

## Legislative and jurisprudential considerations 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 analyse 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

### 1. Introduction

In its rich jurisprudence, the Court of Justice of the European Union holds that human life and health take precedence among the values and interests protected by the TFEU [1] and that Member States must have a margin of appreciation [2] regarding the supply of medicines to the population on their territory.

Considering, in particular, the risks to public health, the jurisprudence of the Court of Justice has recognized that Member States may, in principle, restrict the retail sale of medicines through online pharmacies [3].

### 2. Theory

The illegal sale of medicines to the public on the Internet is a serious threat to public health, as falsified medicinal products can reach the public in this way.

Considering that certain specific conditions for the supply of medicinal products to the population were not harmonized at Union level and that in the European Union there is an alarming increase in the number of medicinal products identified as falsified in terms of identity, history or source, it was necessary to adopt Directive 2011/62/EU [4] which amends

the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

Past experience indicates that falsified medicines reach patients not only through illegal means, but also through the legal supply chain. This represents a serious threat to public health and can induce the patients' mistrust in the legal supply chain.

To prevent medicinal products that are suspected of being a health hazard from reaching the patient, Member States use a system that includes the receipt and management of notifications on suspected falsified medicinal products as well as on suspected quality deficiencies of medicinal products. The system also covers recalls of medicinal products by marketing authorization holders or withdrawals of medicinal products from the market, from all relevant actors in the supply chain, both within and without normal working hours, as ordered by national competent authorities.

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

If the concerned medicinal product is suspected to present a serious risk to public health, the competent authority of the Member State where the product was initially identified shall send, without delay, a rapid alert notification to all Member States and all actors in the supply chain in that Member State.

When it is suspected that falsified medicines have reached patients, urgent public announcements are made, within 24 hours, for the recovery of the respective medicines from the patients. Those announcements shall contain sufficient information regarding the suspected quality defect or falsification and the risks involved.

### **3. Results and discussion**

Without prejudice to national legislation prohibiting the offering for sale to the public of Rx (prescription only) medicinal products over the Internet [5], Member States must ensure that medicinal products are offered for sale remotely to the public, by means of the services of the information society.

So as 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, recognisable throughout the Union, which allows the identification of the Member State in which is established the legal person offering the medicinal product for sale remotely to the public.

This logo must be clearly displayed on the Internet site that offers medicines remotely to the public. The logo is clickable and will display the websites of all EU online medicine retailers that are registered with their national regulatory authority. The national flag and text are an integral part of the logo. Only the national flags of EU member states, as well as those of Norway, Iceland and Liechtenstein can be displayed. A logo showing the EU flag, for example, is not authentic.

In order to transpose into national law the provisions of Directive 2011/62/EU relating to the retail supply of medicines via the Internet, on 24 April 2019 entered into force the new rules regarding the possibility of pharmacies to sell online medicines for human use which do not require medical prescription (the so-called over-the-counter drugs - OTCs) [6].

By implementing this normative act, Romania joined the other European states, regulating the manner and conditions under which traditional pharmacies can remotely sell medicines for human use, through the establishment of online pharmacies.

The authorization of pharmacies for the online sale of medicines will be based on the registration of an additional mention on the health permit to operate issued by the Ministry of

Health [7], since obtaining the online pharmacy qualification requires the fulfilment of a series of criteria.

According to the provisions of art. 31 paragraph (1) of the Regulations, the community pharmacy that sells online needs an additional space of 10 square meters dedicated exclusively to the support of online trade activities (for example, the packaging and storage of medicines).

As for the online pharmacy website, it must meet, in addition to the general conditions regarding e-commerce, several specific requirements. Thus, the online pharmacy website will have a distinct section dedicated to the sale of medicines. The content of this section is strongly regulated, both in terms of the existence of mandatory elements and in terms of the way the medicines are presented.

Thus, authorized online pharmacies will use the common European logo only in compliance with the terms of the License Agreement signed between Romania and the European Commission. In addition, the online pharmacy's website must contain a link to the ANMDMR website, the "Report an adverse reaction" section.

Each online pharmacy must appoint a pharmacist responsible for the online sale of medicines, who has a series of duties related to the end patient's relationship with the pharmacy's website.

The website of the online pharmacy must be built in such a way that the patient cannot buy medicines without first having a contact with the pharmacist (which can be both through a live chat and through less interactive means).

Furthermore, the online pharmacy's website will contain a mandatory questionnaire to be filled in by the patient with general information, which the pharmacist could normally obtain visually (e.g. age, sex, pregnancy status). This is also relevant since medicines can only be sold online to patients over 18 [8].

An interesting aspect, which may have implications including from the point of view of the protection of personal data, is the way in which the interaction between the patient and the pharmacist will take place in the online environment, given the information collected to replace the lack of traditional interaction.

In accordance with the legal provisions in force, the website of the online pharmacy is considered as the virtual extension of an authorized community pharmacy.

Online pharmacies authorized on the territory of Romania can sell and dispense medicines to patients established in other EU member states, in compliance with the legislation on medicines in the country where the patient is located.

The ordered medicines will be delivered by specific means, the online pharmacy having the responsibility to ensure the transport and storage of the parcels containing the ordered medicines in such a way as to ensure their protection against damage, falsification, theft, as well as the temperature requirements in accordance with the manufacturer's specifications.

The control and supervision of the sale and supply of medicines that are released without a medical prescription through the services of the information society is carried out by the authorized personnel of the Ministry of Health.

#### **4. Conclusions**

Applying the provisions of Directive 2011/62/EU, the legalization of the operation of online pharmacies in Romania represents an important stage because the population must benefit from assistance in identifying internet sites that legally offer medicines for sale remotely to the population.

In addition, in cooperation with the European Medicines Agency and the Member States, the European Commission organizes awareness campaigns to warn consumers of the risks involved in purchasing medicines from illegal sources on the internet.

Revelatory in this regard is operation PANGAEA VIII, a global operation coordinated by Interpol, which targeted the criminal networks behind the sale of falsified drugs through illicit online pharmacies. The action led to the launch of 429 investigations, the suspension of 550 online advertisements for falsified pharmaceuticals and of the 2,414 illegal websites, resulting in 156 arrests worldwide and the seizure of \$81 million worth of potentially dangerous medicinal products.

A significant development of online pharmacies is expected in the near future, especially if we consider the accelerated growth of ecommerce in Romania, this being a channel increasingly accessed by both merchants and end consumers.

Since this channel is available to both established pharmacy chains and independent pharmacies, the development of the online channel for the sale of medicinal products has the potential to increase the existing competition in this market.

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