



INTERNET-PHARMACIES – ANALYSIS OF THE WORLD EXPERIENCE

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ABSTRACT

In this article the main organizational features and approaches to legislative regulation of remote sale of medicines and other goods of pharmaceutical range, in particular, through the Internet-pharmacies, are examined. When summarizing the work experience of the internet-pharmacies in a number of countries, such as the USA, Canada, countries of the EU and post-Soviet countries, the basic legislative standards, organizational structures, present problems, possible ways of their solution and further prospects of development of this kind of activity on the world pharmaceutical market are analyzed.

Keywords: Electronic commerce, Remote sale of medicines, Internet-pharmacies, license conditions.

INTRODUCTION

The widespread use of the Internet as a platform for realization of various commercial projects, including those ones on pharmaceutical market, resulted in the possibility of the on-line purchase of almost the whole range of pharmaceutical products including medicines. However, in accordance to the provision of Copenhagen Declaration, which was adopted in May 1994 on the III Annual conference of European forum of pharmaceutical associations and WHO European regional office, medicines cannot be accounted solely as a product. In accordance to the other provision of this Declaration, the law, that regulates issues of supplying population with medicines, must contain a clear definition of notion "pharmacy" and should limit its usage with only those institutions which correspond to this definition.¹

Considering the present provisions and specifics of sale realization through the Internet, most states began to conduct reformation of their legislation for the purpose of creation conditions in which it is possible to combine the use of remote sale advantages given by the Internet and rather strict conditions of state control and regulation of pharmaceutical sector. But, in spite of considerable work experience of legislative bodies of many countries over this problem, the comprehensive law which regulates relationship on the pharmaceutical market on the Internet has not been developed for the time being, and the present normative acts regulate only some aspects of work in the network.

The greatest number of unsolved issues and grave errors are still associated with activity of specialized websites which sell different products of pharmaceutical range, including medicines, and that are known as Internet-, on-line-, cyber-, virtual or electronic pharmacies.

When analyzing the main approaches to the regulation of such pharmacies' activity in different countries, the various approaches to solution of this problem attract attention. This can be caused by different historical, economical, geographical and political factors. And the absence of actual borders between states on the Internet results in an unrestricted entry of various products of pharmaceutical range, including medicines, to a country's territory with no account taken of its regulatory policy in the scope of medicines turnover. Therefore, one of the essential issues of pharmaceutical market still remains the necessity of the further harmonization of regulatory policy in the scope of Internet-pharmacy.

The main aspects of Internet-pharmacies' activities, which are subject to regulation in many countries of the world, are:

- Organizational structure;
- Structure and content of the Internet-pharmacies' websites;
- Advertising of medicines and Internet-pharmacies on the network;
- Writing the on-line prescriptions, distance medical consultations and other kinds of additional service given by some electronic pharmacies;
- Privacy of Internet-pharmacies' clients;
- Import of medicines for personal needs.

States, which have substantial work experience in solving of the problems connected with regulation of medicines' remote sale and activity of electronic pharmacies, were chosen for analysis. The general fact is that pharmaceutical activity, in particular, the retail sale of medicines, is subject to obligatory state licensing in all countries.



THE USA AND CANADA

These countries have the richest and the longest experience on regulation of Internet-pharmacies' work and the most developed and similar in this sphere law which allows to cover in detail the diverse situations arisen when remote selling of products of pharmaceutical range. The first Internet-pharmacies appeared in the USA at the end of 90^s of the last century as the evolved form of medicines order by mail, which had been practiced in this country since 1872.²

In accordance to the USA legislation, Internet-pharmacies are private or legal persons which occupy the sale of prescription and OTC medicines through the Internet and their delivery to the consumers by mail or with the help of delivery service. At federal level, activity of such pharmacies in the USA is regulated by the legislative act «The Ryan Haight Online Pharmacy Consumer Protection Act of 2008». In the USA, the right to occupy the remote sale of medicines can get not only the existent in reality pharmacy, which traditionally occupies this kind of activity, but also some big pharmaceutical giants, such as, for instance, Merck & Co, that have received a permission to open their own websites, which in recent years work as Internet-pharmacies.

In contrast to the USA, in Canada only existent in reality and licensed pharmacy can create its own site on the Internet for legal remote sale of medicines and other products of pharmaceutical range.

In accordance to the legislation of these countries, on the homepage of Internet-pharmacy, in addition to license number and number of registration certificate, there should be specified the following data:

- Name and physical address of the pharmacy (as they are given in the registration certificate);
- Telephone number of the pharmacy and electronic address of the site;
- List of states, in which activity of this pharmacy is licensed;
- Professional degree and license number of the responsible pharmacist;
- Name, address, telephone number, professional degree and license number of physician, who works with this pharmacy by contract basis (provided that pharmacy renders services of distance medical consultation).³

Canadian pharmacies, which offer pharmaceutical help to the population through the Internet, must also prove that on-line aspects of their operations correspond to standards of pharmaceutical practice.⁴

To decrease the risk for consumer to appeal to the site of illegal Internet-pharmacy Food and Drug Administration (FDA) in the USA and National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada recommend

using the sites with logotype of Verified Internet Pharmacy Practice Sites (VIPPS) only. Presence of VIPPS logotype on the site of the virtual pharmacy indicates that this pharmacy:

- Has a license and observes the license conditions which are stipulated by legislation of the state;
- Obligatory publishes information about the medicine which is planned to be advertised, on the VIPPS site;
- Gives the permission on inspection by National Association of Boards of Pharmacy (NABP), if there are strong reasons for this.

To obtain this logotype, the pharmacy should submit a preliminary application to the proper regulatory body with a number of necessary documents (information about license, pharmacy's owner, documents about professional education and qualification level of the staff, etc.) and to undergo the preliminary check by regional inspection. After that the VIPPS inspector examines the preliminary application, evaluates correspondence of the pharmacy's site to requirements of the programme and conducts the inspection of the pharmacy. If the pharmacy meets all requirements of the programme, it obtains permission to place the programme's logotype on its site, and it is entered in the list of the state's certified Internet-pharmacies which is available to the users. In order to verify the logotype, the potential client may just visit the VIPPS site, where there is a relatively small list of Internet-pharmacies which are the members of voluntary certification programme.

Moreover, FDA has placed the additional recommendations for potential clients of Internet-pharmacies which enable to decrease the risk to use the site of Illegal electronic pharmacy and to purchase the low-quality or counterfeited products:

- Not to purchase medicines from pharmacies that do not require prescription written by a personal visit to a physician;
- To keep the personal information only in that case when the pharmacy can ensure its reliable protection;
- To ascertain whether there is a licensed pharmacist at the Internet-pharmacy with whom the client can contact in case of any questions;
- Not to purchase medicines at foreign Internet-pharmacies;
- when starting to take a new medicine, it is necessary to consult with a physician.^{3,5}

The basic legislative act of the USA «The Ryan Haight Online Pharmacy Consumer Protection Act of 2008» does not forbid prescription of medicines, which do not contain substances present in the subject-quantitative account, on the basis of distance medical consultations.



But, as is known, the federal law in the USA is not obligatory to be carried out in each separately taken state, so provision of such services is forbidden in several states at the legislative level. The similar situation is observed in Canada, where the most of sites of regulatory bodies provide information for consumers, urging not to use distance medical consultations. That is why most legal Internet-pharmacies dispense medicines of prescription group only by prescription written by a personal visit to a physician. In practice, the client sends either the copy of prescription by fax, e-mail or the prescription itself by mail. In a number of cases, the client may even invite the physician to the telephone so that he can confirm his prescription.

However, demand for distance medical consultations is quite high, and some certified Internet-pharmacies provide such additional services to their clients. Sometimes the physician communicates with patient by telephone or by voice communication software, such as Yahoo messenger, Skype, ICQ, and sometimes he confines himself with on-line view of the patient's questionnaire on medical history. But, in any case, the physician decides on the assignment of this or that medicine on the basis of information received from the patient only. Naturally, at the pharmacies which provide the service of distance medical consultations the cost of medicines is usually higher than at the pharmacies which do not provide such services.^{6,7}

In the USA and in Canada advertising of prescription medicines, oriented straight towards consumer, is not forbidden by law. This gives the virtual pharmacies an opportunity to advertise any products from their range on the Internet.

But advertising of the electronic pharmacies' sites in the leading Internet search engines and the other sites is controlled by law. According to federal laws of the USA and Canada, the websites are responsible for advertisements placed on them. In accordance to the recent agreement with the Department of Justice of the USA, only companies certified by NABP will be allowed to advertise medicines. In 2011, Department of Justice of the USA has fined the Google Company for \$ 500 mil for advertising of illegal and fraudulent pharmacies from Canada. During the investigation, it was established that the company knew that pharmacies offering a free sale of medicines on subject-quantitative account were advertised on its site.

When the electronic pharmacy wants to place an advertisement of its site or medicines in the search engines, all Internet searches should use a special search programme «Pharmacy Checker» which enables to confirm the legality of this Internet-pharmacy's activity.

For example, the largest Internet search engines Google and Yahoo recognize only Internet-pharmacies, located in the USA, Canada, Australia, and the United Kingdom of Great Britain and Northern Ireland, provided that they meet the certain requirements. Passage of evaluation

process through the programme «Pharmacy Checker» of Internet-pharmacies of the USA and Canada is carried out on the following stages:

- Submission of the Internet-pharmacy's application to «Pharmacy Checker», which checks the presence of this pharmacy's license given by the proper governmental agency;
- Receipt of approval by the programme «Pharmacy Checker» as Internet-pharmacy occupying the relevant activity, which implies compliance with all laws and rules of the jurisdiction, where the pharmacy is located, as well as with each jurisdiction, where it sells. If approved, the Internet-pharmacy is assigned a unique identifier «Pharmacy Checker»;
- Regular monitoring of this pharmacy's license status by this programme, as well as consideration of any complaints received concerning this pharmacy.

In addition, the sign «Pharmacy Checker» placed on the site increases conversion of traffic, and with its help it is possible to obtain the additional inflow of customers from the site pharmacychecker.com, various search engines and portals, which accept only pharmacies certified by this programme.²⁻⁴

COUNTRIES OF THE EU

Recently, the common legislative guidelines which regulate the sector of products of pharmaceutical range electronic sale, were absent in the EU countries. There are three EU Council Directives which indirectly deal with this question. This is Directive 97/7, regulating the remote sale, Directive 97/36, concerning teleshopping, and Directive 92/28 «On the advertising of medicinal products for human use». Article 14 of Directive 97/7 gives permission to all countries – EU members to forbid the remote sales of medicines on the national level up to prohibition of their public advertising.⁸ That is why activity of Internet-pharmacies is legal only in a rather small number of EU countries, among which are Czech Republic, Denmark, Germany, Malta, Netherlands, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland and Great Britain. In the present countries, this kind of activity is strictly regulated with the obligatory special registration. It results that such pharmacies are forced to work within legislative field of the certain country. Approaches to regulation of Internet-pharmacies' activity differ considerably in the countries of continental Europe as compared with Great Britain. In 2 countries – EU members, such as Rumania and Slovakia, status of Internet-pharmacies remains doubtful as national legislation of these countries does not contain the direct prohibition of medicines remote sale, as well as it does not contain any legislative acts which regulate this activity in any way.^{9,10}

In those EU countries where the national legislation permits remote sale of medicines provisions of EU



Directive EC 2000/31/EEC, which regulates electronic commerce, were used for regulation of information which must be present on the site of Internet-pharmacy. In accordance to this Directive, the necessary minimum of information was:

- Name of the pharmacy;
- Geographical address of the present in reality pharmacy offering these services, as well as contact information including telephone number, fax number and e-mail address;
- Professional title of responsible pharmacist and country in which the educational document was received ;
- Professional organization (the order), which registered the responsible pharmacist, and the proper body responsible for regulating and controlling of the pharmacy's activity;
- Directions to the relevant professional codes and standards in the country of pharmacy's establishment and links where they are available.

In 2000, the European Commission has set up the working group that deals with information, advertising and electronic commerce in a sphere of pharmaceutical and medical products, as well as development of common requirements for Internet-pharmacies throughout the EU. The first step in creating pan-European standards for remote sale of pharmaceutical range products was resolution of the Committee of Ministers of the Council of Europe "Good practice in mail distribution of medicines", adopted in 2007. It was an important step in solving the problem of protection of consumers' rights and quality of medicines assurance when their remote selling. The resolution stipulates inter alia the following important points:

- Responsibility and methods of delivery to consumers;
- Compliance with the administration indications of medicines for information given to consumers;
- Obligation to indicate side effects, interactions with the other medicines, conditions of return and possible defects in the quality of medicines, mailed to the consumer and from the consumer;
- Prohibition of remote sale of the medicines which are unsuitable for postal delivery;
- Promotion and advertising of postal delivery;
- Obligatory submission of prescriptions when remote selling of prescription medicines;
- Simplification of international cooperation in this field.

02/16/2011 European Parliament adopted a Directive 2011/62/EU, which among the other issues regulated

these basic requirements. The main provisions of this Directive relating to Internet-pharmacies are as follows:

- 1) Each country – EU member has a right to decide on the national level whether to allow or prohibit activities of Internet-pharmacies on its territory;
- 2) If a country – EU member allows Inter-pharmacies' operation, their activity must conform to the list of requirements, common throughout the EU, notably:
 - Notice of the initiation of activity of the relevant authorities, that give permission for this type of activity and control it;
 - Presence of registration at the fixed physical address;
 - Placement of the logotype, approved by the European Commission, and testifying that this web-site corresponds to the unified pan-European requirements and is associated with the site of the competent controlling unit, on the Internet-pharmacy's site;
 - Placement of contact information on the site;
 - Dispensing of prescription medicines only on prescriptions (in case when the remote sale of prescription medicines is not forbidden by national legislation);
 - Prohibition of sale of unregistered in the country medicines;
 - Compliance with national legislation requirements.^{11, 12}

Thus, by analogy with the USA and Canada, the sites of all legal European Internet-pharmacies should reflect the approved uniform logotype, well-known in all EU countries, so that the consumer can be sure that he deals with the legally operating Internet-pharmacy. All legal Internet-pharmacies should be linked with the central site of the network in each state – EU member, and they will be enumerated on the same site. The various national web-sites, by-turn, will be linked to the central site of the EU. However, unlike in the USA and Canada where the certification programme of Internet-pharmacies and receipt of the right to use the VIPPS logotype is a voluntary process aimed to increase consumer's confidence in the site of the definite electronic pharmacy, in the EU countries it is an obligatory procedure for the Internet-pharmacy to pass certification and to receive the single European logotype. As well as in Canada, only existent in reality licensed pharmacies have the right to open the site and to occupy the remote sale of medicines.

This Directive puts additional requirements on informing visitors of the Internet-pharmacies sites about possible risks associated with the purchase of medicines by the Internet. Namely, this Directive states that:

- 1) The right of consumers to purchase medicines remotely for personal use throughout the EU;



2) Drawing attention to the necessity for consumers to purchase medicines only from the legal Internet-sites of licensed pharmacies. To verify legality of the Internet-pharmacy's site it is necessary to draw attention on the following data:

- Whether the physical address of the pharmacy is hidden;
- Whether the name and the web-site of this pharmacy are given in the list of the central national site of the network of country's all Internet-pharmacies;
- Whether the Internet-pharmacies' activity is allowed on the territory of the state, in which this on-line pharmacy is registered;
- Whether this Internet-pharmacy requires a prescription when selling prescription medicines;
- Whether the prices in this Internet-pharmacy are too low.

Thereby, the visitor of the Internet-pharmacy's site has a certain possibility to verify independently the legality of its activity, so that it reduces the risk of counterfeited medicines and the other products of pharmaceutical range purchase through the Internet.

Some features of national legislation requirements of countries of continental Europe

Some countries of continental Europe which allow remote sale of medicines have their national limits and requirements for operation of Internet-pharmacies. So, Internet-pharmacies of the Czech Republic and Spain have the right to sell only OTC medicines. On the contrary, in Switzerland, sale of OTC medicines is forbidden at the federal level and sale of prescription medicines is allowed in compliance with their safety requirements. However, in some Swiss cantons, the law allows to introduce on-line sale of OTC-medicines provided that the medicine was prescribed by a physician. The patient is able to obtain the necessary consultation and to administer the assigned medicine under medical supervision.

It should also be noted that in a number of EU countries prohibition of the remote sale and mail delivery applies only to medicines and does not apply parapharmaceutical products, which are an integral part of modern pharmacies' range. Also, there are no laws that forbid the existent in reality and licensed pharmacy to open its own site where the information about location, working hours; and some pharmacies place there the price-list containing parapharmaceutical products, especially such popular as dietary supplements, cosmetics and hygiene products, and sell these products remotely, sending them to the customer by mail. Thus, these pharmacies work as parapharmaceutical shops on the Internet.^{9,13,14}

United Kingdom of Great Britain and Northern Ireland

Of all countries – EU members the legislation of this government, regulating the remote sale of medicines, is the most comprehensive and, at the same time, the most rigorous. In the UK, activity of Internet-pharmacies is regulated at the legislative level, and in accordance with government's strategic plan «Pharmacy in the Future», adopted in 2000, sale and delivery of medicines through the Internet are permitted in the case of provision of appropriate quality assurance and compliance with professional standards of practice. In this country, even before the adoption of Directive 2011/62/EU, registration of such pharmacy was required in General Pharmaceutical Council (GPhC) by assigning it a special, single for the whole country, logotype and introduction of this pharmacy in the general list of legal Internet-pharmacies on the GPhC site. Due to historical and political circumstances in the UK, there are two pharmaceutical societies – Royal Pharmaceutical Society (RPhS), which is the regulator in professional association of pharmacists of England, Scotland and Wales, and Pharmaceutical Society of Northern Ireland (PSNI), which unites pharmacists of Northern Ireland. On the sites of these pharmaceutical societies the detailed requirements for registration of Internet-pharmacies on the territory of Great Britain and special codes of ethic of pharmacists, which performance is obligatory including for Internet-pharmacies and quite difficult, are stated.^{9,15,16,17}

In addition, the pharmaceutical societies have developed and posted on their sites professional standards and guidelines for Internet-pharmacies. These professional standards include the following sections:

- Requirements for the design of the Internet-pharmacies' web-sites;
- Security and privacy;
- Protection of patient's choice;
- Selling of prescription and OTC medicines;
- Pharmaceutical information and advice;
- Carriage and delivery of medicines;
- Prescriptions written abroad;
- Accounting.

According to these documents, cooperation with the Internet-pharmacy is not limited to the fact of medicines dispensing, and pharmacies' duties also include monitoring for their proper usage. Pharmacies' workers contact customers by e-mail or telephone in order to verify the correctness of the received dosage. In addition, they are obliged to track how the purchased medicine interacts with the other medicines, positively or negatively, and how successful the course of treatment was. As in the USA, practice of filling in of the pre-questionnaire by the customer is quite widespread. All questionnaires are examined by professional pharmacist, who expresses his opinion and, if necessary, recommends a medicine and/or additional medicines to a client.^{18,19}



The UK law has a rather loyal attitude towards on-line writing of prescriptions and medical consultations. In the British Medical guidance, issued by the General Medical Council (GMC), the remote prescribing is not unambiguously forbidden, but special guidelines about physician's behavior, accounting specific circumstances, are given.

Advertising of prescription medicines in the means of mass media, including the Internet, is forbidden under the Medicines (Advertising) Regulations, 1994.²⁰

As standards to be met by the British Internet-pharmacies are high enough, advertisements of their sites are placed by the leading Internet search engines Google and Yahoo, also after the inspection by the programme "Pharm Checker". Evaluation of the UK Internet-pharmacies by Google search is carried out on such parameters:

- Internet-pharmacy must be the member of RPhS or PSNI;
- registered in the relevant pharmaceutical societies pharmacies must submit an application for registration to the support service AdWords at adwords-ru@google.com;
- for advertising campaigns of Internet-pharmacies and related services, targeting is set only for the UK; these advertisements must not appear in any other countries;
- Internet-pharmacies and related services should not advertise prescription medicines.

COUNTRIES OF THE FORMER SOVIET UNION

During the relatively long time in many countries of the former Soviet Union Internet-pharmacy has not been widespread, and so these states had little or no legislation regulating the remote sale of medicines and Internet-pharmacies' activity. Taking advantage of the absence of an outright prohibition and strict standards of activity of Internet-pharmacy, the sites offering different products of pharmaceutical range mass appeared on all post-Soviet space. Therefore, in recent years, governments of these countries have been seriously confused with the problem of mass distribution of medicines of inadequate quality, unregistered, forbidden for sale medicines and the other negative phenomena, which are a consequence of the chaotic spread of virtual pharmacies. Most post-Soviet countries have chosen to forbid totally the remote sale of medicines, and, as a sequence, the Internet-pharmacies as well, mainly due to the lack of developed at a time norms and standards of their activity.

Ukraine

Until December 2011, there were no clear provisions concerning possibility of Internet-technology use for providing population with medicines and other products of pharmaceutical range. Using the uncertainty of the normative base, Internet-pharmacies mass appeared on

the territory of Ukraine and became quite popular among the population.

Certain restrictions on such Internet-pharmacies' work have been brought by "License conditions of implementation of economic activity on the production of medicines, wholesale, retail sale of medicines", from 09/21/2010 N. 340. They prohibited medicines sale through establishments, not complying with the license conditions and, thereby, made the existence of Internet-pharmacy as a separate business-unit impossible without existence of "real" pharmacy which was authorized to retail sales of medicines. The second important moment of these License conditions concerned the prohibition of postage of medicines, and the only possible way to deliver customer orders remained courier delivery.^{21,22}

12/29/2011 in Ukraine an order, approving the new license conditions which directly prohibit the remote sale of medicines and make it impossible to legalize the activity of Internet-pharmacies on the territory of Ukraine, became effective.²³

Russian Federation

The remote sale of medicines was prohibited in the Russian Federation by the RF Government Decree N. 612 of September 27, 2007 "On approval of rules of remote sales of products". This decree states that remote sale of alcoholic beverages, as well as products free selling of which is restricted or limited by RF law, is not allowed. List of products restricted for free selling, is set by the RF Presidential Decree N. 179 of February, 29, 1992 "The list of products and waste-products which free sale is prohibited". These products, in particular, include:

- Precious and rare-earth metals and articles made of them;
- Precious stones and articles made of them;
- X-ray equipment, devices and equipment with the use of radioactive substances and isotopes;
- poisons, narcotic drugs and psychotropic substances, ethyl alcohol;
- Medicines, except for medicinal herbs;
- Crude drugs, obtained from the northern reindeer breeding (antlers of young Siberian stags and endocrine raw materials).^{24,25,26}

Republic of Belarus

The most rigorous against remote sales of pharmaceutical range products is legislation of the Republic of Belarus, which prohibits the remote selling of not only medicines but dietary supplements as well. This is stated in resolution of Belarus government N. 1091 of 08/19/2009. According to the accepted resolution sales of medicines and dietary supplements, which must be sold only through pharmacies, is not allowed outside the trading facility.²⁷



CONCLUSION

Analysis of international experience in regulation of Internet-pharmacies activity has revealed different approaches to solve this issue, beginning with the radical measures of total prohibition of remote sale of medicines and Internet-pharmacies' activity, as in some EU countries and countries of the former Soviet Union (up to the ban of remote selling of dietary supplements, as in the Republic of Belarus), to the loyalty up to issuance of permission remote sale of medicines by major pharmaceutical corporations, which are not pharmacies as such.

According to the authors, a total prohibition of remote sale of medicines and Internet-pharmacies' activity is not a rational solution of this issue, as in the absence of tangible limits in the network the consumer, interested in this kind of service, can apply to the sites of foreign Internet-pharmacies, where, because of lack of knowledge of language and national laws, it will be difficult and sometimes even impossible for him to determine the legality of this site. In addition, the use of the Internet-pharmacies' sites offers customers a number of obvious advantages compared with a visit to a real pharmacy, such as time savings, convenience of products selection, free access to necessary pharmaceutical information, and is convenient for people deprived of their freedom of movement and those who live far away from the nearest pharmacy. Therefore, the most noteworthy is the experience of those EU countries which are actively engaged in the development and improvement of legislation, regulating the Internet-pharmacy's work, ensuring control and adequate quality of medicines, as well as development of standards of their activities (e.g. the United Kingdom of Great Britain and Northern Ireland), which allow to provide the client, who visited the Internet-pharmacy's site, not only with medicines and other products of pharmaceutical range, but with the necessary level of pharmaceutical care as well.

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