REVIEW OF THE REQUIREMENTS FOR DIETARY SUPPLEMENT IN UKRAINE

Petrovskyi M.
Scientific supervisors: prof. Lebedynets V. O., assoc. prof. Romelashvili O. S.
National University of Pharmacy, Kharkiv, Ukraine
quality@nuph.edu.ua

Introduction. The dietary supplements (DS) market in Ukraine is becoming one of the sectors of economy that is steadily and intensively developing. Over the last three years, the DS market has grown at a high rate and became an independent segment of the consumer market (table. 1).

Table 1. Retail sales volumes of different categories of "pharmacy basket" goods in monetary and natural terms by the results of 2017-2019.

Year	The volume of DS pharmacy sales	The share of DS in the "pharmacy basket",%
Monetary terms, million UAH		
2017	3380,7	3,7
2018	4620,9	5,2
2019	6326,2	6,1
Natural terms, million packs		
2017	62,4	3,7
2018	71,8	4,1
2019	80,9	4,8

This noticeable increase in DS sales is primarily due to the expansion of the customer base. According to the Euromonitor study, almost 48% of Ukraine's population is DS users as a result of the presence or prevention of any disease.

Due to this, the problem of legal regulation of the DS quality and safety is becoming increasingly important. The current legislation of Ukraine defines DS as a food product. They are subject to all food law regulations.

Aim. Overview of legislation regulating requirements for dietary supplements in Ukraine.

Materials and methods. Scientific professional publications, statistical information, current legislation of Ukraine. Methods of comparative and historical analysis.

Results and discussion. Today there are a number of legal acts regulating the processes of production and circulation of food products. The main legislative act of Ukraine in this field is the Law "On Basic Principles and Requirements for Food Safety and Quality". This Law was substantially amended (2014) by the Law "On Amendments to Certain Legislative Acts of Ukraine on Food Products". The Law on State Control of Compliance with Food, Feed, Animal By-Products, Animal Health and Welfare (2017, current version of 02/13/2020), the Law on Information for Consumers on Food (2019), Order of the Ministry of Health of Ukraine "On Approval of Hygienic Requirements for Dietary Supplements" (2013, entered into force 24.01.2016).

The Law "On Basic Principles and Requirements for Food Safety and Quality" regulates relations between executive authorities, food market operators and food consumers, and defines the procedure for ensuring the safety and individual quality indicators of manufactured foods, which are brought into circulation (forwarded) to the customs territory of Ukraine and / or exported (forwarded) from it.

The Law "On State Control of Compliance with Food, Feed, Animal By-Products, Animal Health and Welfare" directly defines the legal and organizational principles of state control that are carried out to verify compliance with food, feed, animal health and welfare, as well as legislation on animal by-products during the import (transfer) of such products to the customs territory of Ukraine.

This law promotes the interests of consumers of food products, as well as balancing the rights and duties of producers and state control bodies; improving the safety and quality of domestic foodstuffs, expanding their markets and strengthening their position on competition with foreign goods.

The Law on Consumer Information on Foodstuffs establishes the legal and organizational framework for providing consumers with information on foodstuffs in order to ensure a high level of protection of citizens' health and to satisfy their social and economic interests.

"Hygienic requirements for dietary supplements" is a single piece of legislation directly applicable to DS and applied exclusively to DS, and does not apply to medicines, functional foods and foods for special dietary use.

Hygienic requirements set the basic requirements for the labeling and advertising of dietary supplements, as well as the list of vitamins and minerals allowed for use in the DS production.

Conclusions. Considering the above, it can be concluded that the Ukrainian legislation mainly regulates general issues related to food safety and quality. However, specific products such as DS have not yet been addressed. This leads to abuse by manufacturers and sellers of DS, which causes both material damage to average consumers and a threat to their lives and health. Due to the lack of control by the state authorities, it is now possible to buy in the drugstore an DS whose quality is questionable. For example, the product may not have the declared components, or their number may not meet the requirements. Another important issue is compliance with the requirements for DS production processes, their quality control and transportation conditions. Our research is devoted to these issues.

ANALYSIS OF MODERN APPROACHES TO ASSESS THE CONFORMITY OF DOCUMENTATION OF THE QUALITY MANAGEMENT SYSTEM

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

Introduction. The relevance of good documentation is explained by the following reasons:

- the need to formulate and communicate goals and objectives from management to all levels of the organization;
- ensuring consistency of actions among the performers of all processes;
- providing factual evidence of proper implementation of processes and conformity of products (services) to the established requirements;
- formation of information base for making reasonable management decisions.

The reasons for the need to control the quality of documents of the QMS:

- the correctness of the document affects the correctness of the actions described in these documents;
- clarity, conciseness and uniqueness are the characteristics that determine the perception of documents by their users;
- for a content and structure of the documents of many industries organizations have been established by regulatory requirements.

Aim: analysis of approaches to assessing the compliance of the organization's quality management system documentation with the model of ISO 9001 standard and development of appropriate methods.

The research objectives are:

- overview of directions of modern quality management;