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STANDARDS OF WORLD HEALTH ORGANIZATION IN HEALTH CARE

Abstract. Healthcare is a fundamental human right and one of the main conditions for prosperity and development. Given the importance of high-level healthcare, there is an objective need for the establishment and operation of a separate organization responsible for regulatory and normative activities in this area. As a result, a specialized agency was established within the United Nations – the World Health Organization (WHO). The areas of activity of this organization are the adoption of norms, standards, programs, etc. in the field of healthcare. A significant set of these documents are standards that set the boundaries within which to develop a particular area of healthcare. The presence of a wide range of

standards, as well as the lack of their proper reflection in the scientific literature necessitates their further study.

Therefore, the scientific article defines the role of the World Health Organization in the field of healthcare, as well as examines the history of this organization. The degree of reflection of research topics in the scientific literature is determined. The results of the WHO activity are analyzed, and also the organizational structure through which there is a realization of its functions is defined. Thus, it is determined that as of 2020 WHO has 194 member-states, and its activities are carried out through 6 regional offices.

In addition, the article identifies the main standards adopted by the WHO in terms of healthcare, namely: Standards of good pharmacy practice, the WHO international standards for osteopathy, GCP standards – good clinical practice, GMP – good manufacture practice, GLP – good laboratory practice, and Standards for organ, tissue and cell transplantation, immunization and Standards for orthosis and prosthetics. We have considered the features of each of them, as well as areas of application. In addition, an important feature of these standards is the voluntary nature of their application in the practice of healthcare in member-countries, as well as their definition not of specific areas of their application, but only a kind of framework in which this process should take place.

Keywords: WHO, Standards of good pharmacy practice, International Standards for osteopathy, GCP Standard, GMP Standard, GLP Standard, organ, tissue and cell transplantation Standards, immunization Standard, Standards of orthosis and prosthetics.

СТАНДАРТИ ВСЕСВІТНЬОЇ ОРГАНІЗАЦІЇ ОХОРОНИ ЗДОРОВ'Я У СФЕРІ ОХОРОНИ ЗДОРОВ'Я

Анотація. Висвітлено, що охорона здоров'я є основоположним правом людини і однією з головних умов процвітання та розвитку. Враховуючи значення забезпечення охорони здоров'я на високому рівні, виникає об'єктивна необхідність у створенні та функціонуванні відокремленої організації, відповідальної за регуляторну та нормативну діяльність у даній сфері. Відтак, було створено спеціалізовану установу в складі Організації об'єднаних націй – Всесвітню організацію охорони здоров'я (ВООЗ). Напрямами діяльності цієї організації є: прийняття нормативів, стандартів, програм тощо у сфері охорони здоров'я. Вагомий комплекс з-поміж даних документів складають стандарти, за допомогою яких встановлюються межі, в яких має розвиватись той чи інший напрям охорони здоров'я. Наявність широкого переліку стандартів, а також відсутність їх належного відображення у науковій літературі зумовлюються необхідністю їх подальшого вивчення.

Розглянуто роль Всесвітньої організації охорони здоров'я у сфері охорони здоров'я, а також досліджено історію її виникнення. Визначено ступінь відображення тематики дослідження у науковій літературі. Проаналізовано результати діяльності ВООЗ, а також визначено організаційну структуру, через яку відбувається реалізація її функцій. Встановлено, що станом на 2020 рік до

складу ВООЗ входить 194 країни-члени, а її діяльність здійснюється через 6 регіональних бюро.

Визначено основні стандарти, які прийняті ВООЗ в частині охорони здоров'я, а саме: стандарти належної аптечної практики, міжнародні стандарти ВООЗ по остеопатії, Стандарти GCP — належної клінічної практики, GMP — належної виробничої практики, GLP — належної лабораторної практики, а також стандарти трансплантації органів, тканин та клітин, імунізації та стандарти ортезування та протезування. Розглянуто особливості кожного з них, а також напрями застосування. Поруч із цим, вадливою рисою цих стандартів є добровільний характер їх застосування у практиці функціонування сфер охорони здоров'я країн-членів, а також визначення ними не конкретних напрямів їх застосування, а лише своєрідних рамок, в яких цей процес має відбуватися.

Ключові слова: ВООЗ, стандарти належної аптечної практики, міжнародні стандарти по остеопатії, Стандарт GCP, Стандарт GMP, Стандарт GLP, стандарти трансплантації органів, тканин та клітин, стандарт імунізації, стандарти ортезування та протезування.

СТАНДАРТЫ ВСЕМИРНОЙ ОРГАНИЗАЦИИ ЗДРАВООХРАНЕНИЯ В СФЕРЕ ЗДРАВООХРАНЕНИЯ

Аннотация. Освещено, что здравоохранение является основополагающим правом человека и одним из основных условий процветания и развития. Учитывая значение обеспечения охраны здоровья на высоком уровне, возникает объективная необходимость в создании и функционировании обособленной организации, ответственной за регуляторную и нормативную деятельность в данной сфере. Следовательно, было создано специализированное учреждение в составе Организации объединенных наций — Всемирную организацию здравоохранения (ВОЗ). Направлениями деятельности данной организации является принятие нормативов, стандартов, программ и т. д. в сфере здравоохранения. Большой комплекс среди данных документов составляют стандарты, с помощью которых устанавливаются пределы, в которых должно развиваться то или иное направление здравоохранения. Наличие широкого перечня стандартов, а также отсутствие их должного отражения в научной литературе обусловлено необходимостью их дальнейшего изучения.

Рассмотрена роль Всемирной организации здравоохранения в сфере здравоохранения, а также исследована история возникновения данной организации. Определена степень отображения тематики исследования в научной литературе. Проанализированы результаты деятельности ВОЗ, а также определена организационная структура, спустя которую происходит реализация ее функций. Определено, что по состоянию на 2020 год в состав ВОЗ входит 194 страны-члены, а ее деятельность осуществляется через 6 региональных бюро.

Определены основные стандарты, принятые ВОЗ в части здравоохранения, а именно: стандарты надлежащей аптечной практики, международные

стандарты ВОЗ по остеопатии, Стандарты GCP — надлежащей клинической практики, GMP — надлежащей производственной практики, GLP — надлежащей лабораторной практики, а также стандарты трансплантации органов, тканей и клеток, иммунизации и стандарты ортезирования и протезирования. Рассмотрены особенности каждого из них, а также направления применения. Рядом с этим, порочной чертой этих стандартов является добровольный характер их применения в практике функционирования сфер здравоохранения стран-членов, а также определения ими не конкретных направлений их применения, а только своеобразных рамок, в которых этот процесс должен происходить.

Ключевые слова: ВОЗ, стандарты надлежащей аптечной практики, международные стандарты по остеопатии, Стандарт GCP, Стандарт GMP, Стандарт GLP, стандарты трансплантации органов, тканей и клеток, стандарт иммунизации, стандарты ортезирования и протезирования.

Formulation of the problem. Ensuring the effectiveness of the healthcare sector is the foundation for the realization of the rights to its protection among the entire population of the planet. Therefore, within each state the postulates of construction of system of public healthcare services characteristic of it are defined. However, the constant development of the international relations, with the deepening of globalization, push the boundaries of the international cooperation, adding to its composition and the field of healthcare. With this in mind, the World Health Organization was created, the preamble of which emphasizes that the state's achievements in improving healthcare are a value for all, from individual countries to the world community as a whole. One of the activities of this organization is the coordination of the member-states to build national healthcare systems by developing norms, standards and various programs. The presence of a signifi-

cant list of standards that determine the principles of construction of the components of the healthcare system determines the relevance of the study, and the lack of a structured list of the WHO standards in the domestic scientific literature that operate in the world further increase the value of this study.

Analysis of the recent research and publications. In the domestic scientific literature the WHO standards in the field of healthcare, unfortunately, are considered only in fragments and do not receive proper definition. Thus, Pasivchnyk O. considered the WHO standards in the field of organ transplantation, Gala L. the standards of good pharmacy practice, Lynnyk S. studied the implementation of the WHO European strategy for the prevention and control of viral diseases, and Shafransky V. covered the use of documents of the World Health Organization in the development of public healthcare in Ukraine. At the same time, such domestic and foreign scien-

tists as D. Clark, N. Kryzyna, V. Lehan, Z. Chernenko, N. Handel considered in their works the provisions of certain international agreements in the field of healthcare, studied the peculiarities of the functioning of the national healthcare systems of different countries, etc. However, the presence of a sector of unexplored issues necessitates in-depth study of research topics.

Purpose of the article. In view of the above, the purpose of this research is to study the existing standards of the World Health Organization in the field of healthcare with the disclosure of their features and areas of regulation.

Presentation of the main research material. The WHO is a specialized agency within the United Nations whose mission is to ensure that all peoples achieve the highest possible level of health. As of the beginning of 2020, the organization has 194 member-countries [1]. The most important document of the WHO – the statute, which was adopted in 1946, defines the functions of the organization that includes the establishment of international standards in the production and circulation of food, medicine, biological and other products [2]. An important remark is that the regulations of this organization are not mandatory, and the direction of their implementation in a mandatory or recommendatory form is determined directly at the level of individual member-states of the organization.

Over the past few years, the WHO's healthcare efforts have yielded visible results and brought the healthcare sector to the top of the political agenda. These issues began to be discussed at political forums, additional financial

resources are directed to this area, and so on.

In order to best define the development priorities of the healthcare sector by region and to maintain close links with the needs of the healthcare systems of the member-countries, the main activities of the World Health Organization are carried out through its regional offices and representative offices. Thus, there are regional offices for Africa, America countries, Southeast Asia, the Eastern Mediterranean, the European Regional Office and the Office for the Western Pacific [1].

The Office of the WHO European Region, which includes 53 countries, including Ukraine, is located in Copenhagen (Denmark) and is headed by the Regional Director. In addition, it includes 4 branch offices, as well as offices located in 30 member-countries [1]. Numerous documents, decrees, decisions, declarations of the specialized medical organization – WHO, which relate to certain areas of combating adverse events in the field of morbidity, as well as improving the level of medicine around the world are very important for specific areas of medicine and undoubtedly form the basis for thorough research and practical actions by healthcare system organizers in the member-countries. One of the types of such documents are the WHO standards, the structure of which can be schematically depicted using Fig. 1.

Starting to analyze the data shown in Fig.1 it should be noted that this list is not exhaustive, but at the same time includes standards that are most widely used by the WHO member-countries. Let us consider them in more detail.

Let us start with the study of the structure of standards of good pharmacy practice (GFP), which were developed by the WHO together with the International Pharmaceutical Federation in 1993, with their subsequent update in 1997 and 2011 [3, p. 88].

The beginning of their use in Ukraine began with the order of the Ministry of Health (MOH) No. 455 of 30.05.2013, which recommended their use in healthcare facilities as a basis for improving the quality of medical care, as well as an information base to form a list of standards of good pharmacy practice [4]. The purpose of the good pharmacy practice standards is to improve the health of people and

help those who have health problems through the effective and efficient use of medicines [5].

However, at the same time, pharmacists, along with other healthcare professionals and patients, must take responsibility for the end result of treatment. In addition, it should be noted that the GFP standards set only a certain framework within which each the WHO member-state develops its own national standards to provide its citizens with quality medicines and related pharmacy products, as well as professional advice and information. Their application in the practice of forming national pharmacy practices is only of a recommendatory nature.

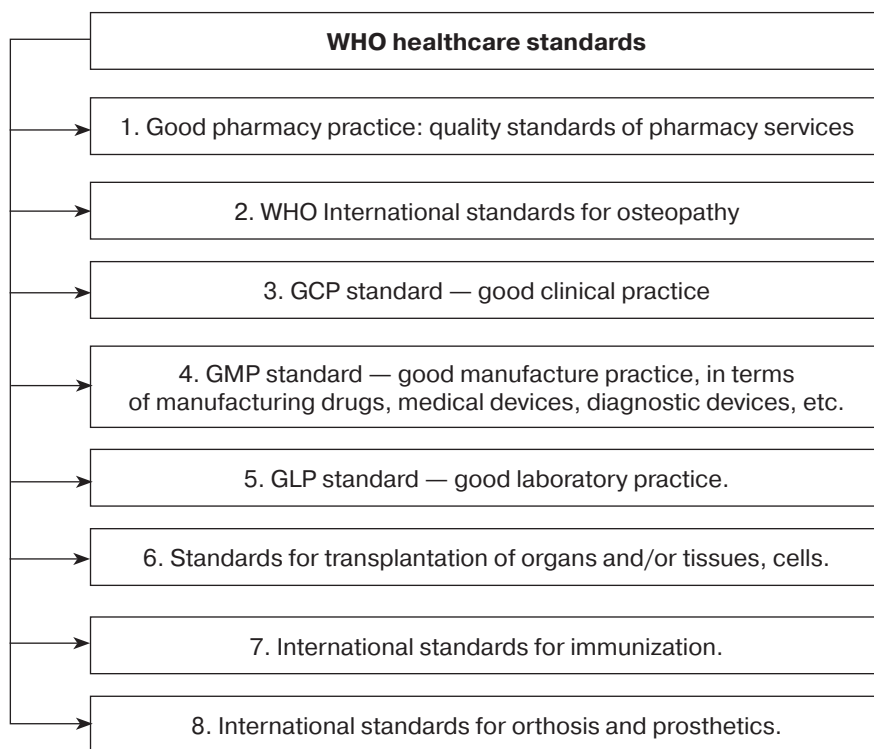


Fig. 1. The structure of the WHO standards in the field of healthcare

Source: author's own development based on [1; 3; 5; 7; 8; 9; 10; 11]

In addition, given the continuous development of the pharmaceutical industry and the desire of the pharmaceutical professionals to provide their services at the highest level, the process of improving the pharmaceutical supply of the population through the application of good pharmacy practice is also becoming continuous and requires proper information to maintain its effectiveness. It should be noted that the professional standards of pharmacy practice in most countries are developed by professional associations, which are responsible for their observance, to ensure the interests of healthcare, safety and welfare of the population.

As already mentioned, the WHO common standards are adapted separately to the national standards of its member-countries. Therefore, we will analyze the professional standards of good pharmacy practice in the world using Table 1.

Thus, from the table we can see that although the application of standards of good pharmacy practice differs in the WHO member-countries, but all of them have their own characteristics, namely the focus on improving the quality of pharmaceutical services and assessing the level of their provision.

In addition, it should be noted that the evaluation of the effectiveness of measures taken to implement the GFP standards is carried out using the following indicators that are defined in a special WHO project on the development and implementation of standards in pharmacies of the newly independent states [5]:

- structure indicators: applied to pharmaceutical establishments, equip-

ment and persons to assess the necessary elements;

- process indicators: used in the assessment of technical and interpersonal activities over a period of time;

- return indicators: used in assessing achievements;

- performance indicators: aimed at assessing the consequences of achievements and determining their impact on the final consumer.

The next standard that we study in the scientific article is the WHO International Standard for osteopathy. The practice of using this area of medicine — osteopathy is relatively new. Its essence is to be treated with the help of hands of a doctor-osteopath. Due to such a primitive direction of treatment, this direction of medicine has not been recognized for a long time by the doctors-supporters of the traditional medicine, which was expressed in frequent manifestations of underestimation of osteopathy, which is wrong.

Taking into account the importance of a new direction of medicine and the development of a mechanism for its implementation in the medical practice around the world, the WHO has developed the International Standards for osteopathy, which defines the philosophy and characteristics of this treatment, models of structure-function relationships within this approach. In addition, the standards describe the process of training osteopaths-doctors that should last at least 3.5–4 years and include sections specified in them. The final element in the structure of the International Standards for osteopathy is a description of contraindications to the use of this area of medicine [6].

Table 1

Professional standards of good pharmacy practice in different countries

Country	Document	Institution responsible for development	Assignment of standards
Great Britain	Professional standards of public healthcare practice for pharmacies	Royal Pharmaceutical Society	– to assist pharmaceutical workers in providing and controlling the quality of services at the appropriate level on the way to improving the health of citizens.
Ireland	Methodical manual on pharmaceutical practice	Pharmaceutical Society of Ireland	– to determine the quality of pharmacy services by the responsible institution; for measurement – for pharmaceutical workers as a guide for self-examination and identification of areas that need special attention; – non-compliance with the requirements adversely affects the registration status of retail pharmacies and the pharmaceutical business.
Australia	Professional standards of practice	Pharmaceutical Society of Australia	– for accreditation of pharmacies by the relevant regulatory authorities; – for pharmacists as a guide for continuous evaluation of their activities and achievement of the desired level of standards of practice.
Canada	Concept of standards of practice of the Canadian pharmacists	National Association of Pharmacy Regulators	– for pharmaceutical regulators to specify the standards against which their work is evaluated; – as a source of explanation for the duties of a pharmacist.
Norway	Standards of pharmaceutical practice	Norwegian Pharmaceutical Association	– for owners of the pharmaceutical business to self-monitor the quality of the pharmacy services.

*Source: author's own development based on [3, p. 89]

In addition, it should be noted that in Ukraine this area of treatment has not become widespread, which is due to the lack of proper training in this area and obtaining permits to practice osteopathy by incompetent specialists,

which often reduces confidence in this type of treatment.

Continuing the outlined line of the research, consider the GCP Standard, which is called – good clinical practice. Thus, GCP (Good Clinical Practice) is

an international ethical and scientific standard for planning and conducting research with human participation as a subject, as well as documenting and presenting the results of such research [7].

Compliance of scientific research with this standard means public compliance with the following [7]:

- the rights of research participants;
- rules for ensuring the safety of its participants;
- the desire not to cause harm;
- requirements for the reliability of the research.

These rules were initiated in the Helsinki Declaration of the International Conference on Harmonization. Together with GMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice), GCP aims to standardize some aspects of the quality of healthcare of the population. GCP, GMP and GLP Standards are considered the “three whales” of evidence-based medicine [7]. Adherence to this Standard serves as a guarantee to the society that the rights, safety and well-being of the subjects are protected and in accordance with the principles established by the Helsinki Declaration of the World Medical Association (WMA), and that the clinical trial data are reliable.

As for the GMP (Good Manufacturing Practice) rules, the practice of their application began in 1969, when the WHO invited member-countries to apply the scheme of quality assurance of drugs in the international trade. Currently, these rules are used by about 140 countries [8]. Within this system of rules there is a confirmation at the request of the participating-countries, represented by their authorized bodies,

the authorization of placing the drug on the market in accordance with the jurisdiction of the applicant-country; the fact of conducting constant inspections and compliance with these rules at the enterprise-manufacturer of drugs; verification of submission for consideration and authorization in the country undergoing certification [8].

The advantages of this system of standards include ease of entry and wide territorial coverage, in contrast to the disadvantages of the lack of guarantee of the reliability of the control system of partners, because the inspection of inspectors or manufacturers can not interfere with external participants.

In addition, it should be emphasized that the WHO does not issue certificates on its own, but only provides the interested participants with a format of possible bilateral cooperation.

As part of the certification of drugs for the international trade, a country that exports drugs at the level of its state does the following (Fig. 2).

All other areas of work not described in Fig. 2. are related and subordinated to the main activities.

In turn, the country-importer of medicines requests certificates and uses them during the registration of new drugs, as well as in the post-registration period to address issues of quality, packaging, labeling, etc.

Within this block of standards, the rules of Good Laboratory Practice (GLP) are also highlighted, the operation of which is aimed at ensuring the quality and reliability of research results [9]. The principles of their implementation occupy an important place in the structure of the rules of Good Laboratory Practice. These principles are an ad-

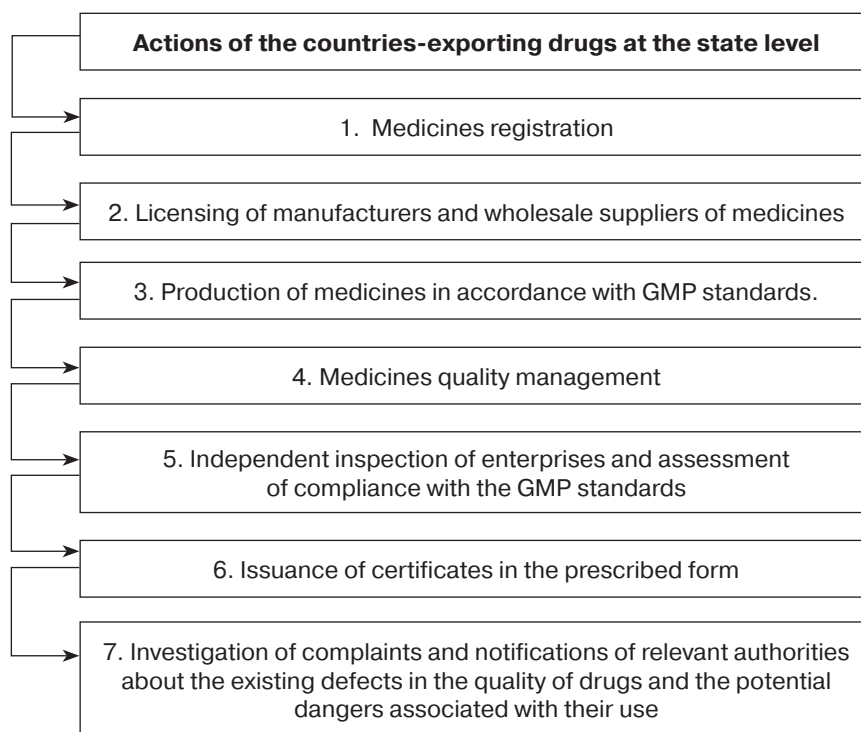


Fig. 2. Actions of the country-exporter of medicines within the framework of GMP standards

*Source: author's own development based on [8]

ministrative concept that includes the organizational process and conditions under which it is planned to conduct laboratory tests, the process of research, their monitoring, registration and storage of data, the formation of a report on research results. The use of the GLP principles is very important for the national authorities and agencies, which are responsible for analyzing the test results and assessing the toxicity of the chemical compounds. In addition, these principles provide for the use of recommended standards for a wide range of tests and are aimed at their regulation at a high level, and also applies to a wide range of chemicals, including cosmetics, industrial, chemical, etc. [9].

Analyzing the world experience of using the GLP rules, we can conclude that it is mostly used in pre-clinical trials, which are very important in the field of healthcare. The use of rules in this direction ensures compliance with high-quality, reasonable data, which are determined by other countries, which ultimately helps to avoid repeated pre-clinical trials, which in turn will save time and costs. In each country of the European Union there is a laboratory certified according to the GLP standards, in addition to the mandatory condition of the National GLP Control Body, the National GLP Program, the National GLP Regulatory Body.

In addition to the above, there are also the WHO standards for transplantation of organs and/or tissues, cells.

The legislation of the WHO transplantation rules was implemented by the adoption of the Guidelines for Transplantation in 1991 and was a kind of reaction of the organization to human organ trafficking for profit [10, p. 189]. The adoption of these principles has influenced the reform of the field of transplantation and the legal framework for its implementation, which eventually led to their revision. Therefore, on May 21, 2010, the World Health Assembly adopted a resolution approving a new version of the WHO Guidelines [10, p. 190].

The updated WHO guidelines for the transplantation of human cells, tissues and organs include 11 key components. Their main purpose is to provide an orderly structural basis for the procedure of acquisition and transplantation for medical purposes with mandatory adherence to the principles of ethics. In addition, a by-product of the development of these principles is the formation of the Global Transplant Database, which should contain all the information about transplantation and donation of organs, cells and tissues within the world [10, p. 191]. The global database consists of four components that have a permanent basis: activities and types of practice; regulatory framework and organizational structure; vigilance, dangers and measures; xenotransplantation. In the near future, it is planned that the Global Transplant Database will be a source of information for all those involved in this issue, including members of the public who, understanding

the value of transplantation, wish to participate in it.

In addition, the Istanbul Declaration on Transplant Tourism and Organ Trade, adopted by the Istanbul Summit in 2008, deserves special attention when considering this issue. This document emphasizes the role of the state in the development of posthumous donation, as well as the cessation of commercialization of organ transplantation, along with the exclusion of the possibility of selling organs during their use from living donors [10, p. 192]. In addition, the document describes the role of promoting medical knowledge among the population, as well as highlighting the humanistic principles of posthumous donation, which will increase the number of such transplants, thus reducing the need to involve living donors for whom such operations pose a health risk. This document also emphasizes the need for a fair distribution of organs, according to medical factors.

A separate group is formed by the International Standards for orthosis and prosthetics, which were developed by the WHO in partnership with the International Society for Prosthetics and Orthopedics (ISPO) and the United States Agency for International Development (USAID) [11]. The implementation of these standards aims to support countries in fulfilling their obligations under the Convention on the Rights of Persons with Disabilities and achieving the goals of sustainable development, including the goals of ensuring a healthy life and improving the well-being of all people of all ages [11].

The standards for orthosis and prosthetics provide guidance for the development of the national policies, plans

and programs for prosthetic services, and orthopedics to the highest standards. These standards are divided into two documents: standards and implementation guidelines. Both documents cover four areas of the healthcare system [11]:

- policy (management, financing and information);
- products (prostheses and orthoses);
- staff (labour force);
- provision of services.

The standards were developed in consultation with experts from around the world through a managing group, a development team and an external review team.

The final element of our study is the analysis of the WHO immunization standards, which regulate the creation of biological reference materials, as well as the development of guidelines and recommendations for the production and control of the biological assets and technologies [1]. These standards are based on the scientific consensus reached through international consultations. They help ensure that the WHO member-states ensure the proper quality and safety of the biological medicines and relevant biological diagnostic tests in all countries of the world.

Ensuring compliance with these standards involves close cooperation with the international scientific and professional communities, regional and national regulators, manufacturers and expert laboratories in all countries of the world. Activities under the WHO program for the standardization of the biological products include the development and implementation of manuals and biological reference materials [1].

Such manuals and reference materials describe the process of production and testing related to quality control, biological drugs to ensure the safety and effectiveness of the products [1]. At the same time, the manuals provide more general information on topics of interest to the national regulators and manufacturers, while the recommendations contain technical specifications for the production and quality control of specific products.

Conclusions from the research.

Summarizing the above, we can conclude that the World Health Organization is actively involved in ensuring a high level of healthcare in the world by providing recommendations and adopting regulations in this area. However, a characteristic feature of all these documents is the voluntary direction of their application by the member-countries of the organization. One of the areas of the WHO regulations is the adoption of standards in the healthcare system. The most popular of these are Standards of good pharmacy practice, the WHO International Standards for osteopathy, the so-called “three whales” of evidence-based medicine – Standards of GCP – Good Clinical Practice, GMP – Good Manufacture Practice, GLP – Good Laboratory Practice, and Standards of transplantation of organs, tissues and cells, Immunization and Standards of orthosis and prosthetics. The functioning of all the above documents provides a single goal – to improve the quality of medical services, as well as to ensure the development of healthcare in the world by eliminating duplication of medical research along with the formation of standards for various medical procedures. As a result,

all this makes it possible to maintain an adequate level of healthcare in all WHO member-countries, which is extremely important.

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