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Pharmaceutical provision as a complex work of pharmacy stakeholders

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Abstract: *pharmaceutical provision plays a leading role in maintaining the proper level of public health and social security. From the perspective of a holistic approach, the pharmaceutical provision system is an integrated structure that combines the processes of manufacturing and circulation of medicines, as well as the implementation of pharmaceutical care and services. However an approach, that would characterize pharmaceutical provision as a complex work of its stakeholders and would describe the role of each of them, has not been formulated yet. The aim of the research was to characterize the approach according to which pharmaceutical provision is a complex work of stakeholders of the pharmacy field and to describe their roles in its context. For the stated purpose, we used content analysis, logical and system analyses. Printed and electronic open information sources, current legislation of Ukraine, and scientometric databases were the materials of our research. As a result of the data analysis, we identified the main stakeholders of pharmaceutical provision system – pharmacies, pharmaceutical manufacturers, wholesale pharmaceutical companies and the state. Pharmacies are a key link for proper functioning of pharmaceutical provision system because their employees are in direct contact with consumers of medicines and medical devices, thus providing pharmaceutical care and pharmaceutical services. It is obvious that the vast majority of medicines is industrially produced, so manufacturing pharmaceutical companies may be considered as flagships of pharmaceutical provision. Their activities promote the development of medicines, around which, in fact, the system of pharmaceutical provision revolves. The work of wholesale pharmaceutical companies creates and maintains supply chains, thereby ensuring continuity and the physical availability of medicines. Pharmaceutical logistics is quite specific with the highest level of responsibility and unconditional compliance with international standards. The state implements pharmaceutical provision for the population through different mechanisms of organizational, economic, social, controlling, legal and educational nature. The generation and support of state authorized bodies and institutions, the approval of national and sectoral regulations help to clearly establish rules for the functioning of all participants in pharmaceutical provision, outline their responsibilities, duties, and rights, and protect consumers of medicines at the same time. And only the coordinated work of all stakeholders can ensure effective pharmaceutical provision to meet society's needs for its own safety and health.*

Keywords: [Drugs](#); [Medication Therapy Management](#); [Pharmaceutical Care](#); [Pharmaceutical Products](#); [Pharmacy Services](#); State Medicine Health Care Economics And Organizations.

Introduction

Pharmaceutical provision plays a leading role in maintaining the proper level of public health and social security. Even temporary unavailability of necessary medicines can cause a real panic among the population, which we observed during the COVID-19 pandemic and during Russia's armed aggression against Ukraine.

According to researchers, the term "pharmaceutical provision" should be considered as an organizational, legal and socio-economic subsystem in the domestic health care system, the purpose of which is to provide high-quality and affordable pharmaceutical care to the population by entities of the pharmaceutical sector of the health care industry, including state institutions, on the principles of the rule of human rights, with certain indicators of the socio-economic efficiency of the specified subsystem, which characterize the state of pharmaceutical provision for the population of Ukraine [1].

The effective pharmaceutical provision allows to optimize pharmacotherapy and to improve access to medicines. These issues have been studied by a number of leading scientists: A. Nemchenko [2] and A. Gonchar [3] worked with pharmaceutical provision of the population with cardiovascular diseases and economic affordability of antihypertensive drugs; V. Nazarkina [4] studied the availability of products for special medical purposes to children with phenylketonuria; I. Kostyuk [5] justified the scientific and methodological approaches of improving pharmaceutical provision for children with bronchial asthma; P. Oliynyk [6] highlighted pharmaceutical provision of the population in extreme conditions of martial law; N. Tkachenko's [7,8] and V. Demchenko's [8] publications were dedicated to legal aspects of pharmaceutical provision and pharmaceutical services.

Pharmaceutical provision is an area that is directly within the sphere of state interests, as it affects the state of social welfare, the health of the population, and therefore the development and potential of the entire society [9].

Health care specialists used to consider pharmaceutical provision as a sum of medicines and pharmaceutical care (services) neglecting

the way how medicines became physically and economically available.

From the perspective of a holistic approach, the pharmaceutical provision system is an integrated structure that combines the processes of manufacturing and circulation of medicines, as well as the implementation of pharmaceutical care and services.

However an approach that would characterize pharmaceutical provision as a complex work of its stakeholders and would describe the role of each of them, has not been formulated yet.

Aim

To characterize the approach according to which pharmaceutical provision is a complex work of stakeholders of the pharmacy field and to describe their roles in its context.

Materials and methods

For the stated purpose, we used content analysis, logical and system analyses. Printed and electronic open information sources, current legislation of Ukraine, and scientometric databases were the materials of our research.

Review and discussion

Modern approaches determine pharmaceutical provision as an integrated system that combines the implementation of pharmaceutical care (PC), pharmaceutical services (PS), and drug provision.

As a result of the data analysis, we identified the main stakeholders of the pharmaceutical provision system – pharmacies, pharmaceutical manufacturers, wholesale pharmaceutical companies and the state. All of them are directly engaged in pharmaceutical provision.

Pharmacies are the key link for proper functioning of pharmaceutical provision system. Pharmacies employees are involved in direct contact with consumers of medicines and medical devices, thus providing pharmaceutical care and pharmaceutical services.

According to the updated version of the Law of Ukraine 'On Medicines' (effective from January 1, 2025, No. 2469-IX), pharmaceutical care is a set of organizational, legal, medical, pharmaceutical and socio-economic measures aimed at ensuring effective pharmacotherapy, rational use of medicines, incorporating solving problems with their individual prescription, which includes the participation of a pharmaceutical worker and

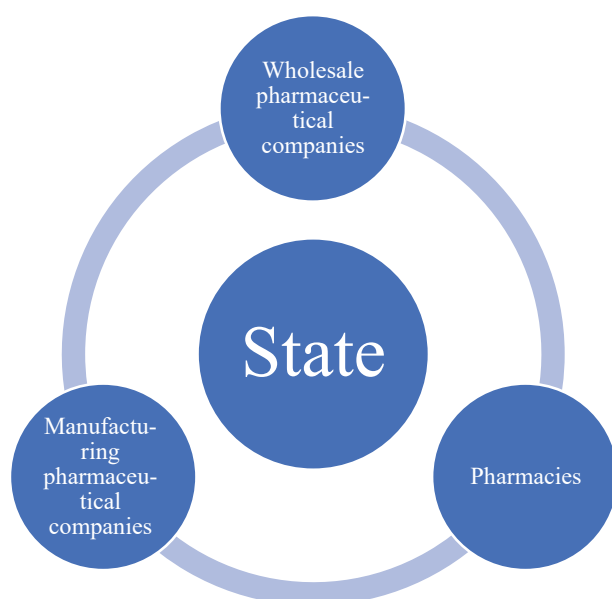


Fig. 1. The schematic drawing of the main stakeholders of the pharmaceutical provision system.

a doctor in the treatment process in terms of substantiating the choice of necessary medicines, advising the patient on their use, monitoring and evaluating the results of pharmacotherapy, achieving optimal clinical results at minimal economic costs, optimizing the system for selecting necessary medicines, as well as generalizing information about them for the population in order to optimize pharmacotherapy [10].

Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services, adopted by the Committee of Ministers on 11 March 2020 at the 1370th meeting of the Ministers' Deputies, defined, that the principal elements of pharmaceutical care are:

- the central role of the pharmacist;
- the patient-centred care approach;
- collaboration with carers, prescribers and other health care professionals (integrated care);
- prevention, detection and resolution of medication-related problems;
- taking responsibility for optimising medication use in order to improve a patient's health outcomes and quality of life [11].

It is worth to note that pharmaceutical care actively develops due to the use of digital

technologies now. Researchers describe the use of mobile applications [12, 13], telephone consultations or online consultations on various platforms [14, 15]. The processes of writing and transmission of prescriptions have also become digitalized due to the spread and active use of different electronic systems. It has solved some of the problems connected with illegibility of handwritten prescriptions [16].

Certain directions for the remote (distance) supply of quality pharmaceutical care with the support of information, telecommunication technologies and infrastructure may be considered as components of the concept of "telepharmacy" – a tool for creating relationships between a pharmaceutical specialist and a patient and/or a medical specialist in cases where they do not have direct (personal) contact with each other [17, 18].

There is successful experience in creating and developing telepharmacies, which shows high customer satisfaction with the services provided by such healthcare institutions [19].

Changes in the concept, and, accordingly, in society's requirements for the supply of pharmaceutical care to the population, necessitate an increase of the variety of pharmaceutical workers responsibilities.

The aforementioned the updated version of the Law of Ukraine 'On Medicines' (effective from January 1, 2025, No. 2469-IX) also defines the concept of "pharmaceutical service": a service for the supply of pharmaceutical care by a pharmaceutical worker of a pharmacy, in particular during the process of medicines dispensing, which includes the sale, information about its use, education and promotion of a healthy lifestyle for a patient and the provision of information about medicines, including within the framework of ensuring responsible self-medication in accordance with the protocols of pharmacists [10].

Researchers have established that 7 types of pharmaceutical services can be provided now, for example:

1. pharmacotherapeutic services aimed to organize proper adherence of medication regimens in accordance with the level of patient compliance;

2. a set of measures that allow to reach effective pharmaceutical care, final product-oriented pharmaceutical services;
3. organization of primary medical care, carrying out sanitary and educational activities;
4. conducting and promoting screening tests in the pharmacy;
5. active participation in socially important projects and events (against drug addiction, obesity etc.);
6. helping to preserve public health and to maintain a decent quality of life for citizens;
7. other modern services, for example, participation in the centralized collection of unused pharmaceutical products, their packaging, etc [20].

However, in the report of the International Pharmaceutical Federation (FIP) («Pharmacy: a global overview 2015-2021». Workforce, medicines distribution, practice, regulation and remuneration»), that presents the results of an analysis of the pharmaceutical services organization in 74 countries around the world, experts counted about 44 pharmaceutical services, that are provided by pharmaceutical workers directly during the communication with clients in a pharmacy [20].

The International Pharmaceutical Federation also emphasizes that pharmacists can provide a range of primary healthcare services, including vaccinations, screening and management of chronic non-communicable diseases, the management of common ailments (including prescribing authority for common conditions), improving the use of medicines and addressing antimicrobial resistance. This needs to be supported by enabling legislation, policies and regulations, but also by an appropriate funding and remuneration models that ensure their sustainability and equity of access [21].

Payment structures and reimbursement models for pharmaceutical care services vary widely, which can be a barrier to widespread adoption. Providing standardized reimbursement systems that recognize the value of pharmacist services is essential [22].

Researches suggest that high-quality pharmaceutical care can positively impact clinical,

humane, and economic outcomes for conditions such as chronic renal failure [23], hypertension [24], and diabetes [25]. We believe that this trend could significantly reduce the burden of chronic diseases on the healthcare system.

We would like to highlight some ethical and deontological aspects of providing pharmaceutical care and pharmaceutical services. Taking into account that patients' personal information is shared with healthcare specialists during the communication, pharmaceutical workers must be extremely careful and delicate. Pharmacists must ensure that patients' confidentiality is respected and they are treated impartially, in accordance with the Ethics Code of Pharmacists of Ukraine [26].

One of the main tasks of any pharmacy is to dispense medicines to the population. It is obvious that the vast majority of medicines is industrially produced, so manufacturing pharmaceutical companies may be considered as flagships of pharmaceutical provision. It is possible to use medicines in order to treat, prevent, diagnose, recover or improve physiological functions due to the production activities of pharmaceutical companies.

According to the rules of Good Manufacturing Practice, the pharmaceutical company is obliged to manufacture medicines in such a way as to ensure their compliance with their intended purpose, the requirements of the registration dossier or the investigational medicinal product dossier for clinical trials (as applicable), and to eliminate the risk to patients associated with insufficient safety, quality, or efficacy of medicines [27].

Pharmaceutical industrial enterprises develop pharmaceutical science and advanced technologies, employ a large number of pharmaceutical specialists and specialists in related fields, and make medicines more accessible through the production of generic drugs.

It is also needed to underline that not only large industrial enterprises can be manufacturers of drugs. It is well known that a pharmacy (if it has a special license, the necessary conditions, equipment and workforce) can also be a kind of manufacturer of drugs. Such production is called extemporaneous.

Pharmaceutical logistics is vitally important link, that ensure that the pharmaceuticals reach the right people in the right place on time. Taking into consideration the distances that medicines have to cross to be available in every corner of Ukraine, pharmaceutical distributors play an essential role because of their great importance in shaping the market structure and increasing the circulation of medicines [28].

The principal task of a pharmaceutical distributor is to coordinate the interests of manufacturers, commercial retail sector entities, medical organizations and the state. Distributors work in all three sectors of the Ukrainian pharmaceutical market:

- 1) commercial retail segment;
- 2) hospital segment;
- 3) public procurement market [28].

Logistics in the pharmaceutical industry is quite specific with the highest level of responsibility and unconditional compliance with all 7R rules: maintaining the highest quality of products, delivering them within a specified time, compliance with storage and transportation conditions, compliance with certification, licensing, and documentary support, the level of service must be exceptionally high because any non-compliance with conditions may result as a danger for human health [29].

In our opinion, the work of logistics intermediaries is very special because a relatively small amount of pharmaceutical specialists are involved in logistics processes, but the results of this work have a great impact on the activities of pharmacies and consumers, thereby ensuring supply chains continuity and the physical availability of medicines.

In terms of organizational and legal forms of activity, the state implements pharmaceutical provision for the population through voluntary and compulsory medical insurance and reimbursement of the cost of pharmaceutical care. In addition, preferential distribution of medicines and medical devices is a supplementary form of pharmaceutical provision functioning in domestic and foreign health care systems [1].

The state is also able to influence pharmaceutical provision by regulating of pharmaceutical sector. These measures involve the use of a system

of state orders, licensing, pricing, setting standards and controlling the production, circulation and use of some drugs, establishing rules for prescribing and dispensing drugs, etc.

The establishment and support of state authorized bodies and institutions, the approval of national and sectorial guidelines help to clearly set the rules for the functioning of all participants in pharmaceutical provision, outline their responsibilities, duties, and rights, and protect consumers of medicines at the same time.

To our mind, the state also influences pharmaceutical provision by giving high-quality pharmaceutical and medical education on its territory in higher education institutions.

In Ukraine, this mechanism works thanks to approved educational and professional standards, as well as the introduction of the Unified State Qualification Examination (EDKI) – the main form of certification of applicants for the field of knowledge “22 Health Care”. This exam was introduced in 2019 to ensure a high level of training of health care workers and unify the standards of their education. The exam results are a criterion for determining the professional suitability of a graduate and issuing a higher education diploma [30].

Internship, regulated by the Regulations on Internship and Secondary Medical (Pharmaceutical) Specialization, approved by the Order of the Ministry of Health of Ukraine dated June 22, 2021 No. 1254, facilitate to increase the level of practical and theoretical training of pharmacist interns, their professional readiness for independent activity in their specialty, which, we believe, also has a positive effect on the further pharmaceutical provision of the population [31].

We also see the certification of pharmacists as a way to improve pharmaceutical provision, since it is carried out with the aim of increasing professional skills, responsibility for the efficiency and quality of work. It is an important form of moral and material stimulation aimed at improving the activities of pharmacy enterprises of all forms of ownership engaged in pharmaceutical activities [32].

Conclusions

Pharmaceutical provision plays a leading role in maintaining the proper level of public health

Table 1. The roles of defined stakeholders in pharmaceutical provision system

Stakeholder	Description of its role in pharmaceutical provision
Pharmacies	<ul style="list-style-type: none"> • providing pharmaceutical care and pharmaceutical services; • "telepharmacy" options.
Pharmaceutical manufacturing companies	<ul style="list-style-type: none"> • medicines manufacturing; • development of pharmaceutical science and advanced technologies; • hiring of a large number of pharmaceutical specialists and specialists in related fields; • making medicines more accessible through the production of generic drugs.
Wholesale pharmaceutical companies	<ul style="list-style-type: none"> • ensuring physical availability of medicines; • unconditional compliance with all 7R rules.
State	<ul style="list-style-type: none"> • voluntary and compulsory medical insurance; • reimbursement of the cost of pharmaceutical care; • reimbursement of the cost of medicines; • preferential distribution of medicines and medical devices; • regulating of pharmaceutical sector (state orders, licensing, pricing, setting standards and controlling the production, circulation and use of some drugs, establishing rules for prescribing and dispensing drugs, etc); • establishment and support of state authorized bodies and institutions; • approval of national and sectorial guidelines; • providing pharmaceutical and medical education.

and social security. Nowadays it is an integrated system that combines the implementation of pharmaceutical care, pharmaceutical services and the provision of medicines. It is necessary to combine the work of pharmacies, pharmaceutical manufacturing companies, wholesale pharmaceutical companies and the state for the successful functioning of such a system.

Pharmacies are the key link for proper functioning of pharmaceutical provision system because their employees are in direct contact with consumers of medicines and medical devices, thus providing pharmaceutical care and pharmaceutical services.

Pharmaceutical care, as a complex of measures of various nature, is aimed to ensure rational and safe pharmacotherapy of patients, optimize costs, and prevent undesirable occurrences during treatment. The rapid development of modern information and telecommunication technologies helps to improve the quality of pharmaceutical care.

Pharmaceutical services include the sale, information about drug use, education and promotion of a healthy lifestyle for a patient and the spreading of information about medicines, ensuring responsible self-medication in

accordance with the protocols of pharmacists. High-quality pharmaceutical care can positively impact clinical, humane, and economic outcomes for certain conditions. We firmly believe that this trend could significantly reduce the burden of chronic diseases on the healthcare system.

Manufacturing pharmaceutical companies may be considered as flagships of pharmaceutical provision because their activities promote the development of medicines, around which, in fact, the system of pharmaceutical provision revolves. In fact both industrial facilities and compounding pharmacies can act as manufacturers of medicines.

Pharmaceutical logistics is vitally important link, that ensure that the pharmaceuticals reach the right people in the right place on time. The work of wholesale pharmaceutical companies creates and maintains supply chains, thereby ensuring continuity and the physical availability of medicines. Logistics in the pharmaceutical industry is quite specific with the highest level of responsibility and unconditional compliance with all 7R rules.

In terms of organizational and legal forms of activity, the state implements pharmaceutical provision for the population through voluntary and

compulsory medical insurance, reimbursement of the cost of pharmaceutical care and medicines, preferential distribution of medicines and medical devices.

A system of state orders, licensing, pricing, setting standards and controlling the production, circulation and use of some drugs, establishing rules for prescribing and dispensing drugs are the main ways of pharmaceutical sector regulating.

The establishment and support of state authorized bodies and institutions, the approval of national and sectoral guidelines help to clearly set the rules for the functioning of all participants in pharmaceutical provision, outline their responsibilities, duties, and rights, and protect consumers of medicines at the same time.

The state also influences pharmaceutical provision by giving quality pharmaceutical and medical education on its territory in higher education institutions and by controlling the level of acquired knowledge.

And only the coordinated work of all stakeholders can ensure effective pharmaceutical

provision to meet society's needs for its own safety and health.

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This study did not receive external funding.

Conflict of interests

The authors declare that they have no conflict of interest regarding this study, including financial, personal, authorship, or other, that could influence the study and its results presented in this article.

Consent to publication

Since this study was performed without the participation of patients, we did not obtain consent to publication of this work from the patients.

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article

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Фармацевтичне забезпечення як комплексна робота стейкхолдерів у фармації

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Анотація: фармацевтичне забезпечення відіграє провідну роль у підтримці належного рівня здоров'я населення та соціальної безпеки. З точки зору холістичного підходу система фармацевтичного забезпечення населення є інтегрованою структурою, що об'єднує процеси виробництва і обігу лікарських засобів, а також реалізації фармацевтичної допомоги та послуги. Проте підхід, який би характеризував фармацевтичне забезпечення як комплексну роботу його стейкхолдерів та описував роль кожного з них досі не сформульований. Метою нашого дослідження було охарактеризувати підхід, згідно з яким фармацевтичне забезпечення є комплексною роботою стейкхолдерів фармацевтичної сфери і описати їхню роль в його контексті. З вказаною метою ми застосували контент-аналіз, логічний та системний аналізи. Матеріалами нашого дослідження стали друковані та електронні відкриті інформаційні джерела, чинне законодавство України та наукометричні бази даних. У результаті аналізу даних ми визначили основних стейкхолдерів системи фармацевтичного забезпечення – аптеки, компанії-виробники ліків, оптові фармацевтичні компанії та держава. Аптечні заклади є ключовою ланкою для належного функціонування системи фармацевтичного забезпечення, оскільки працівники аптек безпосередньо контактують зі споживачами лікарських засобів та виробів медичного призначення, надаючи таким чином фармацевтичну допомогу та фармацевтичні послуги. Очевидно, що переважна більшість використовуваних лікарських засобів є продуктами промислового виробництва, тож виробники лікарських засобів є свого роду флагманами фармацевтичного забезпечення. Їхня діяльність сприяє розвитку лікарських засобів, навколо яких, власне, і обертається система фармацевтичного забезпечення. Робота оптових фармацевтичних компаній створює та підтримує ланцюги постачання, забезпечуючи тим

самим їхню безперервність, а також фізичну доступність лікарських засобів. Фармацевтична логістика є досить специфічною, з найвищим рівнем відповідальності та безумовним дотриманням міжнародних стандартів. Держава зі свого боку реалізовує фармацевтичне забезпечення населення через різні механізми організаційного, економічного, соціального, контрольного, правового та освітнього характеру. Формування та підтримка уповноважених державних органів та установ, затвердження національних та галузевих настанов сприяють чіткому встановленню правил функціонування всіх учасників фармацевтичного забезпечення, окресленню їхньої відповідальності, обов'язків і прав, а також захисту споживачів лікарських засобів у той самий час. І лише злагоджена робота всіх стейкхолдерів може забезпечити ефективне фармацевтичне забезпечення для задоволення потреб суспільства щодо власної безпеки та здоров'я.

Ключові слова: лікарські засоби, управління фармакотерапією, фармацевтична допомога, фармацевтична продукція, аптечні послуги, економіка та організація державної охорони здоров'я.



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