3. The content and conditions for the implementation of the main stages of the QMS expert evaluation are formulated.
4. The method of quantitative determination of the degree of fulfillment of the requirements regulating the QMS processes is proposed. Such an assessment determines the ability of the QMS to ensure the stable fulfillment of all established requirements for activities affecting the quality of products, and also assesses the ability of the QMS to achieve its quality objectives.
5. The measurable values of the QMS, obtained by the methodology of "scoring" through the systematic conduct of audits, make it possible to monitor changes and analyze trends, which ensures conditions for the timely application of corrective and preventive actions, risk reduction.

DEVELOPMENT OF MEASURES FOR MINIMIZATION OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS SPREADING IN UKRAINE

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Introduction. High-quality drugs are extremely important for human health and are needed in any health care system. The spread of counterfeit and substandard medicines is one of the most pressing issues for the global pharmaceutical market. Low and middle income countries are the most affected by this problem, but it is increasingly threatening and rich countries due to the sale of such drugs via the Internet. Online sales generate a market, most part of which is not regulated and not monitored. The Internet is a major source of counterfeit and low-quality drugs entry.

According to WHO, 1 of 10 drugs are of inappropriate quality or falsified. In recent years, the number of detected counterfeit and substandard drugs has increased by 56%.

There is also a tendency that, with the increase of trainings and education of specialists, the number of detected cases of falsification increases.

It is extremely difficult to estimate the real scale of this problem. It should be understood that when the danger becomes visible, many patients have already suffered harm.

Therefore, the purpose of the work was to search and develop measures to minimize the distribution of counterfeit and substandard drugs in Ukraine.

Aim. Search and development of measures to minimize the distribution of counterfeit and substandard drugs in Ukraine

Materials and methods. Having analyzed the current state of the pharmaceutical market of Ukraine, we can propose the use of complex measures of fighting the problem. They are a necessity to inform the society and specialists, to ensure the reliability of supply chains, and to create a reliable regulatory framework for better control of drugs turnover.

Results and discussion. The first method is to introduce a system of authentication and drug tracking, by applying a unique two-dimensional code for each drug package. This allows controlling the ways of medicines supply, quickly stopping the circulation of a specific batch or packaging, making records. This coding must necessarily be present on prescription drugs. This method is convenient for use by patients who can check the purchased products.

This system is already working in European countries in accordance with Directive 2011-62, which came into force in 2013. Ukraine was planning to implement the system by 2017. Already in October 2017, a pilot project on the implementation of this system has started on the example of the drug "Amixin", which was implemented through the distributor BADM and the retail chain of the Public Enterprises "Pharmacy".

Due to the special danger of low-quality parenteral dosage forms, attention should be paid to the technology that guarantees their quality, called SFERA. This is a technology of non-destructive laser engraving inside transparent materials with a two-dimensional bar code. This technology does not jeopardize the strength and content of a dosage form, guarantees the visual authenticity of medicines.

The next technology called TruTag, allows marking each unit of product, not its packaging. Silicon-based grains are added to the components, which are essentially a chip that can be read by a special portable spectrometer based on an optical reader. Particularly relevant it is in the manufacture of tablets.

Also, in some countries are already used as a protective element RF transponders that allow tracking medications, read them at a distance with a phone or other equipment. The disadvantage is the high cost of equipment.

One of the methods of product protection is a hidden hologram, which is a self-assembled photonic crystal. It is invisible under normal light, and becomes noticeable only with strong directional light of, for example, a lantern.

The presented methods have a place for implementation at such stage of carrying out the input control as an examination of the appearance without opening the package.

The next method is to inform specialists and consumers. For specialists it is relevant to create a special web-portal for quality of drugs with the image of the standard packaging of each registered drug. It is worthwhile conducting seminars, distributing brochures with methods of detecting counterfeit medicines. Consumers can be informed via the media, with the help of special mobile applications, which are now very popular.

Conclusions. In order to minimize the spread of substandard and falsified drugs, it is important to create a reliable system of information, detection and control. The use of serialization of drugs will prevent the entry of poor-quality drugs into the market and become an insurmountable barrier to drug falsifiers.

The implementation of the proposed measures will help increasing control over the circulation of medicines, which will reduce the number of falsified medicines in the market. This requires sufficient funding and implementation of IT, which will greatly facilitate the work of government agencies, manufacturers, wholesalers and pharmacy establishments.

RATIONALE FOR THE CHOICE AND THE POSSIBILITY OF IMPLEMENTATION OF QUALITY STANDARDS IN DRUGSTORE ORGANIZATIONS

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Introduction. The dynamic development of the pharmaceutical industry in all countries of the world almost every year dictates new business conditions at all levels of the life cycle of medicines. Pharmacy organizations are no exception. Thus, over the past decades, the priorities in the activities of pharmaceutical workers have changed somewhat. Earlier the basis of the pharmacy organization's work was the sale of medicines with a focus on the trading process.

Now the emphasis has shifted to the patient and providing them with qualified assistance in choosing the necessary medicines for their rational use.

The pharmacist ceases to be a seller, but becomes a confidant of the patient, an important component of the system of medical care for citizens. In all civilized countries the priorities of the state are aimed at organizing the prevention of diseases and the rational use of medicines. In this regard new concepts are introduced such as pharmaceutical assistance, pharmaceutical provision, self-help, self-prevention, etc.

A process of developing quality standards aimed at pharmacy organizations (for example, Good Pharmacy Practice - GPP) is going on intensively all over the world. According to the generally accepted principles of GPP the activities of pharmacy organizations must be substantially transformed in order to enable the transition to a new level of provision of pharmaceutical services. In connection with this the issues of forming management systems in pharmacy institutions that operate on the basis of modern principles, using modern principles and methods of organizing business processes and monitoring their implementation, become topical.

Aim of the study was to identify a set of quality standards that could be used as a methodological basis for developing an integrated management system in pharmacy organizations of both Ukraine and the Republic of Kazakhstan.