PREPARATION OF MEDICINAL PRODUCTS IN PHARMACIES OF UKRAINE

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Abstract: Preparation of medicinal products according to individual prescriptions in pharmacies is an important component of the pharmaceutical supply of the population. An analysis of the world practice shows that in most foreign countries preparation of medicinal products in pharmacies exists. The study of the state of pharmacy drug manufacturing in Ukraine indicates a decrease in the level of extemporaneous drugs in pharmacies. Over the past 15 years the number of producing pharmacies in Ukraine has decreased more than threefold. But the need of extemporaneous drugs despite the wide range of medicines of industrial production is still relevant, because the preparation of medicinal drugs in pharmacies individual pharmacotherapy of patients, in addition, for some vital drugs there are no analogues in the range of medicines of industrial production. Of course, preparation of medicinal drugs in pharmacies can not replace industrial production, however, pharmacotherapeutic and pharmacoeconomic benefits are significant arguments in favor of the drug technology according to the prescriptions of doctors. Today in Ukraine the number of producing pharmacies does not exceed 1.8 % of the total number of pharmacies. Factors that negatively affect the development of pharmacy manufacturing in Ukraine have been identified. The assortment of extemporaneous drugs in the context of their pharmacological orientation and form of release is described. According to the results of the study, there were proposed the ways for further development and optimization of drug production in pharmacies of Ukraine.

Keywords: extemporaneous drugs, quality, pharmaceutical assistance, licence, pharmacy, personal drug, Good Pharmaceutical Practice (GPP), hospital pharmacy, development of drug production, advantage, Ukraine.

1. Introduction

Extemporaneous preparation of medical products is currently a very relevant topic and can be considered from the perspective of development of the Ukrainian pharmaceutical field. The concept of personal drugs is aimed at providing effective individual pharmacotherapy [1]. During military actions in Ukraine, the problem of drug production remains important in the system of medical assistance for disaster medicine and military medicine for a special period. Recently in Ukraine there is a tendency of reducing the number of producing pharmacies. This principle underlies Good Pharmaceutical practice and should be the main philosophy of specialists in the system of medical and pharmaceutical assistance to the population of Ukraine [2]. Save preparation of the medicinal drugs in pharmacies is an important task of pharmaceutical science and practice. Mainly scientific researches are devoted to organizational and economic problems of drug production in pharmacies. Our research is more focused on the problem of extemporaneous preparation of medicinal products as an important element of pharmaceutical service to the population, which is of particular relevance during the period of emergencies and military actions in Ukraine.

Therefore, in connection with the above, the purpose of the study was to establish trends in the development of preparation of medicines in pharmacies, analyze the factors, affecting the state of drug manufacturing in pharmacies of Ukraine and the study of possible ways of further development of this type of pharmaceutical assistance.

2. Methods

The methodological basis of the study was a systemic approach, which makes it possible to identify the main tendences for the extemporaneous preparation of medicinal products in Ukraine and in foreign countries. We used also comparative, documental, statistical analyzes, analytical review and a survey of pharmacy specialists. The materials of the study were the normative documents of the Ministry of Health of Ukraine, analytical articles, scientific publications of Ukrainian and foreign authors, nomenclature of drugs in pharmacies.

3. Result

According to the results of the study, it was found, that due to the expansion of the assortment of ready-made medicines in Ukraine, the volume of products, manufactured under the conditions of pharmacies, has significantly decreased over the past 15 years, a significant number of pharmacies has refused to carry out this type of activity by commencing a purely commercial sale of industrial production. On January 1, 2020, there were 16500 pharmacies in Ukraine, but only 1.8 % of pharmacies with the function of preparation of medicines.

According to **Fig. 1**, there is a significant reduction in the number of manufacturing pharmacies in Ukraine, from 2004 to 2020 years, the total number of pharmacies decreased by 77.3 %, more than three times. We conducted a study of the factors, causing a significant decrease in the volumes of the extemporaneous drugs and the number of producing pharmacies in Ukraine. It is established, that the main factors are: imperfection of the legislative and legal documents of the pharmaceutical field in Ukraine, the difficulty of obtaining a license for the preparation of drugs in pharmacies, problems with the registration of substances, the lack of an approved list of substances, auxiliary substances, pharmacy tableware, primary packaging materials, allowed for use in producing pharmacies, short shelf-life of medicines, the absence of a regulated list of extemporaneous medicinal products, for which there are no industrial analogues, the slow introduction of Good Pharmaceutical Practice in pharmacies [3, 4].

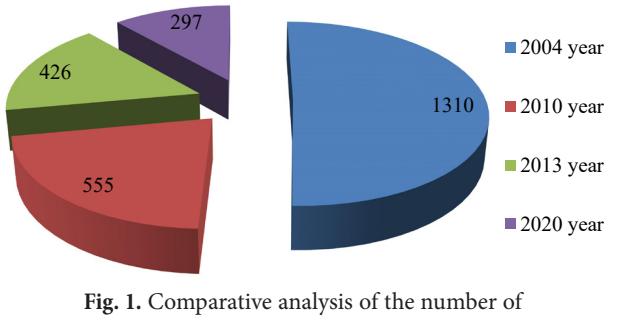

Fig. 1. Comparative analysis of the number of pharmacies with extemporaneous preparation of medicines in Ukraine

The analysis of the world practice in the preparation of medicinal products in pharmacies shows that in most countries of different continents' pharmacies produced medicines in hospital pharmacies, that is, the classical traditions of an individual approach to providing the population with medicines remain with the pharmacy [5, 6]. In economically developed countries there are quite a large number of pharmacies with preparation of sterile and non-sterile drugs according to individual prescriptions, including parenteral nutrition mixtures, as well as drugs for clinical trials (**Table 1**).

Table 1
The prepation of medicinal products in pharmacies in the world

Country	Number of pharmacies with preparation of medicines
Portugal	All
France	All
Germany	All
Poland	All
Sweden	All
Baltic states	Most pharmacies
Hungary	All
Ireland	All
Italy	Most pharmacies
Norway	Most pharmacies
Spain	All
Japan	All
Canada	Some pharmacies
USA	Most pharmacies
Australia	All

In European countries and foreigh countries, producing pharmacies are seen as a way to meet the patient's specific needs, and medicines, prepared at a pharmacy, are considered "personal drugs". This production becomes relevant, when a drug is not available in the pharmaceutical market, in particular when there is no corresponding dosage form, dose or concentration of an active pharmaceutical ingredient, for example, there is no liquid or cream, but there are tablets or ointment, the patient's sensitivity to the auxiliary substances that are present in the industrially manufactured medicine, or the problem of the discrepancy between the taste of a drug, is observed [7, 8]. In this regard, it is important to study the experience of preparation of medicines in pharmacies in the world's leading countries. All over the world it is recognized, that medicines are made by the hands of a pharmacist much more efficiently than analogues of industrial manufacturing.The absence of synthetical pharmaceutical agents, such as preservatives, dye and stabilizers is the main advantage of medicinal products, made at pharmacies over commercially manufactured pharmaceuticals [9, 10].

The next step was to study the nomenclature of drugs in terms of the pharmacological focus of producing pharmacies in Ukraine. The data obtained indicate that the most common are extemporaneous medicines for using in pediatrics, neurology, allergology and dermatology. The study in the producing pharmacies showed that liquid medical forms (mixtures, eye drops, sterile solutions) make up 68.5 %, solid medical forms (powders) – 9.4 % and soft medical forms (ointments, pastes) – 22.1 %. When studying the preparation of drugs in pharmacies, there have been identified medicines that have no industrial analogues. The existing assortment of medicines of industrial production can not fill the whole range of medicines, especially since there are such medicines that are not manufactured by industry for different reasons.

4. Discussion

Preparation of drugs in pharmacies remains relevant today, especially for hospitals, because there is an existing range of drugs for industrial production that cannot fill all the required spectrum of drugs for patients, especially since there are no ones, produced by industry for various reasons. These include: solutions for internal use by newborns, oxidizing solutions, dosage forms of colloidal preparations of silver, electrophoresis solutions, sterile solutions for external use, extemporaneous medicines, made in field pharmacies.

The first group is sterile solutions for internal use by newborns. Glucose solutions 5, 10, 25 % – are prepared for newborns without a stabilizer. The shelf life of glucose solutions for newborns is only 1 month. There is no industrial analogue of solutions of glucose 10 % or 20 % 100.0, glutamic acid – 1.0. Dibazole solutions are also unsuitable for internal use in the treatment of newborns, because the factory preparation contains hydrochloric acid. Potassium iodide solution 0.5 % – no industrial analogue. Ascorbic acid solution of 1 % – the finished dosage form is available only in ampoules and is the sodium salt of ascorbic acid. At that it contains an antioxidant that cannot be used for newborns. There are also no industrial analogues of 1 % of glutamic acid and hydrogen chloride acid solutions. Thus, only producing pharmacies meet the needs of maternity hospital compartments in solutions for internal use by newborns.

The next group of drugs is oxidizing solutions: potassium permanganate solutions, used in concentrations – 5 % for neonatal cord processing; 2–5 % – for lubrication of ulcerative and burn surfaces; 0.2–0.1 % – in gynecological and urological practice. The highest value is currently 0.05 % potassium permanganate solution, which is an integral part of all medical staff workplaces.

The next group is solutions for electrophoresis. Electrophoresis is widely used in many health and care institution. Electrophoresis requires aqueous drug solutions substances: metamizole sodium, dibazole, dimedrol, papaverine, ichthyol, zinc sulfate, potassium chloride and many others. However, the preservatives can not be used because of their electrical non-indifference. Today suitable industrial dosage forms for electrophoresis do not exist.

Another group is drugs of silver. They are used in the form of colloidal solutions for cavity washes and many other procedures – protargol solution 1 %, 2 %, 3.5 %. Oother important moments are: production of pediatric and geriatric medicines, practically nonexistent both in composition and dosage; manufacture of inexpensive eye drops, including those without preservatives, used after surgery.

The advantage of preparation of medicinal products in pharmacies over industrial drugs production is the absence of synthetic auxiliaries, including: preservatives, used to prevent microbial contamination during long – term storage, dyes to provide an attractive exterior appearance, fillers, needed to give shape (tablets, pills, pellets, etc.), stabilizers – to prevent the chemical reactions, leading to the formation of toxic or inactive decomposition products, reduction of the likelihood of allergic reactions to individual drugs, medicines of individual preparation practically do not cause addiction, 100 % no risk of falsification of the medicinal product, individual selection of a drug composition and dosage, lower price, compared with industrial drug due to the lack of storage, shipping, advertising and commercial promotion of the drug, lack of registration procedure for medicines that provides time and cost savings, possibility of making small batches of medicines on the requirements and requests of hospitals, polyclinics and other medical institutions.

The conducted research shows that preparation of medicines in pharmacies is necessary to ensure the special needs of an individual patient. The results of the study suggest possible ways to optimize the preparation of medicinal

products in pharmacies of Ukraine: creation of a separate department at the Ministry of Health, which would coordinate interaction of all links in solving issues of extemporaneous production of drugs, solving the issue of procurement of substances, creating electronic bases of reference literature on organization, technology and analysis of extemporaneous preparation of drugs, use of modern logistics technologies for the delivery of extemporaneous medicines, program development of the revival of the extemporaneous preparation as a state social project.

Preparation of medicinal products in pharmacies is socially relevant and it is actual for today in Ukraine. In modern conditions, the importance of health is being significantly rethought in the light of its understanding as an integral human right, in terms of existing threats and challenges, increasing demands for quality of health, technological and financial capabilities of its provision. Preparation of medicinal products in pharmacies meets the specified requirements, provides individuals with a dual approach to a patient and can also be used during the period of emergencies and military actions.

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