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DEVELOPMENT OF THE NATIONAL MEDICINES POLICY REGARDING THE SYSTEM OF MEDICINES CIRCULATION

1. Introduction

On the way towards European integration, it has been achieved a certain harmonization of domestic laws on medicines circulation, pricing and reimbursement, pharmaceutical quality assurance². The NMP is a key regulatory document that meets WHO guidelines and takes due account of the national particularities of the healthcare system and pharmacy. Ukraine has conducted some activities on the NMP development, but

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² On the peculiarities of the implementation of certain provisions of the legislation of the European Union on the circulation of medicinal products: Draft Law of Ukraine. Retrieved from: http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?Pf3511=58784. (accessed 12 September 2021); On Medicinal Products Law of Ukraine of 1996 № 2168-VIII. Retrieved from: <https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#-Text> (accessed 12 September 2021); On approval of the State strategy for the implementation of the state policy of providing the population with medicines for the period up to 2025: Resolution of the Cabinet of Ministers of 05.12.2018 № 1022. Retrieved from: <https://www.kmu.gov.ua/npas/pro-zatverdzhennarskimi-zasobami-on-period-until-2025-deadline> (accessed 25 August 2021).

there remain many issues that need reforming and implementing at all management levels of the pharmaceutical healthcare sector.

2. Analysis of recent research and publications

A set of contributions by domestic and foreign scientists is devoted to the methodology of setting priorities in the development of the national medicines policy, analysis of the effectiveness of the medicines circulation system. The publications by A. Kotvitska, A. Nemchenko, I. Pestun, V. Khomenko, et al. are worth noticing³.

Statement of research goals. The author tasks to substantiate socio-economic fundamentals of the medicines circulation system while forming the NMP based on WHO guidelines to ensure access and affordability of essential medicines from the National list.

3. Basic material statement

The exercise of constitutional rights of citizens of Ukraine to health and a guaranteed level of qualitative pharmaceutical provision of the population requires the formulation of an efficient NMP. National interests consolidated in the state policy are set by the Law of Ukraine "On Medicines" (Art. 3. State Policy in the sphere of Development, Manufacturing,

³ Nemchenko A.S., Kotvitskaya A.A. (2007) Ocinka socialjnykh aspektiv orghanizaciji medychnoho zabezpechennja naselennja vidpovidno do mizhnarodnykh norm i standartiv [Assessment of social aspects of the organization of medical provision of the population in accordance with international norms and standards]. 5. P. 11–19; Pestun I.V. (2008) Ocinka nacionaljnoji likarsjkoji polityky v Ukraini z vykorystannjam indyktoriv VOOZ [Evaluation of the National Medical Policy in Ukraine using WHO indicators]. Zaporozhye medical journal. [Zaporozhye medical journal].6. P.96–99; Khomenko V.M., Nemchenko A.S., Yarmola I.K. (2004) Metodologichni pidkhody do vyznachennja priorytetiv u formuvanni nacionaljnoji likarsjkoji polityky [Methodological approaches to setting priorities in the formation of national drug policy]. Farmacevtychnyj zhurnal [Pharmaceutical journal].6. P. 3–7; Nemchenko A.S., Susharyna I.V., Khomenko V.M. (2017) Ocinjuvannja efektyvnosti dijalnosti farmacevtychnykh ghromadsjkykh orghanizacij iz vykorystannjam anketnoho opytuvannja fakhivciv [Evaluation of efficiency of pharmaceutical activities non-governmental organizations using the questionnaire survey of specialists]. Farmatsevtichnyi zhurnal [Pharmaceutical journal]. 1. P. 11–19.

Quality Control, and Sale of Medicines). At the same time, medicines circulation belongs to socially important healthcare areas and is the most regulated by the state. The national policy is central to reforming medicines circulation as it determines the state's role in providing the population with medicines⁴.

The State Strategy for the Implementation of State Policy on the Provision of Population with Medicines for 2025 envisages:

- ensuring the proper selection of essential medicines to the National List;
- ensuring affordability of medicines;
- adequate financing of the system of the pharmaceutical provision of the population;
- improvement of the pharmaceutical supply system;
- improvement of state pharmaceutical regulation and quality assurance;
- raising rational use of medicines;
- increasing the investment attractiveness of the pharmaceutical market of Ukraine in terms of drug development and production.

The above strategic tasks stipulate further reforming all spheres of medicines circulation. The systems approach amidst the implementation of the relevant tasks needs scientific and practical justification of the effective system of medicines circulation as an element of the NMP. According to WHO guidelines⁵, the NMP development should be public, open, reasonable, and transparent as required by the state policy on medicines circulation. Therefore, it is obligatory to set goals, elements, and tools, which are illustrated in fig. 1.

Setting goals, priorities, and strategies depends on the level of socio-economic development of the state and the status of resources, cultural and historical features, political and social – cultural characteristics.

⁴ On Medicinal Products Law of Ukraine of 1996 № 2168-VIII. Retrieved from: <https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#Text> (accessed 12 September 2021).

⁵ How to develop and implement a national drug policy. WHO Guidelines (How to develop and implement a national drug policy – 2nd ed. Updates and replaces: Guidelines for developing national drug policies (1988). Geneva: World Health Organization, 2001. 84 p.). *Shhotyzhnevyyk apteka* [Weekly Pharmacy]. 40 (361).

NMP goals and objectives must be well-defined and intelligible to all participants, i.e., society, state authorities, and pharmaceutical organizations. Consequently, it permits outlining a role of different ministries and government units, state and private healthcare sectors and pharmacy, NGOs, and others.

Fig. 3.1. Components of the NMP development and implementation

By relying on the WHO methodology, the NMP should implement global objectives, as follows:

- access (equitable availability and affordability of medicines);
- quality (quality, safety and efficacy of all medicines);
- rational use.

The socio-effective mechanism of the NMP formation provides for the accomplishment of global objectives via relevant elements and tools. The constituent elements include all areas of drug circulation: the development of domestic pharmaceutical production, the system of medicines supply, the pharmacy network of medicines financing, etc. It is worth highlighting the significance of rational use of medicines as part of a goal, element, and tool in realizing the NMP.

The most important socio-economic category in the healthcare system and pharmacy is affordability, which is regarded as global during the NMP development and implementation. Affordability in this system gen-

erally means both the physical capacity to receive service – medical or pharmaceutical, and economic (financial) guarantee that the state pays for service. It is worth highlighting the importance of the implementation of components in ensuring the affordability of drugs at an international scale that primarily refers to the intergovernmental interaction and guidelines for policy development, which is now specified by WHO documents. NMPs of many countries set out basic activities on ensuring equitable access and affordability of medicines, their high quality, and rational use, but these provisions differ in almost all countries.

Fig. 3.2. Priorities in ensuring drug accessibility by management levels under the NMP development

Following outcomes of the conducted analysis of literature sources, the author has singled out priorities of the system of drug accessibility by management levels⁶, as shown in fig. 3.2. In the international con-

⁶ Universal health coverage (UHC) 2019 Retrieved from: <https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage> (accessed 12 September

text of the NMP formation, methodology for ensuring drugs availability takes the lead. It covers intergovernmental cooperation, monitoring of prices and indicators of drug availability, maintenance of international databases of reference prices.

At the national level, the implementation of a social policy on the availability of medicines requires the identification of effective mechanisms of state regulation of prices and reimbursement, as well as the assessment of medical technologies in the development of pharmacotherapy standards and public procurement of drugs.

Regional and microeconomic levels are crucial to the NMP implementation in general and ensuring the affordability of medicines in particular. At the regional level, it is addressed tasks of determining and ensuring the need (purchase) of medicines, control over their consumption, as well as audit and price control. At the level of pharmaceutical companies and pharmacies, the main tasks should include the choice of pricing policy and strategies, pricing methods, stock management, audit and control.

The experience of reforming the pharmaceutical healthcare sector in Ukraine shows the need to study a set of factors influencing the mechanism of public administration of the NMP development.

In the context of the NMP development, the managerial influence of governmental entities (government, authorized bodies of the Ministry of Health of Ukraine, in particular, the State Expert Center, the National Health Service of Ukraine, the State Service of Ukraine on Medicines

2021); Goroshko, A., Shapoval, N., Lai, T. (2018). Can people afford to pay for health care? New evidence on financial protection in Ukraine. Copenhagen: World Health Organization. Retrieved from: <http://www.euro.who.int/en/countries/ukraine/publications/can-people-afford-to-pay-for-health-care-new-evidence-on-financial-protection-in-ukraine-2018> (accessed 25 August 2021); Ocinka proghramy «Dostupni liky» v Ukraini [Evaluation of the affordable medicines programme in Ukraine] (2019). World Health Organization. Regional Office for Europe. Retrieved from: <https://apps.who.int/iris/handle/10665/311229> (accessed 12 September 2021); Ukraine: a review of health care financing reform 2016–2019 Joint WHO and World Bank Report 2019 Retrieved from: <https://www.euro.who.int/en/countries/ukraine/publications/ukraine-review-of-health-financing-reforms-2016–2019> (accessed 2 October 2021); Traditional, complementary and integrative medicine. Geneva: World Health Organization; 2020 Retrieved from: <https://www.who.int/traditional-complementary-integrative-medicine/about/en/> (accessed 2 October 2021).

and Drug Control) on objects, first of all, of institutions of medicines circulation, is carried out through setting target priorities, elements, and tools. The NMP implementation in the pharmaceutical market is conducted through the relevant regulatory policy of the state, which requires a systematic assessment of effectiveness.

The analysis of factors influencing the NMP formation has allowed the author to establish a varied activity and influence peddling on setting priorities of different control objects, principally of political and financial groups, as well manufacturers and large pharmacy chains. Despite the overwhelming number of pharmaceutical workers in pharmacies, their activity and influence on the NMP development are low; this also concerns scientists, the public, and patients. The “voice” of scientists, society, and patients is also insufficient. It should be pointed out that the activity and role of domestic professional associations (unions) have significantly increased during the NMP development; however, such influence is insufficient compared to pharmaceutical associations of different countries of Europe and the world.

According to WHO guidelines, the NMP is based on the concept of essential medicines, which is very important because it aims to protect the patients’ rights and allows determining priorities in the development of health care and public drug supply. The framework of the concept is the use of a limited number of essential medicines, which are reasonably selected given clinical and economic indicators. It improves the supply of drugs, as well as their more rational use and cost reduction.

Thus, the use of essential medicines, the selection of which is pharmaceutically and economically feasible, allows enhancing the quality of care and cutting financial costs. On the one hand, by limiting the number of medicines and on the other – by increasing their consumption, it is possible to achieve significant cost-effectiveness at the national and regional scales through boosting price-based competition. The limitation provides for the optimization of the number of medicines, which are recommended for use as essential, that facilitates the control over their quality and simplifies the conditions of purchase, storage, distribution, and sale. Moreover, there is an option to obtain information about medicines: educational nature for medical and pharmaceutical workers and general for patients. In limiting the number of essential medicines, it

is easier for a doctor to monitor the indicators of effectiveness and cases of drugs interactions and their side effects.

Continuous improvement of the National List of Essential Medicines following WHO guidelines is a priority in guaranteeing the availability of pharmaceutical care, rational use of medicines, as national health systems are usually cannot recover the personal costs of all medicines available on the pharmaceutical market. In Ukraine, the reimbursement level is the lowest in Europe: it is up to 10%, compared to EU countries where this figure is 70–90%.

The WHO methodology for the development and evaluation of NMP is based on indicators, the processing of which allowed the author to identify five groups according to relation degree. *The first group* consists of basic (primary) factors: demographic and statistical data in the context of health care (total population, life expectancy, GDP per capita, mortality rate, etc.).

The second group covers indicators characterizing the pharmaceutical sector in health care (number of prescribers, number of pharmacists and qualified pharmaceutical chemists, total drug costs, number of essential medicines in the national list, number of registered medicines, total domestic production, total import of medicines, number of domestic pharmaceutical manufacturers, the total number of wholesale suppliers, the total number of pharmacies, etc.).

The third group of WHO indicators characterizes the regulation of the pharmaceutical supply sector: general documents on the regulation of pharmaceutical activities, procedures for the selection and registration of medicines, the system of provision of essential medicines, quality control, revision and inspection, regulation of promotion and advertising, etc.

The fourth group includes indicators characterizing pharmaceutical pricing policy, financing in the public and private sector, distribution, logistics, storage of medicines.

The assessment of the performance of the pharmaceutical provision system envisages the application of *the fifth group* of indicators: access (availability) and affordability of medicines, raising awareness of medicines and their rational use by the population, etc.

Indicators that characterize the system of medicines circulation belong to the *second, third, and fourth groups*. The author has analyzed op-

portunities to obtain information for assessing NMP in Ukraine following WHO indicators – it has shown that the main criteria of the system of medicines circulation are available. However, some WHO indicators (individual indicators towards the system of pharmaceutical supply, violations in advertising, awareness-building efforts among doctors and the public, rational use of medicines, etc.) are not subject to evaluation of the system of medicines circulation in Ukraine.

At the end of 2019, the Ministry of Health of Ukraine ordered the WHO to conduct a study to assess the access and availability of essential medicines included in the National List for out-patient treatment.

An innovative tool for collecting data was used in the study: the WHO mobile application (MedMon) for monitoring the availability of medicines and medical products and their prices. MedMon made it possible to identify representative sample at the national level in terms of the sustainable development goals (SDGs) – 3.b.3.

The SDGs are a global category that aims to end poverty and promote well-being for all. SDG objectives in health care include: 3.b. “provide access to affordable essential medicines, in particular, universal access to medicines”. The SDG 3.b.3 indicator (“proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis”) is a crucial evaluation of the execution state of the SDG task. According to this indicator, essential medicines are considered affordable if a health facility has in stock at least 80% of medicines from the National List at an affordable price⁷.

Given the high relevance of this research, the author conducted a secondary analysis of the data obtained to assess the effectiveness of the circulation of medicines, in particular, pharmaceutical provision of the population.

Drug manufacturing is of great socio-economic importance for both the country's health care and economy. Domestic producers, the current number is 115, representing 69.8% of the retail and hospital market in terms of quantity and 37.2% in terms of the total value, i.e., 62.8% of the population consumes imported medicines. Generic and traditional

⁷ Aptechnyj rynek Ukraïny za pidsumkamy 2019 r.: Helicopter View [Pharmacy market of Ukraine following the results of 2019]. Retrieved from: <https://www.apteka.ua/article/531429> (accessed 2 October 2021).

imported medicines dominate the market. According to data on the registered number of domestic medicines compared to imports, their ratio amounts to 30 to 70 %. There is a high concentration on the wholesale market: three distributors supply for almost 82% of all wholesale deliveries of medicines. A significant percentage of pharmacies, namely 89.4%, belong to the private sector. Nowadays, the three largest pharmacy chains maintain 30% of total retail turnover⁸.

Analysis findings show that only 20.5% of health care facilities provide patients with affordable essential medicines when delivering primary care. In addition, there are significant differences in these indicators in facilities depending on the form of ownership. This indicator amounts to 37.5% in public facilities, and only 18.6% of private health care facilities included in the study guarantee an adequate level of access to essential medicines for patients.

The regions have an uneven distribution of facilities that have affordable essential medicines. Four regions from seven covered by the research have an adequate level of availability of medicines: Chernihiv, Kharkiv, Kherson, and Luhansk. In the other three (Volyn, Ivano-Frankivsk regions and Kyiv city), none institution has access to medicines from the National List above 80%. In 21 of 78 studied facilities, the level of availability of essential medicines is below 50%. In other 33% of studied facilities, medicines are available at an affordable price.

An availability indicator of essential medicines under two dimensions – weighted and median – in the mentioned regions is as follows: Kherson – 79.73%, Luhansk – 79.06%, Chernihiv – 79%, Volyn – 78.15%, Kharkiv – 76.70%, and Kyiv city – 75.02%. In the facilities of Ivano-Frankivsk region, a weighted indicator of availability is below 61%, median – 43%. Analysis findings show different indicators of access (avail-

⁸ Infrastruktura rozdrbnogho seghmenta farmrynku: pidsumky 2019 r. ta ključovi tendenciji [Infrastructure of the retail segment of the pharmaceutical market: results of 2019]. Retrieved from: <https://www.apteka.ua/article/531126> (accessed 25 August 2021); WHO Model Lists of Essential Medicines World Health Organization Retrieved from: <https://www.who.int/medicines/publications/essentialmedicines/en/> (accessed 12 September 2021); World Health Organization. Regional Office for Europe. (2021). Assessment of access to essential outpatient medicines in Ukraine. World Health Organization. Regional Office for Europe. Retrieved from: <https://apps.who.int/iris/handle/10665/342433> (accessed 12 September 2021).

ability) and price affordability of medicines from the relevant list in all 78 facilities. At the same time, medicines are sold at an affordable price in almost 63 from 78 facilities (80%), and price is high in 39 from 78 facilities (50%).

The research results indicate the need to improve access and affordability of essential medicines for the population for all regions of the country, in particular, for rural areas, based on the improvement of NMP tools, i.e., pricing and reimbursement of drug costs.

4. Conclusions

Therefore, implementing the state policy on the pharmaceutical provision of the population requires further reforming all areas of medicines circulation, which provides for the formulation of an effective NMP following WHO guidelines with a mandatory determination of goals, elements, and tools. NMP development should be carried out at management levels (international, regional, and microeconomic) and be public, open, valid, and transparent. It is expedient to analyze achievements and challenges of NMP implementation pursuant to WHO indicators. This allows assessing progress in the system of the pharmaceutical provision of the population and elucidating shortcomings subjected to further improvement and practical use.

To implement the State Strategy for the Pharmaceutical Provision of the Population amidst the NMP, it seems reasonable to take the following measures: to substantiate the priority principles of the state policy of support of domestic drug production and develop the program for imports phase-out; to improve the management of the drug supply system by monitoring data on demand and consumption and strength supply chains; to advance the processes of medical prescription and provision of prescription drugs by pharmacies, to work out an electronic prescription system; to promote cooperation and dialogue between all interested parties involved in the development and implementation of the policy of state pricing regulation for essential medicines and their reimbursement, to create information infrastructures.

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Summary

The health of a nation depends on many factors, among which pharmaceutical provision of the population holds pride of place. The appropriate level of pharmaceutical provision under guidelines of the World Health Organization (WHO) requires the development of the National Medicines Policy (NMP), which is implemented through a socially effective state policy on medicines circulation, i.e., creation, production, quality control, and sale of medicines.

According to the WHO methodology, the NMP should pursue global goals: accessibility, quality, and rational use of medicines, on the principles of publicity, openness, reasonableness, and transparency. The author puts forward elements and tools as components of the mechanism of implementation of NMP goals, which embrace all spheres of medicines circulation in Ukraine: pharmaceutical production, pharmaceutical supply system, pharmacy network, rational use of drugs, etc. The substantiation of priority principles in ensuring citizens' access to medicines has shown the relevance of their determination at management levels (international, national, regional, and microeconomic). The NMP priority in achieving the availability of medicines and their rational use is the improvement of the National List of Essential Medicines, as the state cannot reimburse drug costs of the public.

The assessment of the NMP implementation should be conducted under WHO indicators. This makes it possible to carry out an impartial analysis of the pharmaceutical provision of the population and elicit shortcomings at national and regional levels and the level of healthcare institutions.

The NMP implementation in the healthcare system and pharmacy is carried out through the relevant regulatory policy of the state, which needs efficacy evaluation. The analysis of factors influencing the NMP development has al-

lowed the author to establish a varied activity and influence peddling on setting priorities of different control objects, principally of political and financial groups, as well manufacturers and large pharmacy chains. Despite the overwhelming number of pharmaceutical workers in pharmacies, their activity and influence on the NMP development are low; this also concerns scientists, the public, and patients.

Keywords: National Medicines Policy, system of medicines circulation, essential medicines, National list, provision of medicines availability