defined in art. 699, point 16 of Law 95 of 2006, as the intentional excessive, permanent or sporadic use of drugs, which is accompanied by harmful effects on a physical or mental level³.

I. SEDES MATERIAE

The general regulation in the field of advertising is included in Law no. 158/2008 on misleading advertising and comparative advertising⁴. This applies without prejudice to the provisions on advertising for certain products and / or services, as well as restrictions or prohibitions on advertising in certain media, contained in other regulations. (Căpățână, O., 1997)

Or, regarding the advertising of medicines, there are special regulations that will be applicable to the field, namely, Law no. 95/2006 on health care reform and Order of the Ministry of Health no. 194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicines for human use.

II. ADVERSITING OF DRUGS – DEFINITION, CHARACTERISTICS, PROHIBITIONS

Advertising is defined in art. 3 lit. a) of Law no. 158/2008 as, any form of presentation of a commercial, industrial, artisanal or liberal activity, in order to promote the sale of goods or services, including real estate, rights and obligations.

¹ Republished in the Official Gazette, no. 652 of 28 August 2015, amended and supplemented, hereinafter referred to as Law 95 of 2006.

² Published in the Official Gazette, no. 168 of March 11, 2015, hereinafter referred to as the Order of the Ministry of Health no. 194/2015.

³ Drug consumption in Romania - between statistics and the situation on the ground, <http://starea-natiunii.ro/index.php/ro/noutati/facts-figures/25-facts-figures/151-consumul-de-medicamente-in-romania-intre-statistici-si-situatia-de-pe-teren-2>, accese la data 03.11.2021.

⁴ Published in the Official Gazette, no. 454 of July 24, 2013, amended and supplemented, hereinafter referred to as Law 158 of 2008.

Art. 811, paragraph (1) of Law 95 of 2006 stipulates that the advertising for medicines regulated in the law includes any way 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, so we believe that it is also applicable to online sales.

Also, art. 6 of the Order of the Ministry of Health no. 194/2015, provides as a field of application, all promotion methods, as defined in art. 4 point 21 of the same normative act, respectively, 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, without restricting the use of these methods in the online environment. (Tătaru, Ş, 2017).

Advertising for medicines (advertising) is defined in art.11, paragraph 1, of the Order of the Ministry of Health no. 194/2015, as any form of organized activity aimed at informing by direct or indirect methods, as well as any form of promotion intended to encourage the prescription, distribution, sale, administration, recommendation or use of one or more medicinal products for use human. Advertising of medicines can be aimed at health professionals or the general public.

Art. 4, points 25 and 26 of the Order of the Ministry of Health no. 194/2015 defines comparative advertising as any form of advertising which explicitly or implicitly identifies a competing product and / or comparative description, and misleading advertising as any form of advertising which, in any way, including by way of presentation, induces or it may mislead any person to whom it is addressed or who comes into contact with it.

A series of characteristics and prohibitions are regulated for the advertising of the drug intended for the general public (Gavriloaia, R., 2015) which is also the theme of this paper.

(i) the advertising characteristics for a medicinal product are set out in Article 812, paragraphs 2 and 3 of Law 95 of 2006 in conjunction with art. 12, paragraph 1 of the Order of the Ministry of Health no. 194/2015 starting from the principle that, advertising intended for the general public is allowed only for those drugs that, by composition and purpose, are intended to be used without the intervention of a doctor, in order to establish the diagnosis, their prescription or to monitor treatment, being sufficient, if necessary, the advice of pharmacists, namely:

- advertising for a medicinal product must: - be done responsibly, ethically and to the highest standard, in order to ensure the safe use of medicinal products, regardless of how they are dispensed; - to encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, - to be accurate, balanced, fair, objective and complete in order to enable those to whom it is addressed to form their own opinion on the therapeutic value of - to be based on an up-to-date assessment of all relevant evidence and to clearly reflect this evidence, - to encourage the rational use of the medicinal product, by presenting it objectively, without exaggerating its therapeutic properties or qualities;

- advertising for a medicinal product must not: - encourage self-medication or irrational use of the medicinal product, - be misleading, subliminal or misleading by distortion, exaggeration, unjustified emphasis, omission or otherwise, - suggest that a medicinal product or an active ingredient has any special merit, quality or property, if this cannot be scientifically documented; - prejudice respect for human dignity; nationality; - to harm the image, honor, dignity and private life of persons; - to include anything that could be offensive or misleading to the user.

(ii) the interdiction of the advertising of medicines to the general public is regulated by the principles found in the provisions of art. 812 and of art. 813, paragraph 2 of Law 95 of 2006, corroborated with art. 13 of the Order of the Ministry of Health no. 194/2015, which prohibits advertising to the general public for drugs that: - are issued only on medical prescription, -contain substances defined as narcotics or psychotropic by international conventions, such as the United Nations conventions of 1961 and 1971 and national law; have a marketing authorization valid in Romania - are distributed directly to the population by manufacturers for promotional purposes.

(iii) the arrangements for advertising medicinal products are:

1. printed materials (printed matter): scientific/promotional materials intended for health professionals, advertising materials intended for the general public, educational materials intended for patients and their organizations/associations; posters, invitations, reminders.

2. audiovisual advertising (radio, television);

3. billboards or any other form of outdoor advertising or any form of advertising presented on another type of communication channel than pharmacies, medical offices, audiovisual, print media, internet;

4. Internet advertising (web pages, e-mail, forums, blogs or any other form of electronic support)

5. offering samples;

6. promotional items (relevant to medical practice).

According to the provisions of art. 31 of the Order of the Ministry of Health no. 194/2015 to the representative of the marketing authorization holder (DAPP) is the person, commonly known as "local representative", appointed by the marketing authorization holder to represent him in Romania, and according to the provisions of art.15, paragraph 1 of the same normative act DAPP has the obligation to submit to the National Agency for Medicines and Medical Devices-NAMMD for approval all advertising materials for the general public / patients and to put them on the market only after obtaining the advertising visa.(State, D., 2015). According to the provisions of paragraph 2, this rule applies to advertising materials for OTC medicines, as well as educational materials intended for the general public/patients. (Tăerel, R., 2018)

**III. JURISPRUDENCE OF THE EUROPEAN COURT OF JUSTICE
ON THE ADVERTISING OF MEDICINAL PRODUCTS**

3.1. Judgment of the Court of 1 October 2020, the date in question C 649/18

The purpose of the judgment is a reference for a preliminary ruling in a judicial proceeding focused on the protection of public health. The referring court was the Cour d'appel de Paris, and the judgment concerned non-prescription medicines for human use and targeted advertising on a pharmacy's website, examining the basis of the pharmacy's obligation to operate. in one state to require the patient to complete a health questionnaire before validating his first order on the website, the rule applicable in another state, namely, the one in which the general public was targeted by advertising.

3.2. The dispute in the main proceedings and the question referred for a preliminary ruling

A, a company incorporated under Netherlands law, is registered in the Netherlands for the purpose of operating a pharmacy. It also sells medicines online and para-pharmaceuticals through several websites, one of which is specifically dedicated to French consumers. Medicines marketed through this site are subject to a marketing authorization in France and are not subject to compulsory medical prescription.

A carried out an advertising campaign for the online sale of medicines to French consumers. This campaign included the introduction of advertising leaflets in parcels sent by other participants in distance selling (the so-called "cooperative" method), as well as the sending of advertising letters. **A** also published on that website promotional offers consisting of a reduction in the total price of the order when a certain value is exceeded, as well as the purchase of a paid referencing service on search engines.

Daniel B and Others sued **A** at the Tribunal de Commerce de Paris in order to obtain compensation for the damage which they consider to have suffered as a result of the unfair competition which **A** has allegedly suffered by unjustifiably obtaining an advantage from non-compliance with French regulations on advertising and online sales of medicines.

By judgment of 11 July 2017, the Tribunal de Commerce de Paris ruled that Dutch law governed the creation of a website addressed to French customers. However, according to that court, Articles R. 4235 22 and R. 4235 64 of the Public Health Code apply to companies established in other Member States which sell medicinal products on the Internet to French patients.

However, by distributing more than three million advertising leaflets outside the pharmacy, **A** would have attracted French customers by means unworthy of the profession of pharmacist, in breach of those provisions. The Paris Commercial Court concluded that the infringement of those provisions, which gave **A** an economic advantage over other market participants, constituted an act of unfair competition.

He appealed against that judgment to the Cour d'appel de Paris, arguing that Articles R. 4235 22 and R. 4235 64 of the Public Health Code did not apply to him.

Those provisions infringe the principle of the application of the rules of the country of origin laid down in Article 3 of Directive 2000/31 and Article 85c of Directive 2001/83 and the free movement of goods guaranteed by Article 34 TFEU, which are not justified by the protection of public health.

In those circumstances, the Cour d'appel de Paris decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling: '[t]he European regulation, in particular:

- article 34 [TFEU], - the provisions of Article 85c of Directive [2001/83/EC establishing a Community code relating to medicinal products for human use] [and], - the internal market clause in Article 3 of Directive [2000]/31 on certain legal aspects of information society services, in particular electronic commerce, in the internal market] allow a Member State of the [European] Union to impose on its territory pharmacists who are nationals of another Member State of the Union on specific rules concerning:
- the prohibition of attracting customers by methods and means considered to be contrary to the dignity of the profession, in accordance with the current Article R 4235 22 of the [Public Health Code];
- prohibiting the incitement of patients to abuse drugs, in accordance with the current Article R 4235 64 of the [Public Health Code];
- the obligation to comply with good medicine delivery practices established by the public authority of the Member State, which also requires the introduction of a health questionnaire in the online ordering process and prohibits the use of drug delivery practices and the Technical Standards Decree]?"

3.3. Provisions in European and national legislation

▪ European law

'Directive 2000/31-Article 8 (1) provides that' [t]he Member States shall ensure that the use of commercial communications forming part of or constituting a service of the information society provided by a member of a regulated profession is subject to compliance with professional rules concerning, in particular, the independence, dignity and honor of the profession, as well as professional secrecy and honesty towards clients and other members of the profession '.

Directive 2001 / 83- Title VIIa "Distance selling to the general public", Article 85c provides: information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public through information society services, as defined in Directive [98/34], under the following conditions:

(a) the natural or legal person providing the medicinal product is authorized or has the right to supply medicinal products to the public and at a distance, in accordance with the national law of the Member State in which the person concerned is established;

(b) the person referred to in point (a) has notified the Member State in which the person concerned is established of at least the following information: [...]

(c) the medicinal products comply with the national law of the Member State of destination in accordance with Article 6 (1);

(d) without prejudice to the information requirements laid down in Directive [2000/31], the website providing the medicinal product shall contain at least: [...]

2. Member States may impose justified conditions on the protection of public health for the retail supply of medicinal products within their territory by distance selling to the public through information society services. [...]

Directive 2001/83 provides - 'Member States shall prohibit the advertising to the general public of medicinal products which: (a) are available only on medical prescription in accordance with the provisions of Title VI;'

▪French law

The Public Health Code provides - Article R. 4235 22 of the Public Health Code (Public Health Code) provides that "pharmacists shall be prohibited from attracting customers by methods and means contrary to the dignity of the profession". Article R. 4235 64 of that code provides that '[t] he pharmacist must not lure his patients by any method or means to the abuse of medicinal products'.

The Decree on good practice for the supply of medicinal products provides - Section 7.1, entitled "Pharmaceutical advice", in section 7, entitled "Complementary rules applicable to electronic commerce with medicinal products", in the annex to the Decree of 28 November 2016 on good practices for the supply of medicinal products in Community pharmacies, in mutual aid pharmacies and in emergency mining pharmacies, referred to in Article L. 5121 5 of the Public Health Code, provides:

"The e-commerce website is designed so that no medicine can be delivered without an interactive exchange between the patient and the pharmacist in question before the order is validated. "

We note at the outset that, in the event of the online sale of medicinal products, in accordance with the provisions of French law, an automatic answer to a question from the patient is not sufficient to provide information and advice tailored to the particular case of the patient. Personal data concerning the patient are necessary for the pharmacist in order to ensure the adequacy of the order in relation to the patient's state of health and to be able to identify possible contraindications. Thus, in accordance with these regulations, before validating the first order, the pharmacist posts online a questionnaire requesting information on age, weight, height, sex, ongoing treatments, history of allergies, contraindications that the patient has and, if where appropriate, pregnancy and lactation. The patient must certify the veracity of this information and communicate it online to the pharmacist by completing the questionnaire. The questionnaire is completed at the first order, during the order validation process, and if the questionnaire has not been completed, no medicine can be released. The pharmacist then validates the questionnaire, stating that he has read the information provided by the patient before validating the order and an update of the questionnaire is proposed to the patient at each order.

3.4. A's defenses before the Court

- as to the necessity of such a measure as required by French law, To argue that the French Decree on Good Prescribing Practice would already ensure that

patients can receive personalized advice by requiring virtual pharmacies to provide it on request the possibility of an interactive exchange with a pharmacist.

- show that the quantities of medicinal products ordered by an interested person through its website are monitored on a case-by-case basis, on the basis of various parameters, including the history of orders placed by the interested party and that these checks would be sufficient to prevent the risk of improper use of medicines.

3.5. Considerations of the Court

In order to give a preliminary ruling, the Court, in accordance with the case-law, held that:

- the online sale of medicinal products in Article 1 (5) of Directive 2000/31 r is not one of the activities excluded from the application of that directive, so an online sale of medicinal products such as that at issue in the main proceedings may constitute a information society service within the meaning of Article 2 (a) of Directive 2000 / 3- Case Ker Optika C 108/09, paragraph 27⁵;
- the intensive use of advertising or the choice of aggressive promotional messages are likely to be detrimental to the protection of health and undermine the dignity of a health profession - Case C-339/15 Vanderborght [2017] ECR I-0000, paragraph 69⁶;
- that the restriction resulting from the application of national legislation which generally and absolutely prohibits any form of advertising used by health professionals to promote their medical activities goes beyond what is necessary to protect public health and the dignity of a regulated profession. of 4 May 2017, Vanderborght, C 339/15, paragraphs 72 and 75⁷;
- the multiplication of existing interactive elements on the Internet that must be used by the customer before he can purchase medicines is an acceptable measure, which affects less the free movement of goods than a ban on the online sale of medicines, which allows to be done just as effectively the objective of reducing the risk of misuse of medicinal products purchased online - Case C-322/01 Deutscher Apothekerverband [1993] ECR I-0000. ⁸.

3.6. Decision of the Court

In the light of that case-law, the Court considers that:

- it is for the national court to determine whether the prohibition at issue in the main proceedings does not preclude the provider at issue in the main proceedings from advertising outside its pharmacy, regardless of its medium or size, and whether that is the case. , that prohibition would go beyond what is necessary to ensure that the objectives pursued were achieved.

⁵ <https://curia.europa.eu/juris/liste.jsf?language=ro&num=C-108/09>

⁶ <https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=CELEX:62015CJ0339>

⁷ <https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=CELEX:62015CJ0339>

⁸ <https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=CELEX%3A62001CJ0322>

- Directive 2000/31 must be interpreted as not precluding the application by the Member State of destination of a service for the online sale of non-prescription medicines to the provider of that service established in another Member State; national regulations requiring pharmacies that sell such medicines to introduce a health questionnaire into the online ordering process.

Other decisions that we consider relevant in the field of advertising of medicines for human use are:

Judgment of the Court of 11 June 2020 (reference for a preliminary ruling from the Bundesgerichtshof - Germany) in Case C-786/18 Ratiopharm GmbH v Novartis Consumer Health GmbH, „ Preliminary reference - Protection of public health - Internal market - Medicinal products for human use - Directive 2001/83 / EC - Advertising - Article 96 - Distribution of free samples of medicinal products which are available on prescription only to persons qualified to prescribe them - Exclusion of pharmacists from the possibility of distribution - Inapplicability in the case of distribution of free samples of medicinal products not issued on prescription - Consequences for Member States “⁹ and

Judgment of the Court of 8 October 2020 in Case C 602/19 Kohlpharma GmbH v Bundesrepublik Deutschland, 'Preliminary reference - Articles 34 and 36 TFEU - Free movement of goods - Quantitative restrictions - Measures having equivalent effect - Refusal to approve a change in information and documents relating to a medicinal product subject to a parallel import authorization - Protection of health and life of humans - Directive 2001/83/EC."¹⁰

CONCLUSIONS

We find that, in interpreting European legislation, the Court gave precedence to the principle of protection of public health. We also note that in French legislation has been adopted in the sale of drugs to the population online "questionnaire method" to ensure personalized advice by the pharmacist in the online sale of drugs and to limit excessive consumption of drugs and self-medication.

The Romanian national legislation includes the principles of Directive 2001/83 - Community Code on medicinal products for human use¹¹, but does not establish a means of protection for the online purchase of medicines. The solution regulated in French legislation and analyzed above is a good example. The reflection topic launched by this paper is finding such a means of protecting the population at the level of national legislation and formulating a proposal for lege ferenda to complete the relevant legislation, which de facto would include the following steps: -before the validation of the first order online, the pharmacist shall post a questionnaire requesting information on age, weight, height, sex, ongoing treatments, allergic history, contraindications and, if applicable, pregnancy and lactation; order validation

⁹ <https://eur-lex.europa.eu/legal-content/RO/TXT/PDF/?uri=CELEX:62018CA0786&from=EN>

¹⁰ <https://curia.europa.eu/juris/liste.jsf?num=C-602/19&language=RO>

¹¹ <https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=CELEX%3A02001L0083-20121116>

- if the questionnaire has not been completed, no medication can be released - the patient must certify the veracity of this information; -the pharmacist then validates the questionnaire, stating that he has read the information provided by the patient, before validating the order; -the pharmacist should ensure the adequacy of the order sent via the Internet, regarding the patient's health, to be able to identify any contraindications, -updating the questionnaire is proposed for each order.

In the conditions of the pandemic with Covid, considering the fear of the disease and the fact that, the exacerbation of the drug consumption becomes a constant, the advertising of the drugs develops unhindered.¹² This requires that the rules according to which the advertising of medicines for human use is carried out be observed as rigorously as possible, as a component of the desideratum for the protection of public health.

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¹² <https://www.forbes.ro/articles/prima-linie-publicitatii-172628>