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Legislative and Jurisprudential Analysis Regarding the Regulation of Online Pharmacies

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ABSTRACT: As a result of the evolution of information and communication technologies, medicines, like other goods, are now increasingly marketed on the EU internal market through these channels. When examining the compatibility of the conditions for the supply of retail medicinal products with European Union law, the Court of Justice has recognized the specific nature of medicinal products, whose therapeutic effect significantly distinguishes them from other goods. Taking into account all these aspects, this article aims to analyze the centralized regulation of online pharmacies in relation to European Union law, the jurisprudence of the Court of Justice of the European Union, as well as the legislative measures taken at national level to provide medicinal products to the population through the Internet.

KEYWORDS: European legislation, the Court of Justice of the European Union, public health, legislative initiatives, internal market, patient rights

Introduction

In its rich case law, the Court of Justice of the European Union has also stated that the health and life of the people (Rotaru 2019, 201-215) rank first among the values and interests by the Treaty on the Functioning of the European Union (TFEU) and that Member States must have a margin of discretion (see Judgment of 19 May 2009 on Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes* and *Others / Saarland*, paragraphs 19 and 31) in the supply of medicinal products to the population on their territory.

In particular, given the risks to public health, the case law of the Court of Justice has recognized that Member States may, in principle, restrict the retail sale of medicinal products only through online pharmacies (see Judgment of 19 May 2009 on Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes* and *Others/Saarland*, paragraphs 34 and 35).

Theory

Illegal sale of medicinal products to the population through the Internet poses a serious threat to public health, as this way people can get fake medicinal products.

Taking into account that specific conditions for the supply of medicinal products to the population were not harmonized at Union level and that there is an alarming increase within the European Union in the number of detected medicinal products that are falsified in terms of their identity, history or source, it was necessary to adopt Directive 2011/62/EU amending the Community Code for medicinal products for human use (Directive 2001/83/EC) as regards the prevention of falsified medicinal products entering the legal supply chain.

Past experience shows that no falsified medicines reach patients only through illegal means, but also via the legal supply chain. This poses a particular threat to public health and can lead to the distrust of patients, including in the legal supply chain.

To prevent drugs that are suspected to present a danger to health from reaching the patient, Member States use a system that includes the receipt and handling of notifications of suspected falsified medicinal products, as well as suspected quality defects of medicinal

products. The system includes also recalls of drugs made by holders of marketing authorizations or withdrawals of drugs from the market ordered by the competent national authorities from all relevant actors in the supply chain, both during normal working hours and beyond.

The system also allows, if necessary, with the assistance of healthcare professionals, medicinal product recalls from patients who received such products.

If it is suspected that the product in question poses a serious risk to public health, the competent authority of the Member State where the product was initially identified transmits without delay a rapid alert notification to all Member States and all actors in the supply chain of the Member State in question.

If it is suspected that falsified medicinal products have reached patients, urgent public announcements are made within 24 hours to recover these products from the patients. Such notices shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

Results and discussions

Without prejudice to national legislation prohibiting the sale to the public of Rx medicines (which are available only on prescription) via the Internet (See Case C-319/05, Member States must ensure that medicinal products are offered for sale at a distance to the public via the information society services.

In order not to unduly restrict the functioning of the internal market, but also to protect public health in the case of the retail supply of medicinal products sold online, Directive 2011/62 / EU provided for the creation of a common logo, which can be recognized throughout Union and make it possible to identify the Member State in which the legal person offering online medicinal products to the public is residing.

That logo is clearly displayed on the website which offers medicines by distance selling to the public. The logo is clickable and will appear on the websites of all online medicine retailers in the EU that are registered with their national regulatory authority. The national flag and the text are an integral part of the logo. Only national flags of an EU Member State, as well as those of Norway, Iceland and Liechtenstein can be displayed. A logo that displays the EU flag, for example, is not authentic.

In order to transpose into national law the provisions of Directive 2011/62 / EU on the retail supply of medicinal products via the Internet, the new rules concerning the possibility for pharmacies to market online human medicinal products without prescription (the so-called over-the-counter drugs - OTCs) came into force on 24 April 2019 .

By implementing this normative act, Romania has joined the other European states, regulating the way and conditions in which traditional pharmacies can commercialize at a distance medicines for human use, by setting up online pharmacies.

The authorization of pharmacies for the online marketing of medicinal products will be based on the inclusion of an additional mention (Marin, and Botină 2013, 621) on the sanitary authorization issued by the Ministry of Health, which requires a series of criteria in order to obtain the qualification of online pharmacy.

According to the provisions of art. 31 (1) of the Norms, the Community pharmacy that also wants to provide online sales needs an additional 10 sq m space reserved exclusively for online business support (for example, packing and storing medicinal products).

As far as the online pharmacy site is concerned, it must meet, in addition to the general conditions for e-commerce, a number of specific requirements. Thus, the online pharmacy website will have a distinct section for the sale of medicinal products. The content of this section is strongly regulated, both in terms of the existence of mandatory elements and of the presentation of medicinal products.

Authorized online pharmacies will use the European common logo only in compliance with the terms of the license agreement signed between Romania and the European Commission. In addition, the online pharmacy website must contain a link to the Romanian National Agency for Medicines and Medical Devices (ANMDMR) site, ”Report an adverse reaction” section. Each online pharmacy has to appoint a pharmacist responsible for online sale of medicinal products, with a range of tasks related to the end-user relationship with the pharmacy website.

The online pharmacy website should be built in such a way that the patient can not buy medication without first having a contact with the pharmacist (which can be either via live chat or less interactive means).

Moreover, the online pharmacy website will contain a mandatory questionnaire to be filled in by the patient with general information that the pharmacist might normally get visually (for example, age, sex, pregnancy stage). It is also relevant in view of the fact that medicines can be sold online only to patients over the age of 18 years (Marin 2019, 432-433).

An interesting aspect, which may have implications, including from a personal data protection point of view, is how the interaction between the patient and the pharmacist over the online environment, given the information gathered so as to overcome the lack of traditional interaction.

In line with the legal provisions in force, the website of the online pharmacy is considered as the virtual extension of an authorized community pharmacy. Online pharmaceutical units authorized on the territory of Romania can sell and dispense medicinal products to patients established in other EU Member States in compliance with the medicinal products legislation in the country where the patient is located.

The ordered medicinal products will be delivered by specific means, the online pharmacy being responsible for transporting and storing parcels containing the ordered medicinal products in such a way as to protect them against damage, forgery, theft, as well as maintaining the temperature conditions according to the manufacturer's specifications.

Control and supervision of the sale and release through the information society services of medicinal products that are issued without medical prescription shall be performed by the personnel empowered by the Ministry of Health.

Conclusions

Applying the provisions of Directive 2011/62 / EU, the legalization of on-line pharmacies in Romania is a milestone because the population needs to be assisted in identifying Internet sites that legally offer medicinal products for online sale to the population. Additionally, in collaboration with the European Medicines Agency and the Member States, the European Commission is organizing awareness-raising campaigns to alert consumers to the risks involved in the purchase of medicinal products from illegal Internet sources.

Revealing this is PANGEA VIII, a global operation coordinated by Interpol, which targeted the criminal networks behind the sale of counterfeit medicinal products through online illicit pharmacies. The action led to the launch of 429 investigations, the suspension of 550 online ads for counterfeit medicinal products and of 2414 illegal sites, resulting in 156 worldwide arrests and seizure of potentially dangerous medicinal products worth 81 million USD.

In the near future, a significant development of online pharmacies is expected, especially if we have in view the accelerated growth of online commerce in Romania, this being a channel increasingly accessed by both traders and end-users.

Given that this channel is available to both pharmacies and independent pharmacies, the development of an online marketing channel has the potential to increase competition on this market.

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