

LEGISLATIVE BASES OF THE MEDICINES TRADE AND PROBLEMS OF COMPUTERIZATION OF MEDICINES DISTRIBUTION IN UKRAINE AND EUROPE

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Abstracts

The abstracts provide information on the latest legislative documents on wholesale and retail trade in medicines, which indicated effective mechanisms for sale to the public. The analysis and research of computerization problems of distribution of medicines in Ukraine and the countries of Europe are carried out. According to the research plan, the purpose, object, subject, and tasks of developing the automated system for distributing medicines taking into account the last legislative documents, are defined.

Keywords: an automated system, computerization, experience in medicines distribution.

Анотація

У тезах надана інформація щодо останніх законодавчих документів щодо оптової та роздрібної торгівлі лікарськими засобами де були зазначені дієві механізми продажу населенню. Проведені аналіз та дослідження проблем комп'ютеризації поширення лікарських засобів в Україні та країнах Європи. Відповідно до плану дослідження визначені мета, об'єкт, предмет та задачі розробки автоматизованої системи з поширення лікарських засобів з урахуванням останніх законодавчих документів.

Ключові слова: автоматизована система, комп'ютеризація, досвід розповсюдження лікарських засобів.

A year ago, on March 23, 2020, the Cabinet of Ministers of Ukraine adopted Resolution №220 "On Amendments to the Licensing Conditions for Economic Activity in the Production of Medicines, Wholesale and Retail Trade in Medicines, Import of Medicines (except Active Pharmaceutical Ingredients)" [1]. By this norm, the government allowed for coronavirus quarantine to carry out the remote sale and mail delivery of medicines and related medical products to minimize social contacts and counteract the spread of COVID-19. Such an experiment proved to be an effective mechanism for controlling the coronavirus throughout Ukraine. Besides, a new service has become essential for citizens.

Also, in the conditions of restrictive measures, when public transport did not work in cities and towns, and most stationary pharmacies could not meet consumer demand for antiviral medicines, antiseptics, and personal protective equipment in a short time, consumers were given an alternative opportunity to find the right medicines in the pharmacy network. And order their delivery by mail, including directly to your home. Such an important distance trade in medicines has become especially popular among rural and urban dwellers.

In the future, assessing the great prospects for the development of e-pharmaceuticals, legislative initiatives (Fig. 1) are trying to be quite effective, namely:

- increase the factor of availability of medicines to the population;
- ensure competition and hence lower medicines prices;
- introduce strict control over the quality and originality of sold medicines, ensure consumer safety, and start fighting against medicines trafficking.

According to Serhiy Kuzminykh, Chairman of the Subcommittee on Pharmacy and Pharmaceutical Activity of the Verkhovna Rada Committee on National Health, Medical Care and Health Insurance, the bill provides for licensing of online pharmacies, strict requirements for postal delivery operators to comply with the manufacturer's recommendations. Introduction of an electronic prescription, a clear division of responsibilities between the remote pharmaceutical market operators for the quality of medicines received by the end-user, and many other regulatory mechanisms.

Also, legislators plan to regulate the market of distance trade in medicines and related medical goods in Ukraine by the end of this year. Therefore, the parliament is working to create appropriate legislative

changes. Simultaneously, the burden on the transition of the pharmaceutical market to a transparent, competitive, state-controlled Internet format by pharmacy monopolies is growing.

Besides, during the relevant Committee of the Verkhovna Rada on the draft new law "On Medicinal Products" [2], legislators prescribe clear mechanisms for the functioning of the remote market pharmaceutical services with the involvement of postal operators.

According to Directive 2011/62/EU [1], many medicines on the Internet are allowed in the EU. Under the Directive provisions, most EU member states are allowed to sell medicines in pharmacy chains. In some cases, special restrictions are imposed to protect patients.

However, it should also be noted that there are some problems with distributing medicines over the Internet, which are associated with certain negative factors. Such negative factors are minimized through certain restrictions on the sale of medicines over the Internet in the form of a ban. For example, in Belgium, one cannot sell veterinary or pharmacy medicines online. In Northern Ireland, some prescription medicines (such as strict accounting medicines) are not allowed for online leave, even if you have a valid prescription.

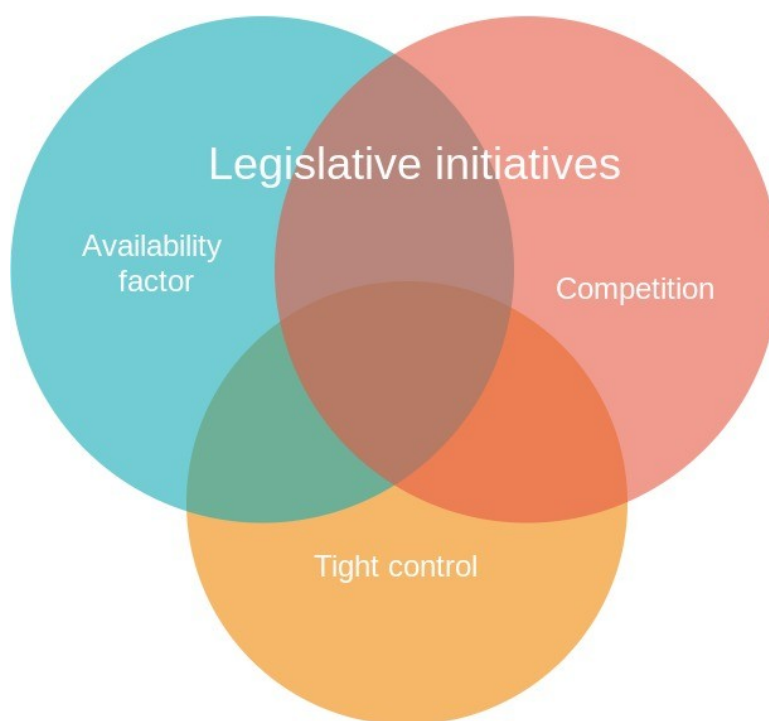


Figure 1. The main factors of effectiveness of legislative initiatives

At the same time, some European countries have allowed the sale of over-the-counter medicines online. This applies to countries such as Germany, Finland, Switzerland, Sweden, and Estonia. Given the potential difficulties associated with the shipment of medicines and the confirmation of the prescription's authenticity, it is advisable to introduce an electronic prescription at the state level.

However, when considering such a step in the introduction of medicines via the Internet, should take considerations of the economic and social factors of each of the countries participating in Directive 2011/62/EU [3] into account. Therefore, such considerations relate to such aspects as:

- technical implementation of online sales regulation;
- technical capabilities to monitor compliance with regulatory requirements of each country;
- potential risks for the pharmacy network and its further development.

Also, economic factors to consider should include:

- potential loss of state revenues from pharmacy taxes due to a decrease in turnover, if foreign pharmacies will be allowed to enter the market;
- potential job loss due to the concomitant closure of the pharmacy network;
- potential risks of national medicines manufacturers, especially in the case of over-the-counter medicines for the population.

This work aimed to develop an automated medicines management system. The object of research was the processes of functioning of the automated system for medicines management. The research subject was methods and software modules of automated system applications that allowed control of medicines distribution processes.

The practical significance of the developed software applications was developing and testing the software part of the automated system for the distribution of medicines.

Following the goal, it was necessary to perform the following tasks:

- to analyze the subject area for the distribution of medicines, taking into account the latest legislation;
- perform a comparative analysis of software that effectively distributes medicines;
- perform the design of an automated system for institutions involved in the distribution of medicines;
- to develop an algorithm and program code for an automated system for the distribution of medicines in a high-level Java language;
- perform testing of the graphic part of the automated system.

Literature

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