SECTION 9. ORGANIZATION OF PHARMACEUTICAL BUSINESS

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9.1 The system of pharmaceutical information and its role in the pharmaceutical industry

In a modern world where medical (pharmaceutical) science is constantly evolving, pharmaceutical information (FI) is becoming a key tool for providing quality medical care and drugs reasonable choice. The essence of FI is the transmission and distribution of objective data on medicines (drugs), their properties, application, side effects and safety of use. This information can be presented in various forms and publications, including medical directories, scientific publications, brochures, instructions for medicinal products (MP), as well as electronic resources and databases.

Features of FI are in a high degree of detail and scientific validity of the presented information. It should be reliable, credible and up-to-date to ensure patient safety and treatment efficiency. In addition, FI should be available to health care professionals in a convenient way so that they can quickly find the necessary information in the process of work.

The relevance of FI in the modern world is difficult to overestimate. Every day, new drugs are coming to the market, research in the field of medicine, pharmacology and pharmacotherapy expand our knowledge of the effectiveness, side effects and drugs interaction.

The growing amount of clinical research data, the development of new technologies in the industrial production of medicines, as well as the need for compliance with safety and efficiency standards, make FI an important tool for modern medicine. In addition, in the context of the rapid development of medical technology and the increasing complexity and prevalence of diseases, pandemics and man-made disasters, the topical FI becomes necessary not only for doctors, but also for patients who are increasingly actively involved in the decision-making process regarding their health.

The organization of the structure of the pharmaceutical industry depends on many factors, including regulation by government agencies, requirements for the quality and safety of medicinal products, availability of medical care and consumer requirements.

FI can be used to analyze the effectiveness and effectiveness of various organizational models of the pharmaceutical market, to study the relationship between drug availability and public health, as well as to predict trends in the development of the industry. One of the key aspects of the pharmacy economy is the cost and availability of medicines. FI can help in studying the factors affecting the cost of drugs, including research and development costs, production, marketing and distribution.

Analyzing these factors, it is possible to develop strategies to reduce the cost of medicines and ensure their availability to a wide range of patients. FI can be used to investigate the effectiveness of various health programs and policies, including insurance programs, health innovation support programs, and price policy regulation.

Thus, the relevance of FI is its importance for ensuring the safety, effectiveness and quality of treatment, as well as maintaining an informed field for patients in the field of medical care. Together with scientific and theoretical analysis, FI is a powerful tool for studying and solving problems related to the organization and economy of the pharmaceutical industry, which contributes to the further development of medical science and improvement of medical practice.

The purpose of this work was to study the peculiarities of the concept of FI, since the adoption of domestic regulatory legal acts to ensure the digital framework of information in Ukraine prompted the authors to study and update the topic, namely, the study of electronic sources of information and work with them, the study of the structure of the domestic system of FI and the study of new requirements for FI.

Chapter 1. Types, features and sources of pharmaceutical information.

FI – information characterizing the pharmaceutical and medical aspects of the drugs circulating in the pharmaceutical field, with a description of pharmacological, chemical, biochemical, pharmacological and economic properties of drugs [289]. FI fully reveals information such as: production, distribution and release of drugs;

management of information flows of financial processes; resources of medical support of the population; information on the economic and information plan exchanged by management systems. FI can be characterized by the following aspects and indicators: Quantity, availability, accuracy, efficiency and timeliness, reliability, completeness. Categories that reflect the content, purpose and features of FI, allow to distinguish the following types: Scientific, normative, statistical, advertising, legal, scientific-practical, popular science, sanitary-educational, educational and other. For health professionals, one of the most significant types is scientific FI – published in professional (specialized) periodicals information, facts that are the original results of scientific research and development in the field of information, intended mainly for use by other scientists and developers, and also for the implementation of health care [291]. Information about drugs – published information, facts about medical, pharmaceutical, consumer and other characteristics of drugs based on scientific information and intended mainly for use by specialists in the field of pharmaceutical and medical practice, as well as for the population. The FI system is a set of institutions, specialists, information processes and technologies, the purpose of which is to collect, process, store and provide data obtained by pharmaceutical science and practice.

FI can be divided by its characteristics into different types. According to the management functions, information is divided into: Planning and accounting, regulatory and reference, reporting and statistical. Planned (directive) information includes the directive values of planned and controlled indicators of business planning for a certain period in the future (five-year, year, quarter, month, day). For example, the production and sale of medicinal products (MP) in natural and cost terms, the planned demand for these products and the profit from its implementation, etc. Accounting information reflects the actual values of the planned indicators for a certain period of time. On the basis of this information, planned information can be adjusted, an analysis of the activities of the organization is carried out, decisions on more effective management, for example, an information center, a clinic, a pharmaceutical enterprise, are made. As accounting information is information of natural (operational) accounting, accounting, financial accounting [294].

For example, the accounting information is: The number of requests for drugs received in the center of information about drugs during the day (operational accounting), the salary of an employee for work (accounting), the actual cost (accounting and financial accounting). Regulatory reference FI contains various reference and regulatory data related to the development, production, analysis, distribution of LP. This is the most voluminous and diverse type of information. Examples of regulatory and reference information can be: State Pharmacopoeia; Standards of production and quality control of MP; cost standards (rates, tariffs); reference data on suppliers and consumers of pharmaceutical products; other information about pharmaceutical products. Reporting and statistical FI reflects the results of the actual activities of a pharmaceutical or medical enterprise. It is necessary for the management of the company, higher management bodies, state statistics bodies, insurance, tax authorities. An example of this type of information can be information provided to public authorities.

FI Classification in terms of control (at the place of occurrence) is divided into input and output. Input information is information that comes to the enterprise (structural unit) from the outside and is used as primary information for the implementation of its functions [296]. Source information is information that comes from one control system to another. The same information can be input for one structural unit of both its consumer and outgoing – for the unit that produces it. The form of FI representation can be in the alphabetical-digital context (in the form of a set of alphabetic, digital and special characters) and in the graphic context (in the form of graphs, diagrams, drawings). Physical media can be paper, magnetic disk, images on the display screen, etc.

There are specific features of FI, which are given below. Number – the amount of data expressed by any quantitative indicator. Accessibility - availability of FI means a real opportunity for a particular specialist or patient to obtain the necessary information about his problem from all known sources in the world. Accuracy: The accuracy of the data is understood to mean their compliance or maximum approximation to the facts of clinical or pharmaceutical practice that exist in real health

practice. An important characteristic of information is its timeliness (efficiency). Efficiency reflects the relevance of information for the necessary calculations and decision-making in the changed conditions. Reliability determines the permissible level of inaccuracy of incoming information so that the inaccuracy does not affect the result and the efficiency of the system is preserved. Sufficiency determines the amount of information necessary to meet the information needs of the consumer. Depth determines the degree of depth of information search.

Consumers of FI are: Scientists, pharmacists, doctors, medical workers, heads of health care, executive and legislative bodies, patients (population) and others. The choice of the participants of the pharmaceutical market of the method, reception, or means of exchange of information depends primarily on information needs, which are determined by their individual preferences [298].

Sources of FI can be: Medical (pharmaceutical) magazines, directories, textbooks; libraries; Electronic directories and resources (Internet); advertising; mass media (programs on television and radio on medical topics); professional information of medical and pharmaceutical associations and scientific societies; conferences; Manufacturers of drugs; liner sheets; colleagues and others

In fact, the consumers of FI are all participants of the pharmaceutical market, but the two main groups are health professionals and the population – consumers of pharmaceutical products. And it is clear that one of the most important conditions for the rational use of drugs is to provide all participants in this market with complete, reliable and objective information about drugs and other pharmaceutical products. Consumers can obtain this information from such sources, but, first of all, from the existing legislative acts approved at the state level [292].

For example, the National List of major drugs. The world experience of the health care system shows that the most effective way to use budgetary resources allocated for pharmacotherapy is the rational use of drugs. This global problem has a significant information component. Therefore, in the mid-70s of the twentieth century. The who began to develop the concept of basic drugs. Currently, about 160 who Member States have the National List of essential medicines – a list of medicines that

provide the minimum needs of the basic health care system, which includes the most effective, safe and least expensive medicines designed to treat the country's priorities for pathological conditions. In Ukraine, the National List of essential drugs, which includes more than 215 international non-proprietary names of drugs, is harmonized with the sample list of who main drugs.

Also, the health care system of developed countries of the world provides for the creation of a formulary system, the main principle of which is the use of medicines with proven effectiveness. This system is provided by appropriate formulas, which clearly define effective, safe and economically feasible drugs, which are constantly used in medical practice. The form provides a multidimensional information support for the rational use of drugs: Indications, contraindications, side effects and complications in the application, etc., and in the information plan is associated with the standards of diagnosis and treatment.

The State Pharmacopoeial Center (SPC) of the Ministry of Health of Ukraine (MHU) is working to update the State drug treatment form, the first issue of which was approved in 2009 [290]. The State Pharmacopoeia of Ukraine of the first edition (SPU 1), which entered into force in 01.10.2001 according to the order of the Ministry of Health of Ukraine No. 95, as well as the addition to the SPU is a legislative document and contains a list of medicinal products recommended for use, with a description of their properties, quality control methods (QCM), storage rules, as well as the statement of general methods of analysis of drugs, appropriate equipment, etc.

Protocols of the pharmacist for the release of over-the-counter drugs approved by the order of the Ministry of Health of Ukraine No. 7 of 05.01.2022 are intended for information support of the release of over-the-counter drugs when the patient is treated without a prescription. There are also other types of FI carriers. Paper media: Instructions for the medical use of drugs; periodicals (specialized for health professionals and popular ones); specialized medical and pharmaceutical literature (monographs, textbooks, manuals, guidelines, abstracts, etc.).

Electronic carriers of information: Official websites of the Ministry of Health of Ukraine and other governmental agencies; Electronic databases containing medical

and FI; sites of manufacturers, distributors and distributors of pharmaceutical products; electronic textbooks, reference books; blogs and social networks. Information on television and radio: Advertising information about drugs; television and radio programs devoted to health, prevention and treatment of diseases. One of types of FI is the knowledge and experience of health care professionals: Medical and pharmaceutical personnel, medical and pharmaceutical representatives of drug companies [293].

Certain characteristics have documentary and electronic sources of scientific information. The source of scientific information is a conventional designation of a scientific document or publication, which serve not only as the most important sources, but also as a means of transmitting scientific information in space and time. The form of presentation of the source of scientific information can be divided into documentary (books, magazines, manuscripts) and electronic (electronic versions of documentary sources, electronic databases, global information networks, etc.). The "documentary source of scientific information" means a document containing a message. Documentary sources contain the main amount of information used in scientific, teaching and practical activities [295].

Characterizing documentary sources of scientific information, it is necessary, first of all, to emphasize their diversity. All documentary sources of scientific information are divided, first of all, into primary and secondary. Primary documents and publications contain, as a rule, new scientific and special information, in secondary – the results of analytical-synthetic and logical processing of primary documents. Evaluation of documentary sources of information includes such criteria as the completeness and reliability of data, the timing of their publication, the presence of theoretical generalizations and critical materials, the reality of their receipt. As for the task of a specific search, each of the listed sources has its advantages and disadvantages. In most cases, any book has such a loss of relevance of the given data [289].

Sometimes a scientific journal may be considered an imperfect source of information. No matter how highly specialized it may be, its subject matter is much

wider than the specific interests of a specialist, materials on any topic are always scattered in a huge number of magazines. The same will be ambiguous assessment of all other documentary sources of information. It is important here, however, to see not only the shortcomings, but also the opportunities that open when using each of their species. It is necessary to remember the originality of such a source as conference materials containing information about research and research and scientific works, their preliminary results [289].

The necessary materials can be contained in special technical editions, and some of them, for example, descriptions of inventions and author's certificates, contain not only information from certain technical devices, but can help to trace the history of a particular invention and get an idea of the modern direction of scientific and technical thought in the pharmaceutical industry. Characterizing certain types of secondary documents and publications, it should also be emphasized that they are all different in their content and purpose. From the above, we can conclude that the importance of knowledge of all documentary sources of information in a particular field and be able to choose from them those that contain the necessary information for work [297].

In the form of scientific documents are divided into: Text (books, journals, manuscripts); graphic or visual (drawings, diagrams, graphs, plans, maps, diagrams); audiovisual (sound recordings, films, diappositives, etc.).

Chapter 2. Domestic system of pharmaceutical information and modern requirements to it.

The development of electronic technologies for the creation, storage and delivery of documents led to the emergence of compact optical disks, global information networks and other electronic sources of information. Depending on the access mode, electronic sources of information can be divided into local access sources (with information fixed on a separate physical media, which must be placed by the user in the computer) and sources of remote access (with information on winchester or other storage devices, or placed in information networks, on the Internet). Materials contained in electronic sources of local and remote access are considered published [299].

Currently, from existing types of electronic sources, the following can be distinguished: Electronic versions of periodicals and newspapers, e-books, computer conferences, global information networks, electronic libraries, electronic media (media) - television, radio, social networks. Electronic library is a digital library, a kind of automated information system in which full-text and multimedia documents are stored and can be used in electronic form, and software provides a single access interface from another point to electronic documents containing texts and images.

The Internet is a global information space based on the most advanced technologies, which has a wide range of information and communication resources and contains enormous amounts of data.

Earlier in Ukraine there was and quite effectively functioned the system of FI, which had a hierarchical structure. It has evolved from the times of the existence of the USSR to modern realities. However, when restoring the system, it is important to take into account modern needs and technologies. For example, the integration of information technology can facilitate access to the FI, make it more accessible and convenient for health professionals, pharmacists and patients. In addition, the creation of centralized databases can facilitate the monitoring and control of the distribution and use of drugs. As for the legislative aspect, it is important to develop transparent and effective mechanisms for regulating pharmaceutical information that would ensure the quality and reliability of information, as well as protect the interests of patients. Compliance with international standards and best practices in this area is also an important step towards building an effective FI system.

In general, restoration and modernization of the FI system in Ukraine can contribute to improving the availability and quality of medical care for the population. The main laws that have a direct regulatory impact on the system of informing about drugs, as well as on the system of FI regulation in general, are the Laws of Ukraine and other regulatory legal acts:

- "Fundamentals of Ukrainian legislation on health care" (2024).
- "About information" (2020).
- "About medicines" (2023).

• "About advertising" (2023).

• "On the main principles of information society development in Ukraine for 2007-2015" (2007).

• "About scientific and technical information" (2014).

• "About television and radio broadcasting" (2022).

• "About information agencies" (2010) [300].

In Ukraine, the restoration of the FI system is carried out through various executive authorities and organizations. MHU is the body responsible for regulating this area. In accordance with the orders of the Ministry of Health, the rules for advertising drugs, requirements for information about their use, and the procedure for monitoring adverse reactions are established.

The State Pharmacological Center (SPC) is a subordinate structure of the Ministry of Health, which deals with the regulation of information on pharmaceuticals. The SPC aims to ensure the safety and quality of the pharmaceutical market by carrying out scientific, expert and advisory activities. One of the tools that specialists use to obtain information is a specialized information service that operates at the State Department of Public Health. For example, the State Register of Medicines of Ukraine, which contains important information about all registered medicines in Ukraine, is posted on the official website of the SPC. Also, the SPC has developed and is monitoring the constant updating of the electronic version of the directory of drugs[302].

Given the growing importance of the availability and quality of FI, it is important to continue to develop these regulatory tools and mechanisms. Such a system allows you to effectively control the quality and safety of pharmaceuticals, as well as provide specialists and citizens with the necessary information for making informed decisions in the field of health care. Legal, organizational and methodical support of the FI system in Ukraine takes place through various bodies of executive power and industry management. The Ministry of Health of Ukraine is the leading body responsible for this area. In accordance with the orders of the Ministry of Health, the issues of

advertising drugs, requirements for information about their use and the procedure for monitoring side effects are regulated.

Certain functions characteristic of drug information centers in Ukraine are performed by relevant divisions of state institutions and institutions, information centers of specialized publications, and leading educational institutions. In accordance with the EU directive 92/27/EEC dated 31.03.1992 "On the labeling of medicinal products for humans and on the annotation-insert in the package", information about drugs has 2 levels:

• consumer, intended for patients - this information is provided in the annotation-tab or on the package;

• professional, intended for doctors and pharmaceutical workers - this information is provided in the instructions for medical use, which is provided separately from the medication package, as well as printed in specialized publications [290].

Information for medical and pharmaceutical consumers regarding the properties and use of drugs should, first of all, contain the necessary data on the safe and correct use of these drugs. According to EU requirements, pharmaceutical information provided to consumers (patients) should be:

• reliable and modern, based on evidence-based medicine;

• to provide an opportunity to compare the benefits and risks of all existing methods of treatment or non-treatment;

• be adapted to the needs of the consumer (understandable and accessible).

By analogy with the Directive of the European Parliament and the Council of the EU 2001/83/EC of 06.11.2001 "On the body of laws of the Community in relation to medicinal products for humans", Ukrainian legislation also requires mandatory placement of information about medicinal products in the leaflet and/ or on the packaging of this medicine. Order of the Ministry of Health of Ukraine No. 1948 of 08/21/2020 "On approval of the Procedure for examination of registration materials for medicinal products submitted for state registration (re-registration), as well as examination of materials on making changes to registration materials during the

validity of the registration certificate" regulates the requirements for information contained on the leaflet, as well as on the primary and secondary packaging. This order has separate annexes that indicate the requirements for information contained in the instructions for medical use for prescription and non-prescription drugs [295].

There is a distinction between passive acquisition of FI by a potential consumer ("push" information) and active search for information by a consumer ("pull" information). Passive is, for example, receiving a FI by a consumer while viewing a drug advertisement. The main law of Ukraine, which regulates the procedure for advertising medicines and the requirements for FI contained in this advertisement, is the Law "On Advertising" in 30.05.2023. № 3136-IX. Ukraine, like the EU countries and the USA, regulates information about medicinal products, which is provided to both patients and medical professionals. EU Directive 92/27/EEC and other legislative acts define two levels of information on drugs: consumer and professional. These levels differ by the target audience and the nature of the information provided. According to these documents, information for medical and pharmaceutical consumers must be reliable, based on evidence-based medicine, provide the possibility of comparing the benefits and risks of different methods of treatment or refusal of treatment, as well as be adapted to the needs of the consumer, that is, understandable and accessible.

Ukrainian legislation also requires mandatory placement of information about drugs on leaflets and/or on the packaging of these drugs. Regarding the advertising of medicines, Ukraine has the Law "On Advertising", which establishes the rules of advertising and requirements for FI contained in advertising. Promotion of medicinal products for medical consumers is carried out in accordance with this law and other regulatory legal acts. FI directions can be different, such as "proactive", "referential", "reactive" and "supportive" information.

In EU countries, such directions are regulated by a number of codes of ethical promotion of medicines. In the US and some other countries, direct-to-consumer (DTC) information is also allowed - information aimed at the patient, which is sent by pharmaceutical companies directly to the consumer. In contrast to the USA, in EU countries such a technique is prohibited, so pharmaceutical companies use the

following categories of information about drugs that are not considered promotional [298]:

1. "Proactive information" provided to the public should be limited to general information about diseases and methods of prevention without mentioning specific drugs.

2. "Reference information" about diseases and medicines, which is available to patients and all citizens in libraries, as well as via the Internet.

3. "Reactive information" about drugs, which is sent in response to requests from patients and citizens.

4. "Supporting information" provided when prescribing prescription drugs.

Ukraine should also consider the implementation of similar codes and standards that would help ensure the quality and reliability of pharmaceutical information provided to consumers and medical professionals [305]. In the EU countries, the main requirements for the FI, which is provided during the promotion of medicines, are set out in the Order of the Ministry of Health of Ukraine No. 457 dated 03.18.2024 "On approval of the List of medicinal products prohibited for advertising, which are dispensed without a prescription".

In the EU countries, there are a number of codes of ethical promotion of medicinal products, such as the Code of Marketing Practices for Pharmaceutical Manufacturers of the European Business Association, the Code of Ethics of the Association of International Pharmaceutical Manufacturers, the Code of Ethics of the International Federation of Pharmaceutical Manufacturers, which also contain FI requirements.

In Ukraine, due to the lack of legally established rules of promotion, there are also no legally approved standards of FI, which is provided during the promotion of drugs. There are only "Rules of Proper Promotion by Pharmaceutical Companies of Medicines to Healthcare Professionals", a Memorandum of Association signed by some pharmaceutical companies operating in the domestic market. But it should be emphasized that joining this memorandum and observing the relevant rules is a voluntary act.

"Ethical standards and rules of conduct for medical representatives of a pharmaceutical company in Ukraine" have been developed, but this document is also only of a recommendatory nature. At the VII National Congress of Pharmacists of Ukraine, the Code of Ethics of a pharmaceutical worker was signed, which includes a section devoted to FI and the role of a pharmaceutical worker in the accumulation, storage, analysis and provision of this information to patients [294].

Chapter 3. The digital framework of domestic information and pharmaceutical information in the context of the digital framework.

In 2023, the Ministry of Digital Transformation of Ukraine approved the Conceptual Reference Framework for Digital Competencies of Health Care Workers and Ensuring the Development of Information Culture, Digital Literacy (Digital Education), Cyber Security and Cyber Hygiene of Health Care Workers. This document was created to implement item 58 of direction 1. "Physical accessibility" of the Action Plan for 2023/2024 for the implementation of the National Strategy for the Creation of a Barrier-Free Space in Ukraine for the period until 2030 (approved by the CMU Order No. 372 dated 25.04. 2023) of the Action Plan for the Implementation of the Concept for the Development of Digital Competencies (approved by CMU Order No. 167 dated 03.03.2021), and the Concept for the Development of Electronic Health Care, approved by CMU Order No. 1671 dated 12.28.2020 [302].

This document was prepared as a result of the cooperation of specialists of the National Academy of Sciences of Ukraine, the Ministry of Digital Transformation of Ukraine, the Ministry of Education and Science of Ukraine, and the National Health Service of Ukraine with the support of the implementers of the project of the United States Agency for International Development (USAID) "Supporting Health Care Reform". This document substantiates the need to create a Framework for digital competence of health care workers. It defines the terminology and conceptual framework for the development of the Framework, gives it structure and describes its components: domains, components, descriptors and levels of mastery. The document also explains the relationships between the various aspects of the Framework. The purpose of the Framework is to support the processes of digital transformation in the

field of health care. It is intended for updating qualification requirements, developing educational programs for training and improving the qualifications of employees, as well as determining the level of their possession of digital competencies. This document is intended for officials who are responsible for the formation of state policy in the field of health care, developers of professional standards and qualification characteristics, as well as for participants in the preparation of educational programs of medical educational institutions and institutions for improving the qualifications of health care workers. This also includes managers of health care facilities of any form of ownership, personnel services, members of attestation commissions and other employees in this guillotine.

The framework reflects the current state and trends in the implementation of digitization tools in health care, as well as the use of computing and the necessary digital skills for the practical use of these technologies by health care workers. The digital framework was developed taking into account the experience of countries that have achieved success in the digitalization of health care, such as Israel, the United Kingdom, the United States, the countries of the European Union, as well as the experience of Ukrainian specialists. During the development of the digital framework, a comprehensive approach was used, which takes into account the peculiarities of medical care in Ukraine, the professional orientation of healthcare workers and the complexity of digital technology. This allows for the formation of the necessary skills for various categories of health care workers, from technical staff to highly qualified specialists, as well as management skills for managers in the field of health care. This approach helps to create a structure The digital framework covers all aspects of electronic health care, formed in Ukraine.

The Law of Ukraine "On Education" recognizes information and communication competence as one of the key factors necessary for successful life activities. The growth of digital technologies in Ukraine covers almost all spheres of social and economic life. However, there are limitations in the implementation of digital transformation in some areas due to the insufficient level of digital literacy of a large part of the population. The electronic health care system (EHCS) in Ukraine is a

complex system of information relations between participants in the medical environment. Today, it faces a number of challenges, including the insufficient level of digital literacy of medical workers, the inconsistency of requirements for the formation of digital skills in the system of medical education and continuous development.

An important component of the central database of the electronic health care system is the patient's integrated electronic medical record (hereinafter referred to as the EMR), which is a systematized and standardized list of the patient's medical records in electronic form, which can be created in various health care institutions. Access to the patient's medical data is available only to the patient's family doctor and a doctor of the relevant specialization whose consultation or services the patient needs (with the patient's consent). Such a mechanism was specially created to avoid the leakage of data on the health status of patients. Centralized storage of all basic data in the central database of the electronic health care system (EHCS) is extremely important. This contributes to the assessment of the general map of the provision of medical services for the entire country and provides the possibility of qualitative analysis and forecasting, which is necessary for making effective decisions in the field of health care. EHCS provides automation of record keeping of medical services and management of health care information. The system is designed to unify, consolidate and protect all medical information and data nationwide.

The main groups of users in EHCS: patients, employees of the health care system, health care institutions. In addition to EHCS, there are other components of eHealth ecosystems that often interact with EHCS to transfer and validate data. Some systems are listed below:

● the electronic system for managing stocks of drug and medical products "E-Stock" is an information and communication system that includes a set of technical and software tools designed to ensure transparency tracking and quantitative assessment, planning of the need for pharmaceuticals purchased at the expense of budget funds and/ or from other sources not prohibited by law;

● the "MedData" information and analytical system is a system that enables comprehensive analysis of data on the state of procurement and monitoring of data on the supply of administrative-territorial units with goods and services purchased at the expense of budget funds and/or from other funding sources not prohibited by law ;

● an electronic integrated disease surveillance system (ELDSS) is a system that integrates infectious disease data collection, demographic information, geographic information, laboratory analysis, sample tracing, epidemiological analysis, clinical information (including disease-specific clinical signs) and interventions response into a single set of information.

In February 2022, a full-scale invasion of the Russian Federation into Ukraine began, which became an extraordinary challenge for the health care system. As a result of active hostilities and the destruction of medical and transport infrastructure, the movement of patients, doctors and ambulances to the nearest medical facility has become problematic and dangerous. Millions of Ukrainians were forced to leave their homes and seek medical care elsewhere. This led to deterioration of health and exacerbation of other diseases, such as mental disorders, cardiovascular, oncological, pulmonary and metabolic diseases. In addition, there is an acute question regarding rehabilitation and remote monitoring of chronic diseases.

The martial law in Ukraine contributed to the rapid development of telemedicine, in particular, the introduction of telemedical consultations as a useful supplement to personal visits to the doctor. There was also an accelerated development of the electronic medical record and electronic prescriptions, referrals and sick leave, as well as the appearance of the patient's electronic office and other electronic services. There have been opportunities to conduct diagnostic tests at home, there have been changes in the interaction between doctors and patients, changes in processes and the emergence of new communication channels both between medical professionals and between doctors and patients.

Therefore, digital technologies should be used as widely as possible in the post-war reconstruction of the country due to the further development of the functionality of the EHCS. Digital transformation, including the emergence of artificial intelligence

and machine learning, telemedicine and robotics in health care, requires new approaches to diagnostic and treatment practices, systematic analysis and the formation of new ethical norms. It is important to develop a Code of Conduct in the digital environment and update the legislation on issues of safety, reliability and protection of personal data, as well as compliance with European Union standards.

One of the main tasks of creating the Framework is to provide all health care workers in Ukraine with a clear understanding of the list and description of the necessary digital competencies, practical skills and knowledge for professional development, self-development, as well as increasing the efficiency of the use of electronic health care and, accordingly, improving medical care and improving access to medical services.

It is expected that the main provisions, approaches, dimensions and conceptual foundations of this Framework will be taken into account when creating professional standards, when updating the qualification requirements of health care workers and educational standards, when developing training programs and continuous professional development of health care workers, for evaluation and self-assessment, overcoming gaps and increasing the level of possession of digital competence of health care workers, as well as when updating the classifier of professions of health care workers, determining job duties, as well as when developing training programs in the system of medical (pharmaceutical) education.

According to the National Classifier of Ukraine "Profession Classifier" [303] and the Handbook of Qualification Characteristics of Workers' Professions Issue 78 "Health Care" [304] for health care workers and employees of management, technical support and accounting of the activities of health care institutions, it is prescribed more than 250 positions. However, at present, none of the qualifications contain requirements for the digital competence of health care workers, do not disclose its components or the level of their mastery. This Framework is created as a unified document for all health care professions and can serve as a reference for updating the Occupational Qualifications Guide and developing professional standards. Thus, this Framework, like any other digital competence framework, is conceptually referential

and unified. Given any list of digital competency requirements and levels of proficiency, general digital knowledge and skills are essential for all healthcare workers.

It is clear that implementing the Digital Competence Framework for healthcare workers requires a comprehensive approach and planning. This requires the following communication strategy:

1. Creation of specialized digital competence frameworks: development and dissemination of clear digital competence frameworks for different professional groups of healthcare workers, corresponding to their functional responsibilities and needs.

2. Development of standards and educational programs: revision and updating of qualification requirements and educational programs taking into account the requirements of the Framework. Development of new educational programs, trainings and methodical materials for increasing the level of digital competence.

3. Modernization of educational and material and technical means: development and modernization of the material and technical base of educational institutions for the implementation of digital innovative technologies. Providing access to modern digital learning tools.

4. Conducting educational and social initiatives: organization of educational and social events to promote digital literacy among healthcare workers.

5. International cooperation and adaptation: cooperation with international partners to adapt best practices and develop a teacher training program.

6. Curriculum updates: regularly update curriculum content to meet changes in digital technologies and employers' digital skills needs.

Such a strategy will help not only to implement the Digital Competence Framework, but also to improve the quality of medical education and the readiness of employees for digital challenges in the field of health care in order to popularize it among health care workers, clarify its purpose and how to use it. It is also recommended to review and update the qualification requirements of health care workers, taking into account the proposed approaches to the definition of digital competence and its levels of mastery when creating professional standards, if

necessary. An audit should be conducted of educational programs of training and advanced training of health care workers for compliance with the requirements of the Framework.

Given the individual focus of the Framework on defining and improving the level of digital competence, it is appropriate to develop a Framework for Digital Readiness of Healthcare Institutions - a digital readiness standard at the organizational level, similar to the European Framework for Educational Institutions (DigComp Org Framework).

Therefore, FI is a key element of the structure of the medical (pharmaceutical) industry, which helps to ensure the safety, effectiveness and quality of pharmacotherapy. It covers a wide range of information on drug characteristics, including pharmacological, chemical, biochemical and pharmacoeconomic properties. FI is provided in various forms, such as scientific, regulatory, statistical, advertising, and other, and also includes information on the processes of production, distribution, and dispensing of drugs.

CONCLUSIONS

The FI system unites institutions, specialists, processes and technologies for collecting, processing, storing and providing data used by pharmaceutical science and practice. Important criteria of FI are its quantity, availability, accuracy, efficiency, timeliness, reliability and completeness. In connection with the development of modern technologies and scientific achievements, FI is becoming increasingly important to support decision-making in the field of pharmacy and medicine, as well as to provide the population with safe and effective access to medicines.

FI can be divided into different categories depending on its management functions and place of origin. The first classification is based on management functions and includes: planning and accounting information, which contains directive values of planned and controlled indicators of business planning and actual values of planned indicators for a certain period of time; regulatory reference information, including various reference and regulatory data related to the development, production, analysis and distribution of LP; reporting and statistical information that reflects the results of the

actual activity of a pharmaceutical or medical enterprise and is provided to state management bodies.

The second classification is based on the level of management (place of origin) and includes: input information that comes to the enterprise from the outside and is used as primary information to implement its functions; source information that comes from one management system to another. Physical carriers of pharmaceutical information can be paper, magnetic disk, images on the display screen, and others. It can be presented both in the form of an alphanumeric context and in a graphic context.

FI has its own characteristics that determine its quality and efficiency of use. Consumers of pharmaceutical information are: scientists, pharmacists, doctors, medical workers, health care managers, authorities, patients and others. The choice of the method of information exchange depends on the information needs and preferences of each market participant. Sources of FI can be medical journals, directories, Internet resources, advertising, mass media, professional information of associations and scientific societies, conferences, pharmaceutical companies, colleagues and other sources.

Major sources of FI include government agencies, specialist publications, product information leaflets, official and commercial websites, electronic databases, television and radio, and the knowledge and experience of healthcare professionals. This information is necessary to ensure the rational use of medicines and other medical products for both health care professionals and the general public. Therefore, it is important to provide access to complete, reliable and objective pharmaceutical information from various sources for all participants of the pharmaceutical market.

Electronic sources of information, such as electronic versions of periodicals, electronic books, global information networks and the Internet, open new opportunities for access to scientific data. They provide quick and convenient access to information from anywhere in the world. However, the evaluation of electronic sources includes the same criteria as the evaluation of documentary sources, as well as the need to check the authority and relevance of information.

FI requirements are determined by the laws of countries, as well as international standards and directives, in particular, the European Union. FI must be submitted at two

levels: for consumers (patients) and for healthcare professionals (doctors and pharmacists). Information for consumers should be reliable, up-to-date and accessible, based on evidence-based medicine, as well as provide an opportunity to compare the benefits and risks of different treatment methods. As for information for specialists, it is provided in the form of instructions on the medical use of drugs and specialized publications that contain data on medicinal products.

In the countries of the European Union, there are specific directives and codes of ethical promotion of medicinal products, which determine the requirements for pharmaceutical information in advertising. Ukraine also has its own requirements for pharmaceutical information, which are regulated by relevant legislation and rules of proper promotion, although standards for this information are not yet mandatory.

In general, FI should be objective, accurate and understandable for different categories of users, providing them with the necessary knowledge for the safe and effective use of medicinal products.

Approved in 2023, the Health Worker Digital Competence Framework reflects the current state and trends in the implementation of digitalization tools in the health care sector, as well as the use of computer technology and the necessary digital skills for the practical use of these technologies by workers in this field. This Framework is created as a unified document for all health care professions and can serve as a reference for updating the Occupational Qualifications Handbook and developing professional standards. One of the main tasks of creating the Framework is to provide all health care workers in Ukraine with a clear understanding of the list and description of the necessary digital competencies, practical skills and knowledge for professional development, self-development, as well as increasing the efficiency of using the electronic health care system and, accordingly, improving medical care and access to medical services. Therefore, in Ukraine it is extremely appropriate to develop the Digital Readiness Framework for Healthcare Institutions - a digital readiness standard at the organizational level, similar to the European Framework for Educational Institutions (DigComp Org Framework).