Federal State Budgetary Educational Institution of Higher Education "Volgograd State Medical University" of the Ministry of Health of the Russian Federation

Department of Management and Economics of Pharmacy, Medical and Pharmaceutical Commodity Science

Factors that preserve consumer properties and quality of medical and pharmaceutical products. Storage, packaging, labeling and transportation of medicines and medical products

Lecture № 5

Discipline: medical and pharmaceutical commodity science

3 course, 5 semester

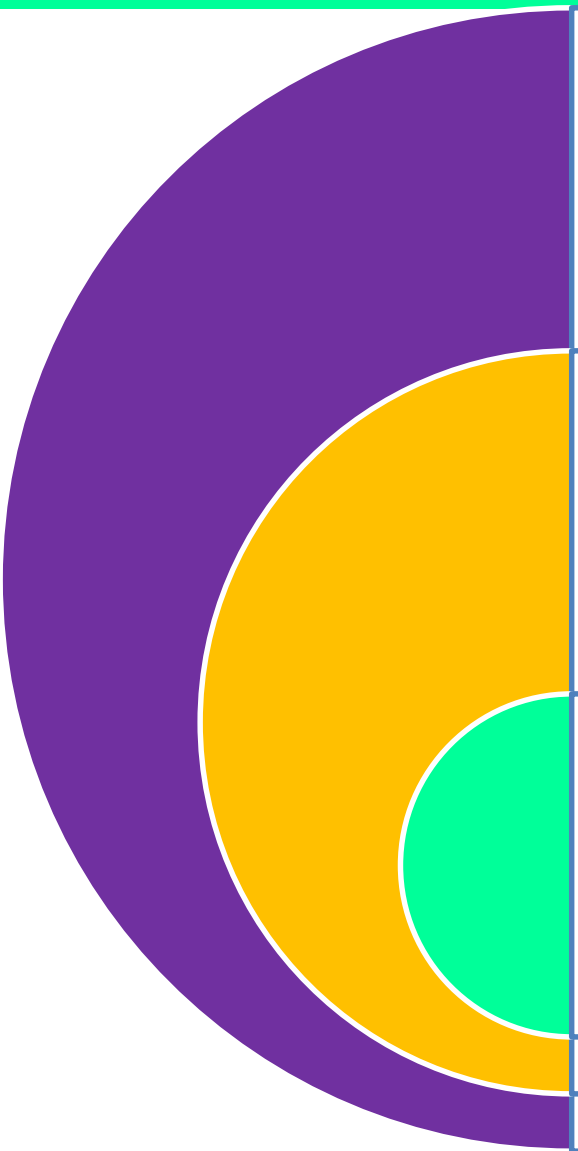
Volgograd -2022

LECTURE PLAN

1. Introduction. Factors affecting the consumer properties of medical and pharmaceutical products
2. Factors that preserve the consumer properties of medical and pharmaceutical products
3. Storage of medicines as a factor that preserves the consumer properties of medical and pharmaceutical products.
4. The main functions and significance of packaging. Packing classification. Container as an element of packaging. Types of container classification.
5. Classification, types of packaging of medicines in accordance with the Global Fund 14. Characteristics of the main elements of packaging.
6. Packaging materials for the production of packaging and packaging elements for medicines. General requirements for the packaging of medicines.
7. Labeling of medical pharmaceutical products: characteristics, types, main elements, labeling carriers.
8. Ecological aspects. Requirements for the environmental safety of packaging .
9. Labeling and transportation of medicines and medical goods.

Factors affecting the consumer properties of medical and pharmaceutical products

Consumer properties and product quality depend on many factors:



In merchandising, they are divided into two groups:

- factors that **shape** consumer properties and quality of goods

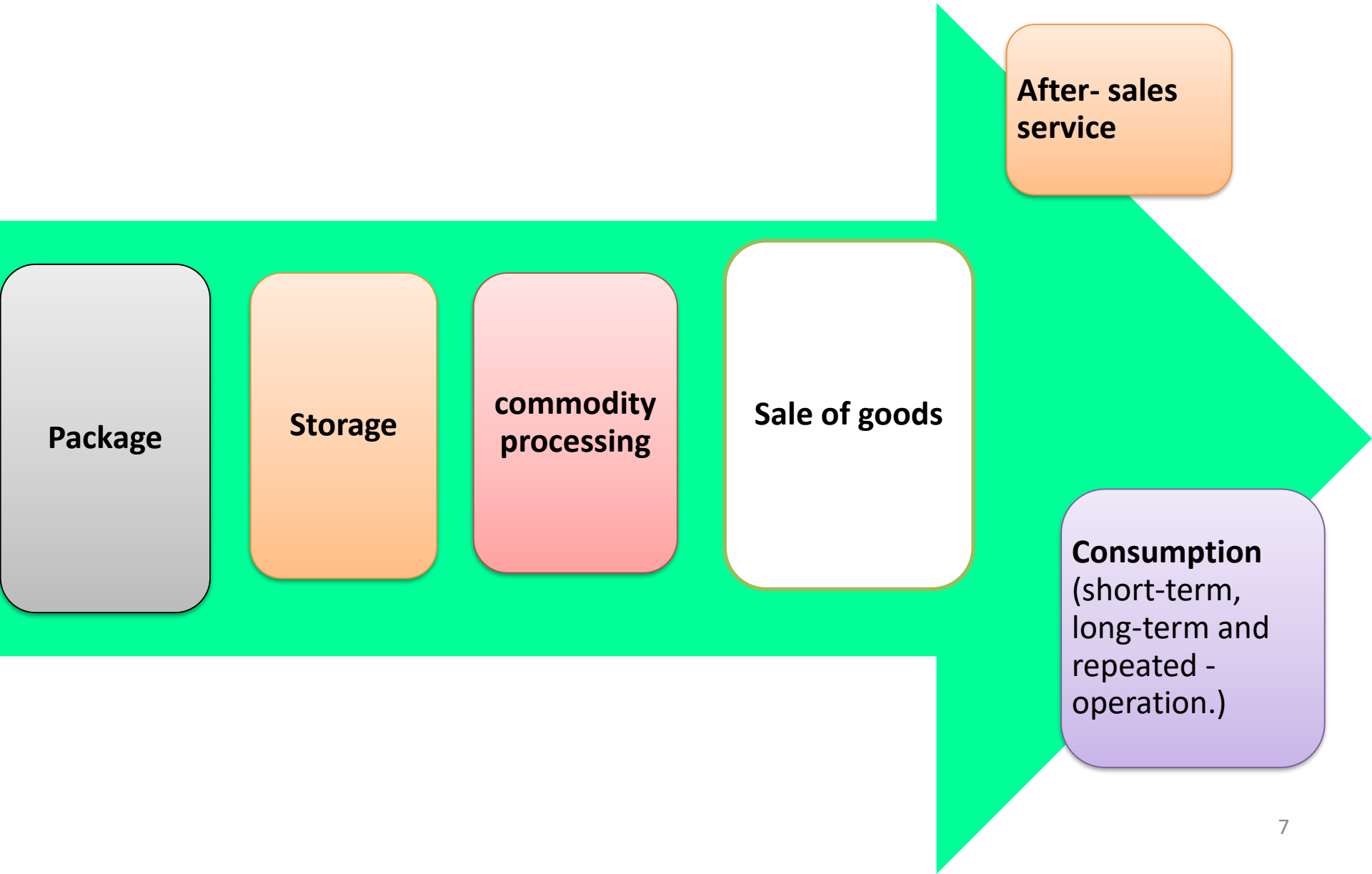
- factors that **preserve** consumer properties and quality of goods.

Factors affecting the consumer properties of medical and pharmaceutical products

- scale and structure of morbidity;
- the level of technology development in the industry;
- quality of raw materials;
- product manufacturing technologies;
- methods of product quality control;
- means of transportation;
- storage features;
- compliance with the rules for the use of this product.

Factors that preserve consumer properties and quality medical and pharmaceutical products

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



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.**

preservation of consumer properties of goods

- **Preservation of consumer properties of goods depends on:**

- packaging quality;
- quality labeling for goods and packaging;
- packing goods into packages;
- transportation conditions;
- storage conditions;
- disinfection method;
- sterilization method;
- conservation method;
- depreservation method .

Factors that preserve consumer properties and quality of medicines (2)

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:

The orange glass container does not transmit light with a wavelength of less than 470 nm and reliably protects compounds that are sensitive to ultraviolet radiation.

A polymer film containing UV absorbents protects the tablets from light, and those containing inhibitors protect them from oxygen.

Conditions for storage and transportation of medicines (1)

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

product properties (PM);

the need for protection against mechanical influences;

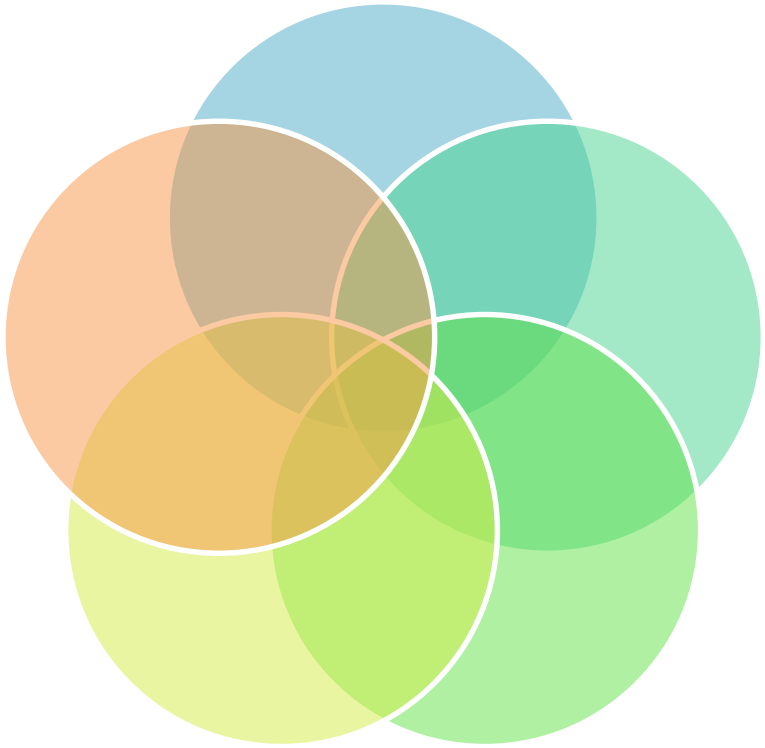
the need for weather protection.

The storage conditions of goods are specified in the storage orders .

Conditions for transporting medicines

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

on the degree of protection of the goods from mechanical and atmospheric influences.



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;

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 (1)

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

Toxicological group (list A, list B, general list)

Pharmacological group

By type of application (for external and internal use)

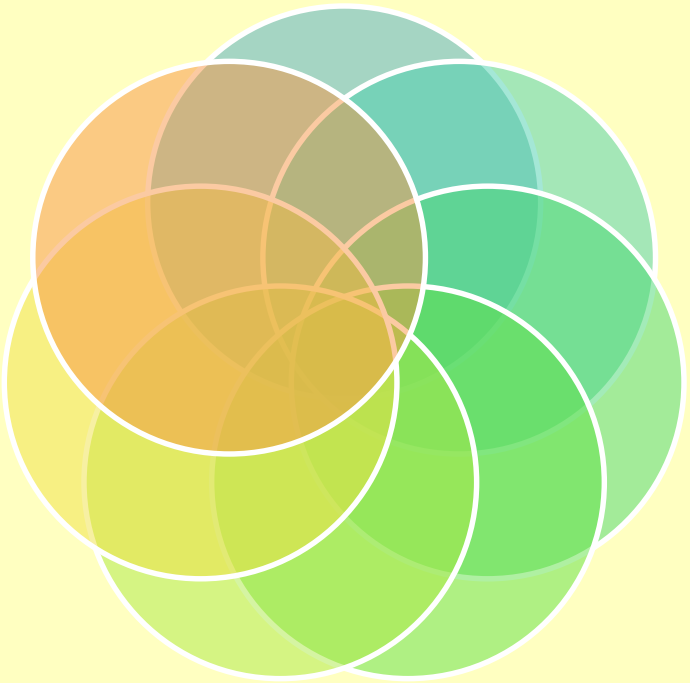
Medicinal substances **" angro ", taking into account the state of aggregation** : liquid bulk, gaseous, etc.

Basic principles of storage of medicines (2)

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

- From exposure to gases contained in the environment

- Requiring protection from light



- From exposure to low temperatures

- From exposure to moisture

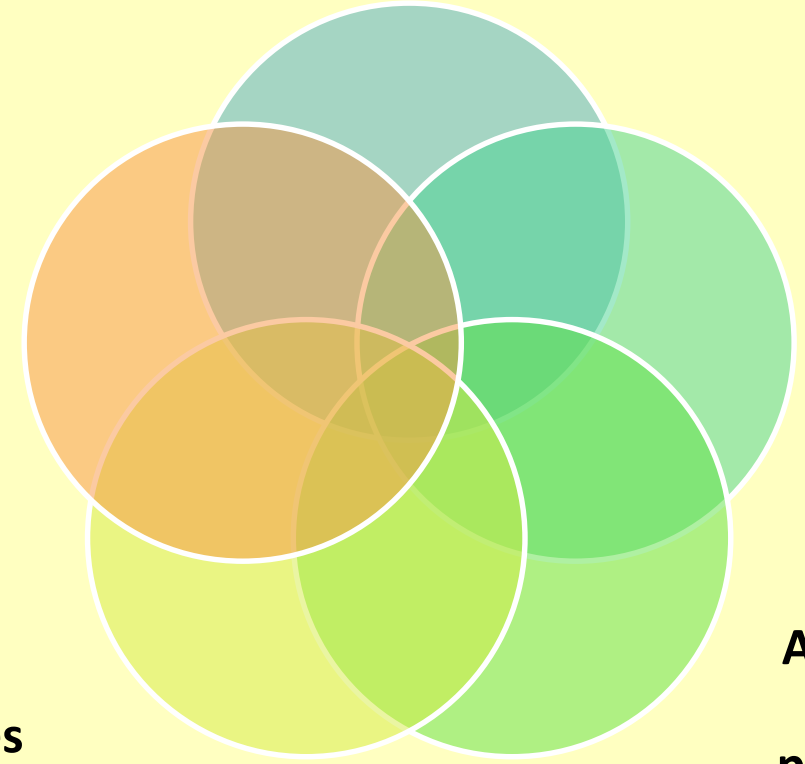
- From exposure to elevated temperatures

- From volatilization and drying

Features of storage of finished dosage forms

Storage of GLF should meet the requirements of the Global Fund and all general requirements for drugs, taking into account the properties of the ingredients that **make up their composition.**

In the stock department of the pharmacy, a card index is maintained by expiration dates.



The storage temperature is indicated on the package .

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

All GLFs are stored in their original packaging with the label facing out.

Temperature regime for storage of medicines (OFS.1.1.0010.18)

The cold place means storage of medicines in the refrigerator at a temperature **from 2 to 8 °C** , without allowing freezing.

Do not freeze. Not lower than +2 °C, unless otherwise specified in the monograph or normative documentation

Cool storage refers to storing medicines at temperatures **between 8 and 15°C** . In this case, it is allowed to store medicines in a refrigerator, with the exception of medicines that, when stored in a refrigerator at a temperature below 8 ° C, can change their physical and chemical characteristics, for example, tinctures, liquid extracts, etc.

Storage under deep freezing conditions provides for a temperature regime below -18 **°C.**

Freezer storage provides the temperature regime of medicines **from -5 to -18 ° C.**

Storage at room temperature implies a temperature regime from **15 to 25 ° C** or, depending on climatic conditions, up to 30 ° C.

Storage of medicinal plant raw materials and medicinal plant preparations OFS.1.1.0011.15

The storage conditions of MPC and herbal medicinal products in warehouses should **ensure the safety of raw materials and drugs in terms of quality indicators that may change during storage within the periods established in pharmacopoeial articles or regulatory documentation** ..

Medicinal herbal products that require protection from light must be stored in a place protected from light and / or in light-protective packaging in accordance with the requirements of the General Pharmacopoeia Monograph “Packaging, labeling and transportation of medicinal herbal raw materials and herbal medicinal products ”.

Medicinal herbal raw materials and medicinal herbal preparations should be **stored at a relative air humidity of not more than 60 ± 5%, depending on the respective climatic zone** (I, II, III and IV A) and the physicochemical properties of the medicinal herbal raw materials/preparation and biologically active substances, included in its composition, in a packaged form in accordance with the **General Pharmacopoeia Monograph "Packaging, labeling and transportation of medicinal herbal raw materials and medicinal herbal preparations".**

PACKAGING OF MEDICINES. MAIN PACKAGING FUNCTIONS

BASIC TERMS AND DEFINITION.

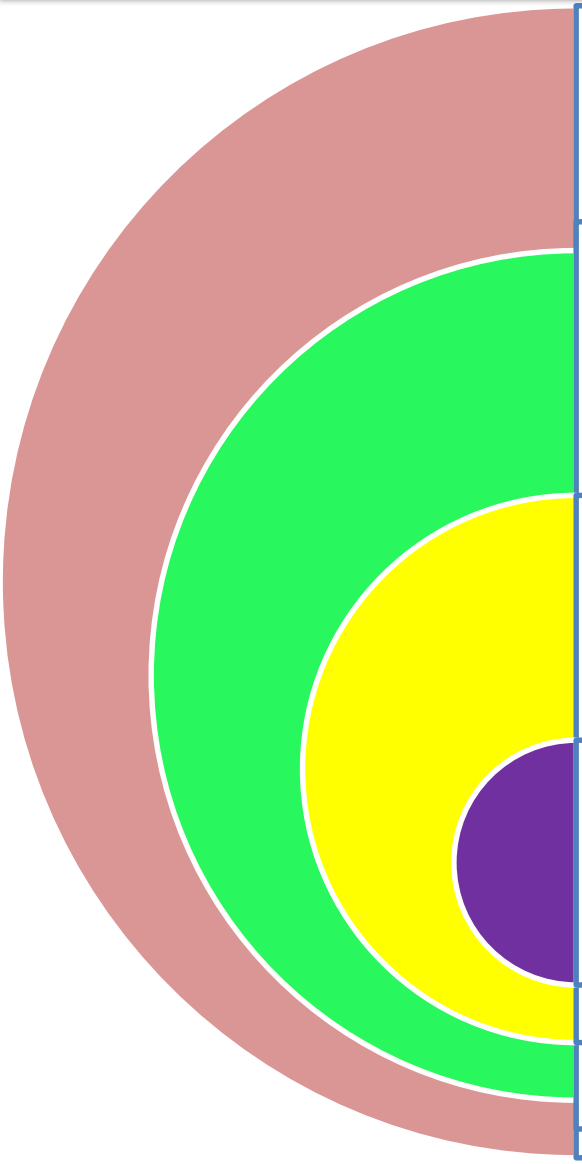
“Packaging is understood as a means or a set of means that ensures the protection of products from damage and loss, the environment, pollution, and also ensures the circulation process.”

GOST 17527-2003 “Packaging. Terms and Definitions"

"Tare is the main element of packaging, which is a product for placing products."

GOST 17527-2003 “Packaging. Terms and Definitions"

BASIC TERMS AND DEFINITION.



Since the meaning of packaging is important in various aspects, there are several more definitions of the term "packaging".

Packaging is a means or a set of means that ensures the protection of products from environmental influences, from damage and loss and facilitates the process of handling (transportation, storage, sale).

Packaging - a complex consisting of containers, packaging material, closures and other auxiliary means that determine the consumer and technological properties of the packaged product.

Packaging is the process of packaging, that is, the preparation of products for transportation, storage, sale, consumption.

BASIC TERMS AND DEFINITION.

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.**

Depending on the direct contact with the medicinal product, primary and secondary packaging are distinguished.

OFS.1.1.0025.18

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.

Factors contributing to the increasing importance of packaging (1):

- **development of a form of self-service - with an increase in the number of pharmacies with open access, the packaging begins to perform the functions of attracting attention to the product: it contains a description of its properties, contributes to the formation of a favorable impression on the consumer about the product as a whole** (important for over-the-counter drugs, dietary supplements, beauty products, personal care products, etc.).

According to the Rules of Good Pharmacy Practice (clause 34 of the order of the Ministry of Health of the Russian Federation of August 31, 2016 No. 647n), **open display of over-the-counter drugs and other pharmacy products is allowed;**

Factors contributing to the increasing importance of packaging (2):

- growth of incomes of the population - an increase in incomes of the population means that consumers are willing to pay for the convenience, appearance, reliability and prestige of improved packaging;

- the opportunity to develop competitive advantages of the product ,

for example: special coated paper for disposable medical instruments ensures 100% sterility and reliability, this special kraft paper has two opposite properties: permeability to sterilization media and impermeability to microorganisms, contaminated particles and water (filtering effect);

Shrink film allows you to very quickly cover the vial with lyophilisate or injection solution and, accordingly, allows you to prevent unauthorized violation of the integrity of the package, guarantee the quality of the product.

Factors contributing to the increasing importance of packaging (3):

Despite the need and importance of packaging as a mandatory component of a medical (pharmaceutical) product, there are the following negative aspects:

high price: in some cases, the packaging costs more than the goods;

scarce resources are spent on packaging, in particular paper, aluminum, glass, which also leads to an increase in the cost of goods;

environmental pollution: for example, about 40% of all solid waste in the United States comes from discarded packaging, which creates great problems with its destruction, which requires labor and energy, and leads to pollution of the biosphere.

PACKAGING CLASSIFICATION

PACKAGING CLASSIFICATION LEVELS

one LEVEL

Division of packaging **according to purpose** into classes: **consumer, transport, production and conservation**

is more general than

industry classification

(food, engineering, chemical, etc.),

or **according to the degree of protective properties** (group, from mechanical damage, moisture resistant, vapor-tight, isobaric packaging, etc.).

PACKAGING CLASSIFICATION LEVELS (2)

The packaging is divided according to its composition : into containers and auxiliary packaging means (VUS).

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 container (T) performs the functions of packaging (U) alone or in combination with auxiliary packaging means (VUS), which are other packaging elements .

2 LEVEL

Thus, **packing is a collection, which is represented by the formula**

U= T+ VUS, and in some cases U=T, or U= VUS.

PACKAGING CLASSIFICATION LEVELS (3)

The third level of classification of containers and auxiliary packaging means is carried out on the basis of design (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.

3 LEVEL

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

The main VUS 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.

PACKAGING CLASSIFICATION LEVELS (4)

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

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

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

4 LEVEL

PACKAGING CLASSIFICATION LEVELS (5)

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

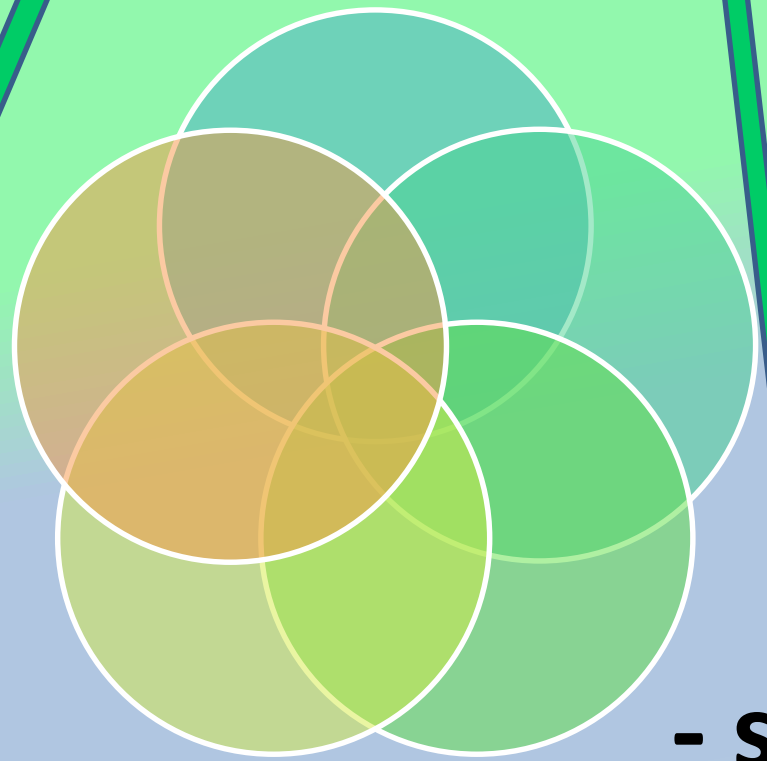
5 LEVEL

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.**

Classification of packaging

by application (1)

On the basis of application, packaging is divided into:



- primary
- secondary
- tertiary

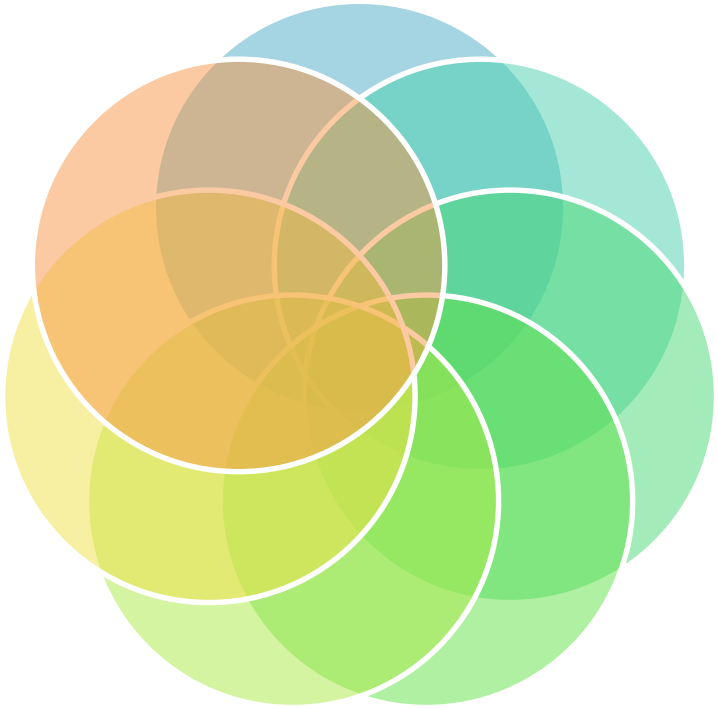
Classification of packaging according to application : primary packaging (2)

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: bottles and jars made of glass with a screw neck, bottles 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 package label.

General requirements for primary packaging of medicines

Primary (individual) packaging has special requirements:



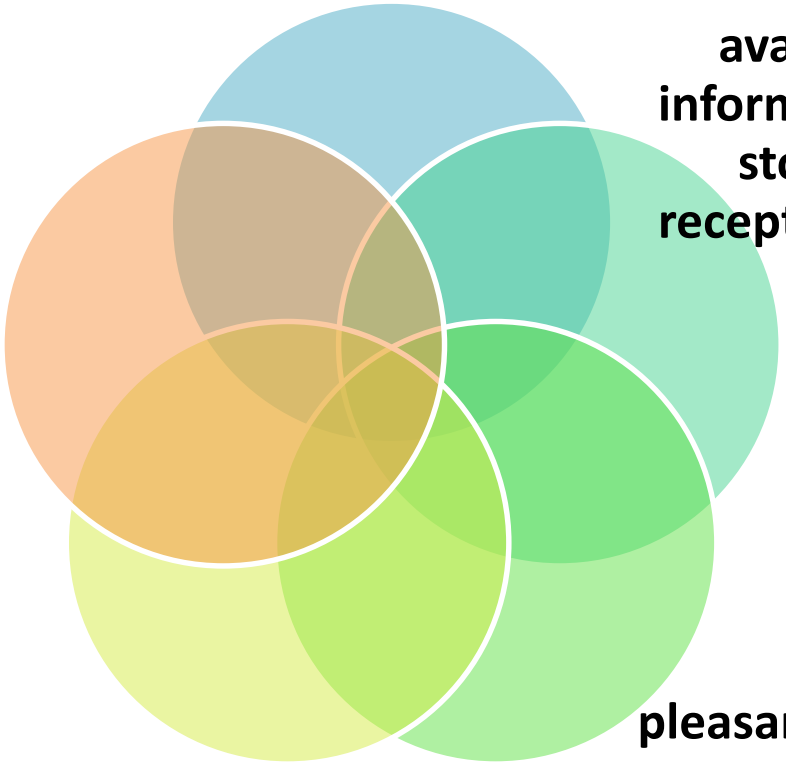
- barrier resistance to microorganisms.
- gas and vapor impermeability ;
- chemical indifference to drugs;
- strength;
- resistance to temperature influences;
- opaque - bridge ;

Necessary consumer properties of the primary packaging of medicines

ease of disposal of used packaging or the possibility of reusing the packaging both for its intended purpose and for other purposes.

transportability of packaging (when wearing, transporting);

availability of information on the storage and reception of drugs;



appropriate dimensions for ease of use and completeness;

pleasant appearance ;

Special requirements for primary packaging

control of the first opening of the package

special placement of drugs with the possibility of repeated use without violating the tightness, sterility

control over the use of drugs

SECONDARY PACKAGING: FUNCTIONS, TYPES

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.

SECONDARY PACKAGING: FUNCTIONS, TYPES

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 PACKAGING: FUNCTIONS

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.

TERTIARY PACKAGING: TYPES

Types of transport packaging :

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

PACKAGING AS THE MAIN ELEMENT OF PACKAGING

PACKAGING AS A PACKAGING ELEMENT

"Tare is the main element of packaging, which is a product for placing products."

GOST 17527-2003 “Packaging. Terms and Definitions"

TYPES OF CLASSIFICATION OF CONTAINERS

By function

According to the materials used

By size

By frequency of use

According to the degree of hardness

By design

By affiliation and terms of use

CLASSIFICATION OF PACKAGING BY FUNCTIONAL PURPOSE

The container according to its functional purpose is divided into:

transport

consumer (packaging)

container-equipment (special group),

which is a product for placement, transportation, temporary storage and sale of goods from it by the self-service method .

CLASSIFICATION OF PACKAGES ACCORDING TO THE MATERIALS USED

According to the materials used, the container is:

- Wooden
- Cardboard
- Paper
- metal
- Polymer
- tissue
- glass
- From combined materials

CLASSIFICATION OF CONTAINERS BY SIZE

The sizes are:

large-sized (applies to shipping containers, the dimensions of which exceed 1200x1000x1200 mm)

small containers

CLASSIFICATION OF CONTAINERS DEPENDING ON THE FREQUENCY OF USE

Depending on the frequency of use, there are:

one-time (intended for one-time use in the supply of products),

returnable (this is a container that was in use and reused)

packaging (designed for its repeated use in the supply of products; it differs in strength indicators and organizational and legal conditions for delivery and return.

Classification of containers according to the degree of rigidity

According to the degree of rigidity of the structure, that is, according to the ability to resist external influences and maintain its original shape, there are:

rigid (does not change its shape and size when filling with products and during transportation and storage of products is able to withstand external influences)

soft (the form changes significantly when filling it with products)

semi-rigid containers (less resistant to external influences, but with slight deformation after filling with goods, it basically retains its original shape).

Classification of containers by design

According to the design, the container is divided into:

- non- **separable,**

- collapsible

- collapsible-folding.

Depending on the presence of a lid or other closure, the container is:

- **closed**

- open .

Classification of containers by design

There are containers:

- dense, the parts of which are interconnected without gaps,

- **lattice** , the details of which are interconnected with given gaps.

By tightness , the container is divided into:

- **sealed**

(Varieties of hermetic containers are dust-, light-, fat-, gas- and vapor - tight containers).

- **leaky**

According to the properties of packaging materials, based on the specifics of the functional purpose and design features, there are:

isothermal (container, inside which the set temperature is maintained for a certain time)

isobaric (sealed container, inside which the specified pressure is maintained)

aerosol container (isobaric container with a spray valve that gives products when consumed in an aerosol state).

Classification of containers according to accessories and conditions of use

According to the accessories and conditions of use, the container is divided into:

production (intended for storage, movement and warehousing of raw materials, blanks, parts, assembly units, finished products, as well as waste in production)

inventory (reusable packaging belonging to a particular enterprise and subject to return to this enterprise)

warehouse (a kind of shipping container used for receiving, storing and picking products in warehouse conditions).

OTHER TYPES OF PACKAGING

A container that provides protection for packaged products from the effects of radioactive and toxic substances, as well as bacterial (biological) agents, is called **protective** .

There is also **an export container** intended for the delivery of products abroad, and an import container.

Depending on the scope of application, a distinction is made between **universal** (used for packaging, transportation and storage of various types of products) and **specialized containers** (for one particular product or for certain operating conditions).

CLASSIFICATION, TYPES, GENERAL REQUIREMENTS FOR PACKAGING OF MEDICINAL PRODUCTS IN ACCORDANCE WITH GF 14

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.

REQUIREMENTS FOR THE PACKAGING OF MEDICINAL PRODUCTS ACCORDING TO THE DEGREE OF PROTECTION (QFS 1.1.0025.18)

By degree of protection

The package may have **several layers of** drug protection.

The elements *of the primary (inner) packaging* are in direct physical contact with the medicinal product and ensure its protection from the influence of environmental influences during the circulation of the medicinal product . In some cases, the primary packaging is a specialized drug delivery system, such as an aerosol or a dosage device adjusted to dispense a single dose of drug .

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

REQUIREMENTS FOR THE PACKAGING OF MEDICINAL PRODUCTS ACCORDING TO THE DEGREE OF PROTECTION (OFS.1.1.0025.18)

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

For the purpose **of additional protection of the** medicinal product or, **based on the characteristics of its use, the primary package can be placed in *an intermediate package*** .

Medicinal products in secondary (consumer) packaging can be placed **in *group (combined) packaging*** , which, as a rule, is cardboard boxes or stacks, followed by wrapping the stack with paper, shrink film in accordance with the instructions of the pharmacopoeial monograph or regulatory documentation.

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

Open protection:

Packaging with protection against unauthorized opening *(packaging with control of the first opening)* .

Child resistant packaging.

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

For protection from external factors:

Well sealed packaging .

Tightly sealed packaging .

Hermetically sealed packaging .

Hermetically sealed packaging

Airtight packaging

Waterproof

If " air -tight" or "moisture-tight" packaging is indicated, it may be substituted for "hermetically sealed".

Light-protective packaging .

Isothermal packaging .

Vacuum packing .

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

By number of uses and number of doses:

Disposable packaging .

Reusable packaging .

Single dose packaging .

***Multidose packaging* . Multi-dose packaging can be dosed (the contents of the package are divided into doses) and undosed .**

Multidose non-dosed packaging is a reusable packaging .

Packing kit .

Set .

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

By type and kind (1)

The classification unit that characterizes the packaging in terms of material and design determines the type of packaging. The classification unit that characterizes the packaging in terms of shape determines the type of packaging.

- ***Ampoule .***
- ***balloon .***
- ***Aerosol can (aerosol packaging).***
- ***Gas cylinder .***
- ***Bank .***
- ***Drum* (Barrels are not classified as a drum).**
- ***Barrel .***

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

By type and type (2)

- ***Bottle .***
- ***bottle .***
- ***Injection syringe .***
- ***Canister.***
- ***Cartridge .***
- ***Container (cargo container) .***
- ***Single use polymeric container for blood and its components .***
- ***Planimetric non - cell packing (strip) .***
- ***Blisters (blister) .***

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

By type and type (3):

Box

A box made from a single blank, closed with valves, is allowed to be called a *pack.*

A box closed with a shell-shaped lid is allowed to be called *a pencil case.*

Bag

Package* (small capacity package can be called a *sachet, sachet)

test tube

Foot

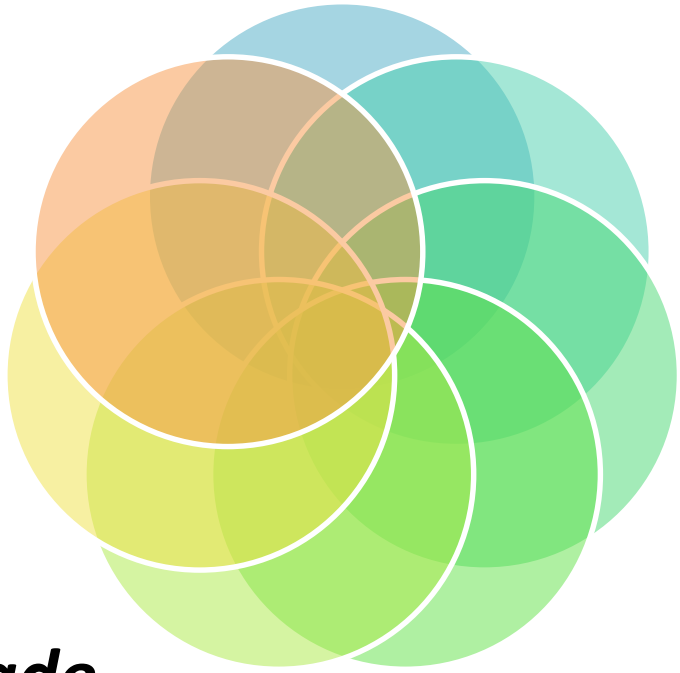
tuba

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

By type and type (4)

Syringe tube .

Tube-dropper .



Flask .

bottle .

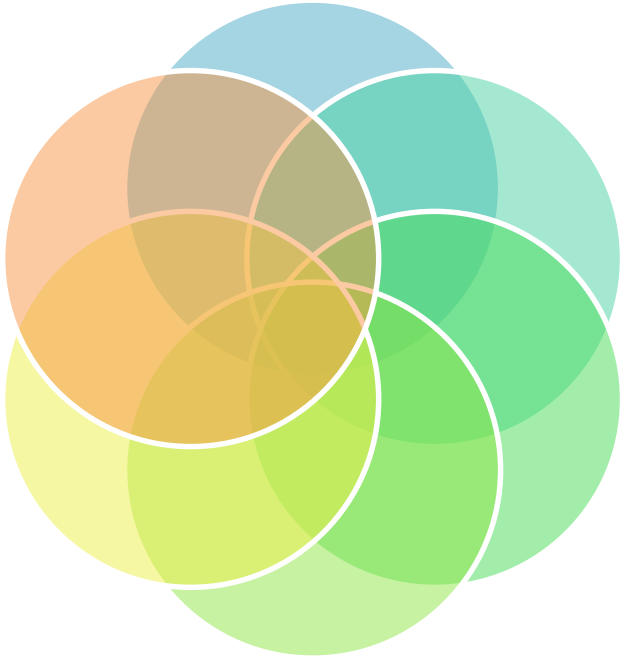
Bottle made of glass tube (drota) .

Dropper bottle .

TYPES OF PACKAGING OF MEDICINES (OFS.1.1.0025.18)

According to mechanical properties:

Flexible packaging - packaging made from easily foldable packaging materials based on paper, foil, polymers, cardboard.



Rigid packing - packaging, the shape and dimensions of which do not change when filling or removing the contents.

Soft packing - packaging, the shape and dimensions of which change when the contents are filled or removed .

Fragile packaging - packaging sensitive to dynamic loads.

PACKAGING ELEMENTS FOR MEDICINAL PRODUCTS

Elements of medicines packaging (OFS.1.1.0025.18)

The complex of products that form the packaging of medicines includes:

- container,
- closures,
- dosing equipment,
- delivery vehicles,
- auxiliary packaging
- other packaging elements regulated by the requirements of a pharmacopoeial monograph or regulatory documentation for a specific medicinal product (protective device, sealing device) .

For medicines, the functional significance of the package is not limited only to its safety, but also implies the achievement of other equally important goals: ensuring the convenience of using the drug, the possibility of dosed use, sterility, control of the first opening of the package, inaccessibility for opening it by children, and so on, which is even more makes the quality of finished drugs dependent on their packaging .

The main *elements of packaging:*

container;

closures - used to seal containers or finished products;

auxiliary packaging means - means that are used to improve consumer properties (droppers, dispensers, files, knives, etc.);

information materials - everything that is included in the packaging for user information (leaflets in medicines, instructions for use, etc.).

Elements of drug packaging (OFS.1.1.0025.18)

Packing elements:

- ***Tara***
- ***closure***
- ***Dosing agent;***
- ***Means of drug delivery;***
- ***Protective device;***
- ***Sealing device.***

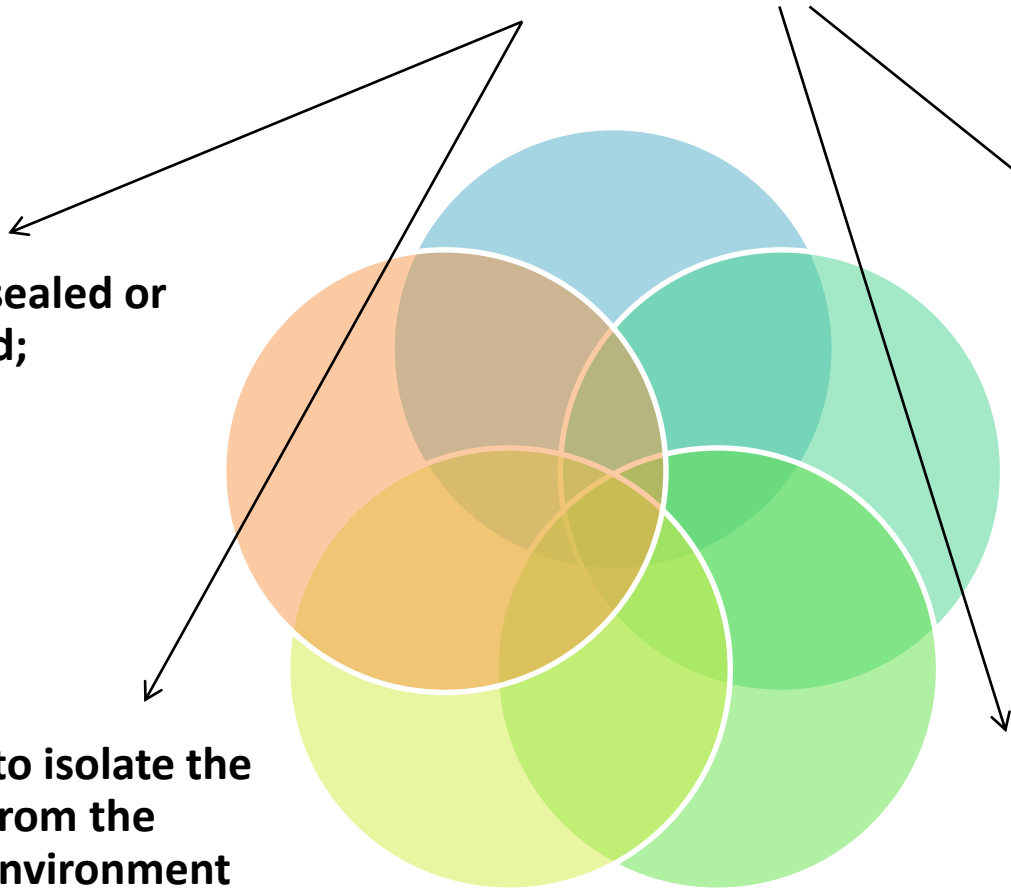
REQUIREMENTS FOR PRIMARY PACKAGING FOR MEDICINAL PRODUCTS (1)

Special requirements are imposed on the material for primary packaging in contact with the medicinal product :

- gas and vapor tightness ,
- chemical indifference to the human body and the ingredients of the drug,
- strength,
- temperature resistance,
- opacity,
- barrier resistance to microorganisms.

REQUIREMENTS FOR PRIMARY PACKAGES FOR MEDICINAL PRODUCTS (2)

Individual packaging must meet the following *consumer properties (1)* :



be securely sealed or closed;

have a marketable appearance, that is, have a pleasant color and uniform color, a smooth clean surface (without grease and mechanical impurities, mold, corrosion, etc.);

it is good to isolate the contents from the external environment during the established expiration date;

be comfortable to use, carry or transport;

REQUIREMENTS FOR PRIMARY PACKAGES FOR MEDICINAL PRODUCTS (3)

Requirements for consumer properties (2):

allow the possibility of sterilization;

allow the possibility of control of the first opening of the package ;

good adhesive performance, characterizing the ability of materials to be connected using adhesives or by heat sealing;

have the same geometric shape for a given batch, providing compact storage;

provide, if necessary, such placement of the medicinal product, which would allow, with repeated use, to maintain tightness, sterility and control of use;

be cheap, not scarce;

allow the possibility of using high-performance, low-waste technology for processing material into packaging;

fit or prepared for labeling or printing;

contain information about the storage and administration of the medicinal product.

Medicinal product packaging elements (OFS.1.1.0025.18) (1)

Container - the main element of the package intended for the placement of medicines, the design of which may include the presence of closures to create tightness or a closed space.

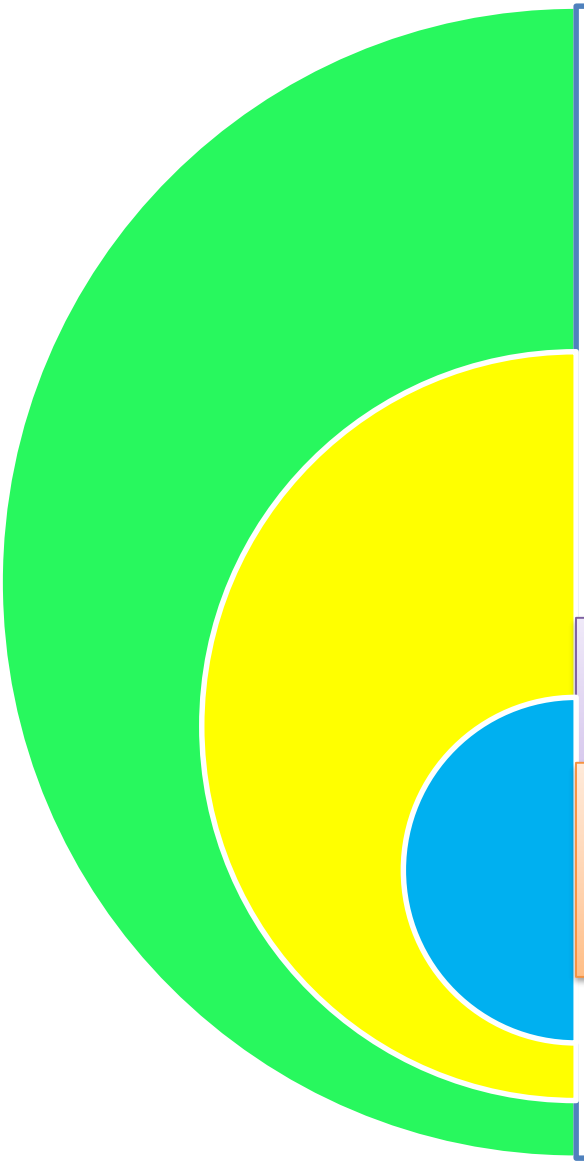
is a product designed to seal a package and preserve its contents .

Closures have a different appearance (shape, external outlines) and type (material and model).

The main types and types of closures:

- ***Cork***
- ***Lid***
- ***Bouchon***
- ***Cap-cap***
- ***Cap***

Elements of the medicinal product
packaging OFS.1.1.0025.18 (2)

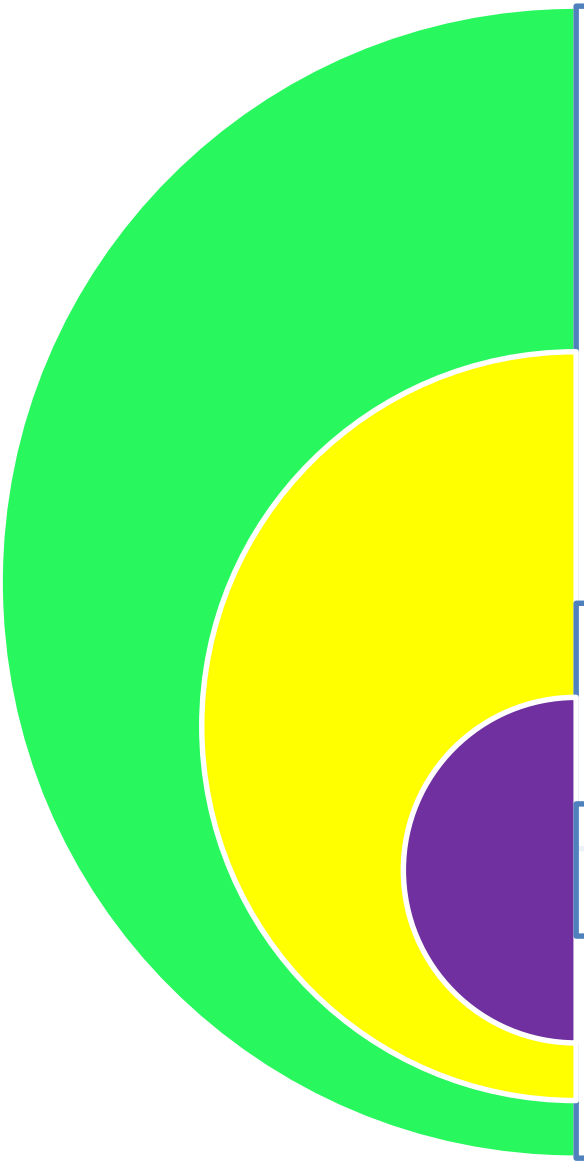


Dosing agent *(dispenser, dosing device)* - ***a functional device for measuring (dosing) a given mass or volume of a medicinal product, which can be an element of a closure*** (dropper inserts, eye and nasal droppers, etc.) or an independent packaging component (measuring spoons / spoons, measuring caps / cups, syringe dispensers, pipettes, vaginal and rectal applicators, etc.):

Dosing nozzle

Dispenser-limiter

Elements of the medicinal product
packaging OFS.1.1.0025.18 (3)



Medicinal product delivery device - a functional device, an element of a package (closure) that ensures the delivery of a medicinal product to the site of its administration.

Aerosol valve

Dosing valve for aerosols

Elements of the medicinal product
packaging OFS.1.1.0025.18 (4)

Protective device **-** an element of a closure that protects the package from unauthorized opening and provides visual control of the first opening .

The protective devices of the packaging are:

- retractable valve disc,
- ferrule,
- control retaining ring
- detachable belt,
- perforation ,
- foil membrane, etc.

Label-package **- a packaging and labeling element** , which is a strip (tape) of packaging material made of paper or combined materials, designed for gluing (banding) a group or consumer package (box) around the entire perimeter with connecting the ends of the strip, to ensure control of the first opening and subsequent marking on the strip (package).

Elements of packaging of the medicinal product

OFS.1.1.0025.18 (5)

***Sealing device* -** a closure element that protects the contents of the package from loss and from the effects of external climatic factors (self-sealing lids, lids with sealing gaskets, lids with a silica gel insert, sealing gasket, etc.).

Packaging materials

(OFS.1.1.0025.18)

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

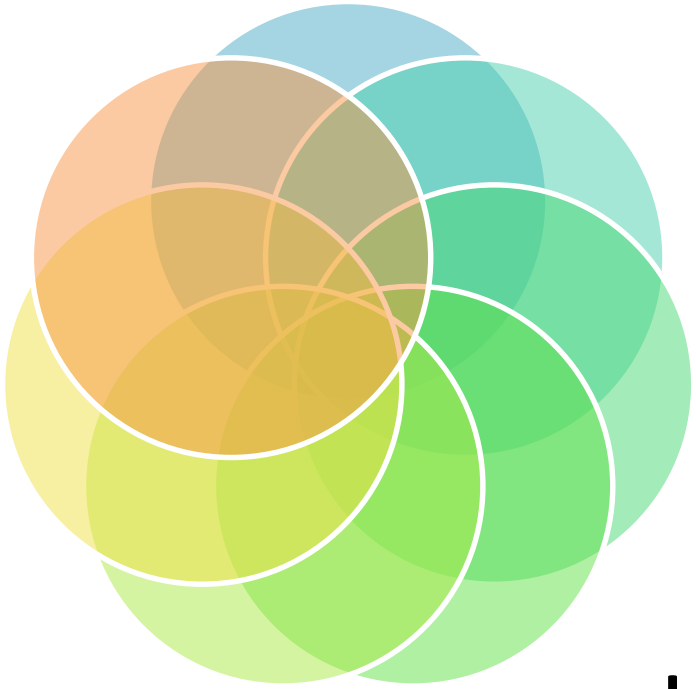
Depending on the presence of direct contact with the medicinal product (dosage form), packaging materials can be:

primary

secondary

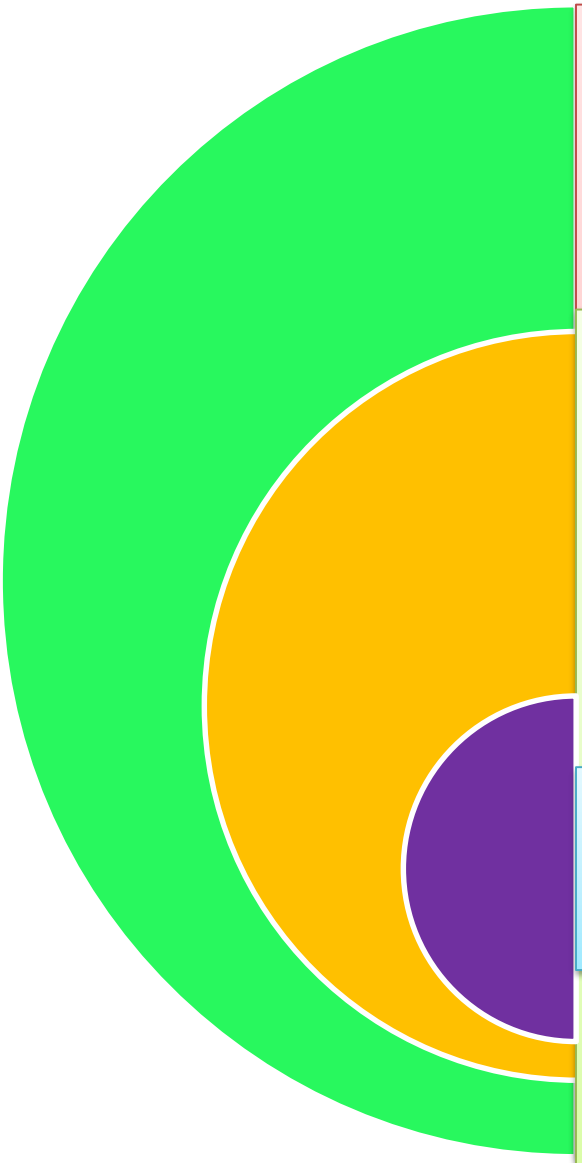
Packaging materials (OFS.1.1.0025.18) (2)

The main raw materials of pharmaceutical packaging materials are:



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

Packaging materials
OFS.1.1.0025.18 (3)



***Glass* -** is the primary packaging material for the production of one of the main elements of the packaging of medicines - glass containers.

Various grades of medical glass are used, differing in chemical composition. The choice of glass brand depends on the physicochemical properties, method of application and other characteristics of the medicinal product and / or dosage form in contact with the primary packaging material - glass.

The brand of medical glass, as a rule, is indicated in the pharmacopoeial monograph or regulatory documentation for the medicinal product.

Packaging materials. *Glass*
OFS.1.1.0025.18 (4)

- **Glass grade XT and XT-1** is chemically and thermally resistant and is used **for the production of syringes.** XT-1 glass can also be used for the production of bottles for storing blood, transfusion and infusion drugs and ampoules.
- **Glass grades HC is a neutral glass. Grades NS-1, NS-1A and NS-3** are used for **the production of ampoules and vials** , while glass of the NS-3 brand can be used for solutions of substances undergoing hydrolysis, oxidation and similar changes, including in syringes, and glass of the NS brand -1 - for solutions of substances less sensitive to alkalis. Colorless medical glass grades NS-2 and NS-2A is intended, as a rule, for the production of glass bottles for storing blood, transfusion and infusion drugs and aerosol cans.
- **Glass brand AB-1** is ampoule, boronless , alkaline glass, used mainly **for the production of ampoules, vials** .
- **Glass brand SNS-1 - light-protective** neutral glass **for the production of ampoules for solutions of photosensitive substances.**
- **For the production of jars and vials** used as the primary packaging of medicines that do not require sterilization, aseptic preparation and are not intended for parenteral use, as a rule, **medical glass grades MTO** (discolored medical packaging) are used, and for photosensitive substances - colored **glass grades OS, OS-1** (orange container).

Packaging materials

OFS.1.1.0025.18 (5)

Polymeric materials are widely used in the production of packaging for medicines and various packaging elements - containers, closures, dosing and delivery devices, auxiliary packaging tools, etc.

The polymeric materials can be primary and secondary packaging materials.

For medicines, only certain types and brands of polymeric materials approved for use are used as packaging materials.

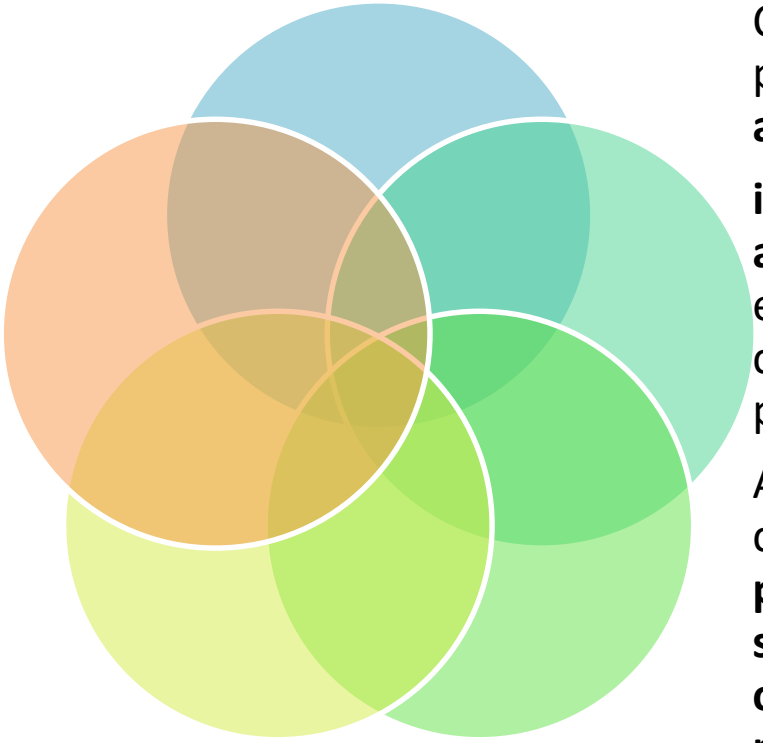
For the production of packaging and packaging elements, polypropylene, low and high pressure polyethylene and their mixtures, polyvinyl chloride, polyethylene terephthalate, polystyrene and other polymeric materials are used.

The composition of packaging polymeric materials can include special additives consisting of antioxidants, stabilizers, plasticizers, lubricants, dyes, impact strength modifiers, etc.

Packaging materials
OFS.1.1.0025.18 (6)

Polymer materials:

Quality indicators and acceptance criteria are established in the regulatory documents for specific types of packaging, depending on its purpose and the nature of the packaged medicines.



Compared to glass, polymer packaging has **the following advantages:**

it is unbreakable, flexible and lightweight , which is especially important when choosing packaging for parenteral solutions.

At the same time, when choosing packaging **for parenteral solutions, the semi-permeability property of polymeric packaging materials should be taken into account.**

Polymer packaging and packaging elements must comply with the requirements of the current standards for this type of packaging.

Packaging materials
OFS.1.1.0025.18 (7)

Elastomeric materials (rubber, silicone elastomers)

Elastomeric materials are mainly used **as primary packaging material for the production of closures** . ***They are a complex multicomponent elastic polymeric material, including an elastomeric component and various additives.***

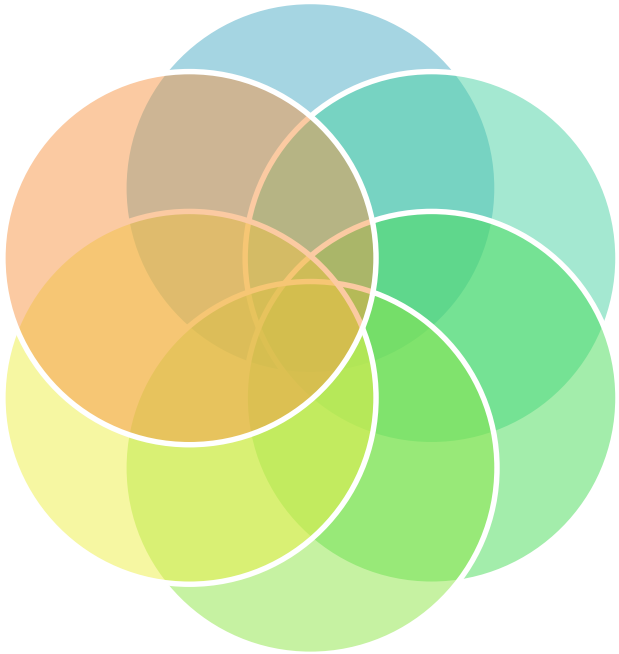
The main properties and characteristics of an elastomeric material significantly depend **on the composition and type of vulcanization (crosslinking) of its base elastomer** , as well as on **additives introduced to provide the desired properties (accelerators, fillers, plasticizers, softeners , stabilizers, antioxidants, etc.**), which can be up to 50% elastomeric mixture.

In the production of rubber stoppers intended for the packaging of medicines, the **rubber mixture based on butyl rubber and halobutyl rubber (chlorobutyl rubber) is most widely used . and bromobutyl rubber**).

Packaging materials
OFS.1.1.0025.18 (8)

Metal

, **etc.** Tin, which is an alloy of steel with an appropriate metal coating, is used mainly for the production of primary packaging - metal cans, tins and lids for them.



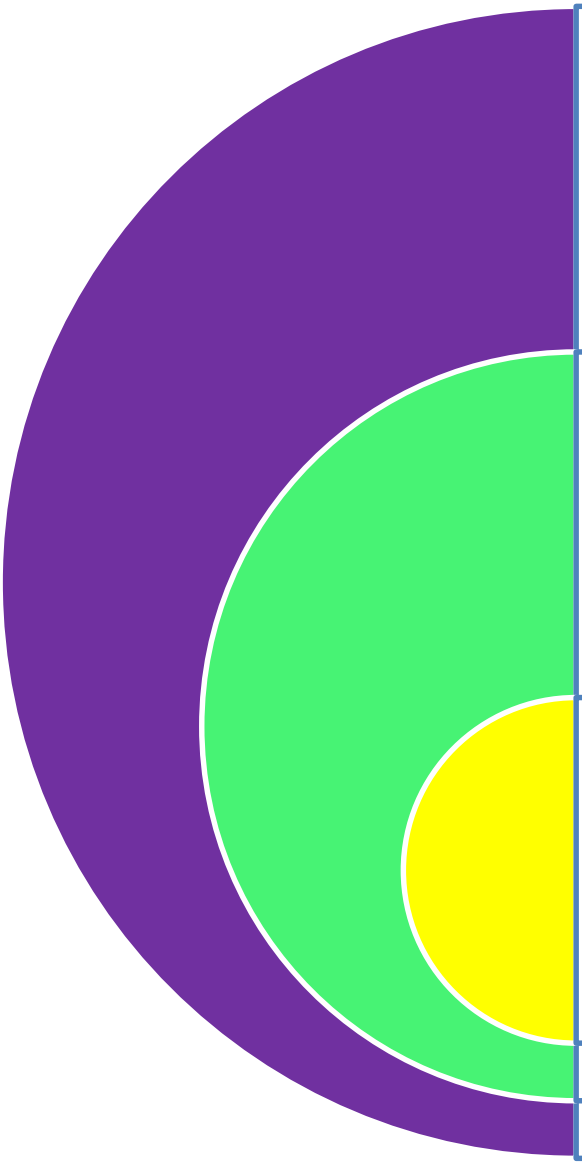
For the production of packaging and some elements of the packaging of medicines, **steel and aluminum metal alloys are used as primary and secondary packaging materials.**

Aluminum is the main component of aluminum alloys used to produce primary packaging (aerosol cans, tubes, cans, test tubes, etc.), transport packaging (drums, barrels, flasks), closures (caps, lids) and other packaging elements .

Aluminum foil is used in the production of flexible contour packaging, various sealing and protective elements of packaging, and together with paper and / or polymeric material is used for the production of combined packaging.

Packaging materials

Metal OFS.1.1.0025.18 (9)



Compared to packaging made of polymeric materials and glass, **packaging made of metals is more durable, impervious to gases, unbreakable, and provides good protection against opening.**

Corresponding grades of metal alloys are recommended **as a primary packaging material for the production of packaging for medicines used under pressure in the form of aerosols, liquefied gases** , etc.

The metal **is not intended for the primary packaging of medicinal products for parenteral use.**

Packaging materials

OFS.1.1.0025.18 (10)

Paper and cardboard

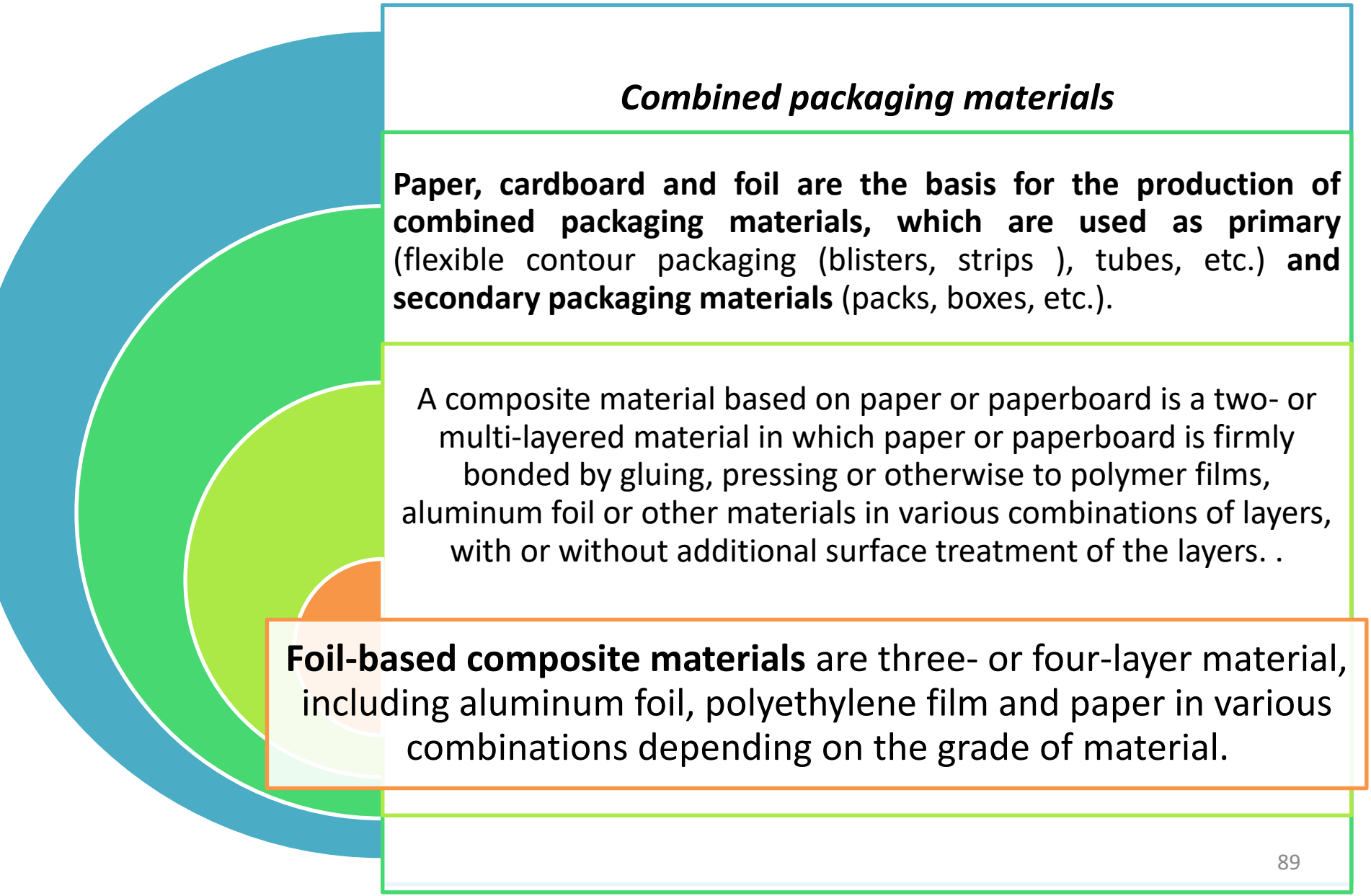
Paper is used as a primary and secondary packaging material for medicines, and as a packaging aid.

Cardboard is most often used as a secondary packaging material in the production of secondary (consumer), group or transport packaging (boxes, packs, etc.).

For the production of packaging, certain brands of various types of paper are used (waxed paper, vegetable parchment, etc.) and cardboard (cardboard for consumer packaging, corrugated cardboard, etc.). As secondary packaging, paper is used: label, writing, bag, etc.

The quality of paper and cardboard used in the manufacture of packaging for medicines must comply with the requirements of applicable standards, and the quality indicators of packaging made using these materials must comply with the documentation for this type and type of packaging, approved in the prescribed manner.

Packaging materials
OFS.1.1.0025.18 (11)



Combined packaging materials

Paper, cardboard and foil are the basis for the production of combined packaging materials, which are used as primary (flexible contour packaging (blisters, strips), tubes, etc.) **and secondary packaging materials** (packs, boxes, etc.).

A composite material based on paper or paperboard is a two- or multi-layered material in which paper or paperboard is firmly bonded by gluing, pressing or otherwise to polymer films, aluminum foil or other materials in various combinations of layers, with or without additional surface treatment of the layers. .

Foil-based composite materials are three- or four-layer material, including aluminum foil, polyethylene film and paper in various combinations depending on the grade of material.

General requirements for the packaging of medicines

General requirements for the packaging of medicines

OFS.1.1.0025.18

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

Packaging and packaging elements (tare, 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 (tare, 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.

General requirements for the packaging of medicines (2)

OFS.1.1.0025.18

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).

General requirements for the packaging of medicines (3)

OFS.1.1.0025.18

The packaging must be the same for each batch of packaged medicinal products.

Packaging must **ensure the preservation of the effectiveness, quality and safety of the medicinal product at all stages of its circulation:** it must not lead to the loss of the medicinal product, including through diffusion or penetration of the medicinal product through it; be strong enough to hold the contents in normal use; do not change under the influence of the components of the drug.

General requirements for the packaging of medicines (4)

OFS.1.1.0025.18

The packaging must have properties that protect the medicinal product from:

adverse effects of environmental factors that can affect its quality or effectiveness (such as light, temperature, atmospheric gases and air vapor),

microbiological contamination,

to prevent the permeability (penetration) of these factors to the medicinal product through the packaging materials and closures.

The packaging must **protect the medicinal product from physical (mechanical) damage.**

General requirements for the packaging of medicines (5)

OFS.1.1.0025.18

The packaging must **ensure the preservation of the mass (volume), quality and stability of the medicinal product** (content of the active substance within the limits established by the Pharmacopoeia Monograph) **during the established shelf life under the declared storage conditions.**

The selected type and type **of packaging should not interact physically or chemically with the medicinal product** inside the package, as this may lead to a change in its quality.

closures chosen for the packaging of the medicinal product must be inert with respect to the contents of the package, ensure the reliability of the closure, and not cause undesirable interaction between the contents of the package and the external environment.

General requirements for the packaging of medicines (6)

OFS.1.1.0025.18

packaging **must ensure compliance with the storage conditions of the medicinal product in accordance with the "Storage" indicator of the** pharmacopoeial monograph or regulatory documentation.

The labeling applied to the packaging must ensure the identification of the medicinal product and provide the amount of information about the medicinal product established by regulatory documents to the consumer and specialists who work with it.

Packaging should **help protect the consumer from counterfeiting, falsification, prevent opening of the medicinal product before use** , as well as ensure convenience and safety in its use.

Dosed packaging should **provide dosed or piece-by-piece extraction of the medicinal product.**

General requirements for the packaging of medicines (7)

OFS.1.1.0025.18

Packaging should have an **aesthetic appearance, be convenient for transportation and storage, economical and comply with modern environmental standards** , require minimal disposal costs.

Packaging intended for narcotic and psychotropic drugs, radiopharmaceutical drugs and some other drugs must comply with the requirements imposed on it by the relevant Federal laws and regulations of the Russian Federation.

Marking

Marking. Definition of the term.

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.

LABELING OF MEDICAL AND PHARMACEUTICAL PRODUCTS

Marking is a text, symbols (signs) or a picture applied to the packaging and / or product, as well as other auxiliary means **designed to identify the product or its individual properties, bring to the consumer information about manufacturers (performers), quantitative and qualitative characteristics of the product .**

Depending on the place of application, there are:

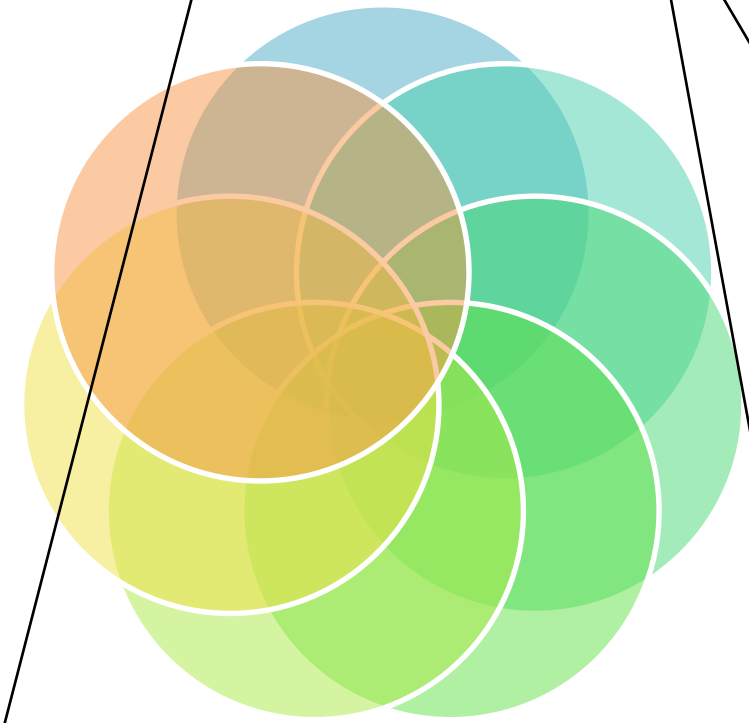
- production and

- trade marks.

Marking functions

Marking features **include :**

The marking is applied to the goods and containers by the manufacturer of the products.



main information

identifying

emotional

motivational

MAIN ELEMENTS OF MARKING

The following main marking elements are distinguished:

- 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.

MARKING REQUIREMENTS:

General requirements:

reliability and objectivity of information about the product, the absence of misinformation and subjectivity in their presentation, misleading information users;

accessibility - language accessibility, demand , understandability;

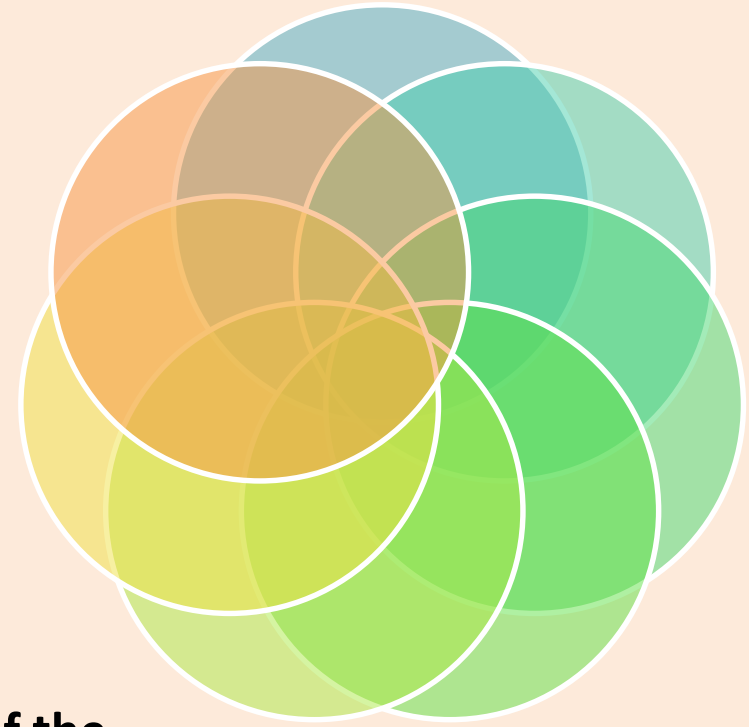
sufficiency - rational information richness.

MARKING REQUIREMENTS:

Specific requirements:

reliability of each label element.

clarity of text and illustrations;



use for marking indelible dyes approved for use in medicine ;

visibility;

compliance of the text with the consumer properties of the product;

the unambiguity of the text;

LABELING REQUIREMENTS FOR MEDICINES

Particularly **stringent requirements are imposed on the production labeling of medicines** , which is regulated

- **Federal Law 61 "On the Circulation of Medicines",**

- Methodological recommendations of the Ministry of Health and Social Development of the Russian Federation **MR 64-03-004-2004 “Graphic design of medicines. General requirements",**

- **State Pharmacopoeia 14**

FZ-61 "On the circulation of medicines" art.46. Labeling of medicines

1. Medicinal products, with the exception of medicinal products manufactured by pharmacy organizations, veterinary pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities, must 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 .

FZ-61 "On the circulation of medicines" art.46. Labeling of medicines (2)

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

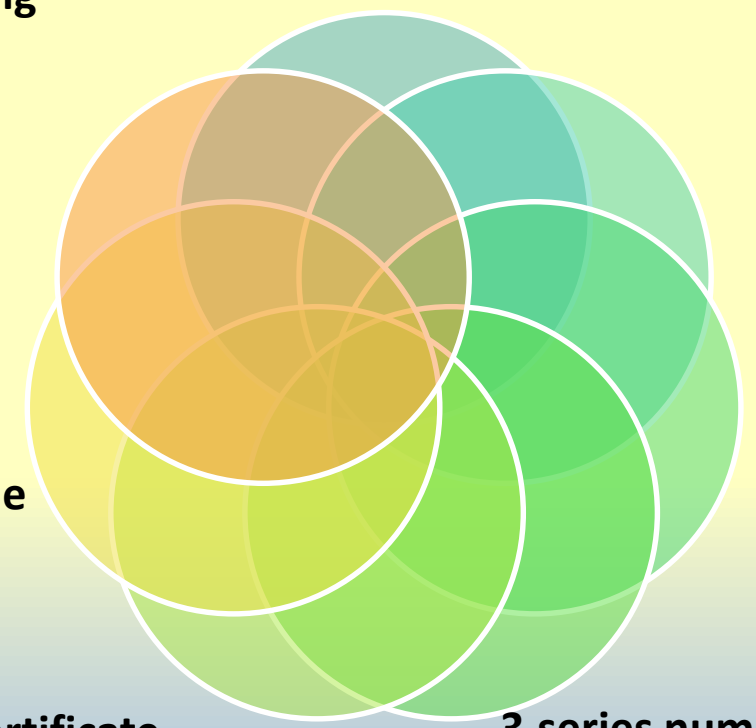
8.dosage or concentration

9.volume

10. activity in units of action or the number of doses in the package

11. dosage form 12. dispensing conditions

13. storage conditions 14. warning labels.



FZ-61 "On the circulation of medicines" art.46. Labeling of medicines (3)

The secondary (consumer) packaging of medicinal products obtained from blood, blood plasma, human organs and tissues must bear the inscription: "Antibodies to HIV-1, HIV-2, hepatitis C virus and hepatitis B surface antigen are absent."

5. The primary packaging and secondary (consumer) packaging of radiopharmaceutical medicinal products must be marked with a radiation hazard sign.

6. The inscription "Homeopathic" must be applied to the secondary (consumer) packaging of homeopathic medicinal products.

7. The following inscription must be applied to the secondary (consumer) packaging of medicinal herbal preparations: "The products have passed radiation control."

8. Primary packaging (if there is a technical possibility for this) and secondary (consumer) packaging of medicinal products intended for clinical trials must bear the inscription: "For clinical trials".

FZ-61 "On the circulation of medicines"
art.46. Labeling of medicines (4)

9. The packaging of medicines intended exclusively for export is labeled in accordance with the requirements of the importing country.

10. On the transport container, which is not intended for consumers and in which the medicinal product is placed, information on:

- name, series of medicinal product, date of issue,
- the number of secondary (consumer) packages of the medicinal product
- the manufacturer of the medicinal product, indicating the name and location of the manufacturer of the medicinal product (address, including the country and (or) place of production of the medicinal product),
- on the shelf life of the medicinal product and on the conditions of its storage and transportation,
- necessary warning labels and handling signs.

MARKING MEDIA

***Marking carriers* can be:**

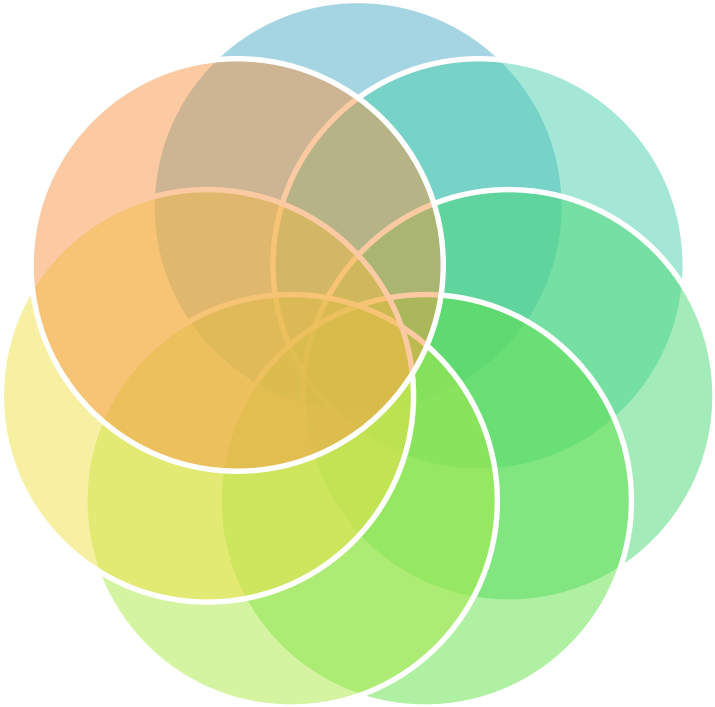
labels

control tapes

hallmarks

stamps

tags



labels

facets of consumer packaging

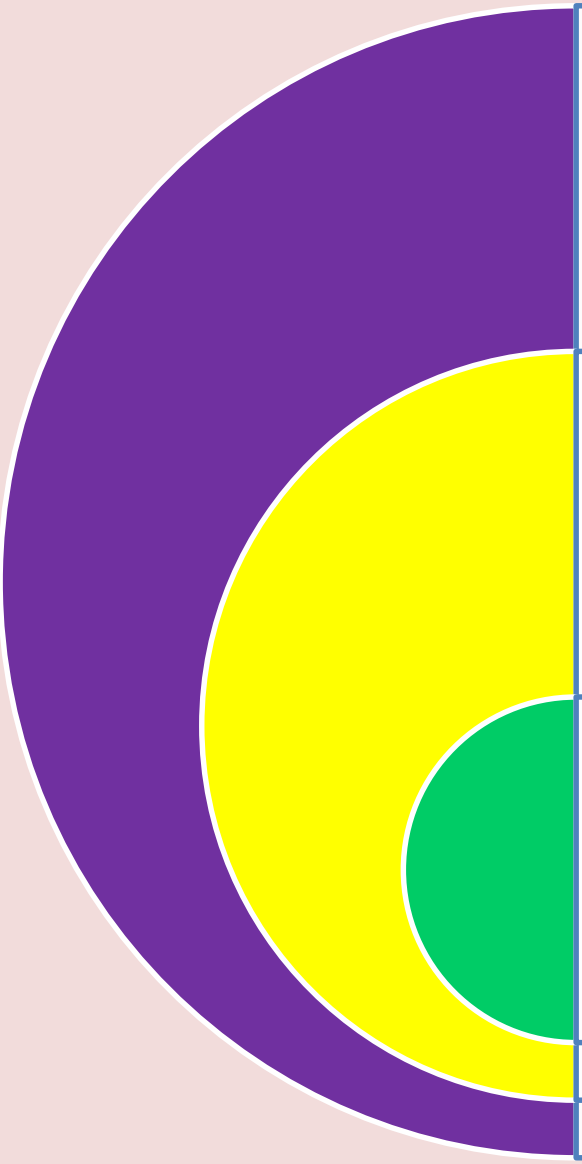
liners

collarettes

MARKING MEDIA

- ***Labels* are** the most common carrier of information for pharmaceutical and parapharmaceutical products. Labels are attached to the packaging or directly to the product. Labels are distinguished by significant information capacity, they contain the most extensive information in terms of the number of characteristics, including all types of information (fundamental, commercial, consumer).
- ***Collierettes* -** type of labels; have a special shape, are glued to the neck of bottles (they are rare, mainly on packages of parapharmaceutical products). Collierettes do not carry a large informational load, their purpose is the aesthetic design of bottles.
- ***Inserts* are** a type of labels that differ in the direction of information about the product. Inserts, as a rule, are used in the presence of double consumer packaging (bottle + carton pack; tube + carton pack; cellular packaging + carton pack, etc.). The role of the insert can be performed by "Instructions for use ...", "Leaflet", "Information sheet".
- ***Tags* and *labels* are** labeling carriers that are applied or hung to the product. Labels are less informative than labels. Used by manufacturers of parapharmaceutical products, balms.
- ***Control Tapes*** - carriers of brief duplicate information performed on a small information field.
- ***Hallmarks* and *stamps*** are information carriers intended for applying identifying symbols on containers, packaging, labels using special devices.

TEXT AS A MARKING ELEMENT



The text can perform all the basic functions of marking, but to a greater extent it is inherent in:

- informational

- identifying functions .

On the packaging of pharmaceutical and **parapharmaceutical products, the text part occupies a significant place** (the share is from 50 to 100%).

The text can be presented in several languages (Russian, Latin, the language of the country of origin of the goods).

DRAWING AS AN ELEMENT OF THE MARKING STRUCTURE

The drawing is highly accessible and does:

emotional

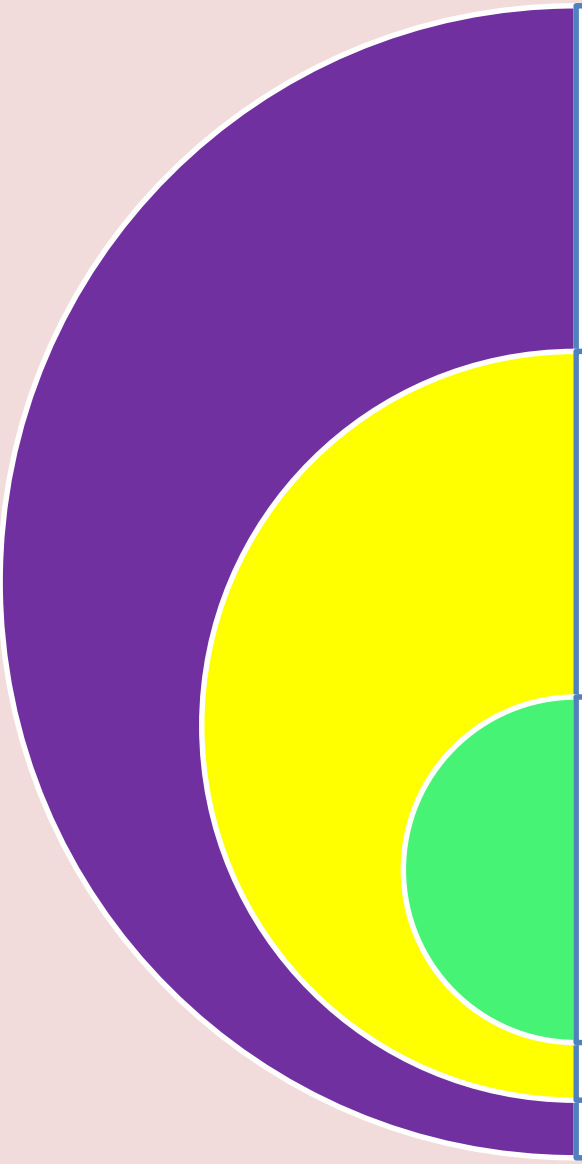
motivational function.

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%.

Drawings are more common on the packaging of parapharmaceutical products .

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (1)



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 is 28-30** %.

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

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (2)

Information signs are divided into:

- trademarks;
- name of the place of origin (place of destination);
- marks of conformity or quality,
- component;
- dimensional;
- manipulation;
- operational;
- warning;
- ecological.

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (3)

Trademarks ***are designations that allow you to distinguish the goods of some manufacturers (suppliers) from homogeneous goods of other manufacturers*** . Registration of trademarks is carried out by the Russian Agency for Patents and Trademarks on the basis of a written application of a legal or natural person.

A certificate is issued for a registered trademark . The certificate certifies the priority of the trademark, as well as the ***exclusive right of the owner to the trademark in relation to the goods specified in the certificate*** .

Word, figurative, three-dimensional or other designations or combinations thereof may be registered as trademarks. ***A trademark can be registered in any color or color combination*** .

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (4)

A trade mark is used to identify the manufacturer of goods . Trademarks are divided **into brand names, brand names proper, expressed through graphic images of a distinctive color, and trademarks.** The latter are registered in the International Register and are legally protected by **the ® sign** next to the name. **An indication that a trademark is the property of the company is denoted as a © sign.**

The name of the place of origin (place of destination) **is a kind of trademark, which is understood as the name of a country, locality, locality or other geographical object** . The name of the place of origin of goods is used to designate goods, the special properties of which are exclusively or mainly determined by the natural conditions characteristic of a given geographical object or human factors, or both at the same time.

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (5)

Marks of conformity or quality . These marks, in turn, are divided **into marks of conformity, marks of circulation on the market and marks of quality.** The first two characters are regulated by the Federal Law "On Technical Regulation", as well as by the international standard - ISO / IEC Guide 2.

A mark of conformity is a duly protected mark applied or issued in accordance with the rules of a certification system indicating that the necessary assurance is provided that a given product, process or service conforms to a particular standard or other normative document.

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (6) - conformity marks

Depending on the scope of application, there are:

national marks of conformity;

transnational marks of conformity.

National mark of conformity - a sign confirming compliance with the requirements established by national standards or other regulatory documents.

It is developed, approved and registered by the national certification body. The main requirements for the image of Russian conformity marks used for mandatory certification are defined by GOST R 50460-92.

Samples of Russian conformity marks: 1 - GOST R mark; 2, 3 - variants of signs of circulation on the market

1

2

3

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (7) - conformity marks

The conformity mark is placed on the product or container, packaging, accompanying technical documentation .

It is applied to the non-removable part of each unit of certified products, and when applied to packaging - to each packaging unit of these products.

The conformity mark can be applied next to the trademark.

Labeling of goods with conformity marks is carried out in ways that ensure a clear image of these marks, their resistance to external influence factors , as well as durability during the established service life or shelf life of the product.

The image of the sign must be contrasting against the background of the surface on which it is applied.

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (8) - conformity marks

Voluntary certification systems use special secure signs, which are a single secure numbered holographic image. When attempting thermal or mechanical impact, this sign of conformity is destroyed.

This system is designed to protect goods from counterfeiting, identify manufacturers and importers and provide the consumer with the opportunity to quickly get acquainted with the data on the certification of goods and their origin.

Foreign-made products can be marked with both *national marks of conformity and marks of conformity of regional international organizations* .

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (9) - conformity marks

Transnational (regional) conformity marks **- signs confirming compliance with the requirements established by regional standards** . They are applied in the countries of a certain region on the basis of agreed standards and mutual recognition of certification results.

An example of a transnational mark of conformity is the CE mark - marking, accompanied by the identification number of the certification body and additional marks, depending on the conformity assessment schemes used and the type of product. The CE mark indicates that the products comply with the essential requirements of the European Union directives.

The marks are placed on the goods included in the list, based on the results of their control at the state level or at the provincial level for two consecutive years.

INFORMATION SIGNS AS AN ELEMENT OF MARKING STRUCTURE (10)

Component signs are intended for information about the food additives used or other components specific to the product.

For example, **all food additives used in such pharmacy products as dietary supplements, baby food, diet food, cosmetics are divided into functional classes depending on the technological functions:**

E 100 - E 182 - dyes (used to color some food products);

E 200 and further - preservatives (used to extend the shelf life of food products);

E 300 and beyond - antioxidants (antioxidants) (slow down oxidation, thereby protecting food from spoilage);

INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (11)

E 500 and further - emulsifiers (support a certain structure of food);

E 600 and further - flavor and aroma enhancers (enhance the taste and aromatic properties of food products);

E 700 and beyond - spare indices ;

E 800 onwards - anti- flamings (reduce the foaminess of food products);

E 1000 - forming group: glazing agents, sweeteners and etc.

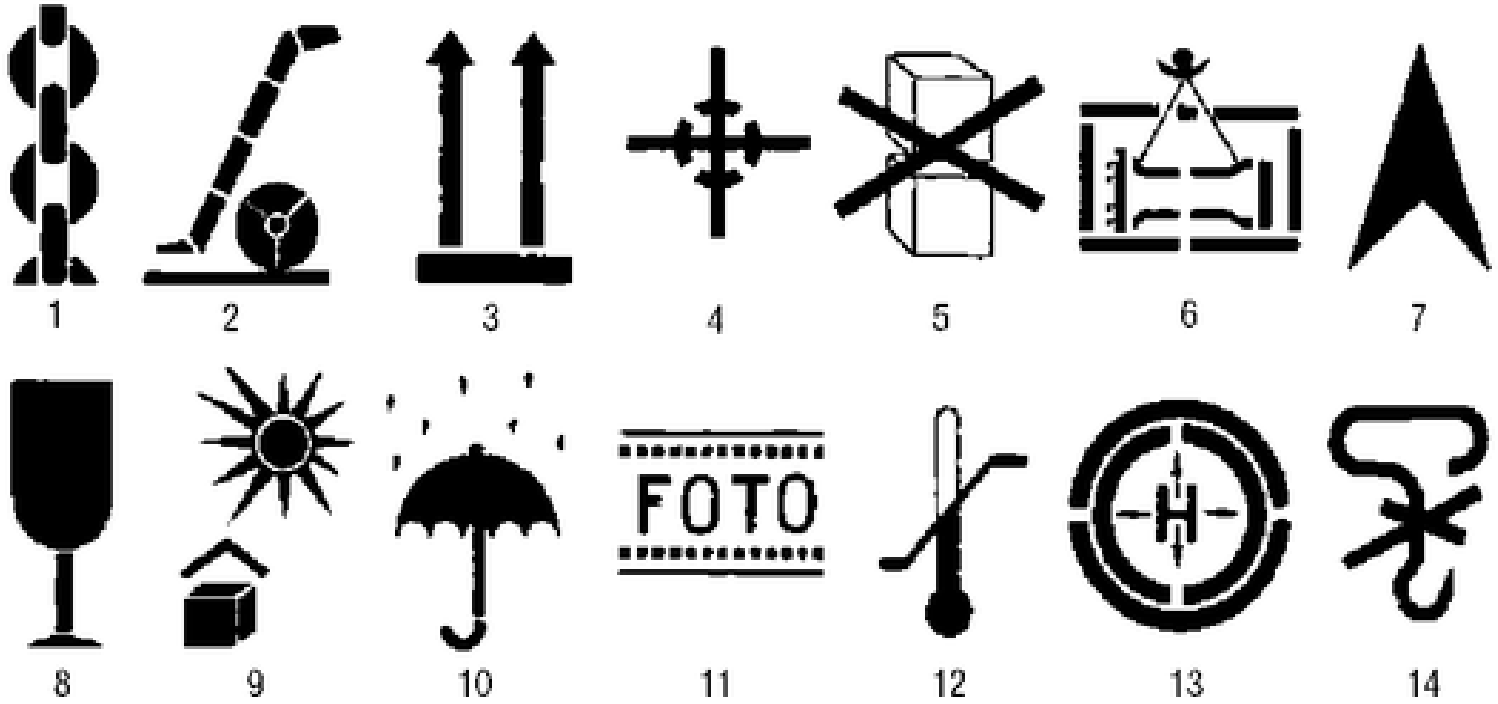
INFORMATION SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (12)

Dimensional signs **are intended to designate certain physical quantities that determine the quantitative characteristics of the goods - for example, net weight, volume.**

The code of dimensional signs is quite simple. The actual size of this quantity in the accepted units of measurement is added to the symbol of a physical quantity. Most often, units of measurement are used in the SI system, much less often in the national units of the importing country (feet, inches, etc.).

It is not difficult to decipher dimensional signs by the numerical value of the dimensional characteristic and the units of measurement used. For example, if 450 ge is marked on the label , this means a net weight of 450 g.

Manipulation marks - images applied to the shipping container, indicating the methods of handling goods : 1 - slinging place ; 2 - a place for lifting by a trolley; 3 - do not turn over the top; 4 - center of gravity; 5 - stacking is prohibited; 6 - lift directly behind the load; 7 - open here; 8 - carefully, fragile!; 9 - afraid of heating; 10 - afraid of dampness; 11 - afraid of radiation; 12 - compliance with the temperature range; 13 - sealed packaging; 14 - during transportation and storage, it is forbidden to open, do not take directly with hooks.



Operational signs **are intended to inform the consumer about the rules of operation, methods of care, adjustment of goods, and in the case of medicines, indicate the method of their use.**

Performance labels help the consumer understand ***how to take a drug or how to properly use a medical device.***

The role of operational signs can sometimes be performed by drawings.

An example of an operational sign "Description of the method of applying the drug"

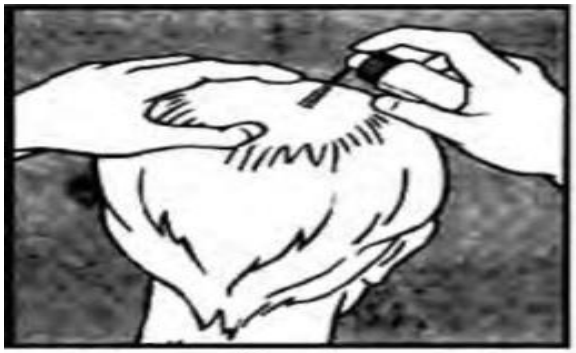


Рис. 1

Рис. 2

Рис. 3

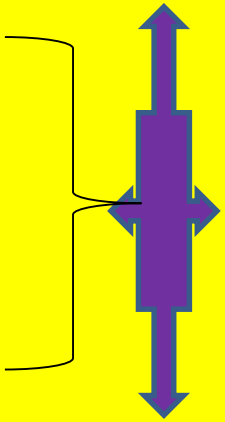
Рис. 4

WARNING SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE

Warning signs **carry information that has** ***the character of a warning about something*** . Warning labeling **includes:**

special designations indicating the conditions under which the product can be used;

a warning regarding the possibility of harm or damage resulting from normal use of the product or possible misuse of the product.



the task of warning labeling is to allow people who encounter dangerous objects at work and at home to quickly and unambiguously identify their potential hazard and determine the safety rules for handling these objects additional information - to obtain information of interest to them from appropriate sources, for example, from instructions operation or safety data sheet of the material (substance).

WARNING SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE (2)

Many industrialized countries have laws and regulations that require **appropriate labeling of potentially hazardous substances to prevent accidents due to careless handling** .

Presence on production, consumer packages and transport containers with hazardous substances and materials (HSM) is provided for labels indicating the types and degrees of danger, precautions and protective equipment, first aid actions in case of injury, if it nevertheless occurred, designations of the substance according to various classifications , as well as a link to the so-called Material Safety Data Sheets [in Russia - safety data sheet of a substance (material)], containing more detailed and complete information on the safe handling of substances.

SIGNAL WORDS AS AN ELEMENT OF MARKING STRUCTURE

To attract the attention of persons associated with the operation of the product, **signal words can be used, taking into account the following hierarchy:**

DANGER - a high degree of risk;

WARNING - medium risk;

BEWARE - potential risk hazard.

An example **of precautionary labeling is the labeling and registration of medicines and medical devices (in terms of mandatory storage conditions, expiration dates and precautions for use).**

Labeling of medicinal products as a guarantee of the authenticity (authenticity) of the goods

Product labeling as a phenomenon emerged in 2017. **The main goal of development then was to guarantee the authenticity of the goods in such a significant and responsible sector as pharmaceuticals.** Everyone has personally or in the media come across information about counterfeit medicines. Manufacturers every year introduced new types and ways to protect their products from unscrupulous manufacturers.

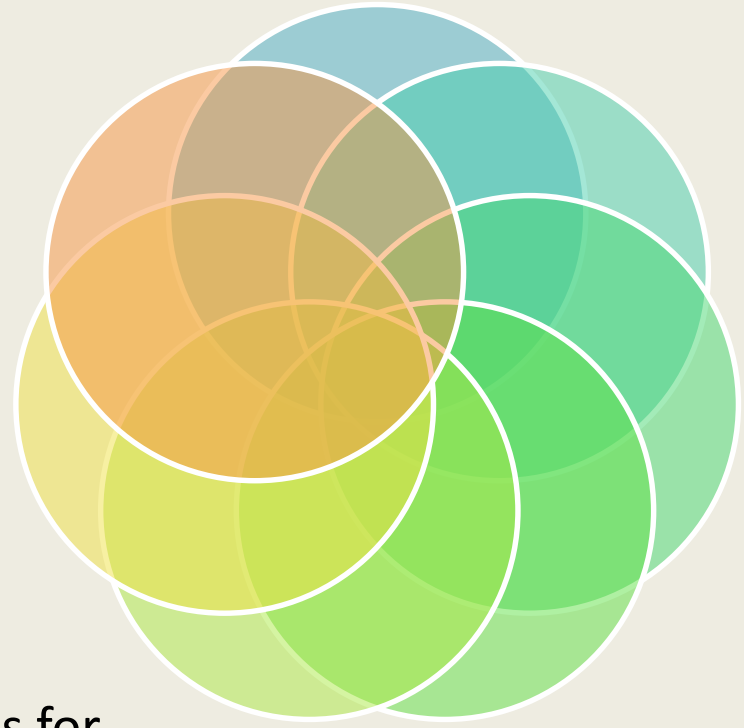
On February 1, 2017, an experiment on the labeling of medicines was launched in Russia in accordance with Decree No. 62 of January 24, 2017. On November 1, 2018, control over the circulation of medicines and pharmacological products was transferred from the Federal Tax Service (Federal Tax Service) to the Center for the Development of Advanced Technologies (CRPT). This is how the national product labeling service "Honest Sign" was formed.

Mandatory labeling of all pharmaceutical products began on January 1, 2020.

LABELING REQUIREMENTS FOR MEDICINES

On February 28, 2017, the Ministry of Health of the Russian Federation developed and implemented Guidelines for the labeling of medicines.

Recommendations include:



- The order of interaction of process participants
- Characteristics of means of identification
- Requirements for the structure and format of marking
- Requirements for equipment for applying and reading markings
- Requirements for FSIS MPPC

Definition of some terms in accordance with the Guidelines (1)

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.

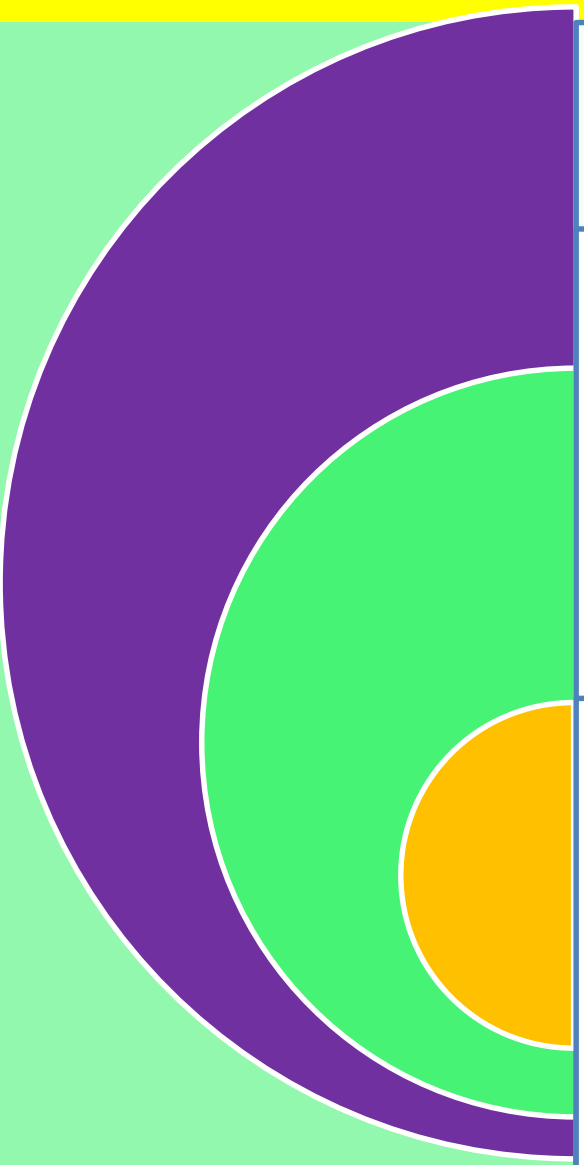
The system for monitoring the movement of drugs for medical use (FSIS MPPC) is a ***federal state information system for monitoring the movement of drugs*** for medical use from the manufacturer to the end user using identification tools for medicinal products for medical use.

Definition of some terms in accordance with the Guidelines (2)

The individual serial number of the secondary (consumer) packaging (in the absence of the primary packaging) is a numeric or alphanumeric sequence compiled in accordance with Appendix No. 1 to the Method. Recommendations.

Group code - a means of identifying a group package of medicines - a combination of symbols unique for each individual tertiary (refill, transport) package of medicines, presented in the form of a bar code generated by the issuer of group codes in accordance with the characteristics, rules and structure presented in Appendix No. 1 Method. Recommendations.

Definition of some terms in accordance with the Guidelines (3)

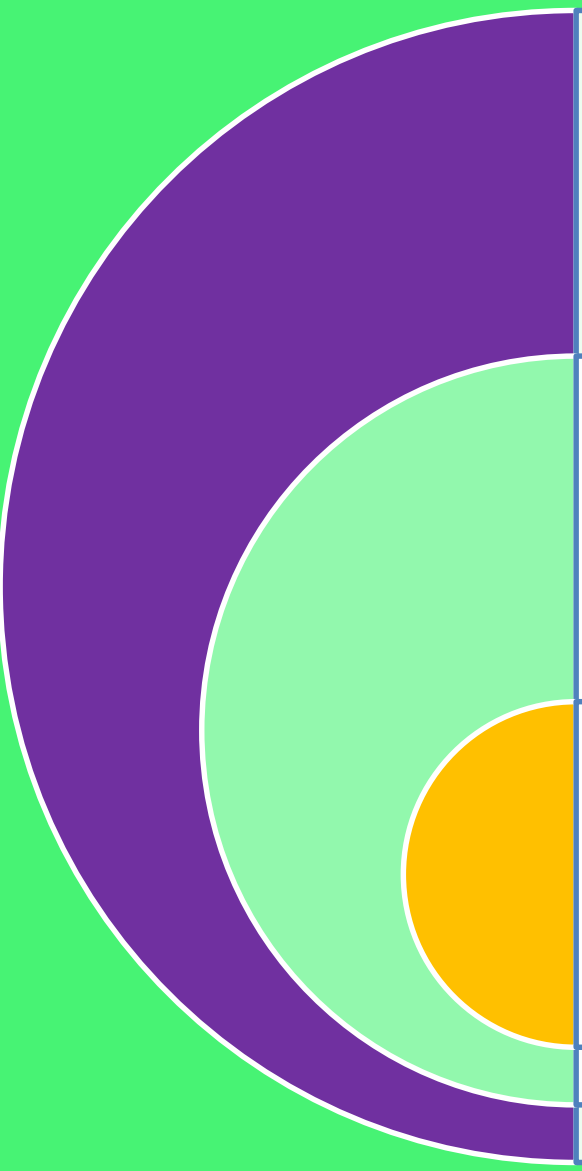


Production series of a medicinal product - the quantity of a medicinal product produced as a result of one technological cycle by its manufacturer.

Global trade item identification number (hereinafter - GTIN , Global Trade Item Number) - a unique code that allows you to identify at least the manufacturer, trade name of the medicinal product, dosage form, dosage of the medicinal product and the completeness of the packaging of the medicinal product.

Serialized global trade item identification number (hereinafter sGTIN , Serialized Global Trade Item Number) is a unique serial number of the secondary (consumer) packaging of a medicinal product, formed by adding an individual serial number of the secondary (consumer) packaging to the global trade item identification number, and in case of its absence - primary.

Definition of some terms in accordance with the Guidelines (4)

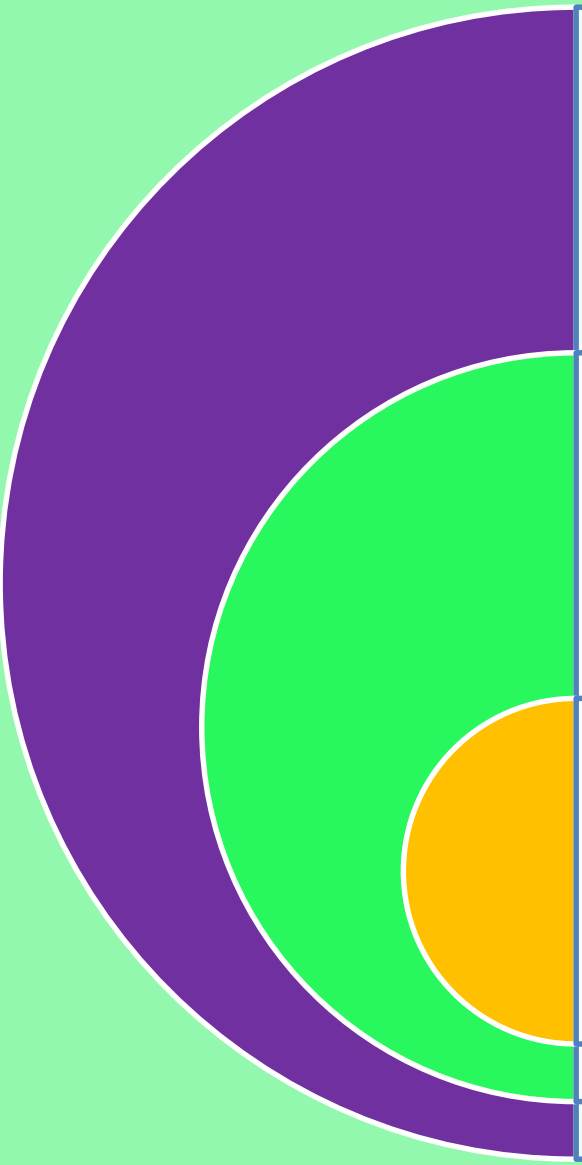


Marking of MD packages - application of identification means to the secondary (consumer) MD package (and in its absence - to the primary package) by the issuer of identification means, as well as group codes to the tertiary (factory, transport) MD package by the issuer of group codes.

MD labeled with identification means - MD marked with suitable identification means, reliable information about which was duly transferred to FSIS MPPC in accordance with these Methods. Recommendations.

Serialization is the process of generating data for the means of identification and labeling of secondary (consumer) MD packages as part of the production cycle stage "MD packaging / packaging in secondary packaging" (and in its absence, in primary packaging) .

Definition of some terms in accordance with the Guidelines (5)



Aggregation is the process of combining medicines into a group package while storing information about the relationship between the identification means of each nested medicine with the group code of the group package being created and applying the corresponding group code to the group package.

Completion of the stage of release of finished products - confirmation by the authorized person of the manufacturer of medicinal products of the compliance of the MD series with the requirements established during their registration.

The owner of the medicinal product is the subject of medicines circulation, which owns the rights of possession, use and disposal of this medicinal product.

Since July 1, 2020, labeling has become mandatory for all medicines. **Manufacturers and importers, when packing drugs, put the Data Matrix code on their packaging. All drug market participants submit data on drug transactions to the monitoring system.**

The unique 2D Data Matrix barcode is a sequence of numbers and letters.

It is made up of two codes:

- identification

- checks .

The identification code has two parts:

The first is the international product code GTIN, it has 14 characters.

The second is an individual serial number, which has 13 characters.

The GTIN and individual serial number of the drug must be duplicated in readable printed text.

That is, not only a barcode, but also a text fragment should be applied to the LP.

The verification code is an electronic signature (also called a crypto-tail).

It consists of a key (4 characters) and a code value (44 characters).

Using this signature, you can check whether the drug circulation is legal.

Data Matrix is placed on the consumer packaging of the drug

For example, on a cardboard box. If it is not available, the code is applied to the primary packaging: blister, ampoule, etc.

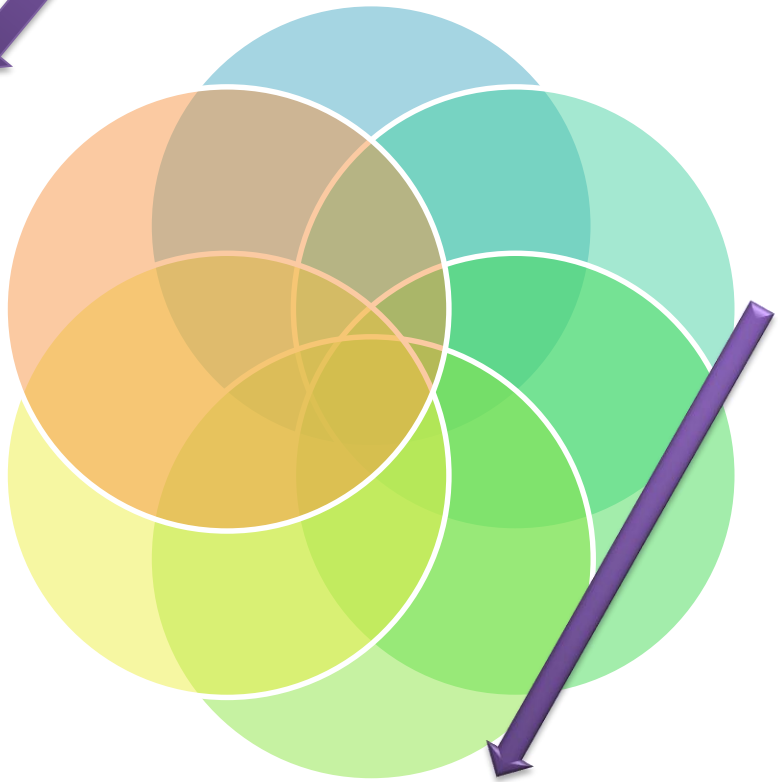
Another option is also possible - to print the code on the label if it cannot be separated from the package without damage.

Transport (tertiary) packaging with medicinal product is subject to labeling.

It is not applied Data Matrix, but a group barcode. It is not necessarily two-dimensional, it is permissible to make it linear.

Equipment for working with FSIS MDLP

(Methodological recommendations for work with labeled medicinal products Version 1.6)



To work with labeled medicinal products, you must use the following equipment:

barcode scanner must be used for the acceptance and retail sale of medicines ;

Retirement registrar 2 must be used to withdraw medicinal products from circulation under preferential prescription or for medical use.

Description of 2D barcode scanner

- 2D scanner - a device for obtaining information from linear and matrix barcodes with a choice of recognition technology and decoding features depending on the type of barcode. An example of a scanner is shown in the figure.

The 2D scanner is purchased by the turnover participant independently. The list of tested devices is available in the Scanner Test section of the Chestny Znak website.

If the participant of the turnover has a scanner, its performance must be checked for correct reading of the marking code. The corresponding instruction is available in the "Checking the Scanner" section on the "Honest Sign" website.

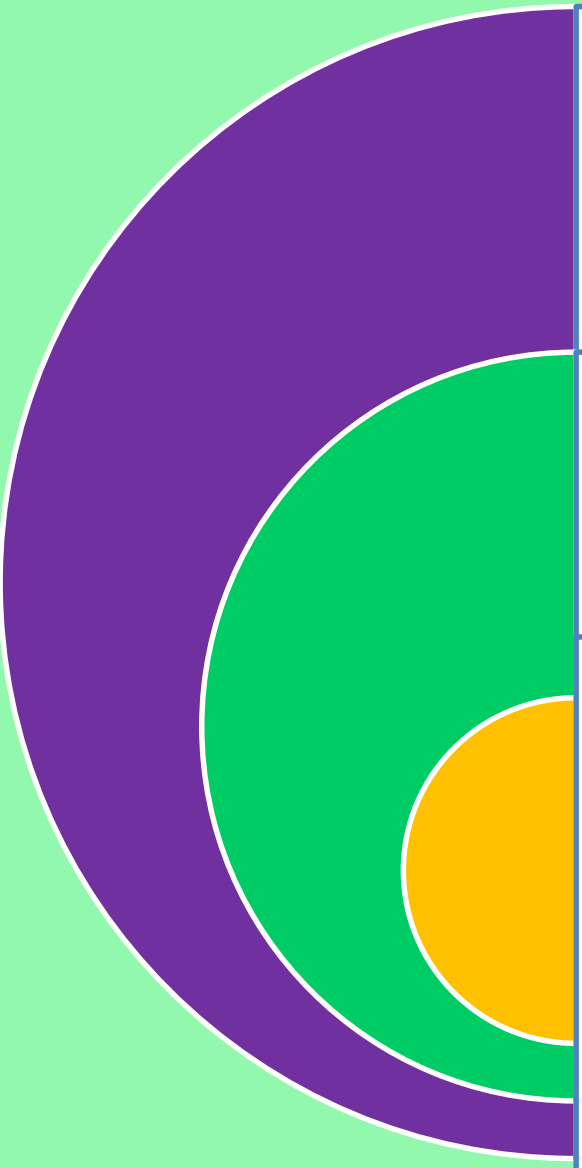
Description of the disposal recorder

- **Disposal registrar (RV) is a device that reads the DataMatrix code , generates data on medicinal products and then transfers to FSIS MDLP information about fixing the fact that the package has been withdrawn from circulation. The device has a software interface and can be integrated with the commodity accounting system (hereinafter referred to as the TUS) of the turnover participant.**
- The disposal registrar is used in the following processes for withdrawing medicinal products from circulation:
- when dispensing a medicinal product under a preferential prescription in a pharmacy organization;
- when dispensing drugs for the provision of medical care in medical organizations.

- **Important! When retailing medicinal products, a disposal registrar is not required.**

The disposal registrar is supplied in two versions (Figure), while the technical and functional content of the devices is identical.

Retail sales of medicines



Information monitoring of the movement of medicines from the manufacturer to the end user is carried out by the Federal State Information System for Monitoring the Movement of Medicines - FSIS MDLP.

Tracking is carried out by entering into this service the relevant electronic documents signed with an electronic signature or an enhanced QES (qualifying electronic signature).

FSIS MPLP ensures the storage of all records on the movement of medicines for the last 5 years. Automated functions of the service make it possible to obtain information about the circulation of medicines in Russia, block the sale of expired medicines, exercise public control over the circulation of medicines, etc.

Characteristics of means of identification

Information about the product, manufacturer, etc. applied to the primary packaging of the goods in the form of a two-dimensional barcode.

At the discretion of the manufacturers, the information contained in the barcode may be duplicated in the form of readable printed text.

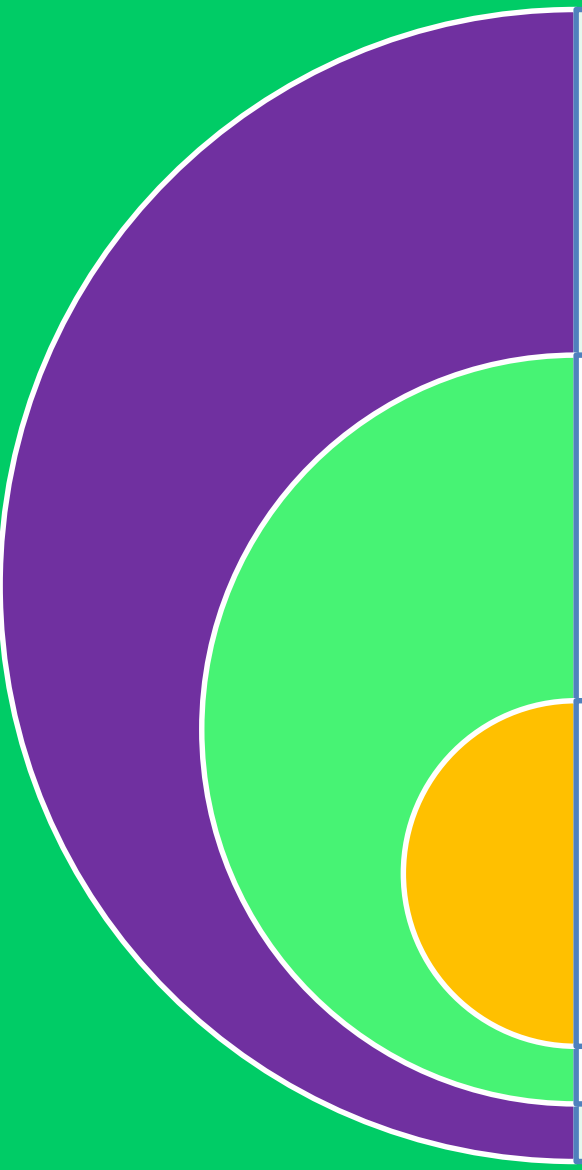
In this case, the identification number of the trade item is duplicated without fail.

It is also allowed to apply a barcode in any free space on the secondary packaging of the medicine, if there is no such marking on the primary packaging.

Requirements for marking equipment

As part of the labeling, it is allowed to apply identification means by direct printing or other labeling methods , without restrictions on the type of equipment used.

WHAT DATA IS APPLIED ON THE PACKAGING

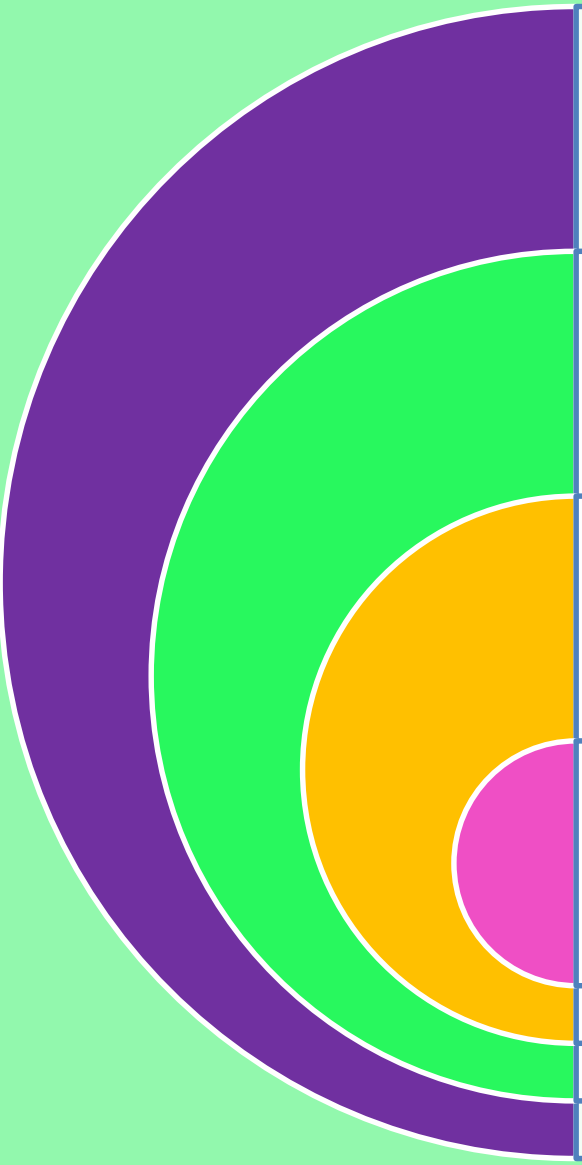


The first group of data is a unique identification number of a trade item: a 14-digit code.

The second group of data is an individual serial number, consisting of 13 characters of an alphanumeric or numeric combination.

The third data group contains the TN VED code. If the TN VED code is not located at the end of the encoded sequence as part of a two-dimensional code, it is necessary to use the final separator character.

What is the benefit for drug users?



Consumers receive guarantees that they have a genuine product of good quality.

Labeling is a serious tool for public control and consumer protection .

Labeling of medicines shows itself as a reliable and effective way to protect the domestic market from fakes and counterfeit goods .

The technology will also **contribute to the correct pricing and setting of maximum retail prices for medicines from the life-saving list.**

ENVIRONMENTAL SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE

Eco-labels **indicate that products comply with environmental regulations and are safe for the environment.**

In the countries of the **European Economic Community, an eco-label in the form of a flower has been adopted. Ecological certification symbol "Scandinavian swan" was adopted by the Scandinavian countries** (Sweden, Norway, Finland, Iceland) in 1990 . Ecolabelling committee).

Sign "Green dot" (Der Grune Punkt) put on their products companies that provide financial assistance to the German recycling program Eco Embalage ("Ecological Packaging") and included in its recycling system. The sign can be black and white, green and white or green.

ENVIRONMENTAL SIGNS AS AN ELEMENT OF THE MARKING STRUCTURE

"Green seal" (Green Seal is an independent US non-profit organization that promotes the purchase of environmentally friendly goods and services. **The Green Seal mark is used to mark products that cause the least environmental damage compared to products of the same type** .

The recycling symbol indicates that the product (packaging) is made from recycled material (recycled) or suitable for further processing (recycled). Manufacturers are advised to place text below the sign explaining what material and how much is used, for example: "Made from 70% recycled cardboard."

The use of this mark is not controlled by any organization .

On products made of polymeric materials suitable for industrial processing, they put a sign in the form of a triangle with a number inside . The number indicates the type of material to facilitate sorting and processing. Under the triangle, there may be a letter designation of plastic.

ENVIRONMENTAL ASPECTS.

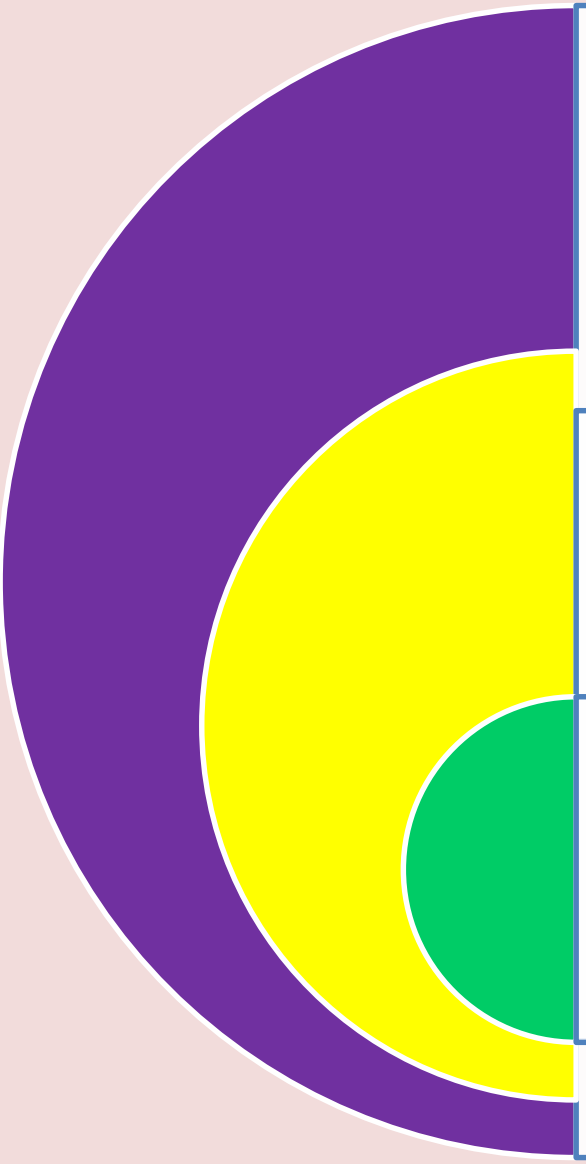
Requirements for environmental safety are one of the main factors in determining the quality of packaging, as this ensures human safety when using the packaging.

All these requirements are spelled out in the Federal Law "On Technical Regulation" and in the Law of the Russian Federation "On Protection of Consumer Rights".

If the packaging, for some reason, was not sent to specialized enterprises, but was simply thrown away, then it can pollute the soil and water for many years.

Many types of packaging (glass and polymer) practically do not break down spontaneously, and some other types (metal) break down in about 10-20 years. Fabric and paper packaging is destroyed as quickly as possible.

ENVIRONMENTAL ASPECTS (2)



At present, in Russia, the legal **framework in the field of handling packaging and packaging waste is presented**

separate norms of the Civil Code of the Russian Federation ,

federal laws

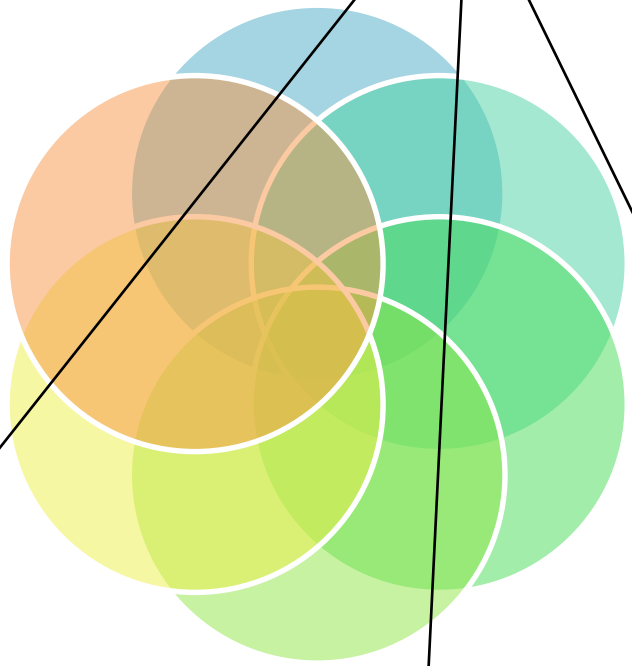
"On Environmental Protection" and

"On production and consumption waste"

GOST R 56268-2014/ ISO Guide 64:2008 Guidance for incorporating environmental aspects into product standards (Amended)

ENVIRONMENTAL ASPECTS (2a)

contain principles, examples, and requirements for environmental labeling , such as declarations of environmentally friendly products.



ENVIRONMENTAL ASPECTS (3)

Recently, the production of packaging materials has been growing all over the world.

Packaging becomes more diverse, functional and colorful.

Therefore, now it performs not only its barrier role, protecting products from the adverse effects of the environment, but also has an advertising purpose, contributing to the promotion of goods on the market.

ENVIRONMENTAL ASPECTS (3)

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

1. 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.

2. Use of secondary raw materials.

3. Reusable packaging.

4. Possibility of recycling and disposal of packaging.

5. Collection of used packaging for subsequent recycling.

ENVIRONMENTAL ASPECTS (4)

The processes **of product packaging and its processing pursue diametrically opposed goals** :

the manufacturer and the consumer want the **packaging not to break, decompose, break, wrinkle** , burn or dissolve in water,

while all **waste recycling processes are designed** specifically for the fact **that packaging materials must be destroyed, burned, chemically decomposed.**

Therefore **, packaging developers are trying to find a "golden mean" that allows them to effectively recycle used containers and packaging.**

ENVIRONMENTAL ASPECTS (5)

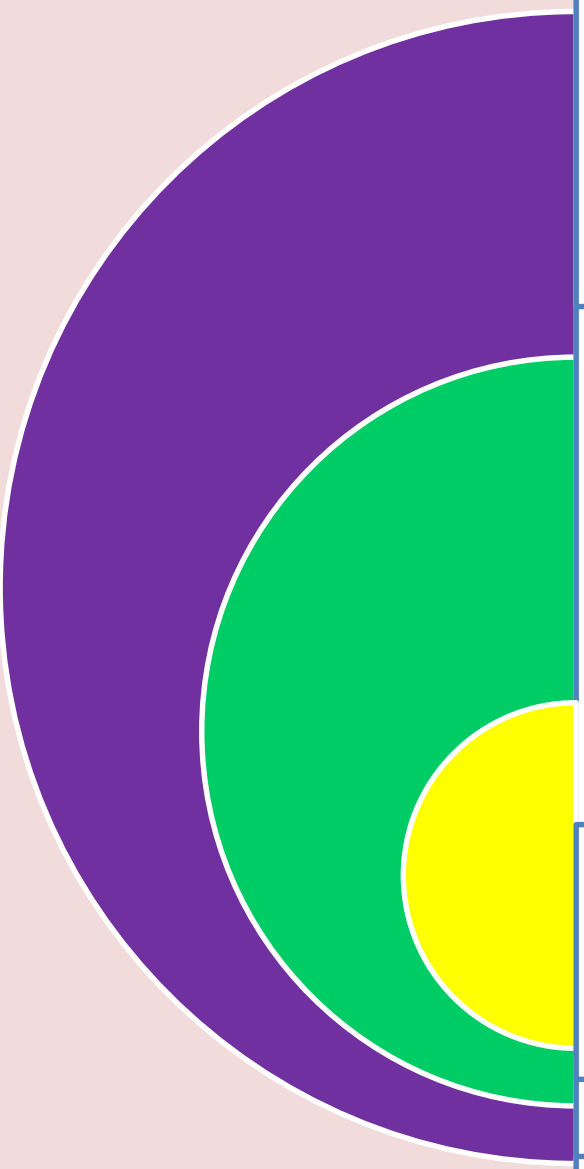
A significant part of the packaging is wood, cardboard and paper, glass and plastic products.

Disposal (or recycling) of materials of natural origin is not difficult,

plastics are problematic because they require special technologies and additional investments for recycling .

Because The use of plastics as packaging is rapidly increasing, it is necessary to create a mechanism that will effectively manage household waste

Directions for reducing the harm caused to the environment by polymeric materials



1. *Recycling of plastics for reuse* *(by* Wellman (USA) developed and implemented a technology for recycling polyethylene tetraphthalate waste).

2. *Creation of plastics capable of self-destruction under the influence of natural factors* (light, ultraviolet radiation, microorganisms). Deutsch W (Germany) has developed and manufactures a new polymeric material Biopol *intended* for packaging pharmaceutical and cosmetic products. The material is based on polymers and microorganisms. When buried, it decomposes within 24 months into carbon dioxide and water.

3. *The development of biologically inert materials* (USA, Japan, Germany) consists in the creation of water-soluble and edible packages (hard gelatin, amylase, collagen artificial edible packages).

ENVIRONMENTAL ASPECTS

In the modern world, cardboard and paper account for about 45-50% of the total volume of packaging produced (**the leader is corrugated cardboard packaging).**

In the Russian Federation **, cardboard is the only packaging material** that is **recycled .**

A special class of modern packaging materials that can compete with pulp and paper products in the future are cheap, environmentally friendly , " oil -independent " plastics - **biodegradable polymers.**

ENVIRONMENTAL ASPECTS

Biodegradable polymers are obtained from renewable plant materials - corn, potatoes, legumes, wheat, beets, tapioca, poplar and aspen wood, which can be used almost continuously.

For example, **packaging made from PLA polymer (polylactide) is able to completely decompose within 45 days** , provided that an appropriate composting structure is created. PLA packaging has already won its segment in the European market.

ENVIRONMENTAL ASPECTS

of Lean 's biodegradable packaging is estimated to be 30-70% less than other competitive packaging.

Thank you for your attention