APPROVED

by Resolution of the Cabinet of Ministers

 as of 2018 No.

**The State Strategy on Implementation of the State Policy for Provision of the Population with Medicines in 2018-2025**

**General Provisions**

This State Strategy has been devised based on the WHO recommendations. According to the recommendations, the State Strategy on Implementation of the State Policy for Provision of the Population with Medicines is defined as a political obligation and guideline to guarantee affordability and efficient use of effective and safe medicines. The State Strategy determines limits for interaction of all participants of this process, in particular, public and private sectors, public organizations, donors and other concerned parties and determines their role in this process.

Provision of the population with medicines and increasing their affordability is an integral part of the state healthcare policy in Ukraine, which is aimed at creating the patient-oriented system, as it exists in the developed European countries.

The State Strategy on Implementation of the State Policy for Provision of the Population with Medicines is a system of actions, measures, regulatory acts and priorities determined in the healthcare system which are aimed at settling interrelated problems in the area of provision of the population with quality, effective and safe medicines.

The State Strategy in the area of funding the system of providing the population with medicines should be aimed at reducing the financial burden on the population, creating effective funding mechanisms and introducing the new model, which will stimulate efficient use of medicines by healthcare facilities and population and will promote increased affordability of medicines.

In accordance with the Law of Ukraine “On State Guarantees of Financial Guarantees of Medical Servicing of the Population” adopted on October 19th, 2017, the state guarantees to the citizens full payment from the State Budget of Ukraine for medical services and medicines, which are listed in the medical guarantees program, based on the tariff. The State Budget also covers public health programs, epidemic counteraction measures, medical and social examinations, forensic medical and psychiatric examinations and other healthcare programs related to state functions based on the list approved by the Cabinet of Ministers.

Rights and guarantees in the healthcare sector related to medical care, provision of medicines, which are granted by other laws for some categories of persons, are funded within individual programs from the state and local budgets, target insurance funds and other sources not prohibited by the legislation. The Ukrainian legislation may set additional state financial guarantees of provision of medical services and medicines.

The law stipulates that medicines included to the National List of Essential Medicines, approved by the Cabinet of Ministers, and the medical guarantees program are paid for from the State Budget of Ukraine.

**Purpose, tasks and terms for implementation of the State Strategy on Implementation of the State Policy for Provision of the Population with Medicines in 2018-2025**

The purpose of the State Strategy on Implementation of the State Policy for Provision of the Population with Medicines in 2018-2025 is to reach high level of the population health; provide the population of Ukraine with quality, effective and safe medicines and ensure their efficient use.

The main tasks of the State Strategy are:

1. to ensure due selection of essential medicines;
2. to make medicines affordable;
3. proper funding of medicines provision to the population;
4. to improve the system of medicines supply;
5. to improve state governance and medicines quality provision;
6. to improve efficient use of medicines;
7. to increase investment attractiveness of the pharmaceutical market of Ukraine in the area of medicines research and development.

In the long term it is planned to implement the State Strategy in 2018-2025. This time is optimal to reach the goal of development priorities of the state policy for provision of the population with medicines.

Tasks of the State Strategy are in line with the Sustainable Development Goals for 2016-2030 approved by the Development Agenda at the UN Summit, which was held in September 2015 within 70th session of the UN General Assembly.

*Ensuring due selection of essential medicines*

The problem to be solved is the following:

Selection of essential vital medicines is one of the key elements of the State Strategy, the aim of which is to ensure availability of such medicines at healthcare facilities in the number necessary to ensure proper functioning of the healthcare system. It will allow for reducing the level of morbidity and mortality.

New expensive technologies in the healthcare area in Ukraine created the need to form and implement the whole system of medicines selection which would be based on assessment of healthcare medical technologies. Such an approach is used in foreign countries in the process of selecting essential vital medicines with a view to their further using.

Total number of consumed medicines do not satisfy real needs of the population. High indicators of self-treatment among the population (about 50%) and low observance of industry standards in the area of healthcare in particular by healthcare professionals, entail critically low consumption of essential vital medicines.

The problem of selecting essential vital medicines can be solved by:

improving the Ukrainian legislation on formation of the National List of Essential Medicines;

regular updating the National List of Essential Medicines based on the principles of transparency and openness of the selection process using the methods of medical technologies assessment given the priority pathological conditions, proofs of comparative effectiveness, safety and economic consequences for the healthcare system and affordability of medicines, as well as industry standards in the healthcare sector and level of medical care funding;

selecting essential vital medicines using the method of medical technologies assessment.

*Ensuring affordability of medicines*

The problem to be solved is the following:

To ensure availability and affordability of quality, effective and safe medicines. Cost of a medicine is important for ensuring affordability of medicines for the population both in hospital and private healthcare sectors.

In Ukraine the population spends a lot on medicines. According to statistical data, annually in Ukraine about 600 families spend huge amounts on healthcare. However, a lot of families cannot afford medical care or medicines.

Increasing affordability of medicines is one of activities of the Cabinet of Ministers of Ukraine determined in the medium-term plan of priority actions of the Government by 2020 approved by Decree of the Cabinet of Ministers of Ukraine No. 275-р as of April 3rd, 2017.

The problem of ensuring affordability of medicines will be resolved by:

improving the state regulation of prices for medicines fully or partially procured at the expense of the state and local budgets;

improving the medicines reimbursement system “Affordable Medicines”;

strengthening price competition among producers, distributors of medicines and pharmacies;

improving the state regulation of prices for medicines fully or partially procured at the expense of the state and local budgets;

 launching special mechanisms of negotiated procurement of expensive medicines for treatment of infectious and non-infectious diseases and rare diseases, guided by the best international experience;

launching the regime of medicines prescription outside the instruction for medical use in exceptional cases if there are no necessary medicines in Ukraine to treat the population;

introducing mechanisms to damp currency fluctuations at export-import operations related to procurement or supply of medicines to Ukraine;

ensuring that original (innovative) medicines are affordable to the population by:

- establishing peculiarities of verifying inventions with medicines objects for compliance with patentability criteria to avoid granting new patents on inventions which are not innovative, but rather offer only slight modifications of the existing patents with slight improvements of effectiveness (“evergreen patents”).

- taking in every specific case necessary measures to increase affordability of innovative expensive medicines (applying, if necessary flexible conditions of the TRIPS Agreement);

- optimizing the procedure for compulsory licensing of rights to inventions with medicines object;

- implementing to the Ukrainian legislation so called “Bolar provision” under which companies may apply for state registration of a generic medicine before expiration of an original medicine patent. After expiration of the patent, the company may immediately put the generic medicine into circulation, which will let reduce time;

- cancelling the necessity to verify patent status of medicines during their state registration;

- regulating patentability criteria for invented medicines;

- launching regime of parallel import of medicines;

- providing for limiting medicines data exclusiveness regime for social benefit.

*Proper funding of medicines provision to the population*

The problem to be solved:

State policy in the area of funding the system of medicine provision to the population should be aimed at reducing the financial burden on the population, creating effective funding mechanisms and launching a new model which will stimulate efficient use of medicines by healthcare facilities and the population and will facilitate affordability of medicines.

The issue of funding the medicines provision to the population system will be solved by:

creating a system for monitoring direct costs of provision of the population with medicines, efficient use of budget funds within the state guarantees program;

improving affordability of essential vital medicines at provision of medical care in out-patient facilities, including by introducing reimbursement of essential vital medicines with further switching to the provision of medicines within compulsory medical insurance;

optimizing public procurement of medicines, their distribution and supply taking into account actual need.

*Improvement of medicines supply system*

The problem to be solved:

The procurement practice existing in Ukraine, under which supply takes place once a year, leads to continuous storage of the great number of medicines and their mandatory distribution in compliance with the provision rules. It leads to exaggeration of real needs of healthcare facilities in order to avoid stock exhaustion.

Storage of big volumes of medicines in regional healthcare facilities significantly complicates their distribution to meet the unexpected needs in other regions. In case of provision of medicines used for first line therapy, healthcare system remains unable to provide medical services to new patients. There some elements of the supply system, such as accuracy of medicines stock recording and timeliness of delivery, are highly effective.

State policy in the area of medicines supply is aimed at ensuring quality at all stages of medicines circulation, starting from production and import till their medical use. The state introduces and constantly improves the mechanisms which are aimed at following the legislation in the area of wholesale and retail trade in medicines.

The problem in the area of medicines supply should be resolved by:

ensuring that public proceuement of medicines will be in line with Good Procurement Practice;

introducing Good Storage Practice standards for commercial subjects which are not engaged in distribution of medicines and within their area of activities and must provide proper storage of medicines;

ensuring gradual putting into circulation of medicines packed in hospital packages in order to save budget funds;

introducing Good Pharmaceutical Practice standards;

introducing control over circulation of medicines imported to Ukraine as humanitarian aid.

*Improvement of state regulation and ensuring medicines quality*

The problem to be solved:

The circulation of medicines is subject to state regulation at all its stages (from creation till medical use) by approving regulatory acts, monitoring their compliance with the international practice, controlling their observing and implementation by all participants of the process.

The current system of state regulation of the circulation of medicines does not fully meet modern requirements, since the implementation of the current legislation is taking place not in all areas, and monitoring is not systemic in nature. Therefore, such a system needs improving by harmonizing Ukraine's legislation with the EU legislation, improving the financial and technical support for this process, as well as human resources.

State governance and ensuring the quality of medicines covers the following areas:

following good regulatory practice including provision of legal basis, sufficient human and financial resources;

independence of state authorities, following anti-corruption legislation to avoid conflict of interests;

following Good Manufacturing Practice, production inspection;

ensuring the functioning of the pharmacovigilance system in order to monitor side effects and other manifestations of the adverse effects of the use of medicines due to their pharmacological properties or peculiarities of the organism's response to quality medicinal products, including biological and similar biological medicinal products;

state regulation of dissemination of information on medicines, in particular their promotion;

international exchange of information.

The problem of state regulation and ensuring of quality of medicines should be resolved by:

in the area of ensuring effectiveness and safety of medicines;

- harmonization of Ukraine's legislation with the EU legislation, taking into account the provisions of the EU-Ukraine Association Agreement;

- simplification of the admission to the market of medicines with the gradual transition to participation in the procedure of mutual recognition of the state registration of medicines with the EU member states;

- further development of the pharmacovigilance system in Ukraine in accordance with European approaches and international recommendations in order to monitor side effects and other manifestations of the adverse effects of medicines due to their pharmacological properties or peculiarities of the organism’s reaction on medicines;

- introduction of Good Regulatory Practice standards, including increased transparency of decision-making and the maximum availability of official information on the effectiveness and safety of medicines;

- increasing the transparency of all elements of the state registration system in line with the EU practice, including the development of a register of independent experts involved in the professional evaluation of data obtained from research of medicines;

- international cooperation on the exchange of information on the effectiveness and safety of medicines with the authorized regulatory authorities of foreign countries (primarily the European Medicines Agency) with further integration;

in the area of ensuring medicines quality:

- development of the system of quality assurance and management at all stages of medicines circulation by the further implementation of the international standards of the quality assurance system for products and services: Good Manufacturing Practice, Good Clinical Practice, Good Laborotary Good Practice, Good Distribution Practice, Good Pharmacy Practice, Good Pharmacovigilance Practice, and others;

- keeping approaches which are used in the EU while exercising state control over quality of medicines;

- improving the system of ensuring quality of medicines by introducing the report on issue of medicine series to be signed by a producer’s authorized person;

- automatic recognizing in Ukraine certificates of Good Manufacturing Practice issued upon inspections by authorized regulatory organs of Pharmaceutical Inspection Cooperation Scheme member-states;

- introducing risk-oriented approach at inspecting commercial entities along the whole chain of medicines supply;

in the area of state regulating dissemination of information:

- granting access to the general public to the information regarding evidenced therapeutic equivalency of medicines admitted to the Ukrainian market;

- development and approval of requirements to suppliers of active pharmaceutical ingredients and the procedure for their certification.

*Increasing the level of efficient use of medicines*

The problem to be solved:

In Ukraine medicines are used inefficiently (polypragma, self-treatment, ongoing practice of non-prescriptive sale of prescription drugs, inadequate consumption of essential medicines against excessive consumption of other medicines, etc.).

Efficient use of medicines is an important element of the State Strategy, which aims to avoid problems of both insufficient and excessive prescription of medicines, inappropriate prescription, and the use of expensive medicines if there are cheaper alternative medicines in the market of Ukraine with the same efficiency and safety level.

Efficient use purports to make patients use medicines to meet their clinical needs, in doses corresponding to their individual needs, during sufficient time and at the lowest cost for them and the society.

The problem of inefficient use of medicines can be solved by:

Taking administrative measures:

- ensuring the availability and systematic updating of industry healthcare standards and the National List of Essential Medicines which should be accessible and contain information for practitioners on the prescription of essential medicines;

- ensuring the formation of pharmacotherapeutic commissions in healthcare institutions, reviewing the procedure for their activities and functions regarding the assessment of the needs of the healthcare institution in medicinal products;

- ensuring the efficient use of medicines, which must be done under an international non-proprietary name;

- creating conditions for responsible self-treatment of the population, including by providing information by the pharmacists to consumers on the medical use of medicines in accordance with the instructions for medical use;

- implementation of electronic document flow, ensuring the functioning of open registers, joint interdepartmental databases;

- pharmaceutical sales staff informing consumers at sale outlets of available generic medicines which are substitutes of the original medicines.

taking regulatory measures:

- reviewing the current legislation of Ukraine in the area of medicine promotion;

taking measures in the area of education and information support:

- improvement of the undergraduate and postgraduate education of medical and pharmaceutical specialists in order to ensure their professional development and advanced training, in particular, taking into account new scientific and technological developments and innovations in the field of health care;

- raising public awareness of the principles of efficient use of medicine;

- improvement of information policy in the field of medicine use.

*Stimulating the development and research of medicines*

The problem to be solved

Stimulating the scientific development and industrial introduction of new medicines at the national and international levels are important steps in providing the population with medicinal products that require additional legislative regulation. Ukraine is focused on further in-depth research on the quality and safety of medicines, adherence to ethical principles and a humane attitude towards patients.

The main problems which cause the necessity to conduct operational research, clinical trials and medicine development research are the following:

limited funding;

insufficient technical and human resources;

emergence of new expensive technologies;

introduction of new technologies;

subjective factor at planning research of medicines and assessing the obtained data;

unregulated by law ethical principles for conducting biomedical research (clinical interventional, non-interventional post-registration and other types of research related to economic and physical availability, prescription of medicines);

low level of understanding by medical professionals, scientists and political leaders of the need to conduct and use research results to improve the strategy and prepare plans for further action on the efficient use of medicines;

rare use of operational research as a tool for studying the economic aspects of provision of the population with medicines, problems associated with the prescription and realization of medicines, in order to understand the peculiarities of their medical use and the degree of influence of these processes on the health system as a whole;

application of unified approaches in order to prove the effectiveness and safety of medicines while conducting clinical trials to study certain dosage forms and types of medicines;

proper level of training for specialists to ensure the quality study of medicines.

The problems in the area of medicines research and development should be solved by:

stimulating development of medicines:

- support of the existing and attracting new sources of funding for national scientific research of medicines;

- state support for the development of scientific human resources, in particular scholarship programs and programs of social protection of scientists;

- creation of infrastructure for research work, modernization of existing research bases in Ukraine;

creation of the environment for clinical trials (national and international):

- compliance with Good Clinical Practice;

- ensuring comprehensive protection of rights, respect for ethical principles and humane attitude towards patients and healthy volunteers participating in clinical trials;

- bringing the legislation of Ukraine regarding the insurance of subjects of clinical research in accordance with international standards;

- regulation of the issue of non-interventional research;

- development of amendments to regulatory acts, guidelines and methodical recommendations for various types of clinical trials;

- creation of proper technical and personnel support for health facilities involved in clinical trials;

- advanced training of medical specialists participating in clinical trials.

**Anticipated results of the State Strategy implementation**

Implementation of the State Strategy will allow for:

increasing the health condition of the population;

increasing the level of access of the population to high-quality, effective and safe medicines;

reducing the expenses of the population on medicines and increasing the level of provision of medicines by the state;

ensuring the rational use of medicines based on the clinical needs of patients;

creating effective mechanisms for allocating funds from the state and local budgets to provide the population with medicines;

expanding public access to socially important information on medicines;

attracting foreign investments in the framework of conducting clinical trials on the basis of domestic healthcare institutions;

increasing the level of protection of the rights of patients and healthy volunteers involved in clinical trials.

**Financial support to the State Strategy implementation**

The financing of measures for the implementation of the State Strategy is carried out from the state and local budgets from the allocations envisaged for the relevant year, as well as other sources not prohibited by law.

The assessment of the implementation of the State Strategy is carried out through annual monitoring using the State Strategic Status Implementation Indicators, which are presented in Annex 1 to the State Strategy.

The current monitoring and coordination of the implementation of the State Strategy is carried out by the Ministry of Health of Ukraine.

The Action Plan for the implementation of the State Strategy is subject to revision every year.