EUROPEAN EXPERIENCE OF REGULATING DISTANCE SELLING OF MEDICINES FOR UKRAINE

EUROPEJSKIE DOŚWIADCZENIA DOTYCZĄCE REGULOWANIA SPRZEDAŻY NA ODLEGŁOŚĆ PRODUKTÓW LECZNICZYCH DLA UKRAINY

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ABSTRACT

Introduction: Some countries have already tried and tested mechanisms of regulating distance sales as form of distribution of medicines that have been used more or less effectively for a fairly long time. Herewith, so far, the approach of the competent authorities of some countries including Ukraine can be called prevailing in quantitative terms under which the official prohibition on distance sales of medicines is set.

Aim: The aim of this study is a detailed examination of the nature of the prohibition of the medicines distance selling in Ukraine, namely the an analysis of advantages and disadvantages of this form of distribution of medicines and identification of appropriate ways for gradual repeal of the prohibition in terms of regulatory reform in Ukraine in the sphere of circulation of medicines due to the process of adaptation of statutory regulation in this area to the EU legislation.

Material and methods: This study is based on Ukrainian regulation acts, Council Directives 97/7/EC, 2000/31/EC, 2001/83/EC, scientific works and opinions of progressive-minded people in this sphere. Such methods as dialectical, comparative, analytic, synthetic and comprehensive have been used in the article.

Conclusion: Reception of the described experience of regulation in EU will allow a further review of the principles of regulation in Ukraine in the sphere of medicines with a shift in the main emphasis in the direction of ensuring adequate consumer rights in this area and preventing the risks of patients' and public health.

KEY WORDS: distance selling of medicines, Ukraine, risks of purchasing medicines.

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INTRODUCTION

Particular characteristics of individual items as objects of social and therefore legal relations necessitate an introduction of special approaches and specific requirements for their involvement into civilian circulation. Medicines are distinguished among such objects by several parameters [1]. On the one hand, they are a commodity concerning which various agreements are entered into in the field of civil relations, from consumer deeds of purchase and sale to contracts on advertising, research projects, etc., and on the other hand, these are items that, as a result of their properties and purpose, have a direct effect on human health, which could lead to positive or negative consequences. Therefore, depending on a category of distribution, medicines can be seen as free or restricted circulatable objects of civil rights and, in statute-established cases, as objects withdrawn from civilian circulation. In statutory acts, this specific nature primarily affects the classification of the medicinal products into those that are a subject to medical prescription and those that are not a subject to medical prescription. In turn, this entails setting out special requirements for a number of processes associated with circulation of medicines depending on their classification group, such as an access to distribution a medicine on the market, manufacturing processes, import and wholesale, labeling and advertising, pharmacovigilance etc.

Under these circumstances, preventive measures to eliminate risks of occurrence of adverse effects for patients' or public health due to the use of medicines impose appropriate restrictions not only for their legitimation on the market, manufacturing or advertising, but also for distribution to patients, consumers of medicines. And though mechanisms of regulation, supervision and control concerning traditional methods of supply of medicines to patients through pharmaceutical institutions have been worked out in the world as a whole and in individual countries, it is not so simple with respect to the latest methods of distribution of medicines. First of all, we are talking about distance sales of medicines, the main form of which is selling through online pharmacies, as well as by mail or otherwise, excluding possibility of direct familiarisation with the goods by a buyer and, more importantly, of personal professional advice when entering into such a contract.

Some countries have already tried and tested mechanisms of regulating this form of distribution of medicines that have been used more or less effectively for a fairly

long time. Herewith, so far, the approach of the competent authorities of some countries including Ukraine can be called prevailing in quantitative terms under which the official prohibition on distance sales of medicines is set. To substantiate such a ban, they have largely proved with unavailability of mechanisms to ensure proper supervision and control of this form of activity for authorized bodies but an in-depth analysis of risks which such a prohibition is introduced to overcome is often not performed.

AIM

The aim of this study is a detailed examination of the nature of the Ukrainian legislative restriction which is typical for all the medicines regardless of their classification, namely the prohibition of their distance selling in Ukraine, an analysis of advantages and disadvantages of this form of distribution of medicines and identification of appropriate ways for gradual repeal of the prohibition. It is proposed to address these issues in terms of regulatory reform in Ukraine in the sphere of circulation of medicines due to the process of adaptation of statutory regulation in this area to the EU legislation and, above all, to the 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 [2].

MATERIAL AND METHODS

This study is based on Ukrainian regulation acts, Council Directives **97/7/EC [3],** 2000/31/EC [4], 2001/83/EC, scientific works and opinions of progressive-minded people in this sphere. Such methods as dialectical, comparative, analytic, synthetic and comprehensive have been used in the article.

RESULTS AND DISCUSSION

It is well-known that the key date associated with prohibition of sales of medicines via the Internet in Ukraine, which is the predominant means of distance selling, is December 29, 2011 - the date of entry into force of the current Licensing conditions for conducting business activities in manufacturing [5], wholesale, retail trade of medicines. Paragraph 2.6 of the mentioned rules provide that "distance (via the Internet) trade of medicines as well as sales of medicines by mail and through any institutions other than pharmaceutical ones, and beyond them ... are prohibited". The above ban is in force at the present time as well, and the State Service of Ukraine on Pharmaceutical Products and Drugs Control has been entrusted with monitoring of compliance with the prohibition.

This step can be seen as a reaction of the government through its authoritied bodies to inability to control challenges and deal with the consequences of distribution of medicines in a manner regulation of which was in its infancy, taking into consideration existence of practically a single statutory document containing rules for selling ordered goods as well as sales outside commercial or office space, and the specific features of medicines as a commodity were not taken into any account. This is confirmed by several court cases heard in Ukraine which concern damages caused by indirect (distance) sales of improper medicines without professional consulting assistance.

In 2015, Ukraine enacted the Law of Ukraine "On Electronic Commerce" [6] which defines the organizational and legal framework of electronic commerce in Ukraine, establishes the order of electronic transactions using information and telecommunication systems and defines the rights and obligations of parties in the sphere of electronic commerce. At the same time, transactions concerning objects withdrawn from civil circulation or limited in civil circulation in accordance with the Law (paragraph 1 of part 2 of Art. 1 of the Law), including medicines, have been removed from the scope of operation of the Law.

Thus, at the moment, there are legal restrictions on distance sales of medicines in Ukraine. Herewith, having no effective mechanisms of influence, the interested public can only observe the legislative process, namely hearing of three registered draft laws aimed at improving regulation of relations in the sphere of circulation of medicines by the Verkhovna Rada of Ukraine as the only legislative body of the state power in Ukraine. In these draft laws, there is a reflection of three completely different approaches to regulation of issues concerning distance selling of medicines. The first one containes a total prohibition on distance selling of medicines; the second one provides for possibility of distance sales of nonprescription medicines but it does not specify any requirements for this kind of distribution delegating dealing with these issues to the authorized state body in the sphere of public health; the third one reproduces the provisions of the 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 with regard to distance selling of medicines almost literally. And a problem of existence or prohibition of distance selling of medicines in Ukraine will be solved depending on which draft law will be enacted. Therefore, use of the European experience and taking into account the positive and negative conditions for resolving this issue is essential for the government at this stage, including in terms of creating a complete free trade area with the EU.

In the European Community, the stages of developing distance selling of medicines can be correlated to some extent with the enactment of the key pieces of legislation in the EU in the sphere of electronic commerce and the aforementioned Community code relating to medicinal products. Enactment of the **Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts** can be identified as being the start of the first stage which defined the responsibilities of the contractor and basic consumer rights in the sphere of distance selling. In particular, the thing is about providing consumers with complete and accurate information about the identity of the supplier, the main characteristics of the goods, their price, the accompanying costs, the arrangements for payment and the existence of a right of withdrawal from the contract, etc.

(Art. 4 of the Directive), written confirmation of the fact of entering into a contract between a supplier and a consumer and its terms and conditions, guarantees (Art. 5 of the Directive), terms and conditions of the right to withdrawal from the contract (Art. 6 of the Directive), time of performance (Art. 7 of the Directive), the prohibition of the supply of goods to a consumer without their consent, restrictions on the use of certain means of distance communication, etc. (Art. 9-10 of the Directive), implementing judicial and administrative means to ensure protection of consumer rights (Art. 11 of the Directive) etc.

Herewith, for the purposes of common interest, Article 14 of the Directive 97/7/EC provided the Member States with the right to impose a prohibition on marketing of certain goods or services, in particular medicinal products, within their own territory by means of distance communication. 19 EU countries have not used this right except Lithuania, Finland, Denmark, Portugal, Hungary and Bulgaria, which have applied restrictions on distance selling of medicines, and Slovakia, which has taken an advantage of this right to restrict selling of tobacco products [7]. Nevertheless, in the early 2000s, there was a possibility of distribution of medicines via the Internet only in the Netherlands, the UK and Sweden and with some restrictions - in Germany, Belgium and Norway.

The next step was enactment of the Directive 2000/31/EC of the European Parliament and of the Council of the 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, which established the basic principle that electronic commerce shall be permitted within the EU and legislation of the Member States shall recognize the validity of contracts concluded electronically. In addition, this Directive determined a minimum required amount of information to be provided to the information service consumer, such as the name of the service provider, his address, registration details etc. In addition, providing this and other information to the competent authorities of the Member State was recognized as a prerequisite for carrying out activities on distance selling of medicines.

An important milestone in the development of distance selling of medicines was the enactment of the 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. This particular document defined the basic requirements for persons authorized or entitled to carry out sale of medicinal products at a distance, an obligation of prior registration of information on them, the amount of required information to be available on the website used for sale of medicinal products; it established a common logo that is recognisable throughout the EU, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is registered, and verification of the authenticity of the person according to the entry of the person in the list; it ordered the competent authorities of the Member States to create a website providing regulatory and reference information on medicinal products for sale at a distance to the public; it secured the need for the competent authorities to conduct or promote information campaigns to raise consumer awareness of the risks related to medicinal products distributed illegally and so on.

An important role in understanding "the rules of the road" regarding distance selling of medicines according to the Community code relating to medicinal products was played by the European Court in the case of DocMorris (Case C-322/01 Deutscher Apothekerverband eV v. 0800 DocMorris NV (11 December 2003) [8]). In particular, the conclusions regarding the admissibility of distance sales of medicinal products by a seller located in one country in another Member State were made; the related subjects concerning consequences of different classifications of medicinal products in these countries and possibility of their advertising were tackled. This decision reflected particular aspects of insufficient scope of regulatedness in the sphere of distance selling of medicinal products in the global market but, what is the most important, it actually confirmed the possibility of functioning of online pharmacies in the EU but with some restrictions.

It should be noted that the process of implementation of the Directive 2001/83/EC in the countries of Europe is still under way to this day. Member States are gradually dropping a complete ban on selling medicines via the Internet. The latter countries include Italy where relevant legal provisions regarding the possibility of distance selling of nonprescription medicines came into force from 1 July 2015. In general, this process affirms that the Member States are following the relatively single-option path by establishing rules of such a distribution and strict control over complying with them because they find impossible to resist the development of new methods in the sphere of distribution of medicines.

In addition, there is an active discussion of the need for a global approach to the resolution of issues related to the distance selling of medicines. A global approach can include a UN-lead programme (possibly by the World Health Organisation–WHO) to develop international agreements, and help harmonise national legislation to result in common policies (that reflect international standards) on areas such as: online medical consultations (without a physical examination by a doctor); online prescribing; the advertising of prescription drugs to the public; the certification of medical websites; the naming of drugs and dosage instructions; the classification of drugs, especially prescription drugs; and the hosting (by Internet Service Providers) of pharmacies (and other websites) involved in illegal activities [9, p. 24-25].

This global approach/strategy should entail cooperative agreements (e.g. for enforcement), and the harmonisation of national policy and legislation, to reflect internationally agreed standards. Failure to address this problem may result in serious consequences (in the future) for the health and well-being of the global community [9, p. 25].

The main deterrent to the general introduction of distance selling of medicines is existence of a rather wide range of negative consequences of such a decision. Moreover, it is necessary to ensure evaluation of opportunities to extricate from them or at least to reduce them through implementation

of preventive measures provided by the Directive 2001/83/EC. In this case, the benefits for medicine consumers due to expanding their distribution methods should also be taken into account not least of all. Among these are possibility of obtaining medicines at more favorable prices than offered by local pharmacies, ease of ordering and receiving a purchase order, possibility of getting a pharmacist's consultation remotely (optional), leveling the territorial criterion of availability of medicines, supply of a wider range of medicines, possibility of preview of the official information on a medicine and statistics on their proven efficiency and so on.

Among the negative effects, we can mark out as follows:

- *an increased risk of purchasing substandard medicines*. This deficiency can be treated in several ways, including a failure to comply with the requirements concerning quality through distributing medicines that are fake or those with an elapsed or remaining minor shelf life that makes it impossible to use these medicines for the necessary course of treatment, or distribution of medicines in violation of requirements for conditions of storage, transportation and etc.

According to the data from the World Health Organization, more than 50% of medicines offered for sale via the Internet are fake [10]. A negative factor for this is also the fact that medicines produced not only in the country of their sale but in other countries by different manufacturers as well are offered for the sale via the Internet. For these reasons, a consumer who, for example, can identify a specific medicine by a certain manufacturer or countries of production is also absolutely vulnerable to defrauding by suppliers of an identical medicine by other manufacturer. In addition, different requirements to labeling and packaging of a certain medicine may be valid in different countries. This risk can also be seen in terms of the consequences of the current problems in the production of medicines in developing countries [11].

- *the risks of distribution of illegal medicines*. In this case, the point is both narcotic drugs and prescription medicines prohibited for selling through agreements concluded remotely in most European countries. This risk is in evidence because of the inability to provide a complete and comprehensive control of the medicines offered for sale remotely, given the current level of technology and a lack of a special supervisory body for distance selling in most countries. The issues related to the extension of jurisdiction of the competent authorities of the country to the Internet pharmacies operating from abroad and the possibility to use effective measures to them are also difficult to solve.
- *the risks associated with a lack of professional pharmacist's consulting in the sale of medicines.* A lack of consulting is also proposed to understand as the situation in which the sale of medicines is performed only after undergoing questioning by a buyer at a seller's website without further evaluation of the gained results by a pharmacist. These risks have several effects and among them an increased likelihood of iatrogenic effects as adverse (side) effects of a use of purchased medicines or excessive use of them, which sometimes leads to antibiotic resistance; adverse medicine reciprocal interactions due to a lack of an expert analysis of doctor's orders or patient's pharmaceutical records etc.

To assure patient safety and avoid liability, many on-line pharmacy sites reject an order if a buyer's questionnaire suggests that the drug may be medically inappropriate. However, on many sites, the process of analysing the questionnaire appears to be quite haphazard. For example, a newspaper reporter in Seattle contacted an Internet site, claimed normal weight, but was still able to order a prescription weight loss drug. Equally, a TV reporter ordered and got sildenafil for her 6-month-old son, using his actual height, weight, and birth date. Another investigator received the same drug after giving vital data for his cat. Though there are sites that do cull through questionnaires and reject inappropriate buyers, these systems remain ripe for abuse [12].

- *the risks related to protection of medicine consumers' personal data*. These risks are beyond the buyer's control and they are difficult to overcome with the help of regulatory mechanisms. After all, even purchasing from a trusted provider who is complying with the legislation on the protection of personal data cannot guarantee full confidentiality of the substance of relations between a seller and buyer. Increasing facts of personal information leakage from databases with a much higher level of protection than those that should be ensured by sellers involved into distance selling can serve as evidence of this.
- *the risks to consumer protection.* The causes of these risks are not specific only for the sphere of circulation of medicines but also other products. However, in some cases, the specificity of medicines as a commodity for a buyer due to their purchase objectives and importance of obtaining timely increases negative effects of abusing consumer rights in distance selling by suppliers. As an example, it can be a violation of deadlines of a commodity delivery established by the law to the agreements concluded remotely; a refusal to supply or a short delivery; difficulties of a return or exchange of a defective commodity; complicated mechanisms for prosecution of unscrupulous suppliers, recovery of damages to a buyer and others.
- *the risks associated with inability to obtain insurance compensation for purchased medicines*. In practice, a failure to comply with the requirements for the purchase of medicines prescribed by a doctor or violation of the requirements related to proper execution of an agreement on distance purchase of medicines often leads to financial losses of customers that are not covered by insurance payments.
- *other risks.* This category of risks can include those ones that are generally characteristic for the sphere of circulation of medicines, for example, the risks associated with violations of requirements concerning advertising of medicinal products, implementation of information policy, a lack of adequate pharmacovigilance of medicinal products sold online etc.

Various preventive measures are taken by the competent authorities of the EU to overcome the above mentioned negative effects. In particular, national legislations of the Member States provide for limiting lists of medicines available for sale via the Internet or special measures to control

and liability in the field of distance selling of medicines. Herewith, the provisions of paragraph 2 of Article 85C of the Directive 2001/83/EC are applied that allows the Member States to establish conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

CONCLUSION

Reception of the described experience of regulation in EU will allow a further review of the principles of regulation in Ukraine in the sphere of medicines with a shift in the main emphasis in the direction of ensuring adequate consumer rights in this area and preventing the risks of patients' and public health. Amendments to the legislation of Ukraine in the field of electronic commerce, including the Law of Ukraine "On Electronic Commerce", and enactment of the new Law of Ukraine "On Medicines", taking into consideration the provisions on distance selling in accordance with the Directive 2001/83/EU, should be the first steps in this direction.

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