Seminar No. 13

Topic “Containers and packaging. General characteristics. Classification. Labeling of medicinal products. General and specific requirements for the labeling of medicinal products. "

Purpose of the lesson:

Deepening, consolidating and systematizing the theoretical knowledge gained in lectures and during independent work with the recommended literature. The study of the main elements of packaging, features of the packaging of medicines and medical products.

The main questions to be discussed at the seminar:

1. Container. Concept definition. Container classification. The difference between packaging and packaging.
2. Types of containers in accordance with the purpose. Materials and commercial types of containers.
3. Requirements for consumer properties of containers and packaging materials.
4. Packaging materials. Types of packaging materials for medicines.
5. Closures. Types. Materials. Consumer properties.
6. Goods labeling (text, drawing, symbols). marking functions. Labeling requirements (general and specific). Trademark.
7. Requirements for the labeling of MD packaging. Labeling of medicines in the system for monitoring the movement of medicines in the Russian Federation.

Means of identification of medicinal product - a unique sequence of characters in a machine-readable form or presented using another means (technology) of automatic identification.

A closure *is a* product designed to seal a package and preserve its contents.

Packaging material - any material intended for the production of packaging and packaging elements of a medicinal product, pharmaceutical substance, excipient or intermediate product.

A container is the main element of packaging, which is a product for placing products.

Packaging material - any material intended for the production of packaging and packaging elements of a medicinal product, pharmaceutical substance, excipient or intermediate product.

In accordance with the purpose, three types of containers are distinguished:

- primary (individual), having direct contact with the material of the pharmaceutical product;
- secondary , containing one or a number of primary packages;
- group, containing a certain number of primary or secondary packages;
- transport , in which products are delivered from manufacturers to places of distribution (wholesale link) or sales (retail link).

Primary packaging includes vials, jars, test tubes, bags and other containers made of glass, cardboard, metal and polymeric materials and equipped with closures if necessary.

Secondary packaging includes cardboard boxes, bags and packs, paper casings, as well as bags made of kraft paper or film polymer materials with instructions, a leaflet, a label, etc. Secondary packaging should provide the simplest and most convenient accounting and control of products packed in individual packaging. Often, secondary packaging is called consumer packaging , since it carries the information necessary for the consumer, applied directly to the outer surface of the package.

Shipping containers are used to move products in the logistics system. It includes boxes of various sizes, corrugated cardboard boxes, metal barrels, glass bottles, etc.

In practice, there may be various combinations of primary, secondary and transport packaging. For example, when transporting ointment bases, alcohol, etc., metal barrels are used, which are both primary packaging and transport.

For the packaging of medical devices and medicines, various materials are used:

- based on cellulose ethers (corrugated cardboard, wrapping paper, waxed; parchment, parchment, cellophane, packaging paper, plywood, etc.);

– silicate materials (neutral glass, discolored medical container glass; orange glass, chemically and thermally resistant glass, porcelain).

-metal materials (aluminum foil, more often in combination with various papers, polymer films and varnishes, which makes it possible to obtain multilayer materials with good protective, technological, ergonomic and aesthetic properties).

– polymeric materials (various types and grades of polyethylene, polyvinyl chloride, polypropylene, etc., rubber based on natural and synthetic rubber).

Marking - information in the form of inscriptions, signs, symbols, pictograms, digital, color and conventional designations applied to the packaging and / or label, accompanying documents to ensure identification, inform consumers, how to handle packaged products during transportation and storage, to speed up information processing during loading and unloading operations.

There are the following main **marking elements** :

- ✓ name or type designation of the product and its number according to the manufacturer's numbering system;
- ✓ manufacturer's trademark
- ✓ Year of manufacture
- ✓ designation of standards or specifications for a product
- ✓ mark of conformity adopted in the certification system for this type of product.

Specific requirements:

- ✓ clarity of text and illustrations;
- ✓ visibility;
- ✓ the unambiguity of the text;
- ✓ compliance of the text with the consumer properties of the product;
- ✓ use for marking indelible dyes approved for use in medicine;
- ✓ reliability of each label element.

Fhe federal law "On the circulation of medicines"

Art.46. Labeling of medicines

Medicinal products, with the exception of medicinal products manufactured by pharmacy organizations, veterinary pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities, should be put into circulation if:

1) on their primary packaging (with the exception of the primary packaging of herbal medicinal products) in a well-readable font in Russian are indicated:

- ✓ name of the medicinal product (international non-proprietary, or grouping, or chemical, or trade name),
- ✓ series number,
- ✓ release date (for immunobiological medicinal products),
- ✓ best before date,
- ✓ dosage or concentration, volume, activity in units of action or number of doses.

2) on their secondary (consumer) packaging, in a well-readable font in Russian, the following are indicated:

1. name of the medicinal product (international non-proprietary, or grouping, or chemical and trade names)
2. name of the manufacturer of the medicinal product
3. series number
4. release date (for immunobiological medicinal products)

5. registration certificate number
6. expiry date
7.method of application
8.dosage or concentration
9.volume
10. activity in units of action or the number of doses in the package
11. dosage form
12. vacation conditions
13. storage conditions
14.warning labels.

Marking carriers can be:
labels
facets of consumer packaging
collarettes
liners
tags
labels
control tapes
hallmarks
stamps

The labeling structure consists of text, a picture and symbols (information signs), which differ in the ratio and degree of availability of product information, breadth of distribution and some other functions.

Text is the most common marking element, consisting of words, letters, numbers and their combinations. The text is characterized by a high degree of information availability. The text can perform all the basic functions of marking, but to a greater extent it has informational and identifying functions. On the packaging of pharmaceutical and parapharmaceutical products, the text part

occupies a significant place (specific gravity from 50 to 100%). The text can be presented in several languages (Russian, Latin, the language of the country of origin of the goods). The main part of the information intended for consumers is carried out in text, for example, the name of the drug, the method of administration, doses, warning labels, the pharmacological action of the drug, etc.

Pictures are not always present on the packaging. Although recently there have been many over-the-counter medicines that have pictures on their packages. Much more often, drawings are found on the packaging of parapharmaceutical products. The drawing has a high degree of accessibility and performs mainly emotional and motivational functions, and in some cases - motivational and identifying functions (when information on the operation or use of the product is given in the form of drawings). The proportion of figures in the total mass of information ranges from 0 to 50%. Depending on the information contained in the figures, they can be conditionally divided into the following groups:

a) contain information about the origin of the product (raw material source, individual components, place of production), or about the authors of the product . An example is the drawings of medicinal plants on packages; image of the area (for example, the nature of the region by bottling mineral water);

b) specify the scope of possible application . For example, drawings of organs on which the therapeutic effect of the drug is manifested (drawings of the throat, stomach, eyes, etc.);

c) limit the segment of possible use of the product by gender or age (for children - the image of cartoon characters, for women - the image of a female figure, etc.)

d) reproduce the way the product is consumed . By repeating the actions shown in such pictures, the consumer learns how to use the packaging or the product itself correctly.

e) have an indefinite appearance that creates a background or participates in the creation of an

overall packaging design . An example of such drawings can be images of atoms, molecules, etc.

The colors of the drawings also differ from each other: they can be performed both in black and white, and using bright colors (this gives an advertising character). Drawings play an important role in creating the packaging style, making it recognizable to the consumer, which is important for the formation of consumer preferences. We also conditionally include reproductions of paintings or photographs used in marking product packaging as drawings.

Information signs are symbols designed to identify individual or cumulative characteristics of a product. Information signs are characterized by: brevity, expressiveness, visibility and quick recognition. Their share in the total mass of commodity information ranges from 0 to thirty%.

Separate words, letters, numbers, pictures, symbols can act as information signs.

Information signs are divided into:

- commodity;
– name of the place of origin (place of destination);
– marks of conformity or quality, technological marks;
- component;
- dimensional;
- manipulative;
- operational;
- warning;
– ecological;
– bar coding;
- others.