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## **RESEARCH ARTICLE**

# Analysis of Stages of Implementation of International Concept of Essential Medicines in the System of Health of Ukraine

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#### **ABSTRACT:**

The article contains results of research of implementation of international concept of essential medicines in the system of health protection of Ukraine. The authors analyzed three National lists of essential medicines, which had been approved in 2001, 2006 and 2009, and their last editions. They used historical, comparative, logical, mathematical statistic and other methods of research. The authors determined that since the first National list of essential medicines in Ukraine had been approved in 2011, there hasn't been a single approach (by methodology) to a selection and inclusion of medicines to the composition of the above-mentioned list. Moreover, there hasn't been a single approach to the formation of National list of essential medicines as well. It was the third National list of essential medicines (2009) by the formation and order of medicines presentation, which followed international recommendations of World Health Organization. In different years, the number of medicines, which were showed in the lists, has fluctuated gisnificantly. Thus, a minimum number of medicines was in the third National list of essential medicines (251 medicines by INN, 2009) and a maximum number was in the second edition of the second National list of essential medicines (780 medicines, 2008). Specific weight of sales volume of medicines, which were included in the National list at pharmaceutical market, has been changing proportionally to the change of their number by years. The biggest volume of retail sale was in 2008 (42.43%), and the smallest-in 2009 (13.45%). A significant obstacle to the efficient implementation of international concept of essential medicines in Ukraine is absence of National list of Essential Medicines for children.

**KEYWORDS:** World Health Organization, Essential Medicines, National list of Essential Medicines of Ukraine, pharmaceutical market of Ukraine, Ukraine.

### **INTRODUCTION:**

At the modern stage of development of our society, the health and high-quality life of citizens are considered to be of the highest value. In most countries of the world the increase of humanistic tendencies is predominant characteristics of the development of the society<sup>1,2</sup>.

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At the International conference in medical sanitary aid, which took place in 1978 in Alma-Ata, basic principles of national systems of health protection regarding implementation of humanistic concepts of society development were accepted<sup>2-4</sup>. Since that time most countries of the world have already developed and are using efficiently strategic plans of increasing the level of accessibility of medical and pharmaceutical aid to people despite of their social and financial status in the society<sup>2,5-7</sup>. On the way to the implementation of humanistic principles in national systems of health protection, World Health Organization plays the key role<sup>2,7-10</sup>. To use the above-stated principles of health

protection of different countries at the internationmal level efficiently, a strategyof the formation of National medical politics has been developed <sup>11-13</sup>. Recommendations of World Health Organization as to the formaton of socially-oriented models of relations between the subjects in the system of pharmaceutical provision of the community stipulates fulfillment of the following tasks:

- Equitable availability and affordability of essential medicines, including traditional medicine;
- Quality: the quality, safety and effifiency of all medicines:
- Rational use: the promotion of therapeutically sound and cost-effective use of medicines by health professionals and consumers<sup>11</sup>.

Our government has to assist in the formation of management, which is adequate to transformation of the whole society in general, to ensure the development of a transparent system of its functioning, to improve informational support and functioning of the whole industry in general. Moreover, our government has to reform the system of scientific provision and professional education effectively, which will meet upto-date requirements of the society as to the formation of efficient ways of providing doctors, pharmacists and consumers of pharmaceutical services with necessary and demonstrative information<sup>11,14,15</sup>. As proved by the facts from special literature, the necessity to use the key goals of national politics has already been declared by the government in more than 150 countries of the world 3,11,16,17. In defferent countries of the world the the above-mentioned goals are achieved using various mechanisms and measures<sup>8,11,18-20</sup>. In the opinion of international experts, one of the most important tools to achieve the goals of National Drug Policy development and implementation of the List of essential medicines at the international level<sup>3,6,11,21,22</sup>. It is worth mentioning that different countries of the world have already acquired certain experience of implementation some mechanisms of regulation of accessibility, quality and rational use of medicines in national systems of health protection<sup>6,7,19,20,23-28</sup>. It is interesting to know that prior to the development of the first edition of WHO Model List of Essential Medicines (1977) certain countries have already made some steps in using the concept of National lists of Essential Medicines in practical health protection<sup>8,13,29,30</sup>. For example, the first list of medicines financed by the government was developed in 1959 in Ceylon (today Shri Lanka)<sup>29,30</sup>. One of the first prototypes of National list of Essential Medicines was created in Tanzania in 1970<sup>2,3,7,31</sup>. Since 1977 WHO Model List of Essential Medicines increased from 204 names of medicines to 433 medicines in the 20th Essential Medicines List, published on 06 June 2017. The updated edition of WHO Model List of Essential

Medicines (2017) included medicines to treat the viruses of immunodeficiency, hepatitis C, tuberculosis and oncological diseases<sup>9,32,33</sup>. At the moment, most countries of the world have already developed and constantly update National lists of Essencial Medicines. To our mind, Ukraine requires experience of using the concept of essential medicines in practical health protection of those countries, which are at the stage of reformation of national health system or are developing under the conditions of insufficient government financing<sup>1,2,12,13,19,24,25,34-36</sup>. First of all, they are India, China, Malasia, Thailand, Brazil, Mexico, Africa and Middle East. Rational use of medicines, which are included in National lists of Essential Medicines, allowed to save significant material resources, which the government can use to solve more important problems practical medicine and the society general<sup>5,12,19,20,25,37-39</sup>.Herewith. efficiency of implementation of the above-stated plans in practical health protection depends on the whole set of indicators <sup>40,41</sup>. A significant role in this issue is given to the ability of political authorities of the countries to solve difficult problems of health protection and pharmaceutical provision under the condition of deficiency of resources and increase of requirements of the population to the quality of medical and pharmaceutical services.

Currently, health protection in Ukraine as well as the society is in crises. Under the conditions of unstable financial situation and lack of efficient mechanisms of social protection of the population by the government, a significant part of the population cannot buy necessary medicines. It is worth mentioning that in 2016 our government started to introduce programs reimbursement the cost of medicines. Thus, government implemented the program«Accessible medicines»for cardio-vascular diseases, bronchial asthma and diabetis of II type<sup>42,43</sup>. Efficiency of implementation of the above-mentioned program directly depends on theoretically-applied approaches, which were used in the formation of National list of Essential Medicines<sup>11,18,44</sup>. The above-stated information stipulated the goal of our research.

The goal of our research was to analyze the key stages of implementation of international concept of essential medicines in practical health protection and a system of pharmaceutical provision of the Ukrainian population.

#### MATERIALS AND METHODS:

The object of our research was the data shown on the official site of World Health Organization in the section«Essential medicines and health products», and legislatve and regulatory principles regarding the problems of medical and pharmaceutical aid in Ukraine, public registration of medicines, which is shown on the official site of State Enterprise «State Expert Center of

the Ministry of Health of Ukraine»and retail sales volume of medicines at the pharmaceutical market. Moreover, we used special literature in the issues of efficient implementation of the concept of of essential medicines in different countries of the world, first of all, those countries, which begin making reformations in the system of health protection or suffer from political and social economic crises.

To achieve the goal of this research we have developed the folloding tasks: to analyze the appropriate national legislative and regulatory principles in order to determine the documents which formed theoreticallyapplied approaches to the efficient implementation of international concept of essential medicines in national health protection and a system of pharmaceutical provision of the population; to analyze the composition and content of national lists of essential medicines. which existed in Ukraine during various years of research; to determine their basic characteristics and to their conformity with international assess recommendations indicated in different editions of WHO Model List of Essential Medicines for a certain period; to determine specific weight (%) of retail sale of medicines from the National list of Essential Medicines according to the price at the pharmaceutical market of Ukraine; to outline trends of improving the process of implementation of the concept of essential medicines in Ukraine as to the acceptance of the 20th Essential Medicines List, published on 06 June 2017.

We used historical, comparative, logical, graphical, and mathematical statistic methods of scientific research. All statistic calculations were performed using the statistic package StatSoft. Inc. (2014). STATISTICA version 12.0, and Excel spreadsheet. A p-value<0.05 was considered as statistically significant.

#### **RESULTS:**

By the results of research, we have determined the following. During the independence of Ukraine (from 1991), three National lists of Essential Medicines have been developed and implemented. Thus, the nabovementioned lists were implemented in 2001, 2006 and 2009 (Table 1) 45-47. It means that implementation of the international concept of essential medicines started in Ukraine from the promulgation and confirmation in a certain order in 2001 the first National list of Essential Medicines<sup>45</sup> The Regulation about National list of Essential Medicines was confirmed at the beginning of 2002 by the Decree of the Ministry of Health of Ukraine dated from 22.02.2002, № 70. As shown in Table 1, the given list was called «National list of essential (vitally important) medicines and medial products». To make the analysis of three National lists of Essential Medicines easier in chronological order we gave conventional names and ordinal numbers, that is List

№1 (2001), List №2 (2006) and List №3 (2009).

Table 1: National lists of Essential Medicines in Ukraine

Official name of the list of Essential	Normative-legal document, which	Number of changes and
Medicines	confirmed the list	amendments,
	of Essential	which were
	Medicines	made to the list
National list of	Decree of the	No amendments
Essential (vitally	Cabinet of	and changes
important) Medicines	Ministers of	
and medical products	Ukraine dated	
(conventional name in	from 16.11.2001,	
research–the List №1)	№1482	
National list of	Decree of the	2 amendments
Essential (vitally	Cabinet of	and changes,
important) Medicines	Ministers of	which were made
and medical products	Ukraine dated	to the
(conventional name in	from 29.03.2006,	composition of
research–the List №2)	№400	the list
National list of	Decree of the	7 amendments
Essential (vitally	Cabinet of	and changes, two
important) Medicines	Ministers of	of which
and medical products	Ukraine dated	contained
(conventional name in	from 25.03.2009,	amendments to
research – the List №3)	№333	the list

The composition of the List №1 has not been changed practically for 5 years. Two changes and amendments were made to the List №2 during three years. Before the composition of the List №2 was confirmed by the Decree of the Ministry of Health of Ukraine, a new regulation«Regulation about National list of Essential Medicines and medical products»had been confirmed, and also«Regulation about Expert Council in the formation, changes and amendments to the National changes and amendments to the National list of Essential Medicines and medical products»(2005). In 2016«Regulation about National list of Essential Medicines» was confirmed, which exists currently with changes and amendments.

The biggest number of changes and amendments was made to the third National list of Essential Medicines (the List №3). Herewith, out of seven changes and amendments only two changes were entered as to the increase of the list of medicines. The rest changes have been confirmed to adjust the prices for medicines during their distribution and retail sale in the pharmaceutical market. Moreover, editings as to the names of medicines in Ukrainian or English were made in a separate regulation of the Cabinet of Ministers of Ukraine (04.07.2017), and also they have increased a list of the forms of manufacturing of those and other names of medicines significantly.

The next stage of our research was analysis of the structure and composition of three National lists of Essential Medicines, which has existed in Ukraine since 2001. Results of research are shown in Table 2.

Table 2: Results of structural analysis of National lists of Essential Medicines in Ukraine

Lists of Essential medicines	Characteristics of lists formation	Number of medicines by INN shown in
		the lists
	Medicine code acc. to Anatomical Therapeutic Chemical	Over 500 names of medicines including
	(ATC) classification system	combined medicines (without ATC code)
	2. Group of medicines, for example:	
	A10 A Antidiabetis medicines	Most medicines produced in Ukraine
List №1	A10 A Insuline and its analogues, etc. 3.INN (International	(56,0%)
	Nonproprietary Name) without ATC code	
	4. A separate mark showing medicine included to the list-	
	domestic or foreign production	
List №2,	Ordinal number of medicine	431 names of medicines represented acc.
Edition dated from 29.03.2006	2. Medicine INN and its ATC code, for example:	to ATC codes
Edition dated from 30.05.2007	Azytromicin J01F A10	751 names of medicines represented acc.
		to ATC codes
Edition dated from 9.07.2008		780 names of medicines represented acc.
		to ATC codes
	1. Class. Group or subgroup, INN (International	215 names of medicines without ATC
	Nonproprietary Name) in Ukrainian and English	codes in different frorms of production
	2. Form of production, a dose of medicine, for example:	
List №3, edition dated from	I. Anaesthetics	
25.03.2009	1.Means for general anesthesia and oxygen:	
	Halotan (Halothane)-a solution for inhalation	
	Isoflurane (Isoflurane)-a solution for inhalation, etc.	
Edition dated from 16.03.2017		367 names of medicines without ATC
		codes in different frorms of production
Edition dated from 13.12.2017.		421 names of medicines without ATC
		codes in different frorms of production

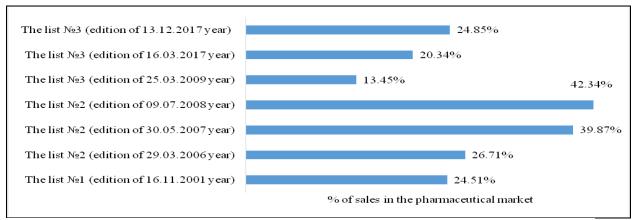


Figure 1: Results of research % of retail sales volume of essential medicines in the pharmaceutical market of Ukraine (2001-2017)

All three National lists of Essential Medicines had different approaches to the structure and representation of medicines in them. Despite of the fact that the List №1 and the List №2 had official name «National list of essential (vitally important) medicines and medical products», there haven't been any medical products in their composition.

We have determined that the number of medicines, which were included to the composition of various National lists of Essential Medicines, has changed significantly by years. The biggest number of medicines (780 names of medicines) was included in the List №2 in the edition 2008. The smallest number of medicines (215 names of medicines) was typical of the List №3 in edition 2009. Thus, in the List №3 the number of medicines was reduced as compared to the last edition of

the List №2-by 3.6 times. Moreover, it is worth mentioning that the second edition of the List №2 increased the number of medicines from 431 names acc. to INN to 751 names of medicines acc. to INN (2007). That is, the number of medicines increased by 1.74 times.

Then our task was to analyze specific weight (%) of essential medicines sales volume represented in the Lists №1, №2, №3 in the retail pharmaceutical market. For the analysis we have selected sales volume of essential medicines of all trade names registered at the moment of confirmation or making changes and amendments to the composition of National lists of Essential Medicines. In the research, we used only those forms of production, which have been mentioned at thew National lists of Essential Medicines. The analysis of specific weight was

delivered in cost indexes—sales volume in retail pharmaceutical market. Results of research are shown in Figure 1. We have determined that specific weight (%) of sales volume of essential medicines has changed significantly by years.

#### **DISCUSSION:**

Making systematic analysis of our research, we can single out the following problems in the process of efficient implementation of the above-mentioned concept in Ukraine. Thus, from 2001 in Ukraine together with the Nagtional list of Essential Medicines there have existed and are currently available a few lists of medicines with the help of which our government regulates the issue of physical and social-economic accessibility of medicines for the population. During two decades the National list of Essential Medicines in Ukraine has not been considered as a priority in providing the population with pharmaceutical aid. For example, regulation of trade mark-ups (%) in the process of distribution and retail sale of medicines has taken place with the help of implementation of some lists of medicines. As shown by the result of retrospective analysis of the corresponding legislative, regulatory and legal acts, all three National lists of Essential Medicines had different structure, sometimes inappropriate to international recommendations. As we see in Table 1, the List №1 and List №3 were built without taking into account ATC codes of classification on each name of the medicine according to INN. The List №2 contained medicines according to INN taking into account ATC codes. This means that in Ukraine there has not been developed a single approach to the structure and presentation of medicines in National lists of Essential Medicines. From the moment of implementation of the concept of essential medicines in the Ukrainian Health, three editions of Regulation about National list of Essential Medicines was confirmed in Ukraine (2002, 2005 and 2016). The above-stated regulations were confirmed by the decrees of the Ministry of Health of Ukraine. This means that implementation of three National lists of Essential Medicines was connected with the confirmation of three«Regulations about National lists of Essential Medicines». Therefore, we can ensure regular revision of the key principles and order of selection of medicines and formation ofd National list of Medicines. World Essential Herewith, Health Organization has already developed recommendations and principles regarding the order of selection, formation and revision of the composition of lists of essential medicines in the national systems of the health <sup>2,9,13,16,23,29,44</sup>. Only in the last of the confirmed principles in Ukraine (2016) it was mentioned for the first time that the National list of Essential Medicines should be based on the last edition of WHO Model List of Essential Medicines 47. It means that in Ukraine from 2001 to

2009 the international concept of essential medicines in the form of one of its most important constitutent part, namely National lists of Essential Medicines (List №1 and List №2) has been implemented without taking into account WHO recommendations. Thus, the List №3 in the editions dated from 16.03.2017 and 13.12.2017 was built preserving the structure of WHO Model List of Essential Medicines and by the content corresponded to the 19th Essential Medicines List and 20th Essential Medicines List for 67.0% and 75.4%. Thus, the List №3 in the last edition was divided into sections containing medicines by INN and the appropriate medical forms. Herewith, one and the same name of medicine by INN may be presented in different sections of the list. Moreover, medicines for anesthesia and those names, which are used to provide first aid, were included in the National list of Essential Medicines for the first time in Ukraine. Taking into account the fact that the prices for medicines and mechanisms of medicines reimbursement, which are included in the National list of Essential Medicine, are regulated by the government, the inclusion of these groups ensures increase of the level of accessibility of pharmaceutical aid provided for the population in Ukraine.

It is worth mentioning that National lists in Ukraine had different names, which did not meet their high-quality composition. Thus, for example, the List №1 and the List №2 were called «National lists of essential (vitally important) medicines and medical products». Herewith, they contained only those medicines, which met international requirements. The List №3 was called «National list of essential medicines», they excluded the notion «medical products» from the list. Absence of a single approach to the development and the procedure of including medicines in the National lists of Essential Medicines, is confirmed by the fact that they were confirmed and updated without a specific chronological order, as the composition of WHO Model List of Essential Medicines is updated on a regular basis. Therefore, any changes or amendments have been entered to the List №1 during five years of its existence. Two changes and amendments have been entered to the content of the List №2. Finally, the List №3 has been developed and confirmed three years after the List №2 was confirmed. Seven changes and amendments have been entered to the composition of the List №3, two of which significantly increased the number of medicines, out of 251 names to 421 medicines. Thus, the increase of the number of medicines was equal to 95.8%, which is practically twice more. As far as we know, WHO Model List of Essential Medicines is updated once in two years. Therefore, we can say that National lists of Essential Medicines in Ukraine have been developed and updated in the way, which did not correspond to the periods of acceptance of WHO Model List of Essential Medicines.

The next issue, which should be considered separately, is a significant divergency in the number of medicines represented in National lists of Essential Medicines in different years. As we see in Table 2, in different years the number of medicines included in the National lists variated in a wide range of knowledge, from 215 (the List №3, 2009) to 780 (the List №2, 2008). By comparing data of WHO Model List of Essential Medicines in different years with the data of National lists of Essential Medicines we can state the following. Out of three lists of National lists only the List №3 mostly corresponds to the composition of the 20<sup>th</sup> Essential Medicines List by the following high-quality characteristics: pharmaco-therapeutic groups medicines and their INN. According to the number of medicines included in the National lists during different years of research, the specific weight (%) of their retail sale at the national pharmaceutical market has been changing. As we see in Figure 1, the sales volume of medicines included in National lists of Essential Medicines during 2001-2008 increased from 24.51% to 42.34% from sales at the pharmaceutical market. By accepting a new National list of Essential Medicines in 2009 (the List № 3), the sales volume has reduced significantly (13.45%) and reached a minimum number during the whole period of research. The decrease of the number of medicines in the list, and as a result, their sales volume at the retail pharmaceutical market in 2009 (the List No3) was connected with the revision of the government position regarding its financial ability to prodide accessible medicines for the population. So, the government moved from a simple declaration of accessibility of medicines to a specific implementation of the concept to provide the population with highquality, accessible and rational in use medicines. During 2017 two changes and amendments have been entered to the List No3, which significantly changed its composition and allowed to extend the volume of accessibility to provide pharmaceutical care for the population. It was connected with the implementation of government programs «Accessible medicines», the use of which means introduction of mechanisms of reimbursement of the cost of medicines for patients suffering cardio-vascular pathologies, bronchial asthma and diabetis of II type<sup>42,43</sup>. We cannot hide the fact that in Ukraine we do not have a National list of Essential Medicines for children, which WHO recommends to develop and implement in practical health protection since 2007<sup>10,48,49</sup>

#### **CONCLUSIONS:**

By ascerting the results of research, we can say for sure that the process of implementation of international concept of essential medicines in Ukraine has a complicated character of development. During the last two decades, Ukrainian government is trying to build efficient mechanisms for providing the population with accessible, high-quality and rational in use medicines, which means to introduce the key goals of National politics. Unfortunately. medical absence scientifically-motivated and single (by methodology) approaches of implementation of the international concept of Essential medicines in practical medicine, stipulates a low level of realization of humanistic principles declared by our government after 2014. One of perspective ways of increasing the level of efficiency of the concept of essential medicines in Ukraine is fruitful cooperation with international organizations and implementation of positive experience of the countries, which are developing and are in the process of reformation of national systems of health protection.

## **CONFLICT OF INTEREST:**

The authors declare that they have no conflict of interest to disclose.

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