Modern problems of homeopathy and ways to solve them. Provision system of proper quality in homeopathic technology

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The modern problems of homeopathy and how to solve them.

quality in homeopathic technology

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SUMMARY

The article is devoted to the issues of homeopathy, technology for the preparation of homeopathic medicines (GomLS) and the system for ensuring their quality. A comparative analysis of the application of homeopathy and the regulatory framework in the world and in Russia is given. The features of homeopathic technology within the framework of the Russian quality assurance system GomLS are considered. Contradictions, inconsistencies and gaps in the existing documentation have been identified. The specificity of homeopathy and the originality of homeopathic technology in the preparation of GomLs are noted.

Proposed solutions to problems and imbalances on the basis of domestic and foreign experience, WHO recommendations, as well as new opportunities for specialized self-regulation in the regulation of the production of GomLS by the professional community.

Key words: homeopathy, homeopathic technology, systemquality assurance, proving.

RESUME

Article is devoted to questions of homeopathy, technology of homeopathic remedies (HomR) and their quality ensuring system. The comparative analysis of homeopathy and standard documentation in the world and in Russia is made. The features of homeopathic technology within the Russian system of quality assurance HomR are considered. Contradictions, inconsistencies and gaps in existing documentation are found. The specificity and uniqueness of homeopathy, homeopathic technology in the preparation of HomR are noted.

Solutions to problems and imbalances on the basis of domestic and foreign experience, the advice of WHO, as well as new opportunities in specialized self-regulation of HomR production by professional community are suggested.

Keywords: homeopathy, homeopathic technology, quality assurance system, proving.

The provisions of the Federal Law of 12.04.2010 N 61-FZ "On the Circulation of Medicines" [1], which for the first time determined the belonging of homeopathic medicines to medicines prepared using a special homeopathic technology, require an explanation of this concept.

Homeopathic technology in the production of homeopathic medicines means a system of technological rules, techniques and applied methods for the preparation of these medicines. Various components of this technology in different periods were presented in a number of normative documents (manuals, guidelines) and monographs [2–5]. Unfortunately, there is currently no complete system of presentation of special homeopathic technology in our country. The situation with homeopathic medicines (GomLS) is aggravated by the absence of the Homeopathic Pharmacopoeia or a special homeopathic section in the State Pharmacopoeia of the Russian Federation [6, 7]. In this regard, the state of the system for the production of homeopathic medicines and its prospects in comparison with world experience are lagging and losing.

Let us consider as an example approaches to the regulation of homeopathic production and control of homeopathic technology in different countries of the world.

In the European Union, for example, there are a number of Directives regulating the circulation of GomPlS [8, 9]. The most extensive Directive 2001/83 / EC has Chapter 2 "Special provisions for homeopathic medicinal products", which regulates the state of production of GomPlS, specific aspects of registration and all aspects of their circulation on the pharmaceutical market. At the same time, the specific features of specific techniques and applied developments of homeopathic technology were transferred directly to the manufacturers of GomLS [10]. The quality issues of this type of medicines are correlated with the issues of creating a quality assurance system at each specific enterprise in accordance with their existing system of good manufacturing practices (GMP), in accordance with the current regulatory requirements [10].

In the USA and Canada, the production of GomLs is regulated by the rules of government regulators in accordance with GMP rules [11-14]. Moreover, the production of a homeopathic product is regulated as the production of drugs on the basis of a special bill of the President of the United States of 2001 [11]. These products are manufactured according to a separate Homeopathic Pharmacopoeia [26], regulated by the US Food and Drug Administration (FDA), and have not been evaluated for safety [14].

In India and Brazil, there is not only expanded government regulation of the production of GomPlS, but also their comprehensive government support in all aspects. In these countries, special State Acts have been adopted, which not only legitimize the presence of GomLs on national pharmaceutical markets, but also prescribe comprehensive support for homeopathy [15–17]. However, the requirements for homeopathic medicines are also strictly regulated there in accordance with the system of good manufacturing practices [17].

In the former countries of the socialist camp and in the post-Soviet space [18], not only the main criteria for state regulation of the production of GomPlS have been determined, but also measures to support and stimulate the development of their production.

What is the situation with us? The position of homeopathy is still not very well defined. After the Ministry of Healthcare of the Russian Federation signed Order No. 335 in 1995, which officially recognized the homeopathic method of treatment, there was no further development of the organizational provisions of this document. It was not fully implemented by Appendix No. 2 to this order, where the list of approved one-component GomLs was published. Subsequently, this list was included in a number of State Registers of medicines permitted in the Russian Federation [5]. However, the issues of registration of GomLS have not yet been resolved. The 1998 Federal Law “On Medicines” first mentioned homeopathic medicines, but only in the “labeling” section, disregarding the issues of registration of homeopathic medicines.

Since the publication of the above-mentioned order of the Ministry of Health and Medical Industry, in organizational and methodological terms, homeopathy has been classified as traditional medicine. However, this direction was de facto abolished by the closure of FNCECTMDL in 2010 and de jure confirmed by not including homeopathy and other methods of traditional medicine in the list of specialties and areas subject to licensing (Resolution of the Government of the Russian Federation of 04.16.2012) [19]. To this it is necessary to add the rejection in 2010 of the Ministry of Health and Social Development of the Russian Federation "Methodological recommendations for the examination of the registration of homeopathic medicines", proposed by the homeopathic community [20].

On the other hand, all manufacturers of GomLs, who received a license earlier from the Ministry of Health and Social Development, and now in the Ministry of Industry and Trade of Russia, presented their production for licensing in accordance with the above-mentioned standards [2,3]. that is, in each of the productions a system of required good manufacturing practices was created, which was implemented by the GomLS production quality assurance system and was confirmed by the internal production standards of the manufacturing enterprise (STP).

In all countries of the world where there is a system of state regulation of GomPl circulation, their production is carried out in accordance with similar requirements. However, the classification of GomLS as drugs is not carried out in all countries (for example, in the USA they are classified as dietary supplements). In a number of countries, the requirements for GomPlS are singled out in separate legislative acts, different from the requirements for allopathic drugs (India, Brazil), or are separated into a separate separate section (European Union).

Determining the very homeopathic technology of GomLS in their manufacture and industrial production, it is necessary to emphasize the most significant and distinctive features.

This is, first of all, the need for the use of mandatory technological methods and operations carried out in the process of preparing GomLS. The most important of these are the exact adherence to the dilution system and the implementation of

specific dynamic effect on intermediate intermediates and final products (shaking, grinding). Of no small importance is the need to use the technological methods of the operator who prepares the intermediate products. As well as throughout the world, in domestic homeopathy, the initial process of production technology begins with the processing of primary homeopathic raw materials (stocks - homeopathic primary raw materials), described in the State Pharmacopoeias of various countries. Moreover, the application of the concept of "pharmaceutical substance" to primary homeopathic raw materials very rarely coincides with those substances and products that are defined as analogous in the synthetic production of allopathic medicines. In the absence of a Russian homeopathic pharmacopoeia, preparation of primary homeopathic raw materials, quality control, are carried out on the basis of borrowing translations of various private pharmacopoeial monographs from foreign pharmacopoeias [21-24]. However, in all the homeopathic pharmacopoeias of the world, there are general pharmacopoeial monographs that allow the manufacturer to release any homeopathic preparation described in the homeopathic literature according to the approved homeopathic technology. Those. the priority in homeopathic production is the correct implementation of homeopathic technology, because it is this technology that creates a completely safe homeopathic product. The latter gets the right to be homeopathic, i.e. to be applied according to the rules of the homeopathic method of treatment, only if there is a description of its proving - a system of testing its effect on humans. [eighteen]. A proving specifies both the indications for the use of the drug in practice and the method of its use. Due to its absolute non-toxicity, the final homeopathic product is always safe. This fact is now recognized by everyone, including the medical community.

At the same time, the problem of clinical trials and registration of homeopathic medicines remains the cornerstone problem of domestic homeopathy. The system existing in our country, contrary to world experience, does not distinguish between homeopathic and allopathic remedies. And there is little hope for a change in the situation. What to do? Perhaps it is appropriate to consider the American version of classifying homeopathic medicines as dietary supplements?

After all, when using v quality subsidiary carrier a homeopathic product of food substances (sugar granules, aqueous solutions, hydroalcoholic solutions, syrups, vegetable oils, etc.), a homeopathic preparation can be considered as a food product with the potential for healing the body. If the carriers are pharmaceutical products (injectable sterile solutions, tablets, etc.), they should be classified as medicines. External remedies (ointments, opodeldoks, oils, gels, plasters, toothpastes, etc.) in all countries of the world are classified as perfumery and cosmetics, why don't we go this way?

It should be borne in mind that in the United States, the FDA, which is a federal food regulator (including biologically active

additives to food) and drugs, has only supervisory and control functions. Manufacturers of all products operate on the basis of self-regulation. Homeopathic remedies are included in the section of food products with their own separate status.

In our country, all domestic manufacturers of GomLS have been selected according to strict criteria for evaluating production in accordance with the requirements of good manufacturing practice and have created a quality assurance system for GomLS production. [2, 3] Therefore, the release of homeopathic remedies as dietary supplements will not affect their quality in any way. Of course, it is desirable to have self-regulation of manufacturers' activities. At the same time, a homeopathic product will come out of the insoluble framework of unauthorized requirements currently imposed on GomLs when registering homeopathic products and when clinically evaluating their effectiveness according to criteria unacceptable to homeopathy [4, 18, 27].

What will give this option for the development of homeopathy? First of all - the possibility of using new homeopathic medicines, which have already been tested according to the rules of homeopathic proving - the main system for assessing the effectiveness and safety of any homeopathic remedy. This is most important because the criteria for drug registration requirements, according to the so-called “evidence-based medicine” according to the “Good Clinical Practice” standard, where there is no mention of homeopathy [27], are not acceptable for homeopathy [18]. For 200 years, all over the world, a homeopathic preparation has been introduced into circulation and medical use only after clinical trials (proving), in accordance with the requirements of homeopathic clinical practice. That is, the system of evidence in homeopathy is fundamentally different from the requirements for clinical trials of allopathic drugs, which have formed only in the last twenty years. It is through proving and further clinical application with the demonstration of the effectiveness reflected in the homeopathic literature that homeopathy has shown its effectiveness and has been helping patients for over 200 years [18, 27].

The minimum of side effects due to the absence of toxicity of small doses of used homeopathic dilutions ensures the safety of homeopathic preparations. This has been proven by more than two centuries of its existence as world homeopathy and is recognized by the WHO [28].

The problem, as it becomes clear, is in the plane of rationing the circulation of GomPlS, including the principles of their registration, criteria for assessing their clinical efficacy and approaches to assessing the quality of their production. All these criteria for homeopathy are fundamentally different, which is confirmed by the specific approach to homeopathy around the world. Unfounded and harsh statements and attacks on homeopathy by so-called apologists. "Evidence-based medicine" in recent years, including through the WHO, with distortion of reality, dictate the need to change the position of homeopathy in the system of modern medicine [29]. That is, it is necessary to separate homeopathy into a separate independent group, in the form of a section within the framework of modern medicine, and relocate the emphasis in relation to homeopathic medicines

within the framework of current legislation. Of course, a significant addition to the regulatory framework of domestic homeopathy is needed. This work has long been carried out by the homeopathic community and is based on many years of scientific research in the field of homeopathy carried out in leading scientific institutions, such as, for example, the First Moscow State Medical University named after I.M. Sechenov. Its results are projects submitted to the Ministry of Health and Social Development of Russia [20]. But for homeopathy, it is also necessary to approve its own legal framework, including the most important aspects of homeopathic technology, registration of homeopathic products and their circulation on the market. In this regard, the recently created National Council for Homeopathy, which unites almost the entire homeopathic community, can become a center and a link between homeopaths, the medical community,

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