

for public discussion. The analysis of the draft document showed the necessity of its certain addition in order to comply with European standards and current tendencies of development of the cosmetic industry. In particular, it is recommended that the requirements for state market surveillance be specified, that the competent authority take the necessary measures to prohibit or restrict the making available on the market of cosmetic products or them from sales within the limits of inconsistencies made by the responsible person.

In order to effectively implement the Regulation, the question arises of the implementation of its requirements in Ukraine, namely: the creation of a sectoral domestic regulatory framework, the adaptation of documents and the identification of competent organizations that will monitor their implementation. We have proposed a set of actions for the effective implementation of the TR, namely, the development of a draft resolution of the Cabinet of Ministers of Ukraine on the plan of measures for its implementation, development and approval of by-laws, which regulate the procedure for the implementation of the main statements of the TR and the like. Thus, a complex of multi-vector management actions is required for the implementation of the TR, which requires the uniting of efforts as authorized state bodies, industry non-governmental organizations and participants of the cosmetic market as a whole.

**Conclusions:** The economic perspective of the products of the domestic cosmetic industry for the national economy of Ukraine is demonstrated. The imperfections of the national legislative framework governing the circulation of the cosmetics in the domestic consumer market and the need to reform the cosmetic industry as a whole have been established. The process of reforming the domestic cosmetic industry requires the introduction of QMS throughout the cycle of circulation of cosmetic products, taking into account its specific features at the current stage of development. The issue of implementation of QMS, in particular, in the activities of industrial enterprises of the industry, is the key to ensuring the proper quality, safety and efficiency of the cosmetics in accordance with the requirements of TR. However, it is obvious that the level of application of QMS in the activity of the Ukrainian cosmetic industry does not correspond to the world experience of effective management, which is one of the reasons for the imperfection of the standardization system of domestic cosmetic products. According to our estimates, it is the use of modern models of QMS at all stages of the vital activity of cosmetic products that can improve its competitiveness and become a catalyst for the further development of the domestic cosmetic industry as a whole. In view of the above, it is promising to continue working on the development of regulatory documents that regulate the standardization of cosmetic products, taking into account the experience of international technical regulation and the features of the development of the modern cosmetic market. The introduction of effective management through the use of QMS at all stages of the cosmetic products should ensure a systematic modern approach to the standardization of products and increase its competitiveness in the context of European integration of Ukraine as a whole.

## **THE PROCESS OF SECUREMENT THE QUALITY OF MEDICAL DEVICES AT THE STAGE OF THEIR IMPORTS IN THE TERRITORY OF UKRAINE**

Kobylka M. O.

Scientific supervisor: assoc. prof. Zborovska T. V.

National University of Pharmacy, Kharkiv, Ukraine

marina17alex@gmail.com

**Introduction.** The issue of correct realization of the order of importation of medical devices with the purpose of their further introduction into circulation in the territory of Ukraine is becoming more urgent today. The results of such of realization depend on the preliminary analysis of the provisions of the legislation, which require committing complex actions to taken to resolve the legal relations between the parties and provide for the need for the executor to have specialist knowledge and experience.

**Aim.** The aim of our research began to study the normative support for the process of importing medical devices and develop instructions for their import into the territory of Ukraine in accordance with European standards.

**Materials and methods.** To achieve this goal, we use research the regulatory basis. The first of all, it is necessary to examine the Technical Regulation on Medical Devices, approved by the Resolution of the Cabinet of Ministers of Ukraine of October 2, 2013 № 753, № 754, № 755.

**Results and discussion.** For regulation of legal relations in the sphere of production and circulation of medical devices, the normative fixing of their basic provisions is required. It should be provided exclusively by the state, as is accepted in all countries of the world.

The legislative and regulatory technical documentation for medical devices must be constantly improved and updated in a timely manner to replace outdated quality indicators in line with needs today . Due to the fact that the EU directives on the circulation of medical devices have already been updated, a similar update will take place in Ukraine in the coming years.

The system of technical regulation in Ukraine is notably different from what is understood by standardization, certification or conformity assessment in Europe and in developed countries. The foreign producers who do not have their authorized representatives in Ukraine, in fact, avoid liability for the supply of substandard and dangerous products.

This is due to the fact that the organizational structure of the state control in Ukraine does not meet the requirements of the EU Regulation 882/2004 on the official state control body, which should cooperate with the European safety authorities of both food and medical products, and ensure effective coordination and cooperation between the established controlling bodies. This will avoid duplication of control functions between central government bodies authorized by the state.

The procedure for importing medical devices for the purpose of putting into circulation in the territory of Ukraine can be divided into the following main stages:

- Appointment of an authorized representative in Ukraine.
- Regulation of intellectual property issues (if necessary).
- Completion of the conformity assessment procedure.
- Resolve distribution issues
- Customs clearance of imports of medical devices.
- Advertising and promotion (if necessary)
- Analysis of the circulation of medical devices.
- Representation of the manufacturer's interests.

Accordingly, in order to determine whether the product belongs to the category of medical devices or not, the Ukrainian conformity assessment body will use the relevant European documents. The basic guideline is the delineation and classification of public regulation for medical devices. Version 1 of April 19, 2018.

Imports of medical devices into Ukraine must first be subject to a technical conformity assessment procedure and a Certificate of Conformity must be obtained. Depending on the risk class of the product and some other factors, there are 4 schemes of the following procedure:

1. Self-declaration.
2. Test parts product.
3. Audit of the quality management system.
4. Recognition of EU certificates.

In most cases, certification in Ukraine is equally compulsory for domestic manufacturers and importers, largely without taking into account foreign certificates of conformity previously obtained. Although there are many specific instruments for regulating the circulation of imported goods. To implement some of them, Ukraine has acceded to international agreements, simplifying the existing method of certification and building a system that is harmonized with European requirements.

**Conclusions.** The having read the regulatory basis for the process of importing medical devices and instructions for their import into the territory of Ukraine, it should be noted that the norms of circulation of medical devices are confirmed by a clear approach of state regulation in this field and revealed a number of inconsistencies in the regulatory framework, which need to be paid attention and introduced with European standards.

## **OPTIMIZATION OF THE INTERNAL AUDIT PROCEDURES AT A PHARMACEUTICAL ENTERPRISES**

Kopchyshyn H. K.

Scientific supervisor: prof. Lebedynets V. O.  
National University of Pharmacy, Kharkiv, Ukraine  
v.o.lebedynets@gmail.com

**Introduction.** Functioning of the Quality Management Systems (QMS) at the any pharmaceutical companies requires mandatory systematic internal audits.

The more effectively the internal audit is performed, the more effective is the quality management system of the organization.

Given the important importance of quality assurance of medicines, the issue of audits for domestic pharmaceutical companies is particularly relevant.

A large number of domestic pharmaceutical companies do not pay due attention to audits, often performing them formally or not taking care of their performance.

**Aim:** identify the roles and analyze current approaches to conducting internal audits of the quality management systems of drug companies, in compliance with ISO 9001 and GMP requirements, and develop application suggestions for optimizing the audit process of the research object.

Research objectives:

- analyzing of the regulatory requirements for internal audits of QMS;
- studying the experience of audits on the basis of pharmaceutical companies;
- developing of the proposals for optimization of the main stages of the audit process for their implementation on the pharmaceuticals companies.

Object of research: quality management system of a manufacturing pharmaceutical enterprise.

Subject of research: the process of internal audits of QMS.

**Materials and methods.** To carry out our research, we carried out studies on the provisions of ISO 9001 and ISO 9000 as part of an overall management system based on the quality risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS.

**Results and discussion.**

Often, the following are not available at Ukrainian pharmaceutical companies:

- the methodology for evaluating the performance of the audit process and the relevant eligibility criteria;
- rules for asking questions in questionnaires (audit checks);
- rules and criteria for the systematic assessment of the competences of internal auditors and experts involved;
- application of PDCA methodology and others.

Critical audit elements we have identified:

- Audit planning and preparation of audit reports within the PDCA cycle.
- Selection of the audit team.
- Developing questionnaires and maintaining other audit documents.
- Professionalism of auditors.