

ORGANIZATION OF DEVELOPMENT AND PRODUCTION BASED ON MARKETING OF NEW MEDICINAL PRODUCTS IN POLYMER PACKING

Shevchenko V.O., Rolik-Attia S.M., Domar N.A.

Institute of Pharmacy Professionals Qualification Improvement,

National University of Pharmacy

SVAVON@ukr.net

Foreign medicines are becoming increasingly popular due to the tendency of Ukraine's accession to the European Union. They are widely known in the domestic pharmaceutical market for their quality and safety.

The development of parenteral and oral medicines in Europe has gained a new wave in the pharmaceutical industry of the world. So, ensuring quality and safety of products is one of the main tasks for long-term storage. It's important to choose the packaging that is used in this case when solving this problem. From the quality of packaging depends the delivery of products without losses from the manufacturer to the consumer, the simplification of warehouse and transport operations, the provision of the necessary time for storage. The type of packaging and materials used in this case, in many respects determine not only the quality of products, but also storage conditions, storage methods, etc.

Based on the foregoing, the introduction of the modern form of packaging for parenteral and oral solutions, which include the substance of a different chemical structure in its composition, into the industrial production is actually.

The purpose of the researches was to prove the relevance of the development and production of oral and parenteral solutions in polymeric packaging based on conducted marketing researches.

The pricing policy of medicines is an important aspect of the pharmaceutical market in Ukraine, especially in times of crisis. Marketing analysis which we conducted allowed to put different groups of drugs in a polymeric package, along with the production of similar drugs in the glass, while the quality of the products met all the criteria of GMP.

According to marketing researches of the pharmaceutical market in the world, most for example German pharmaceutical manufacturers use polymeric packaging containers for medicinal products (about 43%), while drugs the glass or metal packaging make more not than 25%. This is due to the fact that medicinal products manufactured in polyethylene containers have a number of advantages in comparison with glass containers. Thus, the production technology provides the tightness of the container, which prevents the entry of foreign objects and microorganisms into the solution (including small particles of glass that can be in glass packaging). In addition, the welding

of capsules with a rubber gasket take place on an already sealed bottle, which ensures that there is no contact of the solution with rubber, while the needle's contamination and the drug during puncture of the vial is excluded. Additionally, the sterilization of vials with solutions in an autoclave is carried out in production.

A unique line of production of parenteral and oral medicines in polymeric packaging for the first time in Ukraine was launched by the pharmaceutical company NIKO Ltd. (Kyiv region, Klavdievo-Tarasovo urban type village). Their production uses BFS technology, which is carried out on the Bottlepack® equipment purchased from the leading supplier - the Swiss company Rommelag.

BFS technology includes the following processes:

- extrusion - blowing of polyethylene and blown off the sleeves;
- forming a vial / ampoule;
- filling - after cooling the vial / ampoule they are immediately filled with a solution;
- sealing – pressurization a vial / ampoule.

So how safety is one of the most necessary tests, the State Sanitary and Epidemiological Examination on vials and ampoules of polyethylene for medicinal preparations manufactured in accordance with technical conditions U 25.2-20390397-001:2007 was carried out, as a result of which they meet the requirements of the current sanitary legislation of Ukraine and can be used in the claimed scope of application.

Researches have also been conducted on the following indicators: convenience of opening a medical product, convenience of selection (dosing) of liquid medicinal products from a medical device, visual control of the use of preparations packaged in medical products, completeness of emptying, stability of the medical product to the sanitary-hygienic treatment, convenience of utilization of a medical product, convenience of transportation of a medical product in the group packaging of finished medicinal products and their storage. In the studies, these characteristics of the vials were compared with the characteristics of analogues - "Containers made from polyvinyl chloride (PVX)" production «Jiangsu Kanghua Medical Equipment Co., Ltd. (China). Analogues of ampoules were not used.

Based on the conducted marketing research of parenteral and oral medicines, it has been proved that the application of new technologies in ensuring the quality of this group of medications and, in particular, the use of new modern packaging, is relevant. We have improved not only the commercial appearance of parenteral and oral medicines with helping the new packaging, but also the convenience and lightness of using, which has been confirmed by appropriate clinical researches.