

O. D. BLAGUN, V. P. BOBRUK, M. V. BALYNSKA, M. A. DUCHENKO

*National Pirogov Memorial Medical University*

## SOME ASPECTS OF STATE QUALITY CONTROL OF MEDICINAL PRODUCTS AT REGIONAL LEVEL

**The aim** of this article is the analysis of normative legal acts that characterize changes in the legislation on the quality control of medicines, regulations and orders of the State Medical Service of Ukraine regarding the prohibition of the implementation of medical devices in the last 5 years and the substantiation of the conclusions aimed at further improving the quality assurance medical products (m/p).

**Results.** It was revealed that of the 41 supplier countries in Ukraine, the predominant number of m/p that were banned from marketing, was found in 9 countries (67.98 %). The largest number of m/p that fell under the ban falls to Ukraine (32.25 %), India (15.98 %) and Germany (15.68 %), the lowest number of such m/p is represented by Belgium (5.03 %). Under the prohibition on the implementation of m/p by the release forms, the most commonly banned m/p in tablet form (43.63 %). Anti-hypertensive agents (18.23 %), antiseptic and disinfectants (15.63 %), as well as hormonal (15.63 %) were the leaders among the m/p for the pharmacological groups that most often fell under the prohibition on implementation.

**Conclusions.** The analysis of the orders and instructions of the State Service of Ukraine to ban the sale of drugs in 2015-2018 indicates a significant decrease in their number in 2018, which indicates the improvement of the state drug quality control system. The largest number of drugs that were banned were found in Ukraine, India and Germany; predominant drugs in pill and liquid forms; Most often, antihypertensive, antiseptic, disinfecting and hormonal agents were banned. The introduction of a unified system for monitoring drug trafficking by labeling medicines with control identification marks based on 2-D coding will allow you to track the entire supply chain of medicines from the manufacturer to the end user and, accordingly, strengthen control over the quality of medicines, their production and import, which will counteract the ingress to Ukraine counterfeit or counterfeit drugs.

*Key words:* State Customs Service of Ukraine; regulation; Medicines; quality control

O. D. БЛАГУН, В. П. БОБРУК, М. В. БАЛИНСЬКА, М. А. ДУЧЕНКО

*Вінницький національний медичний університет ім. М. І. Пирогова*

### ОКРЕМІ АСПЕКТИ ДЕРЖАВНОГО КОНТРОЛЮ ЯКОСТІ ЛІКАРСЬКИХ ЗАСОБІВ НА РЕГІОНАЛЬНОМУ РІВНІ

**Метою** роботи є аналіз розпоряджень і приписів Держлікслужби України щодо заборони реалізації лікарських засобів (ЛЗ) у 2015-2018 рр., які підпали під заборону реалізації за країною-постачальником, за формами випуску та фармакологічними групами, а також обґрунтування висновків, спрямованих на подальше вдосконалення забезпечення контролю якості ЛЗ.

**Результати.** Виявлено, що з 41 країни-постачальника ЛЗ в Україну домінуюча кількість ЛЗ, що була заборонена до реалізації, виявлена в 9 країнах (67,98 %). Найбільша кількість ЛЗ, яка потрапила під заборону, припадає на Україну (32,25 %), Індію (15,98 %) та Німеччину (15,68 %), найменша кількість таких ЛЗ представлена Бельгією (5,03 %). Під заборону щодо реалізації ЛЗ за формами випуску переважно підпали ЛЗ у таблетованій формі (43,63 %). Лідерами серед ЛЗ за фармакологічними групами, які найчастіше підпадали під заборону щодо реалізації, були антигіпертензивні засоби (18,23 %), антисептичні та дезінфікуючі засоби (15,63 %), а також – гормональні (15,63 %).

**Висновки.** Проведений аналіз розпоряджень і приписів Держлікслужби України щодо заборони реалізації ЛЗ у 2015-2018 рр. свідчить про значне зменшення їх кількості у 2018 р., що свідчить про удосконалення державної системи контролю якості. Найбільша кількість ЛЗ, яка потрапила під заборону, була виявлена в Україні, Індії та Німеччині; переважали ЛЗ у таблетованій та рідкій формах; найчастіше підпадали під заборону щодо реалізації антигіпертензивні, антисептичні, дезінфікуючі та гормональні засоби. Впровадження єдиної системи моніторингу обігу лікарських засобів шляхом маркування ЛЗ контрольними ідентифікаційними знаками на основі 2-D кодування надасть можливість відслідковувати весь ланцюг постачання ЛЗ від виробника до кінцевого споживача та, відповідно, посилить контроль за якістю лікарських засобів, їх виробництвом та ввезенням, що протидіятиме потраплянню в Україну фальсифікованих або контрафактних препаратів.

*Ключові слова:* Держлікслужба України; нормативні документи; лікарські засоби; контроль якості

О. Д. БЛАГУН, В. П. БОБРУК, М. В. БАЛИНСКАЯ, М. А. ДУЧЕНКО  
 Винницкий национальный медицинский университет им. М. И. Пирогова

#### ОТДЕЛЬНЫЕ АСПЕКТЫ ГОСУДАРСТВЕННОГО КОНТРОЛЯ КАЧЕСТВА ЛЕКАРСТВЕННЫХ СРЕДСТВ НА РЕГИОНАЛЬНОМ УРОВНЕ

**Целью** работы является анализ распоряжений и предписаний Гослекслужбы Украины о запрете реализации лекарственных средств (ЛС) в 2015-2018 гг., которые попали под запрет по реализации по странам-поставщикам, по формам выпуска и фармакологическим группам, а также обоснование выводов, направленных на дальнейшее совершенствование обеспечения контроля качества ЛС (лекарственных средств).

**Результаты.** Выявлено, что из 41 страны-поставщика ЛС в Украине доминирующее количество ЛС, которые были запрещены к реализации, обнаружено в 9 странах (67,98 %). Наибольшее количество ЛС, которые подпали под запрет, приходится на Украину (32,25 %), Индию (15,98 %) и Германию (15,68 %), наименьшее количество таких ЛС представлено Бельгией (5,03 %). Под запрет по реализации ЛС по формам выпуска преимущественно подпали ЛС в таблетированной форме (43,63 %). Лидерами среди ЛС по фармакологическим группам, которые чаще всего попадали под запрет к реализации, были антигипертензивные средства (18,23 %), антисептические и дезинфицирующие ЛС (15,63 %), а также – гормональные (15,63 %) средства.

**Выводы.** Проведенный анализ распоряжений и предписаний Гослекслужбы Украины о запрете реализации ЛС в 2015-2018 гг. свидетельствует о значительном уменьшении их количества в 2018 г., что указывает на совершенствование государственной системы контроля качества ЛС. Наибольшее количество ЛС, которые попали под запрет, было обнаружено в Украине, Индии и Германии; преобладали ЛС в таблетированной и жидкой формах; чаще всего попадали под запрет к реализации антигипертензивные, антисептические, дезинфицирующие и гормональные средства. Внедрение единой системы мониторинга оборота лекарственных средств путем маркировки ЛС контрольными идентификационными знаками на основе 2-D кодирования позволит отслеживать всю цепочку поставки ЛС от производителя до конечного потребителя и, соответственно, усилит контроль за качеством лекарственных средств, их производством и ввозом, что будет противодействовать попаданию в Украину фальсифицированных или контрафактных препаратов.

*Ключевые слова:* Гослекслужба Украины; нормативные документы; лекарственные средства; контроль качества

#### STATEMENT OF THE PROBLEM

State quality control of medicinal products is a set of organizational and legal measures aimed at compliance by business entities regardless of ownership and subordination to the requirements of the legislation on quality assurance of medicinal products [1]. Quality control is theoretically the first concept based on the position of uniformity of quality of products and samples taken for control [2]. Quality control of medicines (medications) has always been in the center of attention of the state, its organizational system has been developed and improved with the development of Ukraine as an independent state. For this purpose, appropriate state institutions were established to which the functions of quality control of medicinal products at the level of the state and territorial communities were delegated.

The presence on the pharmaceutical market of exclusively high quality medicinal products is an important sign of the overall state of the state health-care system. That is why the issue of prevention of inflow of low-quality (substandard) and falsified medicinal products to the domestic market is the main task of the state system of quality assurance of medicinal products.

#### ANALYSIS OF RECENT RESEARCH AND PUBLICATIONS

At present, there are cases of detection of low-quality medicines and falsifications, including medicines of foreign origin, on the pharmaceutical market [3].

Drug quality control is one of the subsystems of state control, which is aimed at detecting inconsistencies in the drugs at different stages of their life cycle. Absence of low-quality medicinal products on the pharmaceutical market is ensured by control over compliance with license conditions for conducting business activities in the field of circulation of medicines.

Bardakova L. V. notes that in the pharmaceutical market there is a need to strengthen quality control of medicinal products from production to sales [4]. At the same time, 85.4 % of the authorized persons admit that they lack knowledge of the provisions of the modern concept of quality assurance of medicinal products [5]. Issues of training specialists in the field of quality assurance of medicinal products at the stages of wholesale and retail sales in the context of implementation of good practices (GMP/GDP/GPP) are the subject of the work of domestic scientists A. S. Nemchenko,

Z. M. Mnushko, V. A. Zagoria, S. M. Kovalenko, Y. V. Podruchnikova, V. O. Lebedintsa, A. V. Kaydalova, V. I. Gorodetskaya and others [6].

At the level of state regulation and state control in the field of pharmaceutical activity in Ukraine there is a certain effective mechanism of protection against benign drugs [7].

According to N. O. Vetyutneva, [8] the main tasks in the field of quality assurance of medicines are further development and improvement of standards of quality assurance of medicines harmonized with international legislation, creation of a single information network of relatively low-quality and falsified medicines, introduction of a pharmacovigilance system, development of instructional and methodological materials for the creation of quality systems at various stages of the "life" cycle of medicines.

#### IDENTIFICATION OF ASPECTS OF THE PROBLEM UNSOLVED PREVIOUSLY

Since the introduction of import licensing in Ukraine (PKMU dd. 30.11.2016 No. 929 "On Approval of the Licensing Terms and Conditions for conducting business activities for the production of medicines, wholesale and retail trade in medicines, import of medicines (except for active pharmaceutical ingredients)"), a system of double control of medicinal products has emerged, as in accordance with Directive 2001/83 of the EU full laboratory quality control is carried out when importing medicines from third countries, even if they are members of PIC/S. That is, if it is a question of harmonization with the relevant EU and WHO directives and guidelines, it should be understood that all imports, without exception, in the form of PIC/S countries, as is the case today, are subject to laboratory control. The procedure during wholesale and retail trade of medicinal products is controlled by authorized persons of economic entities, approved by the Order of the Ministry of Health of Ukraine from 29.09.14 years № 677. This procedure should be brought into line with the new requirements of the European legislation, because it does not take into account that a business entity may have two licenses: «for import and wholesale trade simultaneously and such entity shall perform input control twice.

The current system of state quality control in the field of circulation of medicines is constantly improved by harmonizing the legislation of Ukraine with the EU legislation and improving the financial and technical support of such a process, as well as providing human resources

#### OBJECTIVE STATEMENT OF THE ARTICLE

The purpose of the work is to analyze the orders and instructions of the State Service on Medi-

nal Products of Ukraine regarding the ban on the sale of medicinal products in 2015-2018, which fell under the ban on the supplier country, by form of production and pharmacological groups, as well as to justify the conclusions aimed at further improving the quality control of medicinal products.

#### PRESENTATION OF THE MAIN MATERIAL OF THE RESEARCH

*Materials and methods.* The research materials included public information of the State Service on Medicinal Products and Drug Control of Ukraine, as well as reporting documents of the State Service on Medicinal Products and Drug Control in the Vinnytsia region for the period 2016-2018; regulatory documents governing the quality assurance of medicinal products, scientific articles, analytical materials. The methods of comparative analysis, review, bibliographic and graphical modelling were applied.

*Results and their discussion.* The primary task of state supervision in the field of medicinal products' circulation is to ensure access of citizens of Ukraine to quality medicines, which includes state control at their importation into the territory of Ukraine, control by authorized persons and control by inspectors of State drug and medicinal inspection of Ukraine of economic entities during scheduled and unscheduled inspections.

In Ukraine there is a 3-level system of quality control of medicines, which includes: state control at their importation into the territory of Ukraine; control by authorized persons of economic entities; control by inspectors of territorial subjects of the State Service on Medicinal Products of Ukraine during scheduled and unscheduled inspections of economic entities.

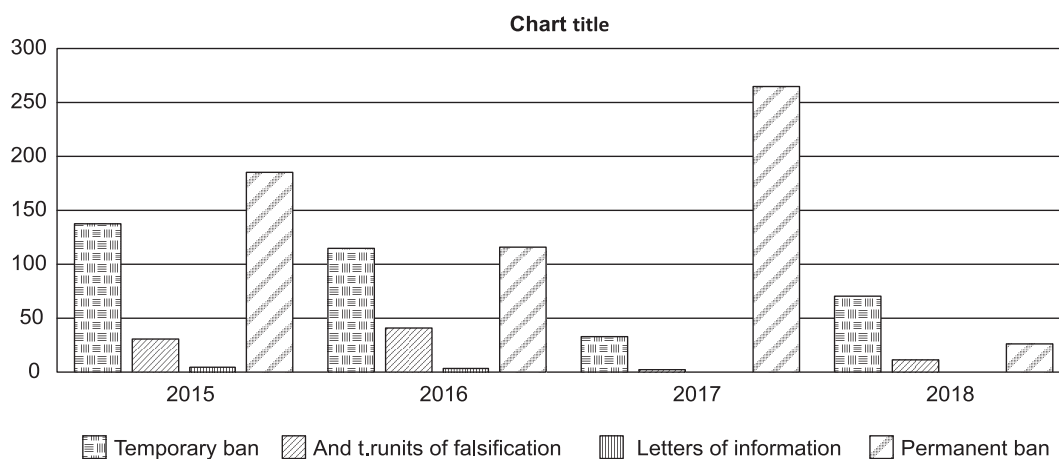
The State Service on Medicinal Products is the central executive authority that implements the state policy in the field of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, as well as the turnover of narcotic drugs, psychotropic substances and precursors and counteraction to their illegal turnover.

In its activities, the State Service on Medicinal Products of Ukraine shall be guided by the tasks approved by the PCMU as of August 12, 2015, No. 647 "On Approval of the Regulation of the State Service of Ukraine on Medicinal Products and Drug Control" as amended by the PCMU as of August 29, 2018, No. 687.

According to the Decree of the Cabinet of Ministers of Ukraine dd. 01.06.2016 No. 355 "On Establishment of Territorial Bodies of the State Service on Medicinal Products and Drug Control", 25 territorial bodies were established.

As of today, control over medicinal products imported into the territory of Ukraine is carried





**Fig. 1** Order to ban the sale of medicines in 2015-2018

out in accordance with the PKMU dd. 14.09.2005 No. 902 “On Approval of the Procedure for State Quality Control over medicinal products imported into the territory of Ukraine” with amendments approved by the PKMU dd. 7.10.2015 No. 804.

The priority direction of work of the State Service on Medicinal Products of Ukraine is to strengthen quality control of medicinal products. These services indicate the presence of falsified and substandard medicinal products in the country’s market. Information about the detected and prohibited medicinal products is regularly posted on the official website of the State Service on Medicinal Products and communicated to the authorized persons of pharmacies for immediate decision-making.

Our analysis of orders and instructions regarding the prohibition of the sale of medicinal products in 2015-2018 has shown that the State Service on Medicinal Products issued in 2015. 327 prescriptions prohibiting the sale (trade), storage and use of medicinal products in 2016 – 234, in 2017 – 298, in 2018 – 97. The share of temporary bans in 2015 and 2016 was almost the same, at 42.20 % and 49.15 %, respectively; in 2017, they dropped sharply to 11.07 % and jumped to 73.20 % in 2018.

Accordingly, the share of permanent bans in 2015 and 2016 was slightly higher than the share of temporary bans and was almost the same over the years (56.57 % and 49.57 %, respectively); in 2017, the share of permanent bans was predominant (88.93 %); in 2018, it was only 26.80 %. That is, the ratio of temporary and permanent bans in 2017 and 2018 was the opposite.

Among the suspicious temporary bans in 2015 and 2016, 22.46 % and 35.65 % were suspected of falsification of medication, compared to only 6.06 % in 2017; in 2018, there was an increase to 15.49 %, but it did not reach 2015.

The share of newsletters was insignificant – 1.22 % in 2015 and 1.28 % in 2016. No newsletters were issued in subsequent years (Fig. 1).

In the Ukrainian pharmaceutical market during 2016-2018, 41 countries were suppliers of foreign medicinal products.

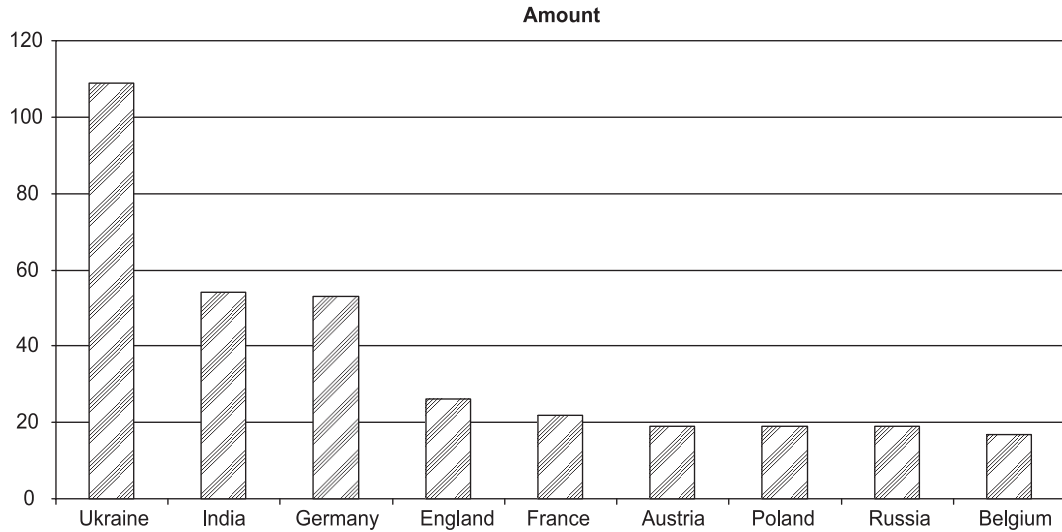
The overwhelming majority of medicinal products prohibited for sale were found in 9 countries (67.98 %), while other countries accounted for 32.02 % of medicinal products. As Figure 2 shows, among the 9 supplier countries, the largest number of medicinal products that were banned was found in Ukraine (32.25 %), a significant number of medicinal products were provided by India (15.98 %) and Germany (15.68 %), the smallest number of such products was provided by Belgium (5.03 %) (Fig. 2).

As Figure 3 shows, of all the medicinal forms prohibited for sale, 43.63 % were tableted, 31.16 % were liquid, 17.56 % were powdered, and 7.65 % were capsules. Other forms accounted for 27.96 %.

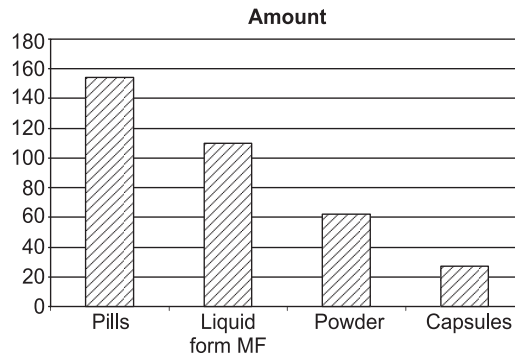
The leaders among medicinal products by pharmacological groups that were most frequently prohibited were antihypertensives (18.23 %), antiseptics and disinfectants (15.63 %), and hormones (15.63 %). The smallest share is accounted for vasodilators, antidiabetic and local anesthetic – 1.04 % each (Fig. 4). Others are not shown in Fig. 4, medicinal products falling under the ban make up 20.17 %.

Further improvement of the drug supply system is connected with the adoption by the Government of amendments to the legislation of Ukraine, which are aimed at improving the efficiency of quality control of medicinal products:

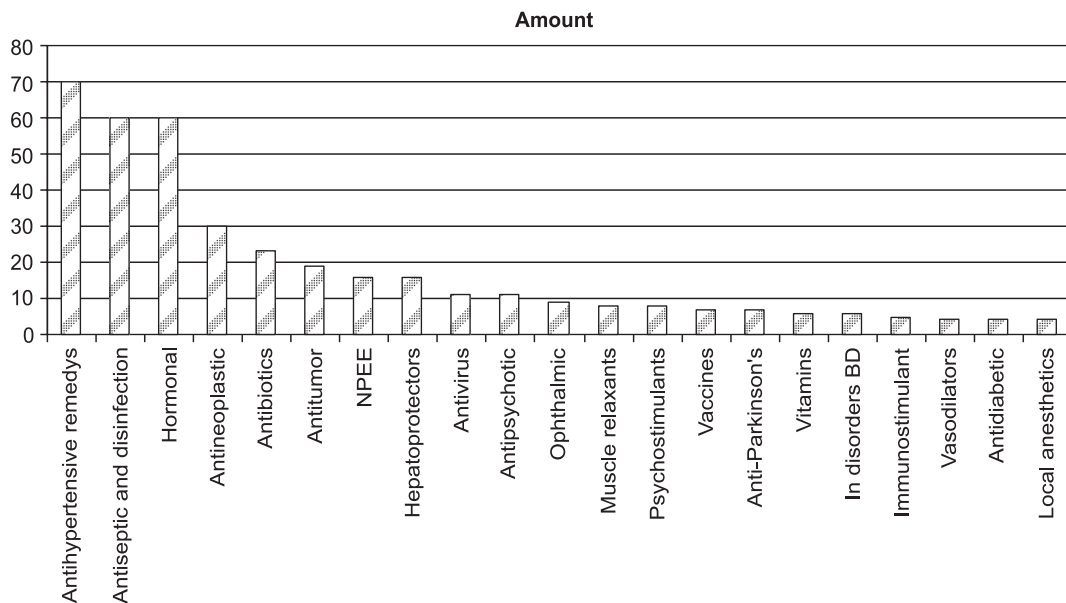
1. The Cabinet of Ministers of Ukraine adopts Order No. 301-r dated April 3, 2019 “On Approval of the Concept of Implementation of the State Policy on Prevention of Falsification of Medicinal Products and Approval of the Action Plan for its Implementation”.



**Fig. 2** Distribution of medicines that are prohibited for distribution to the supplier country



**Fig. 3** Distribution of medicines that have been banned for sale by form of production



**Fig. 4** Distribution of medicines that have been banned for sale by pharmacological groups

The Government's concept of implementation of the state policy on prevention of falsification of medicines defines the following mechanisms to prevent falsification of medicines

- Gradual implementation of marking with control (identification) signs on the basis of 2D-coding of packages of medicines according to the list defined by the Ministry of Healthcare;
- Creation of a unified system for monitoring the circulation of medicines (hereinafter referred to as the Unified System), which will store information on all 2D codes applied to pharmaceutical packaging;
- Ensuring that the end user checks the accuracy of information about the medicinal product.

Concept is planned to be implemented in 2019-2023r. In three stages.

2. Resolution of the Cabinet of Ministers of Ukraine dd. 24.07.2019 No. 653 introduces a pilot project on labelling with control (identification) marks and monitoring of medicinal products' circulation throughout Ukraine. The Resolution also approves the Procedure for implementation of this pilot project, which will be implemented in the period from September 1, 2019, to December 31, 2020. Procedure for introduction of the pilot project on labelling with control (identification) marks and monitoring of drug circulation. This Procedure determines the mechanism of introduction of the pilot project on labelling with control (identification) marks and monitoring of drug circulation (hereinafter – the pilot project)

*The objectives of the pilot project are:*

- 1) development of rules on introduction of safety means for medicines;
- 2) determination of the effective characteristics and technical conditions of the control (identification) mark, the mechanism for checking the safety means for medicines;
- 3) definition of terms of reference for the creation of a unified state system of monitoring the circulation of medicinal products;
- 4) creation of a unified state system for monitoring the circulation of medicines and ensuring interaction between pilot project participants at the stages of its use;
- 5) determination of efficiency and effectiveness of the unified state system of monitoring of medicine circulation at all stages of medicine circulation from the manufacturer to the end consumer in the context of prevention of falsification of medicines.

3. The Draft Law of Ukraine was published, which proposes to amend Article 2 of the Law of Ukraine dd. 5.04.2007 No. 877 "On Basic Principles of State Supervision (Control) in the Sphere of

Economic Activity" (hereinafter – Law No. 877). Thus, the draft document proposes to exclude from the scope of the Law No. 877 the state quality control of medicinal products.

The argument in favor of the adoption of this draft law is the need to obtain objective results of inspections in the implementation of state quality control of medicines. Since Law No. 877 provides for the need to notify economic entities 10 days in advance of the beginning of the inspection, the regulator believes that this makes it difficult to obtain objective results of the inspection.

4. The Draft Order of the Ministry of Healthcare of Ukraine "On Approval of Amendments to the Procedure for Confirmation of Conformity of Manufacturing Conditions of Medicinal Products to the Requirements of Good Manufacturing Practice" (hereinafter – the Draft Order) has been developed in order to ensure proper state control over the quality of medicinal products in the state, as well as harmonization of Ukrainian legislation with EU legislation.

These legislative changes cover: development of the system of quality assurance and management at all stages of medicine circulation through further implementation of the provisions of the international standards of the system of quality assurance of products and services: good manufacturing practice, good clinical practice, good laboratory practice, good distribution practice, good pharmacy practice, good pharmacovigilance practice, etc.; compliance with the requirements of the international standards of the system of quality assurance of products and services at all stages of medicine circulation; compliance with the requirements of the international standards of the quality assurance system: good manufacturing practice, good clinical practice, good laboratory practice, good distribution practice, good pharmacovigilance practice, good pharmacovigilance practice, etc.

#### CONCLUSIONS AND PROSPECTS FOR FURTHER RESEARCH

1. The results of the analysis of orders and instructions of the State Service on Medicinal Products of Ukraine regarding the ban on the sale of medicinal products in 2015-2018 indicate a significant decrease in their number in 2018. The reduction of the number of orders and prescriptions of the State Medical Service of Ukraine on the prohibition of the sale of medicines in 2018 was due to the removal of the moratorium on inspections.

2. The largest number of medicinal products that fell under the ban was found in Ukraine in

India and Germany; tableted and liquid formulations prevailed; antihypertensive, antiseptic, disinfectant and hormonal agents were most often prohibited.

3. Dissemination of information about the quality and safety of medicinal products among pharmaceutical industry employees, as well as continuous improvement of qualifications of authorized persons of economic entities, will ensure the supply of quality medicinal products to the pharmacy network.

In our opinion, the introduction of a unified system of monitoring of drug circulation by means of marking drugs with control identification marks based on 2-D code is promising, which will enable to monitor the entire supply chain of drugs from the manufacturer to the end consumer and, accordingly, will strengthen control over the quality of drugs, their production and import, which will prevent the penetration of counterfeit or counterfeit drugs in Ukraine.

**Conflict of interests:** authors have no conflict of interests to declare.

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Адреса для листування:

21018, м. Вінниця, вул. Пирогова, 56.

Тел. 067 850 1110. E-mail: [blagun.oksana2017@gmail.com](mailto:blagun.oksana2017@gmail.com)

Вінницький національний медичний університет імені М. І. Пирогова

Благун О. Д. (ORCID – <https://orcid.org/0000-0001-9287-0430>)

Бобрук В. П. (ORCID – <https://orcid.org/0000-0003-3891-3852>)

Балинська М. В. (ORCID – <https://orcid.org/0000-0003-0992-603X>)

Дученко М. А. (ORCID – <https://orcid.org/0000-0002-1119-8281>)

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