Seminar № 12

Topic: Factors that preserve consumer properties and quality of medical and pharmaceutical products. Classification and basic requirements for packaging. The main elements of packaging. Environmental aspects of packaging. Packaging quality indicators (functional, ergonomic, aesthetic). Requirements for packaging materials and closures.

The main questions to be discussed at the seminar:

1. Factors that preserve the consumer properties of medical and pharmaceutical products
2. The main functions and significance of packaging.
3. Packing classification.
4. Classification, types of packaging of medicines in accordance with the state pharmacopoeia 14 editions. Characteristics of the main elements of packaging.
5. General requirements for the packaging of medicines.
6. Packaging materials for the production of packaging and packaging elements for medicines. Requirements for packaging materials and closures.
7. Ecological aspects. Requirements for the environmental safety of packaging.

Packaging - a means or a set of means that jointly ensure the protection and safety of medicines from damage and loss, as well as the environment from pollution in the process of circulation (transportation, storage and sale) of medicines.

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

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.

The elements *of the primary (inner) packaging* **are** in direct physical contact with the medicinal product and **provide** its protection from the influence of environmental influences during the circulation of the medicinal product.

The elements of the secondary (outer) packaging **do not come** into direct contact with the medicinal product, but provide the necessary protection in order to maintain stability.

The secondary packaging containing the necessary information for the intended use is usually the **consumer** packaging.

Preservation of consumer properties of medical products depends on:
– the quality of the packaging;
– the quality of labeling for goods and packaging;
- packing goods into packages;
– conditions of transportation;
– storage conditions;
– method of disinfection;
– sterilization method;
– conservation method;
- depreservation method.

The quality indicators of all the listed parameters are indicated in the quality standards for a specific product. Pharmacists in their practice, when accepting goods in terms of quantity and quality in pharmaceutical organizations, should pay attention to the conditions for transporting goods, the safety of packaging and labeling, and their compliance with the standards for accepted

goods. In addition, they must organize the proper storage of goods, and, if necessary, sterilization, preservation and re-preservation of medical instruments, devices and equipment.

The factors that preserve the consumer properties of the product include:

- Package
- Storage
- commodity processing
- Sale of goods
- After-sales service
- Consumption (short-term, long-term and repeated - operation.)

In the process of circulation and operation of goods, their consumer properties change under the influence of factors:

- ✓ physical and chemical (humidity, temperature, light, oxygen, various gases and other air components)
- ✓ mechanical (compression, stretching, bending, impacts, shocks, shaking, etc.),
- ✓ biological (impact of microorganisms, insects and rodents).

The types, nature and size of the damage they cause are determined by the intensity of the impact and the properties of the material of the product.

Factors that preserve consumer properties and quality of medicines

The stability of drugs largely depends not only on their chemical composition, but also on the properties of the packaging material, in particular, permeability and light transmission. Examples: Orange glass containers do not transmit light with a wavelength of less than 470 nm and reliably protect compounds that are sensitive to ultraviolet radiation. A polymeric film containing UV-absorbents protects the tablets from the action of light, and containing inhibitors - from the action of oxygen.

Conditions for storage and transportation of medicines:

When choosing **storage and transportation conditions, it is necessary to take into account** :

- ✓ product properties;
- ✓ the need for protection against mechanical influences;
- ✓ the need for weather protection.
- ✓ The storage conditions of goods are specified in the storage orders.

Conditions for transporting medicines:

The preservation of the quality of goods during transportation largely *depends on* :

- ✓ rationality of the choice of packaging and its quality;
- ✓ on the density of packing of goods in containers, and containers with goods - in containers and vehicles;
- ✓ on the degree of protection of the goods from mechanical and atmospheric influences.

TRANSPORTATION

Goods, depending on their type and properties, as well as the type of transport , are transported in various types of packaging.

Products must be: packed tightly, empty spaces filled with appropriate packing materials with shock-absorbing ability.

When loading and unloading it is necessary to pay attention to: warning signs and inscriptions on containers, cleanliness of vehicles.

Falling loads and excessive shocks must not be allowed.

Basic principles of storage of medicines.

Classification features of the organization of storage of medicines, taking into account:

Toxicological group

Pharmacological group

By type of application (for external and internal use)

Medicinal substances "angro" taking into account the state of aggregation: liquid bulk, gaseous, etc.

In accordance with the physico-chemical properties and the influence of various environmental factors, drug groups are distinguished:

- ✓ Requiring protection from light
- ✓ From exposure to moisture
- ✓ From volatilization and drying
- ✓ From exposure to high temperatures
- ✓ From exposure to low temperatures
- ✓ From exposure to gases contained in the environment

Features of storage of finished dosage forms

Storage of finished dosage forms should meet the requirements of the state pharmacopoeia 14 editions and all general requirements for drugs, taking into account the properties of the ingredients that make up their composition.

The storage temperature is indicated on the packaging.

All finished dosage forms are stored in their original packaging with the label facing out.

A shelf card is attached to the racks and shelves for each series of the drug.

In the stock department of the pharmacy, a file is kept by expiration dates

The main functions of packaging:

protection of goods from spoilage and damage;

creation of rational cargo units for transportation, loading and unloading of goods;

creation of rational units for their storage;

creation of optimal (by weight and volume) units for the sale of goods;

product advertising.

The division of packaging according to its intended use into classes: consumer, transport, production and preservative is more general than classification according to the industry principle (food, engineering, chemical, etc.), or according to the degree of protective properties (group, from mechanical damage, moisture-resistant, vapor-tight, isobaric packaging, etc.).

According to this design feature, consumer packaging is divided into tubes, cans, bottles, bags, etc.

The container is the most important, and sometimes the only element of the package , which is a product for product placement, made in the form of a closed or open case.

The third level of classification of containers and auxiliary packaging means is carried out **according to the design feature (type),** which determines the shape, dimensions, ratios and methods of connecting elements.

On this basis, consumer packaging is divided into tubes, cans, bottles, bags, etc.

Transport packaging - for bags, boxes, barrels, canisters, drums, etc.

The main auxiliary packaging materials structures used in consumer and transport packaging include closures, labels, coatings, wrappers, sealing, fastening and shock-absorbing elements, substances that create a protective atmosphere inside the package, etc.

The fourth level of classification is the materials from which the container (packaging material) and auxiliary packaging materials are made.

The container is divided into the following main types: metal, paper, cardboard, glass, wood, polymer, combined.

For the manufacture of auxiliary packaging materials, all types of packaging materials are used, as well as peel, lubricants, inert gases, corrosion inhibitors, etc.

Classification is carried out **on the basis of** manufacturing technology: glued, welded, stitched, thermoformed, injection molded, blown containers auxiliary packaging materials, in addition, according to manufacturing technology, they can be glazed, smeared, sprayed, compounded, printed, etc.

Auxiliary features (subclasses) for the classification of packaging can be dimensional stability (rigid, semi-rigid, soft), compactness (collapsible, non-collapsible, folding), color, transparency, surface texture and texture, artistic design.

On the basis of application, packaging is divided into:

- primary
- secondary
- tertiary

Primary (individual) packaging is intended to create the necessary conditions to ensure the long-term preservation of the products contained in it.

The primary packaging includes: vials and jars made of glass with a screw neck, vials and jars made of drot, glass jars with a triangular rim, bottles for blood and blood substitutes, polymer containers, capsules, aluminum tubes, single-use syringe tubes, aerosol cans with a protective polyethylene or polymer coating based on polyvinyl chloride, bags made of polymeric materials or paper, test tubes made of droit, metal or plastic, contour packaging, wrapping a briquette (medicinal plant material) in a parcel label.

Primary (individual) packaging has special requirements: gas and vapor tightness; chemical indifference to drugs; strength; resistance to temperature influences; opacity;
barrier resistance to microorganisms.

Necessary consumer properties of the primary packaging of medicines

- ✓ transportability of packaging (when wearing, transporting);
- ✓ availability of information on the storage and reception of drugs;
- ✓ pleasant appearance;
- ✓ appropriate dimensions for ease of use and completeness;
- ✓ ease of disposal of used packaging or the possibility of reusing the packaging both for its intended purpose and for other purposes.

Secondary (group) packaging combines a number of primary packaging and is intended to ensure their safety.

The main functions of secondary packaging are:

1) the safety of the primary packaging from atmospheric influences;
2) the possibility of the most simple, convenient accounting and control of products;
3) meeting the needs of consumers in information about drugs.

Types of secondary packaging:

- a cardboard box with instructions and a label attached,
- packaging made of polymer film and foil,
- glass jar,
- kraft paper bags or sacks,
- film bags made of polymeric materials,
- paper wrapper with a parcel post and a label (for sanitary and hygiene items).

Tertiary or transport packaging is designed to deliver products to distribution and sale points. As a rule, it does not reach the consumer.

Transport packaging must protect the drug from exposure to precipitation and dust, solar radiation, and mechanical damage.

Types of transport packaging:

- corrugated cardboard box
- wooden boxes
- container,
- plastic bags
- kraft paper bags
- fabric bags.

Classification of packaging of medicines (OFS.1.1.0025.18)

- ✓ by degree of protection
- ✓ for protection against opening;
- ✓ protection from external factors;
- ✓ by the number of uses and the number of doses;
- ✓ by type and kind;
- ✓ by mechanical properties.

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

Depending on the presence of direct contact with the medicinal product (dosage form), packaging materials can be:

- ✓ primary
- ✓ secondary

The main raw materials of pharmaceutical packaging materials are:

glass
polymer materials
elastomeric materials (rubber, silicone)
metal
paper
cardboard

The packaging of the medicinal product must be of good quality.

Packaging and packaging elements (containers, closures, etc.) must be made **in accordance with the requirements of the standards in force in the Russian Federation** according to duly approved regulatory documents (and / or drawings) for packaging (containers, closures, etc.) for specific types of products.

The shape (design), dimensions, permissible deviations from the dimensions of the package and its constituent elements, as well as the regulated indicators of the quality and safety of the package and the elements of the package, must meet the requirements of the current standards.

For the production of packaging and its constituent elements, packaging materials suitable for contact with the packaged products must be used in accordance with the requirements of standards and technical documentation for specific types of packaging and recommendations for the use of certain types of packaging materials for packaging medicines.

Packaging materials must be non-toxic, compatible with medicinal products approved by the Russian Ministry of Health for use in contact with them.

Primary and secondary packaging materials must be allowed for the production of this type of packaging, taking into account the route of administration of the medicinal product.

Primary packaging materials must be released in accordance with Good Manufacturing Practices (GMP).

To minimize the negative impact of the packaging industry, the following methods and technologies are used:

Reducing the cost of processing raw materials and manufacturing packaging. Complete refusal (if possible) or the lightest packaging, the use of large packaging of goods.

Use of secondary raw materials.

Reusable packaging.

Possibility of recycling and disposal of packaging.

Collection of used packaging for subsequent recycling.