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The Role of Pharmaceutical Security in Realization of the Right to Health

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Abstract

Objectives: The articles analysis the role of convergence and harmonization of pharmaceutical regulation, as a basic component, ensuring pharmaceutical security and guarantying the realization of the right to health. **Method:** To achieve the main aim of the study national laws and documents of international organizations have been analyzed to identify main steps of human security concept formation and the role of access to healthcare in its realization. According to existing socioeconomic trends, main threats and challenges of pharmaceutical sector were identified showing the role of harmonization and convergence processes in its protection and realization of the right to health. **Findings:** An analysis of the processes taking place in different regions of the world, demonstrated the positive impact of regional integration to improve the health management system and the formation of common rules, regulating the drug market. Integration processes take into account regional specificities, providing point impact on the existing threats and challenges in the pharmaceutical sector, which allows neutralize differences in the capabilities of States to ensure the quality control of medicinal products within the same region. Focus on the convergence and harmonization of the legal framework will improve the drug regulatory system on a global level and ensure the quality of products used by patients, it is necessary to strengthen and provide numerous benefits for both regulators and the pharmaceutical industry and have a positive impact on the protection of public health. **Improvements:** The study result identifies main areas of harmonization and convergence of pharmaceutical regulations, which can be applied during regulation formation of any regional integrative organizations.

Keywords: Harmonization, Pharmaceutical Security, Regulation, Right to Health

1. Introduction

Individual security, or, according to the definition of the former Canadian Minister of Foreign affairs, "personal security" is the core element of an effective international security system, based on the liberal democratic ideals. Respect and protection of fundamental freedoms are the basis of all the other forms of security.¹

Security, as the basic value and human right for the first time began to be considered as part of the Western world in the revolutionary period of its history. The Bill of Rights of 1689, adopted in England, in the American Declaration of Independence of 1776 and the French

Declaration of the Rights of Man and of the Citizen of 1789, directly or indirectly, indicated security as a natural human right, along with freedom, property, and resistance to oppression.

The first concept of human security has been formulated with the creation of the International Committee of the Red Cross and subsequently developed in the UN Universal Declaration of Human Rights.

A significant contribution to the formation of the human security and right to health concepts made the "four freedoms", was created by US President Franklin. D. Roosevelt in his address to the US Congress.² In his speech, the president spoke about "freedom of speech,

freedom of worship, freedom of want and freedom from fear". According to the concept proposed by Roosevelt, the protection of human rights, including social and economic rights is fundamental to the maintenance of global peace and security. Further, President John F. Kennedy raised the question of expanding the existing concept of security in his address to the United Nations General Assembly in 1961.³

The question of the human security concept formation was also raised in the Palme Commission Report on Disarmament and Security 1982, Commission on Global Development Report (1983), World Commission on Environment and Development Report (1988) and the Commission on Global Governance Report (1995).4-6

Formation of modern "human security" concept began in the early 1990s. Going beyond military issues, the UN began to focus on the prevention of non-military processes, directly threatening the lives of people around the world. For the first time in 1992, the UN Secretary-General Boutros Boutros-Ghali in the report "Agenda for Peace" has put forward the idea of non-military threats to global security.²

However, the main provisions of the modern concept of human security were presented in the report "New human security dimension", prepared by the UNDP in 1994.8 Protection of human health has been identified as one of seven areas under the threat. According to the UNDP's position, health security has been defined as protection from diseases, opportunity to live in a safe and healthy environment, availability of effective medical care.

In 2001 the UN Commission on Human Security, established to incorporate effectively human security issues in the activities of the UN system organizations, in the report "Human Security Now" (2003) defined human security as an important part of the state security. Among 10 recommendations formulated in the report, equal access to basic health care has been identified as one of the priorities.⁹ The WHO Commission on Macroeconomics and Health in its report also pointed out that a healthy population is the basis for economic growth and social development of the state and security in the world.¹⁰

New vision of collective responsibility and analyzes of the main threats to international peace and security have presented in the report "A more secure world: our shared responsibility by a Working Group on Threats, Challenges and Change to make proposals to strengthen international security." Among the new threats to humankind were defined nuclear terrorism, transnational organized

crime, communicable diseases, and environmental degradation. These threats can be revived from the context of pharmaceutical regulation, as access to medicines is the key component of combating infectious diseases, and transnational crime nowadays is directly linked with counterfeiting of medicines.

Availability of essential medicines as one of the basic elements of the human right to health was underlined by Committee on Economic, Social and Cultural Rights (CESCR), in the General comment No14, which formulated four interrelated elements: availability, accessibility, acceptability and quality (AAAQs). Each of the mentioned elements is considered as interrelated component of pharmaceutical security.

In 2005, the UN General Assembly in the final document of 60th session stressed that all people, including vulnerable groups, are entitled to freedom from fear and want, with an equal opportunity to enjoy all their rights and fully develop their human potential. The General Assembly pledged to formulate further the concept of "human security".¹²

The problem of access to medicines is central to the three Millennium Development Goals (MDG) established by the United Nations: combat HIV / AIDS, malaria and other diseases; improve maternal health and reducing child mortality, as well as directly mentioned in one of the objectives of Goal 8: to ensure access to essential medicines in developing countries.

Sustainable Development Goals succeed the MDGs and will guide global development over the 15 years to 2030. Universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all is identified by WHO report "Health in the 2030 Agenda for Sustainable Development" as a basic target for reaching goal №3 "Ensure healthy lives and promote well-being for all at all ages".

2. Access to Health Care - Basic Component of National Security Concepts

In the context of globalization of the international political and economic relations, formation of new threats and challenges to international peace and security, major changes have touched the concept of "national security". These trends shifted a focus from the issues of maintaining military might to the need of regulating those spheres that can turn into new non-military threats, especially to health and welfare of the population. 13 National security strategies, based solely on the provision of military defense to the country, are insolvent in the face of new non-military threats of the XXI century.

By the end of XX century traditional approach to the definition of health security considered infectious diseases and biological weapons as the only threats to security. 14,15 However, the new millennium demonstrated a fundamentally new demographic situation, characterized by an increase in the proportion of elderly people in the total population of the world and the rise of chronic non-communicable diseases. According to the WHO estimation the number of elderly people number will increase to 1 billion in less than 10 years, and by 2050 it will increase by 2.5 times and reach billion (22% of world population).16

According to the existing threats and security challenges, the leading countries have developed their national security strategies, which formulate strategic goals for the health of the nation and the development of health care, including security control, quality and efficacy of medicines as mandatory provisions of national security. In 2010, the UK has prepared National Security Strategy "Strong Britain in an age of uncertainty". In the preamble of the document, Prime Minister D. Cameron pointed out that state's ability to confront new threats is directly linked with economic security and ability to overcome the budget deficit. Rapid development of industrial technologies has affected the efficiency and legitimacy of the ethical use of new technologies for the production of medicines. World population situation and its impact on the economic welfare of the state are reflected in the document.

Huge impact on global health issues and the development of modern approaches to public health safety issue were described in "Global health strategy for 2008-2013.", adopted by the UK government. The document identified five components, which have to be implemented at the national level to address current global health threats: strengthening of global security in the health sector; ensuring safe, fair system of access to health services, including essential drugs; improving the efficiency of the activities of international organizations; strengthening health fair trade system.

The value of the health sector emphasized in the national security strategy of the USA: "Although we have reached considerable heights in ensuring military security, we faced serious consequences of insufficient attention to education, energy, health, science, which are the basis for the well-being and security of the state".18 Health security is considered as a basis for economic growth and the country's competitiveness in the global economic market. In order to counter existing threats in the US Department of Health has developed a "Global health strategy", in which among the priorities are established: the development of international research activity, strengthening of security systems of production and supply of medicines and medical products, the improvement of international standards through the development of international cooperation. 19

The need to change the existing architecture of international security and legal mechanisms to ensure it is emphasized in "National Security Strategy of Russian Federation until 2020"signed by the President in 2009.20 According to the Strategy, national security should be ensured by the development of the strategic national priorities: health care, science, education, the environment, national defense and state public safety. A separate section of the document is devoted to safety in the health sector. The document identifies the following objectives to ensure state security: quality control, efficiency, and safety of drugs. Guaranteed supply of the population with high quality and affordable medicines is also mentioned in the context of improving the quality of life. One of the key provisions of the updated national security strategy is the most effective use of internal resources of the country. In particular, it emphasizes the need to create conditions for the development of the pharmaceutical industry to overcome its raw material and technological dependence on foreign suppliers, as well as the availability of high quality, effective and safe medicines. The role of medicines in national security in particular is highlighted in the list of the Presidential orders on additional measures for the development of the pharmaceutical industry of the Russian Federation, adopted in February 2016. In particular, the Russian Government was requested to submit proposals on the nomenclature of drugs, production of which has to carry the full technological cycle in the Russian Federation. These provisions have been confirmed in a new version of Security Strategy signed by President in December 2015.21

3. Threats and Challenges in the Pharmaceutical Sector

In any society, an effective health system is an important element of the state functioning, along with the democratic political system and a fair justice system. However, in many countries, ineffective health sector regulation, in particular in the pharmaceutical area, result in extensive human rights violations.

Many aspects of globalization had a significant impact on the scope of pharmaceutical regulation worldwide. Socio-demographic processes, increased economic instability, epidemiological transitions and disproportionate access to health care have led to increased demand for health services, including safe and effective medicines and an increase in the cost of health care and social security.²²

Every year the number of funds spent on health care in the world, increases at an average of 3-5 %, outpacing the total growth of the world economy. This leads to the fact that regardless of the economic wealth of the state health sector begins to feel the shortage of funds. Drug expenditures are the dominant part of total healthcare system costs. Providing access to drugs and their rational use have a direct impact on reducing the economic burden of many diseases, as well as helping to reduce the overall cost of medical care. The development level of drug supply system depends on the efficiency of the national health system, which, in turn, has a significant impact on the level of socio-demographic indicators, the incidence of people in different age and social groups, including the working population, as well as the military forces.²³

Pharmaceutical sector is a complex system, structural components of which are in constant interaction with the various spheres of human activity. In the pharmaceutical industry, there is a number of systemic problems on the international, regional and national levels, which evidence of a serious threat to human security.

Firstly, it is the **imbalance between world consumption and world production**. The global structure of drug consumption is extremely disproportionate. According to WHO, 15% of the population accounts for 90% of total drug consumption. The cost of medicines in countries with high levels of economic development is \$ 400, which is 100 times higher than the average cost of developing countries. However, access to the drug is an important social security system component. Today, approximately 75% of the world population (5.1 billion) does not have a

full-fledged social protection, and 40% do not even have basic protection.

Secondly, a high rate of countries **depends on import** of medicines, which limit the provision of essential drugs and limit the control of counterfeit, substandard products. Currently active substances, intermediate substances and shaping components for drug production can be produced in different regions of the world. Imports of pharmaceutical products in the United States exceeds production. In 2011 24 m ln. products delivered in the USA under the control of FDA were out of the 228 foreign jurisdictions. China and India are the most attractive regions for pharmaceutical manufacturers. The production cost of active pharmaceutical ingredients in India is 15-40% less than in the US. Currently half of all active pharmaceutical ingredients are produced in India and a significant portion of generic drugs comes from the rapidly developing markets.24 The high requirements at each stage of the pharmaceutical production, requires significant investments in material and technical base in particular from generic manufacturers, which lead to the abandonment of production and as a result to a shortage of certain categories of medicinal products on the market. A trend exacerbated by the rapidly increasing demand for drugs for the treatment of non-communicable diseases, due to the current demographic situation and changes in the structure of morbidity.²⁵

Over the past few years, **the deficit of drugs** in low as well as in high-developed countries became a serious concern. Shortages of essential medicines are being documented in most parts of the world with increasing frequency. Drug shortages are caused by many factors such as low production capacity, the lack of interest of pharmaceutical companies in the production of cheap generic drugs and etc. Many shortages have been linked to products that are older, off-patent or difficult to formulate and that have a tightly-defined shelf life and few manufacturers (or a sole manufacturer). The deficit more influences countries with a low-level of pharmaceutical consumption because they are perceived by pharmaceutical companies as a less interesting for the marketing of such products on a commercial basis. 27

Special attention has to be paid to the problem of ensuring the **reliability of the results of clinical trials and transparency of regulatory agencies**. In 2014, the total investments in the development of new drugs amounted to \$ 141.6 billion. ²⁸ Currently, the cost of development of development of the cost of dev

oping a drug exceeds \$ 1.38 billion S compared to \$ 138 million in 1975.²⁹ According to other sources, the total cost of registration of drugs ranges from \$ 2.3 to \$ 4.9 billion.³⁰ The inability to predict the possible result is the main cause of a significant investment, only a small proportion of the molecules will fall on the pharmaceutical market, and the unit can only recoup the investment.31 In 1998-2014 among all the drugs that are in clinical studies, only 12% have been registered.

Research activity becomes interregional. About a quarter of all clinical trials are conducted simultaneously in the EU and in third world countries, and about 60% of patients participating in clinical trials of medicinal products in the EU are non-EU citizens.32 While Europe and North America are leaders in the number of ongoing clinical trials, a reasonable increase expected in developing regions of the world.33 The shift of clinical research in developing countries raises many concerns regarding the protection of data integrity, ensuring compliance with ethical standards identical, threat posed by the double standards, confidence in the local regulatory authorities.

Pharmaceutical sector is vulnerable to corruption activity. Corruption and unethical practices contributes to the spread of counterfeit, substandard and ineffective medicines; leads to a direct increase in budgetary spending on health, erodes public confidence and reduces investment in research and development by the private sector. Currently there is no full credible evidence of the real extent of counterfeiting in the pharmaceutical market, due to the absence of full-fledged research and the extreme complexity of the process of drug circulation. According to the World Economic Forum, the total market volume of counterfeit medicines is 200 billion.34

Despite numerous reports of detection of low-quality and counterfeit drugs, such information is not systematized at the international level. Research can only provide a limited picture of the situation at a given time. Counterfeiters apply extremely sophisticated techniques to fake products and to exclude the possibility of its detection. Techniques and methods of falsification are constantly being improved, so the results of research carried out in this area are constantly out-dated.³⁵ Producers of counterfeit drugs use the "weak points" in the supply chain, imperfection of legal regulation, and absence of specific control procedures. Existing national and regional mechanisms are not able to fully counteract transnational criminal activities by counterfeiting of medicines.

Summing up all mentioned above pharmaceutical security means ensuring that people, influenced by any internal and external factors have access to all medicines needed for their health and quality of life.

4. Harmonization of **Pharmaceutical Regulation**

Expectations and requirements of consumers regarding the safety of medicines significantly increased. Each drug has certain side effects, incidence of which must be constantly monitored by regulatory authorities and made available to patients and health care workers to prevent any negative consequences.

Nowadays state authorities, regulating pharmaceutical market, regardless of their size, face lack of financial or other resources for the implementation of all regulatory functions necessary to ensure the quality, safety and effectiveness of medical products on their markets.

Even regulators with a highly developed material and technical base, such as Food and Drug Administration USA (FDA), are not able to carry out successfully their work without a significant improvement of the legal framework and implementation of the highest safety and quality standards in the work of the partnership institutions in developing countries. Significant differences in the regulation has become an important concern of manufacturers, who have to duplicate research and registration procedures for the distribution of their products on a global scale.

The continuous emergence of new requirements, significantly complicate the administrative procedures of regulatory authorities. Together with the increasing role of private sector in the development of legislation and standards, rises a concern of the medical community and patients in relation to the conflict of interest and increase of corruption factor, which lead to excessive financial costs, reduces the effectiveness of health systems, undermining the faith and confidence in the system to ensure medicines.36

The introduction of unified standards at the international level - it is a long process, especially if these standards relate to complex processes. However, the harmonization of regulatory requirements in the pharmaceutical sector at the global level is gaining momentum. At the root of this trend is an increasing degree of globalization of the pharmaceutical industry.37

Regulation in the pharmaceutical area should be defined as a combination of legal, administrative and technical measures taken by governments to ensure the safety, efficacy and quality of drugs, as well as the accuracy and reliability of information about the product.³⁸

At the international level, the system of pharmaceutical regulation is based on the many branches of international law. However, the interdependence of all stages of the drug market and the need to use existing international standards of interconnection determines the formation of the international legal regime regulating the drug market, primarily aimed at ensuring human security.³⁹

To improve pharmaceutical regulation system at international level and to ensure the quality of products used by patients, it is necessary to strengthen the emphasis on the harmonization of the legal framework that will provide numerous benefits for both regulators and the pharmaceutical industry and have a positive impact on the protection of public health. Increasingly important becomes to stimulate of co-operation between regulatory authorities in different regions of the world and the convergence of technical standards.

Globalization, growing interdependence, increased competition in the global market, the new challenges facing humanity - all this requires a fresh look at the opportunities and the need for harmonization of legal systems at national, regional and international level. The processes of harmonization and economic indicators are in complex relationships. Most regional development initiatives aim to harmonize the initial creation of trade blocs, requiring the reduction of trade barriers in all sectors, including the pharmaceutical and the creation of common requirements and standards. The level of economic integration directly affects the degree of harmonization.

Solution of the manifested challenges in the pharmaceutical sector requires structural changes, with the active cooperation of all participants of the pharmaceutical and related industries. It is critical to create an effective foreign policy and the legal framework at the national level, as well as improvement of the existing international and regional mechanisms of regulating each step of drug supply to address the most important problems of this sector.

Pharmaceutical security at national and international level requires harmonisation of the following areas²²:

Protection of human rights on access to medicines

- Development of legal and administrative mechanisms to ensure a balance between world production and consumption of drugs, as well as between supply and demand on its domestic and regional markets;
- Ensure the development of safe and effective medicines (control of clinical trials);
- Improvement of national legislation in the field of regulation of the drug market;
- Development and improvement of international pharmaceutical regulation.

An analysis of the processes taking place in different regions of the world, demonstrated the positive impact of regional integration to improve the health management system and the formation of common rules regulating the drug market. Integration processes take into account regional specificities, providing point impact on the existing threats and challenges in the pharmaceutical sector, which allows neutralize differences in the capabilities of States to ensure the quality control of medicinal products within the same region. To improve the drug regulatory system on a global level and to ensure the quality of products used by patients, it is necessary to strengthen the focus on the convergence and harmonization of the legal framework that will provide numerous benefits for both regulators and the pharmaceutical industry and have a positive impact on the protection of public health.

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