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

Commodity analysis of medical and pharmaceutical products

Lecture № 6

Discipline: medical and pharmaceutical commodity science

3 course, 5 semester

Volgograd -2022

LECTURE PLAN

1.Introduction. Commodity analysis. Basic definitions and concepts.

2. Features of commodity analysis. Peculiarities and interrelation of expertise and merchandising analysis. The main types of expertise.

3. Function, goals and objectives of commodity analysis in health care.

4. Principles, information basis of commodity analysis.

5. Methods of commodity analysis. Classification. General characteristics. Types of commodity analysis.

6. Commodity analysis in the professional activity of a pharmacist.

7. Organization of commodity analysis. Methodology for conducting merchandising analysis.

8. Measures to prevent the circulation of counterfeit medicines and medical devices.

9. Schemes of commodity research analysis of consumer properties and technical characteristics of medical and pharmaceutical products.

10. Special conditions for the supply of medical products, acceptance of medical and pharmaceutical products.

COMMODITY ANALYSIS. BASIC DEFINITIONS AND CONCEPTS

At all stages of product distribution in the process of circulation of goods **, it is necessary to evaluate its quality for various purposes.** This **process** is called **product examination.**

The terms **"commodity analysis" and "commodity expertise" are not equivalent.**

Examination (from lat. e x pertus experienced) - analysis, research conducted by involved experts.

Analysis (from the Greek. analysis - decomposition) - a method of scientific research, consisting in the mental division of the whole into its constituent elements.

COMMODITY ANALYSIS. BASIC DEFINITIONS AND CONCEPTS

Commodity analysis is a method of scientific research of goods, which consists in mentally dividing them into constituent elements in order to comprehensively study the quality of the goods and assess their safety.

The circulation of commodities is an exchange through purchase and sale.

COMMODITY ANALYSIS. BASIC DEFINITIONS AND CONCEPTS

Merchandising *(English)* movement of goods - the movement of goods) - the process of moving goods from the manufacturer through the wholesale and / or retail trade to the consumer.

A distinctive feature of the examination is that, unlike commodity analysis, it is carried out by leading experts in the relevant field, and it is carried out only in the process of applying.

FEATURES OF COMMODITY ANALYSIS

Commodity analysis must be carried out:

starting from placing an order (choosing the type of product from the assortment offered by the supplier);

carry out at all stages of the distribution,

including when the goods are moved inside the pharmacy and health care facilities (after the implementation of the act of sale).

FEATURES OF COMMODITY ANALYSIS (TA)

Commodity analysis is carried out:

- pharmacist,

- chief and senior nurses in health care institutions.

PROCESSES IN WHICH COMMODITY ANALYSIS IS CARRIED OUT:

- selection of the optimal assortment

goods for pharmacies,

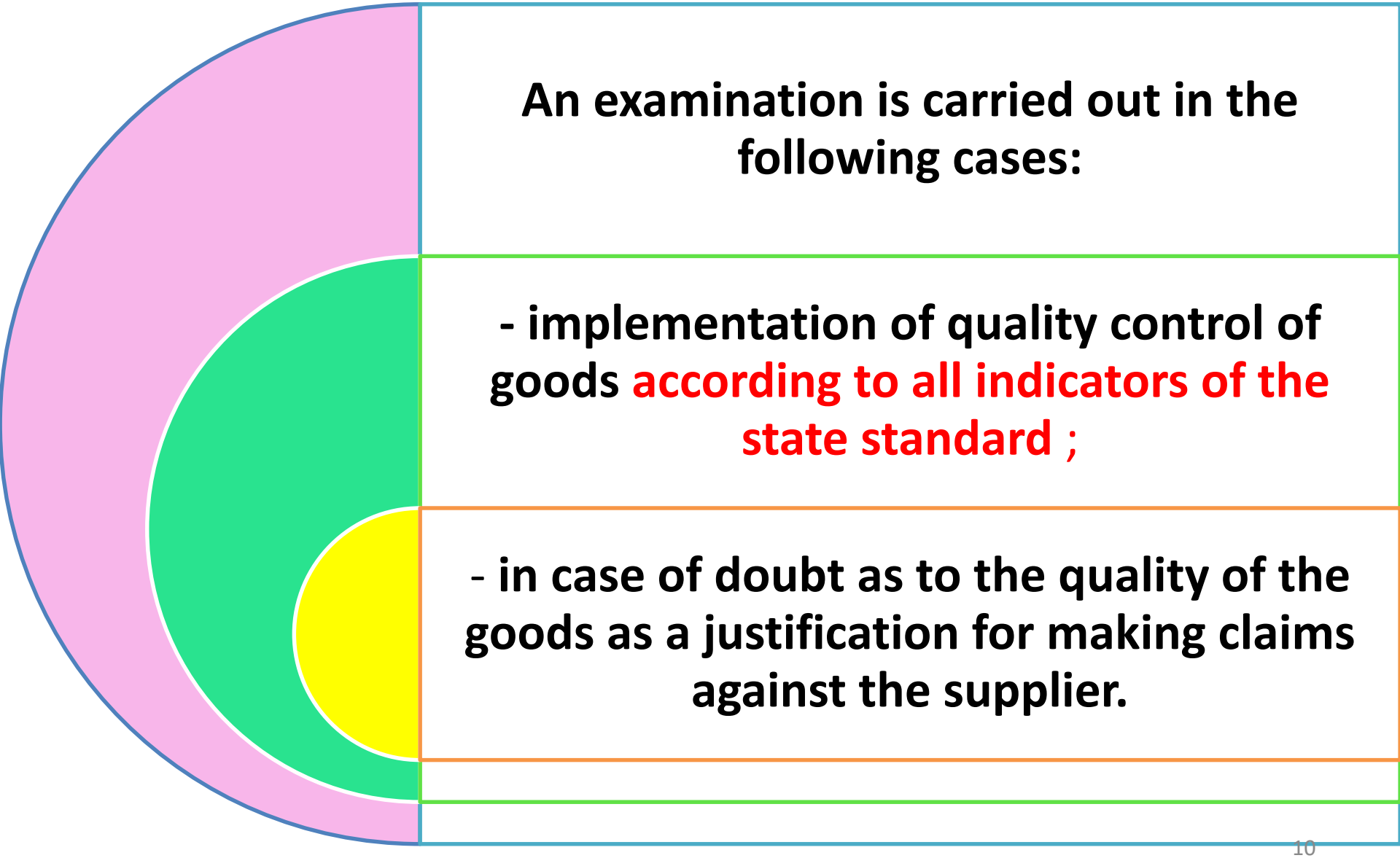
health facilities or departments;

- Acceptance of goods in terms of quantity and quality.

organoleptic methods are most often used , because a little time is allowed for the acceptance of goods in terms of quantity and quality.

Main types of expertise

FEATURES OF THE EXPERTISE



Features and relationship of expertise and commodity analysis

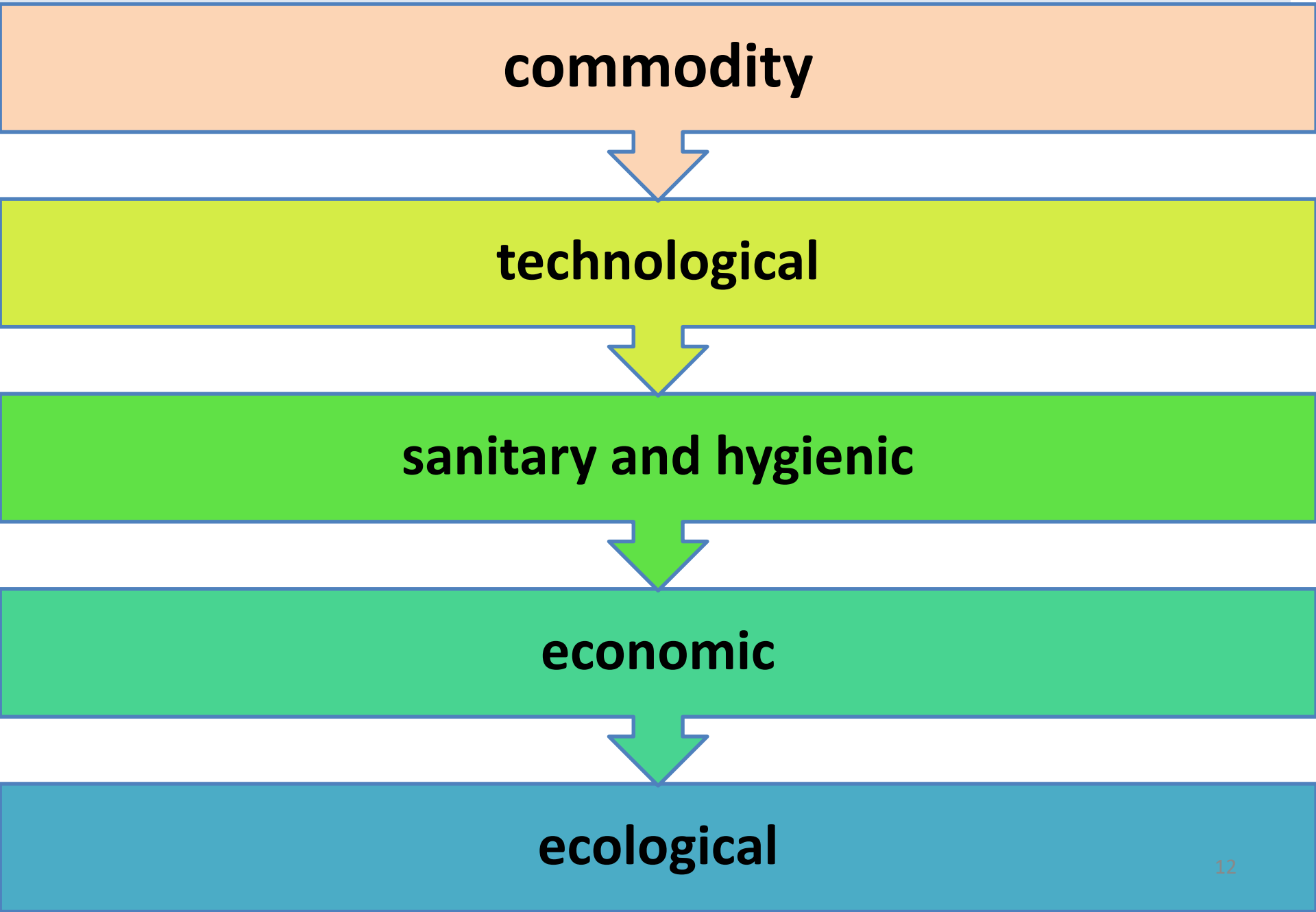
In the process of conducting a commodity examination, if it is necessary to verify the authenticity of a product, it is subjected to physical, physico -chemical, chemical, biological, microbiological and other types of control .

To do this, an expert of the Bureau of Technical Expertise (BTE) is involved, who himself conducts a commodity examination using instrumental methods of analysis or sends the goods to a testing center, a standardization and metrology laboratory, a research laboratory, territorial centers for standardization and metrology (CSM), laboratories of Rospotrebnadzor , etc. .

Upon completion of the check, the expert draws up an act - one of the important documents that appears in arbitration and judicial instances when considering disputes arising between the supplier (manufacturer) and the recipient.

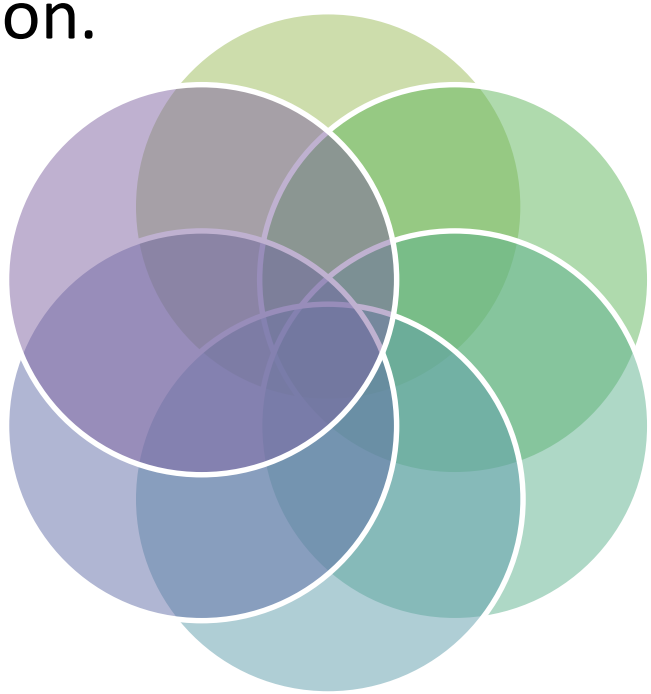
Thus, commodity analysis is a preliminary step to identify counterfeit or low-quality goods.

MAIN TYPES OF EXAMINATION:



COMMODITY EXPERTISE

Commodity examination is used in cases **where it is necessary to establish the conformity of the properties of the goods with state standards** and (or) **contractual conditions between the supplier and the buyer** in the process of circulation.

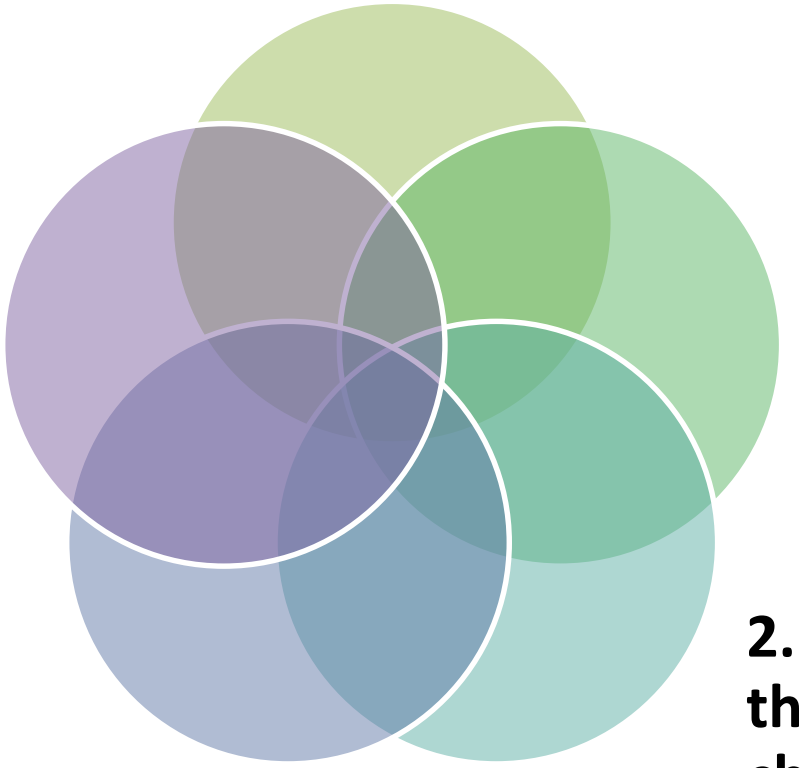


TECHNOLOGICAL EXPERTISE

Technological expertise

applies in cases:

1. the need to establish the conformity of products with the technological modes of production of goods, standards for quantitative and qualitative composition



2. establishing the correct choice of equipment

3. determining the influence of production factors on consumer properties, etc.

TECHNOLOGICAL EXPERTISE

Technological expertise is important for a pharmacist, chief and senior nurses when choosing a manufacturer with whom they will conclude contracts for the supply of products ,

because depends on the technological equipment, for example,

- the quality of medical instruments, the bioavailability of the drug,

quality of packaging and labeling of goods.

Sanitary and hygienic expertise

held

for those groups of goods, the registration of which provides for such a check (example: medicinal plant materials, products made of polymeric materials, etc.).

Environmental assessment **establishes the impact of the purchased pharmaceutical product or medical equipment product on humans and the environment in the process of their manufacture, transportation, unloading, packaging, storage and consumption.**

Environmental impact assessment is important, because the consumer, being included in the "man-goods-environment" system, directly experiences this effect.

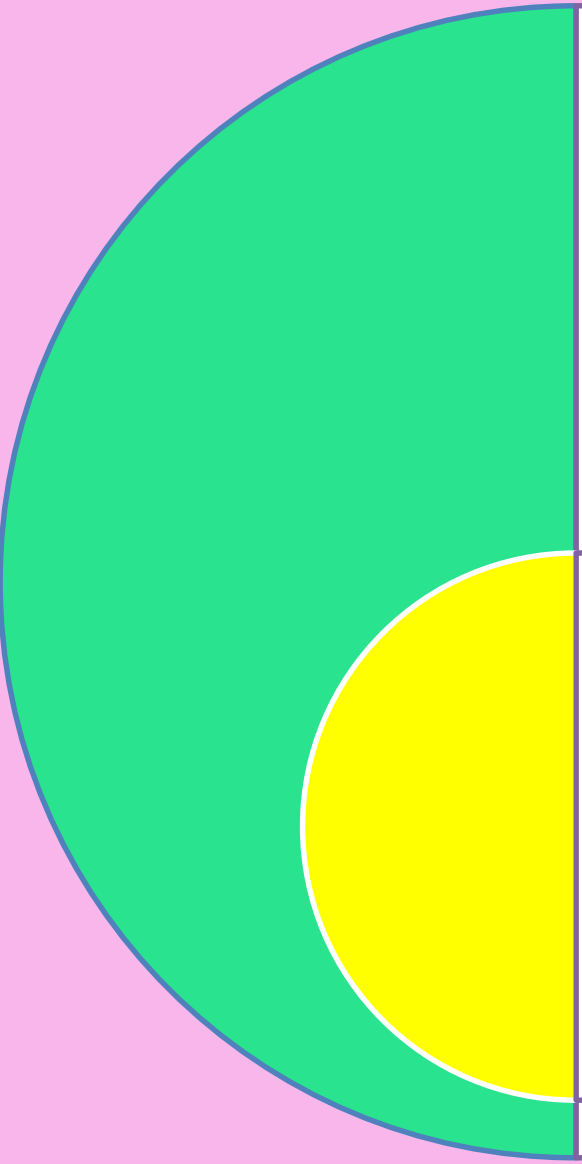
Environmental indicators according to the degree of their impact on the environment are divided into two groups:

indirect impact

(contamination of pharmacy and factory equipment, and then the environment).

direct exposure (harmful impurities released into the water or air environment during the manufacture, operation and disposal of medical and pharmaceutical products);

Environmental impact assessment (continued)



When studying **environmental indicators of direct impact** , it is necessary to take into account their harmful effects on the human body exposed to certain methods of diagnosis and treatment, as well as the degree of impact on those who use this product in the provision of medical and pharmaceutical care.

Ecological expertise helps to choose the best options for solutions aimed at improving the consumer properties of goods.

When studying **the environmental indicators of indirect effects** in the manufacture of medicines, it should be taken into account that in the process of contamination of factory equipment with impurities harmful to the human body that have a cumulative effect (the ability to accumulate in the human body), poisoning is possible even at low concentrations of these impurities in each batch.

This is especially true for drugs taken for chronic diseases.

ECONOMIC EXPERTISE

Economic expertise is carried out in order to increase the profitability of a medical facility or a wholesale or retail pharmacy link and is aimed at establishing:

causal relationships that led to the deterioration of the economic mechanism of the medical facility, pharmacy warehouse (base) or pharmacy;

possible falsification of medical and pharmaceutical products;

the correctness of determining the cost of goods;

the expediency of using certain technological standards laid down in the specifications, FSP, etc.

GOALS, OBJECTIVES, PRINCIPLES, FUNCTIONS OF COMMODITY ANALYSIS

Function, goals and objectives of commodity analysis in health care

The main function of commodity analysis **is to ensure the protection of consumer rights to receive timely and high-quality pharmaceutical and medical care** .

Commodity analysis evaluates the consumer properties of goods according to
-organoleptic,
-physical and chemical
-microbiological indicators,
-as well as quantitative characteristics
by conducting tests (measurements) and/or questioning and/or on the basis of information on the label and in the shipping documents.

Goals of commodity analysis:

- to establish the conformity of the received goods with the ordered quantity;

- establish the conformity of the consumer properties of this product with a set of requirements and indicators that together determine its quality - compliance with regulatory documentation for a number of defining indicators.

The main tasks of commodity analysis (1)

establish the assortment of goods;

establish the conformity of the goods with the class, group, type or variety of goods specified in the accompanying documents;

establish compliance of execution of accompanying documentation with the requirements for it ;

identify the compliance of the quantity of the ordered goods with the specified quantity in the accompanying documentation;

identify the compliance of the actual values of the quality indicators of the goods with the requirements established by the quality standard (assessment of appearance, functional properties, and other quality indicators by organoleptic methods);

The main tasks of commodity analysis (2)

identify counterfeit goods by such indicators as "Description", "Marking", "Packaging";

evaluate the safety of medical products;

draw up appropriate documentation in case of discrepancy between the quantity and quality of the goods;

send counterfeit or low-quality goods for commodity examination.

Thus, merchandising analysis is preliminary for identifying falsified or low-quality goods.

PRINCIPLES OF COMMODITY ANALYSIS

- Objectivity
- Competence
- Independence
- Systems approach
- Efficiency
- Goods safety

INFORMATION BASIS OF COMMODITY ANALYSIS

METHODS
COMMODITY ANALYSIS

METHODS OF COMMODITY ANALYSIS

The method of commodity analysis is a way to achieve the final results of expert evaluation of goods .

Commodity analysis evaluates the consumer properties of the product according to

- organoleptic,
- physical and chemical,
- microbiological indicators, quantitative characteristics.

Classification of methods of commodity analysis

Heuristic:

1. organoleptic,
2. expert:

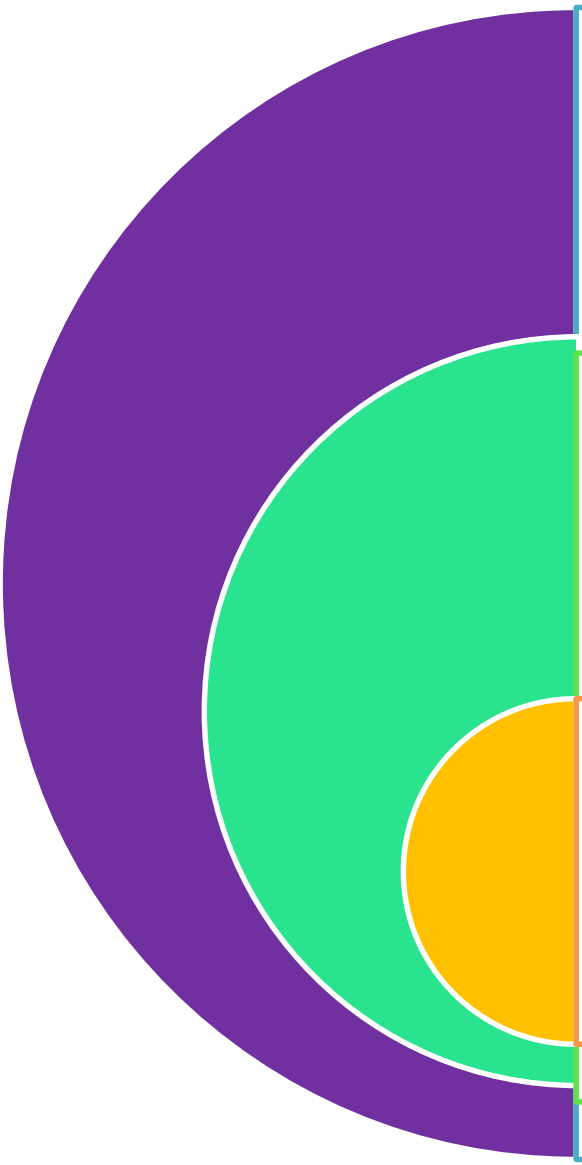
- statistical methods,
- processing of expert assessments,
- methods of expert assessment of quality indicators;

3. sociological.

Objective:

- measuring, - registration.

heuristic methods. (1) Organoleptic method.



With the help of **heuristic** methods, the final results of commodity analysis are achieved - the suitability of the product for its intended use.

Organoleptic the method allows you to evaluate the quality indicators of goods using the senses (appearance - smell, color, taste, consistency, integrity, surface condition).

With their help, the **identification of goods** (authenticity) is carried out.

Heuristic methods.(2)
Expert and sociological methods

Expert methods are used to assess the properties and performance of goods under conditions of uncertainty and risk, carried out with the participation of experts. These include methods - a group survey of experts, mathematical and statistical methods for processing expert assessments, methods for expert assessment of quality indicators.

Sociological methods establish a consumer assessment of goods based on a survey of buyers.

Features of commodity analysis of medical and pharmaceutical products:

Very high quality requirements are imposed on medical and pharmaceutical products .

They are made from a number of different materials and differ significantly from each other both in terms of sources of raw materials and in the technologies for their manufacture.

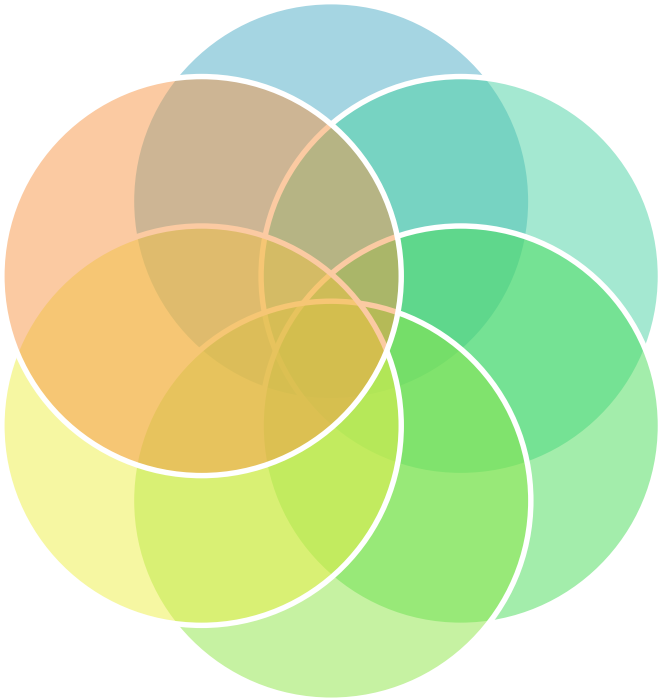
KINDS
COMMODITY ANALYSIS

Types of commodity analysis (1)

qualitative

quantitative

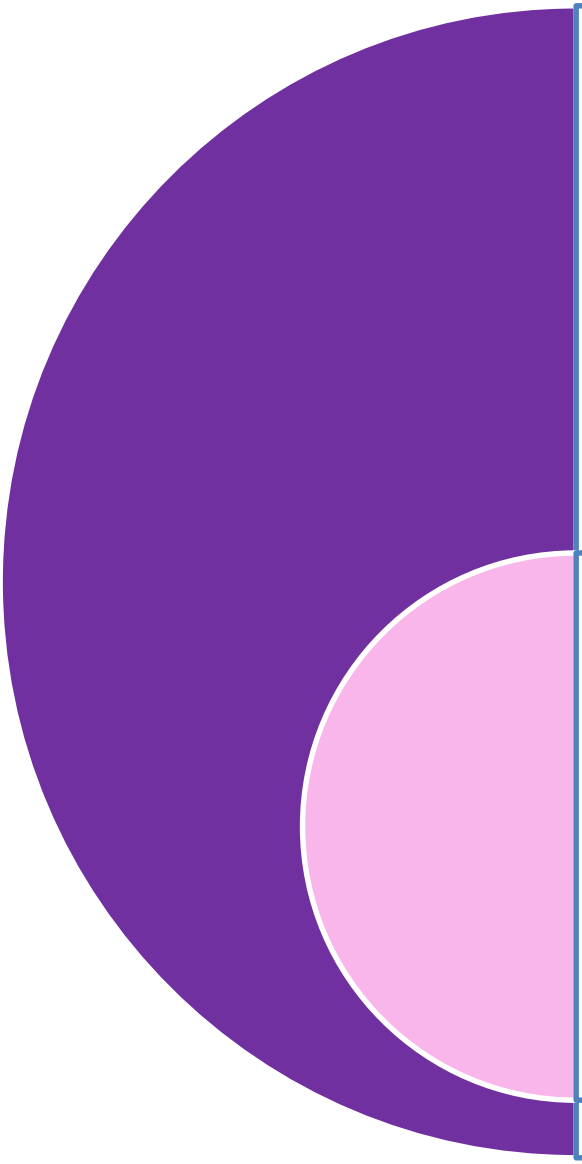
complex



documentary

assortment

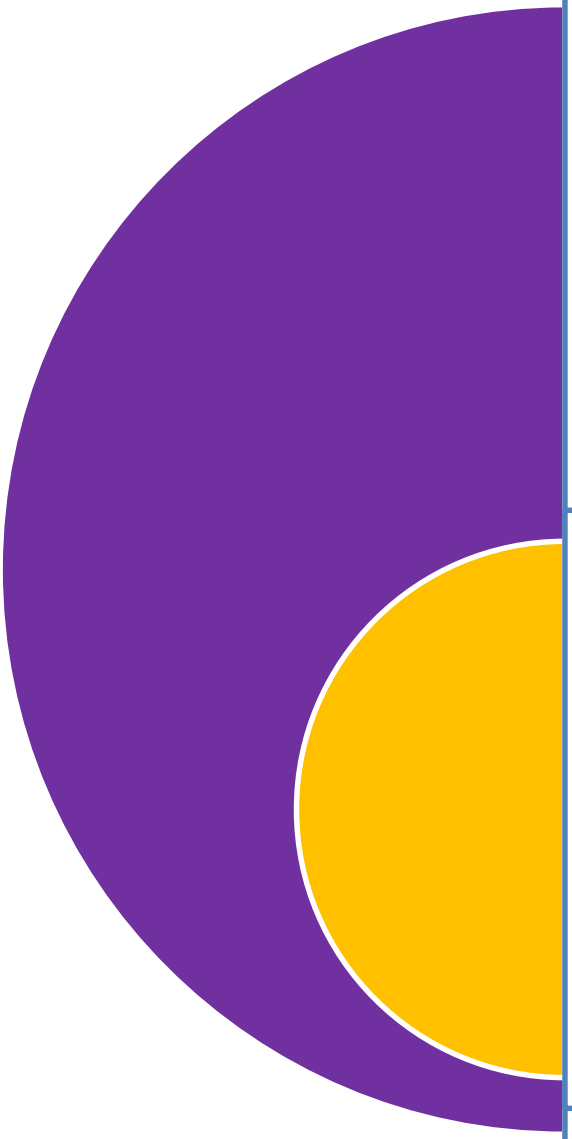
Types of commodity analysis (2)



Qualitative Analysis provides for an assessment of the quality characteristics of the goods to establish their compliance with the requirements of regulatory documents.

Quantitative analysis involves the evaluation of the quantitative characteristics of the product. This type of analysis is used when accepting goods by quantity, as well as to establish quantitative losses of goods and the reasons for their occurrence.

Types of commodity analysis (3)



Assortment analysis consists **in an expert's assessment of the quantitative and qualitative characteristics of a product in order to establish its assortment affiliation** . As an independent type of analysis, it is carried out when there are disagreements between suppliers and buyers, the seller and the consumer regarding the assortment of goods belonging to a certain group.

Documentary analysis consists **in an expert's assessment of the commodity characteristics of the goods , based on information in the accompanying, technological and other documents.** This type of analysis is a mandatory element of the other types of analysis mentioned above. The compliance of the quantity and quality, the name of the object of examination with the information specified in the accompanying documents (waybills, certificates / declarations of conformity, operational documents, etc.) is checked.

Types of commodity analysis (4)

A comprehensive analysis is an assessment by an expert of all the characteristics of a product based on their testing and analysis of documents.

This type of analysis is used in cases where a comprehensive assessment of the goods is necessary, taking into account the positions of the seller, consumer, as well as the current market conditions .

FOR THE COMPETENT CARRYING OUT OF THE COMMODITY ANALYSIS THE PHARMACIST SHOULD BE ABLE TO:

work with official sources of information regulating the quality of goods;

choose methods for assessing consumer and other properties of medical products;

ensure the safety and integrity of the selected samples (samples) when sending them for testing;

to carry out a competent assessment of the objects of commodity examination;

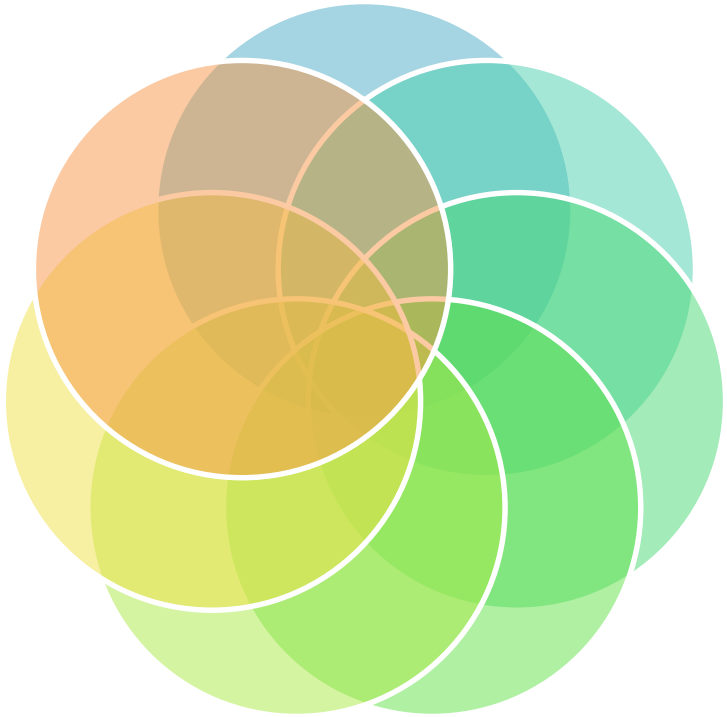
interact with various organizations that carry out those types of control that are necessary for a deeper assessment of consumer properties and other quality indicators of goods in order to identify them.

FOR THE COMPETENT CARRYING OUT OF THE COMMODITY ANALYSIS THE PHARMACIST IS NECESSARY:

- comply with applicable laws, regulations in the field of quality, environmental protection measures, standardization, metrology, certification, consumer protection;

- to show objectivity and independence when conducting TA;

- resist attempts to exert pressure on the part of interested parties.



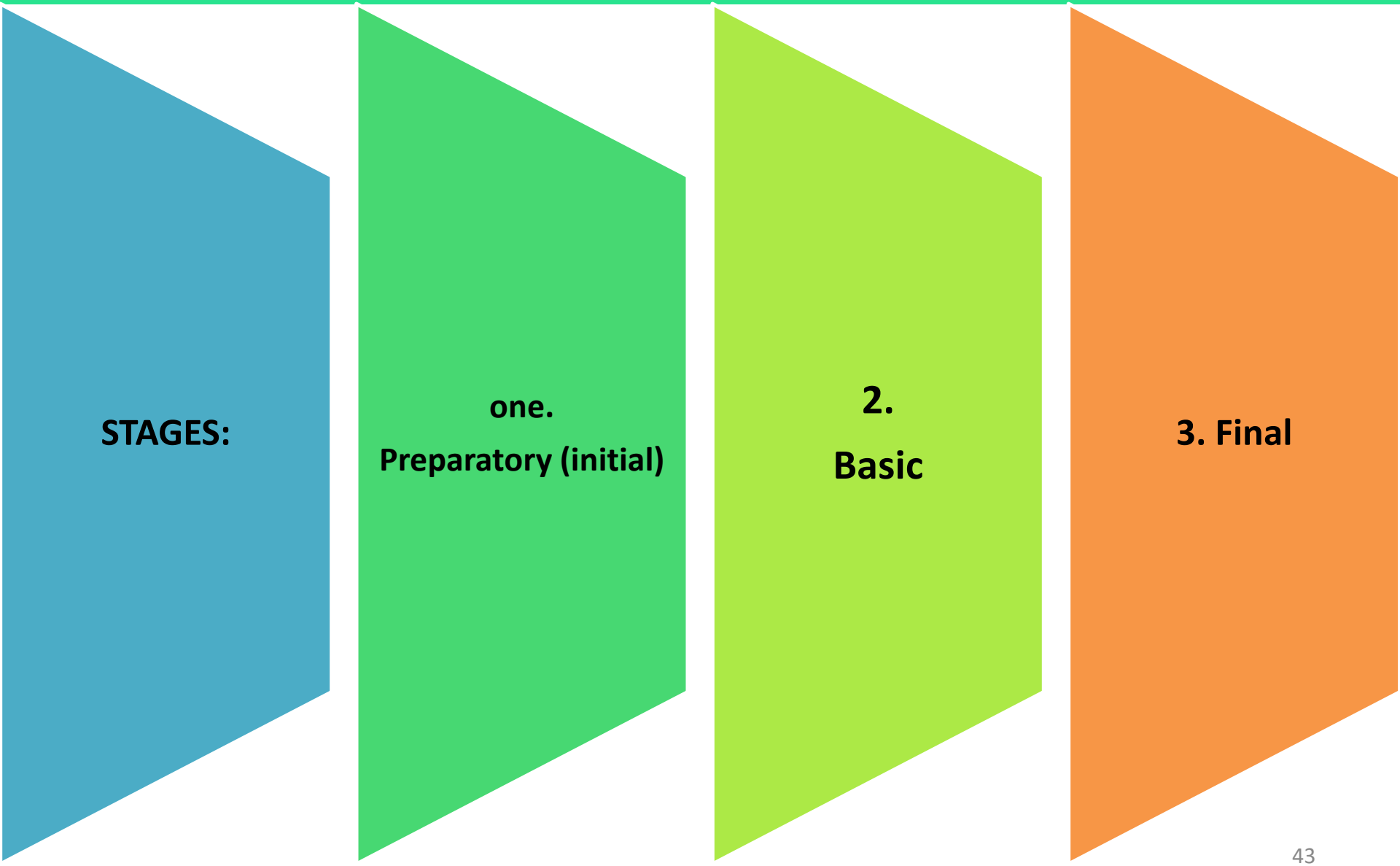
- provide reasoned evidence of the correctness of the assessments made and the reliability of the results obtained ;

- ensure the confidentiality of the information received as a result of TA;

- comply with ethical standards;

ORGANIZATION COMMODITY ANALYSIS

ORGANIZATION OF COMMODITY ANALYSIS



ORGANIZATION OF COMMODITY ANALYSIS. STAGE CONTENT (2)

1. Prepare a workplace for an expert, the necessary documents, equipment and measuring instruments, standard samples (if necessary); prepare goods for examination (sorting by batches, series) and provide free access to it.

2. Commodity analysis is carried out in accordance with the instructive materials and regulatory documents on the analysis of this group and type of goods. If necessary, preliminary sampling is carried out in compliance with all the rules, which is reflected in the act. If a discrepancy between the actual and normative indicators is found, this fact is reflected in the protocols or acts.

STAGE 3 consists in evaluating the results obtained and documenting the examination

STRUCTURE OF THE EXAMINATION ACT

The examination act (conclusion, protocol) consists of three parts :

1. general (protocol)

2. ascertaining (documents of analysis, methods, date of analysis, quantitative characteristics of goods and other results of expert evaluation)

3. final (issued on the basis of the results obtained with the assessment and conclusion of an expert on the quality of the product and its suitability for use by the consumer).

GENERAL STEP-BY-STAGE SCHEME OF COMMODITY ANALYSIS

A step-by-step scheme for conducting a commodity analysis for specialists working in healthcare facilities and pharmacies:

1. selection of goods for analysis;

2. choice of consumer properties and technical indicators to be analyzed;

3. analysis of consumer properties and technical indicators.

Analysis of consumer properties and technical indicators depending on the goals :

Analysis of consumer properties and technical indicators, depending on the goals, is carried out by one or more methods:

a) by the organoleptic method according to the indicators specified in the state standard;

b) the method of expert assessments with the help of experts;

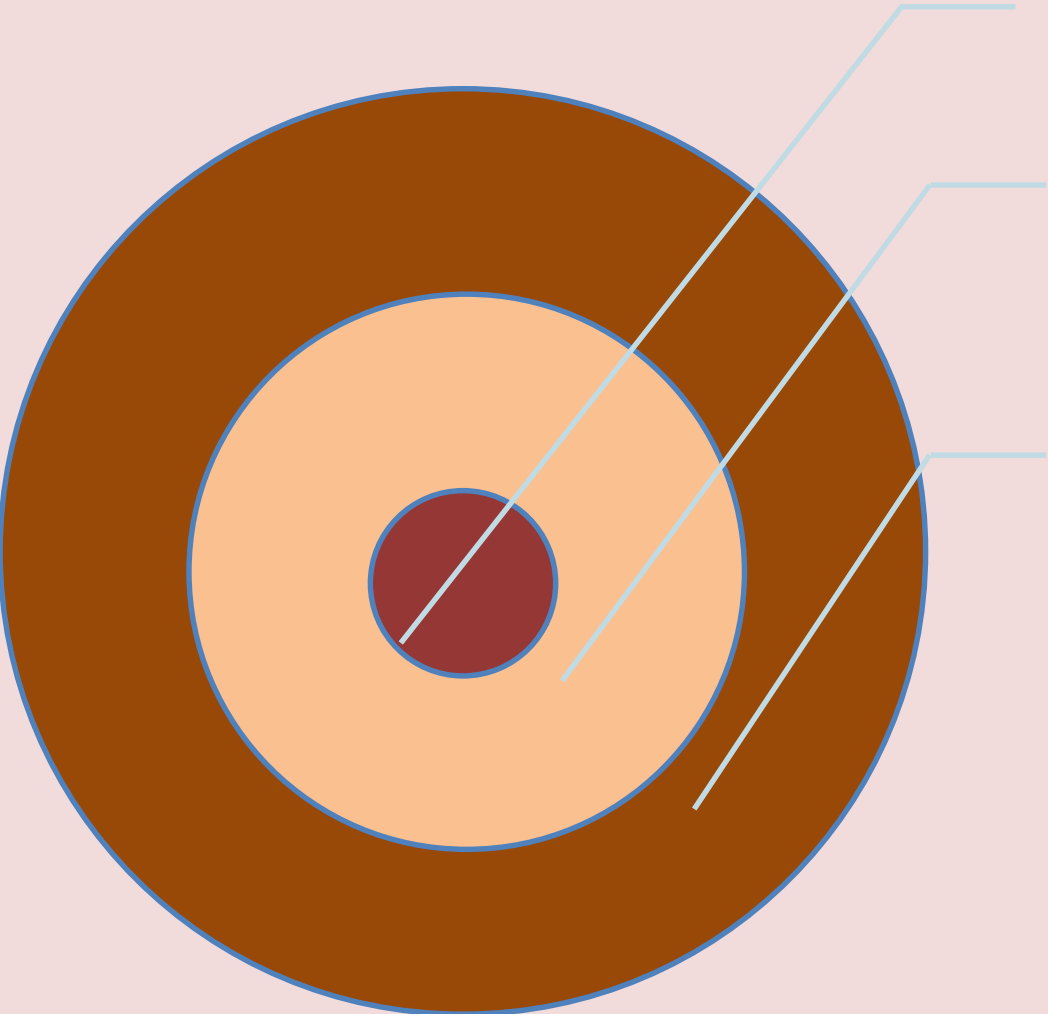
c) the method of questioning consumers (patients, doctors, nurses);

c) instrumental methods in laboratories and testing centers.

METHODOLOGY CARRYING OUT COMMODITY ANALYSIS

METHODOLOGY FOR COMMODITY ANALYSIS OF MEDICAL AND PHARMACEUTICAL PRODUCTS (9)

XIV . Place in storage locations (check the correct organization of storage)



1. Define the MFT storage group.

2. Determine the conditions for the placement and storage of goods in accordance with the ND.

TRAFFIC OF FALSIFIED, POOR-QUALITY, COUNTERFEIT MEDICINES AND MEDICAL DEVICES IS PROHIBITED!

Counterfeit medicinal product - a medicinal product accompanied by false information about its composition and (or) manufacturer

Poor-quality drug - a drug that does not meet the requirements of a pharmacopoeial article or, in its absence, the requirements of regulatory documentation or a regulatory document

Counterfeit drug - a drug that is in circulation in violation of civil law

The concept of "counterfeit" products is clearly defined in paragraph 1 of Article 1515 of the Civil Code of the Russian Federation (CC RF) - "goods, labels, packaging of goods on which a trademark or a confusingly similar designation is illegally placed are counterfeit."

Also, clause 3 of Article 1519 of the Civil Code of the Russian Federation states the following: “goods, labels, packaging of goods on which the names of the places of origin of goods or confusingly similar designations are illegally used are counterfeit.”

It follows from this that in cases where the manufacture, distribution or other use, as well as the import, transportation or storage of material carriers in which the result of intellectual activity or a means of individualization are expressed, lead to a violation of the exclusive right to such a result or to such a means, such material media are considered counterfeit (clause 4 of article 1252 of the Civil Code of the Russian Federation).

In addition, counterfeit products are recognized without the labeling required by law. At the same time, the recognition of a product as counterfeit does not always indicate its quality.

Classification of counterfeit drugs

Medical fakes sold on the Russian pharmaceutical market are divided into 4 groups.

1 group. Medicines that do not contain active ingredients, the so-called "placebo".

In theory, their use does not pose danger and harm, but if you take a dummy nitroglycerin during a heart attack, then there can be quite sad consequences.

2 group. LP containing ingredients that are not mentioned on the package . In this case, a bottle of glucose is labeled with a medicine to treat a serious illness. The danger lies in the lack of the necessary therapeutic effect.

3rd group. Medicines that contain the least amount of ingredients.

4 group. Medicinal preparations-copies . For example, in a box from a well-known foreign-made drug, they put a medicine from a local manufacturer. Of course, this will not harm the patient as a result, but the desired therapeutic effect may not be achieved . Usually , such medicines contain the same active substance and in the same quantities. Often in this case it is quite difficult to understand how to distinguish a medicine from a fake.

All medicinal counterfeits are dangerous to health. The reason is that counterfeit drugs do not pass the quality control prescribed by law, which carries certain risks. The use of such drugs can lead to serious problems.

Methods of combating drug counterfeit

- Pharmaceutical holding associations are actively fighting against counterfeiting, for example, recently many companies have been changing packaging, using special stickers, holograms, barcodes . However, all this does not guarantee 100% protection against counterfeiting.

Basic methods of struggle:

Efficient conduct of criminal investigations in order to identify sources of production of illegal products.

Confiscation of production facilities with subsequent destruction of substandard medicines.

Timely informing the population about the fact of fixing falsified pharmaceutical products .

Updating the legislative framework, promptly making appropriate adjustments in order to combat counterfeiting .

Cancellation of licenses from companies that are additionally involved in the sale of counterfeit goods .

In order to combat counterfeiting , the regulator of the law also introduced mandatory labeling of medicinal products. Pharmaceutical market participants are required to scan relevant information for transfer to a single system. This allows consumers, government agencies and other interested parties to verify the legitimacy of the medicinal product and trace it all the way from production to distribution.

To combat counterfeiting, adjustments were also made to legislative norms.

In Art. 238.1 of the Criminal Code of the Russian Federation contains rules regarding the circulation of counterfeit pharmaceuticals.

Recently, adjustments have been made to the administrative code.

All legal reforms were aimed at bringing to administrative and legal responsibility those involved in the production, sale and marketing of counterfeit drugs.

Scheme of analysis of consumer properties and technical characteristics of medical and pharmaceutical products (according to V.N. Strelkov)

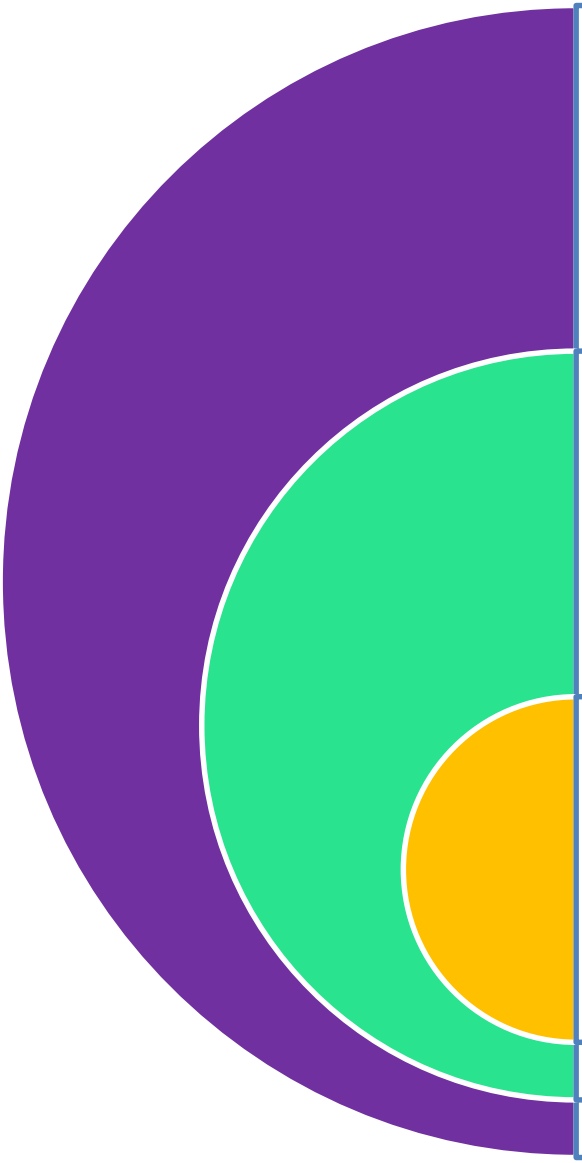
Scheme for the analysis of consumer properties and technical characteristics of medical and pharmaceutical products (according to V.N. Strelkov)

What to do	How to do	What to use	How to use	How to check the correctness of the performed action
one	2	3	four	5
1. Classify the group of goods under study	**Classification is carried out on the basis of any specific feature; functional, materials science , constructive , etc.**	OKPD 2, State Register , standards, etc.	Guidance in the standard by the section " Classification ", table of contents , etc.	Comparison of the documents specified in clause 3
2. Set the names of commercial types and varieties	Highlight structural, materials science , functional or other features	Standards, OKPD 2, etc.	Use the relevant sections of the standards and OKPD 2	Using standards and OKPD 2

3. Determine the requirements for consumer properties of pharmaceutical products	**From various sources, select materials according to the requirements related to this product, type or group**	**Standards, registers, registers, encyclopedias, reference books, instructions**	**In the standards, use the section: "Technical requirements", in the reference literature sections: "Composition and form of release", "Characteristics", etc.**	**The material recorded in the protocol must correspond to the information set out in the standards and official reference publications.**
4. Define acceptance rules	**The acceptance rules should be drawn up in the form of an instruction describing the acceptance method that can be used in a pharmacy, pharmacy warehouses. Pay attention to completeness**	**Standards**	**In the standard, use the sections " Completeness ", "Rules of acceptance"**	**By comparison with the standard**

Commodity analysis for educational purposes

The stages of commodity analysis are different depending on the goals of the analysis.



Commodity analysis for educational purposes:

When conducting commodity analysis for educational purposes, they are limited to a fairly simple plan, based on available sources of information.

Plans for conducting a commodity analysis of medicines and medical equipment are different.

Plan for conducting a commodity analysis of medicinal products for educational purposes

- name of the medicinal product (trade and international non-proprietary);
- class and subclass of goods;
- classification group;
- type of goods;
- the chemical composition of the active substance;
- the name of the pharmacotherapeutic group;
- main pharmacological action;
- application;
- types of dosage forms;
- package;
- marking;
- storage;
- Merchandising from the supplier to the consumer, the procedure for dispensing from the pharmacy;
- types of quality control upon acceptance at a pharmacy warehouse, pharmacy, health care facility (organoleptic and instrumental, in accordance with the FS).

Plan for conducting a commodity analysis of medical equipment for educational purposes

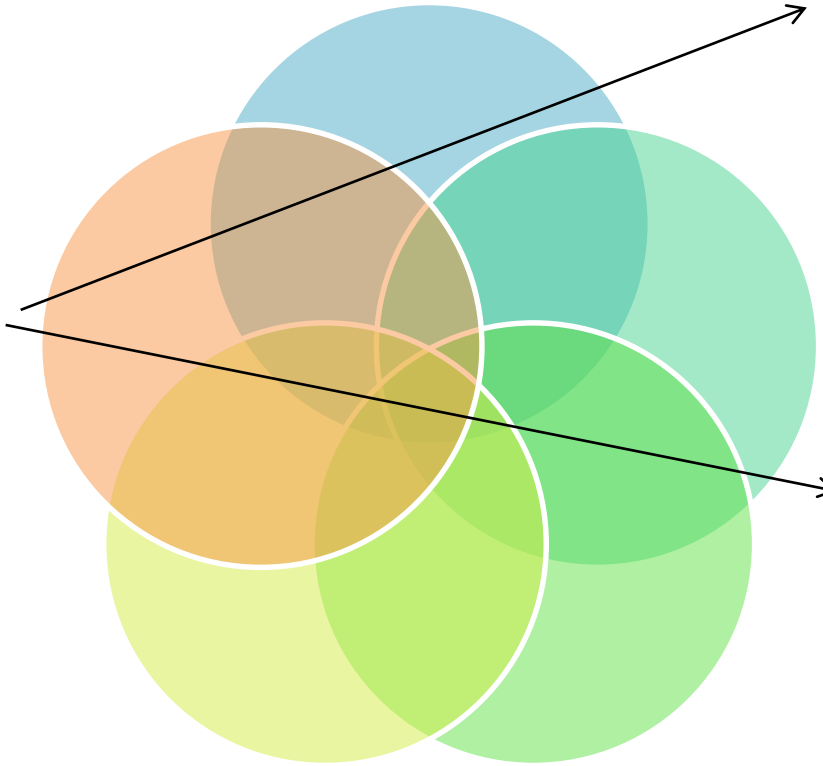
- Product Name;
- class and subclass of goods;
- classification group;
- type of goods;
- appointment;
- raw materials (alloy grade, its corrosion resistance);
- commercial varieties, standard sizes;
- functional properties;
- design features;
- package;
- marking;
- storage;
- disinfection;
- sterilization;
- goods movement from the supplier to the consumer, the procedure for dispensing from a medical equipment store or pharmacy;
- types of quality control upon acceptance at a warehouse, medical equipment store, pharmacy or medical facility (organoleptic and instrumental in accordance with GOST or TU).

STAGES OF THE ORGANOLEPTIC METHOD COMMODITY ANALYSIS

When checking by organoleptic method, the analysis consists of the following steps (1)

Stage 1. Determine the classification group and subgroup of goods (based on information about the purpose of the goods, consumer properties, manufacturing method, appearance features, etc.).

2. stage. Identify and decipher product codes



Determine and decipher digital codes according to the classification part of OKPD2.

Identify and decipher bar codes on containers or packaging (if there is a group container or packaging).

When checked by the organoleptic method, the analysis consists of the following steps: (2)

3. stage. Determine the type of goods, trade names.

3.1. Examine the appearance of the product:

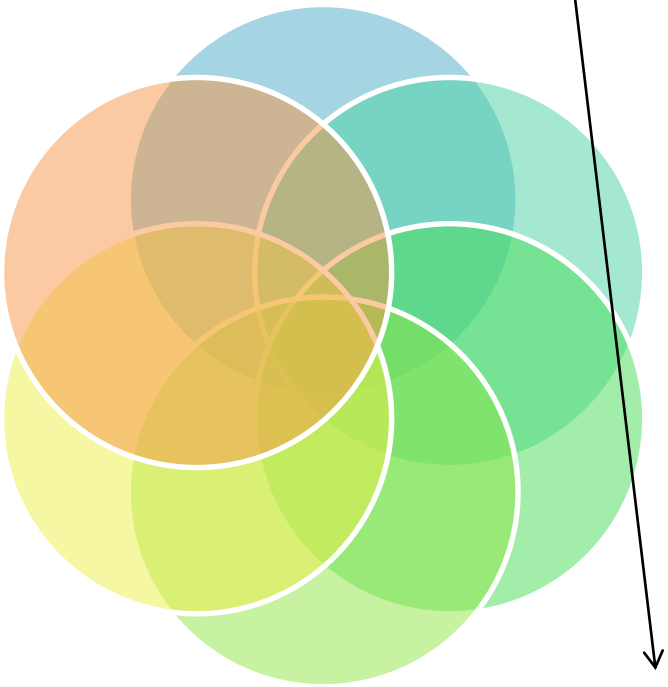
For medical equipment, instruments : the number of parts, the nature of the connection of parts, the type of lock, the nature of the curvature of the working part: along the plane or vertically, along the edge or horizontally, along the radius, at an angle, type of notch, type and quality of the teeth, design of the rack, etc. ;

For medicines : pharmacotherapeutic group, composition, dosage form, etc.

3.2. Determine the geometric dimensions and characteristics of the variety of goods .

For medicines : number, weight, dosage, number of units of one dosage form, etc.

For medical equipment, instruments : length, width, height, diameter, capacity, etc.;



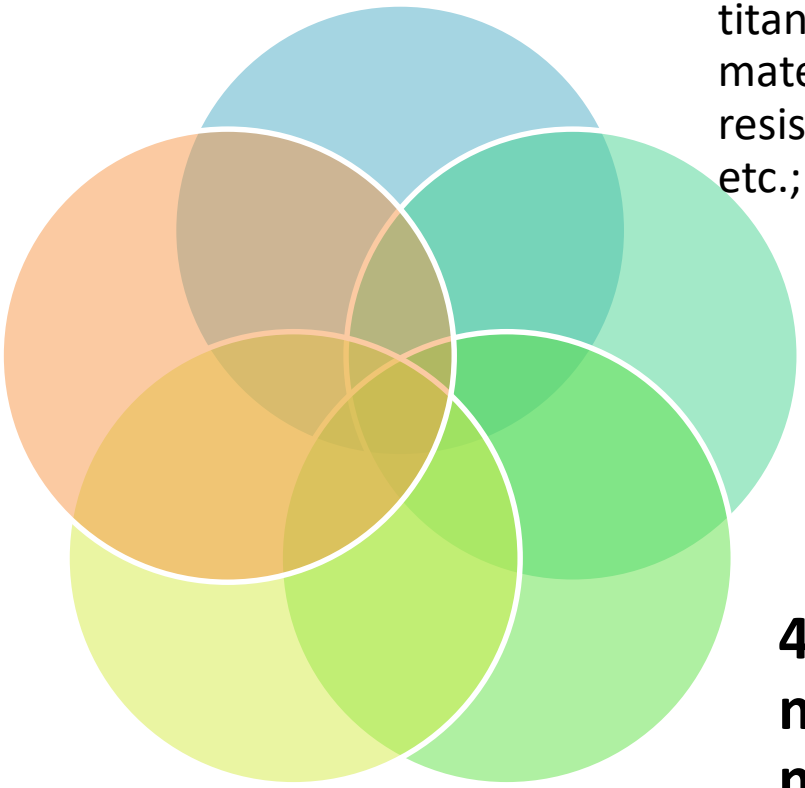
When checked by the organoleptic method, the analysis consists of the following steps: (3)

Stage 4. Set the technological characteristics of the product.

4.1. Determine the material from which the goods or individual parts are made.

for medical equipment, instruments: metal or alloy - carbon steel, stainless steel, titanium, brass; polymeric material, rubber, heat-resistant or chemical glass, etc.;

for medicines: the active substance, and other components that make up a specific dosage form.

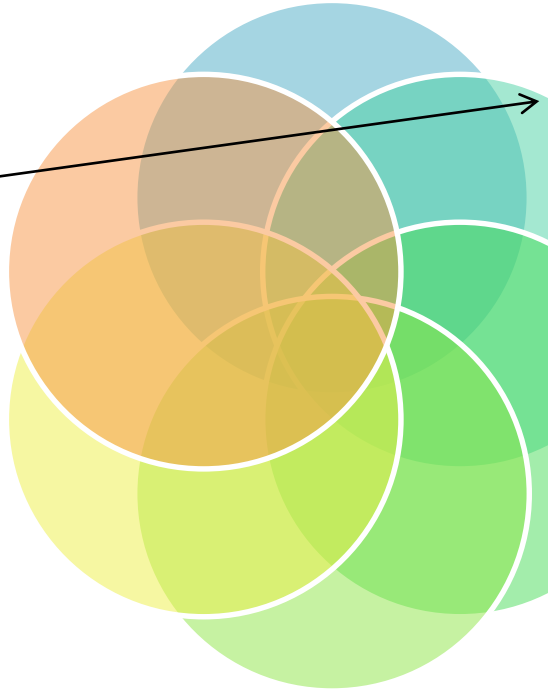


4.2. Establish the method of manufacturing goods.

When checked by the organoleptic method, the analysis consists of the following steps: (4)

Stage 5 Carry out acceptance of goods in accordance with the requirements of regulatory documentation.

5.1. Evaluate the appearance of the goods by external inspection .



For other items: measure the product and establish the presence and location of all components, the absence of unacceptable defects and manufacturing defects (tears, punctures, signs of aging, foreign inclusions and odors, sealing leaks , etc.).

For medical products (equipment, instruments, etc.) *:* measure the product and establish the presence and location of all components and the absence of unacceptable defects: scratches, cracks, nicks, shells, crumbled places, burrs on the surface, peeling of the protective coating (for goods having a protective coating of metals), traces of corrosion, misalignment of the working parts, play in the lock, malfunction of the ratchet and spring, mechanical deformation, malfunction of the screw connection of the components, clouding of the glass and illegibility of graduation (for syringes).

For medicines *:* color of tablets or solutions, absence of sediment, inclusions, etc. impurities in solutions, absence of defects on the primary packaging, etc.

When checked by the organoleptic method, the analysis consists of the following steps: (5)

5.2. Assess the completeness by external inspection.

For medical equipment, instruments **: establish the correspondence of accessories (for example, for an electrocardiograph - electrodes; for instruments - removable blades, spoons, etc.) and spare parts to the product specified in the regulatory and operational documentation (GOST, TU, passport, technical description , instructions, etc.).**

For medicinal products: **match the quantity of medicinal products in the primary package with the secondary package; the presence, for example, of blades for opening ampoules, tips for aerosol packaging, etc.**

When checked by the organoleptic method, the analysis consists of the following steps: (6)

5.3. Explore the functional properties of goods.

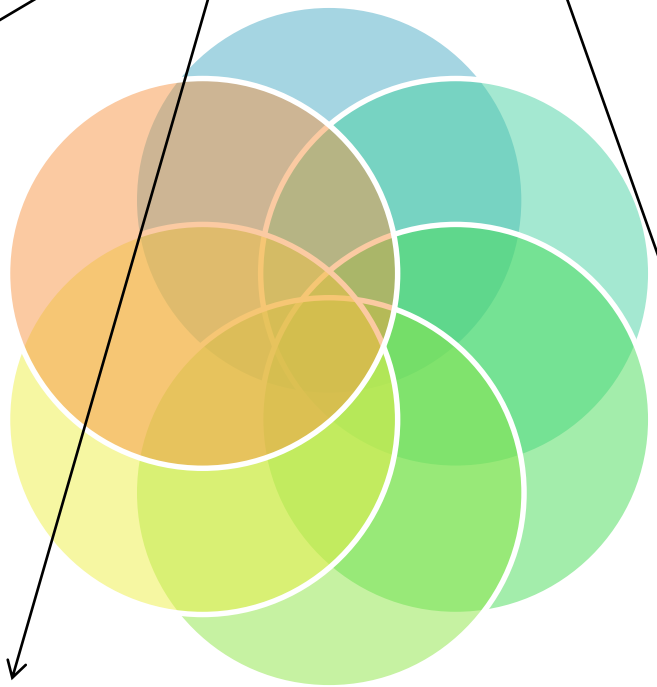
For medical equipment, instruments: **(for a robotic device, establish compliance with the functional properties specified in the regulatory and operational documentation in the prescribed modes; for cutting instruments: sharpness and the ability to maintain it (resistance); for clamping instruments: automaticity and strength of holding tissues, etc. .P.); expanding tools: elasticity, strength;**

For medicines: authenticity; in aerosol packaging: sprayability .

For other products: **to establish compliance with the functional properties specified in the regulatory and operational documentation** (for example, for syringes: heat resistance, leakage ; for suture materials: strength, the same diameter along the entire length, etc.; for dressings: absorption capacity, capillarity, reaction of the medium in a water extract, etc.; for sanitary and hygiene products made of rubber: tightness, mechanical performance, etc.).

When checked by the organoleptic method, the analysis consists of the following steps: (7)

Stage 6 Evaluate product packaging.



Check for the presence of preservation oil on the goods (only for tools and devices), **the presence of paraffin or inhibitor paper.**

Determine the presence of primary, secondary, group and transport packages.

Evaluate the quality of the packages by external inspection (the surface should not have distortions, cracks, tears, folds, etc.).

Evaluate the protective, consumer and aesthetic properties of packages .

When checked by the organoleptic method, the analysis consists of the following steps: (8)

Stage 7. *Analyze product labeling.*

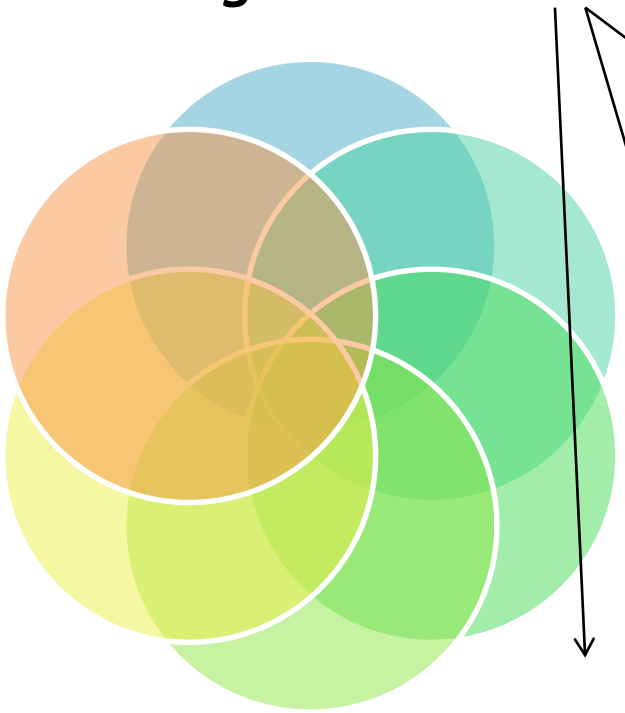
Establish the presence of markings on goods (for devices, medical instruments, sanitary and hygiene products made of rubber), decipher it, assess compliance with the requirements of regulatory documentation .

Assess the conformity of labeling on packages of all types with the requirements of regulatory documentation.

Determine the suitability of goods by expiration date (sterility, warranty period): establish by means of marking (on goods or packages) the date of manufacture of goods; see the expiration date (sterility, warranty period) according to the regulatory documentation; give an opinion on the suitability of goods for this indicator.

When checked by the organoleptic method, the analysis consists of the following steps: (8)

Stage 8. ***Organize or check the correct organization of storage and transportation of goods.***



Define a storage group for items.

Check correct storage in accordance with orders.

If necessary, give recommendations on storage, represervation (only for general surgical instruments) and transportation of the studied goods.

Stage 9 ***Select or recommend methods of disinfection and sterilization of goods*** (if necessary).

Exemplary schemes for commodity analysis of medical and pharmaceutical products

Approximate scheme of commodity analysis of medical devices

- 1. Name.
- 2. Classification group.
- 3. Appointment.
- 4. Commercial types, standard sizes.
- 5. Raw material.
- 6. Design features.
- 7. Technical requirements (quality control).
- 8. Packing.
- 9. Marking.
- 10. Storage, transportation.
- 11. Sterilization, disinfection.

Approximate scheme of commodity analysis of medicines

- 1. Name.
- 2. Pharmacotherapeutic group.
- 3. Main pharmacological action, application.
- 4. Code according to OKPD 2, ATH
- 5. Types of dosage forms.
- 6. Packing.
- 7. Marking.
- 8. Storage, transportation.
- 9. Quality check:
  - a) upon admission to a wholesale institution;
  - b) upon admission to a retail institution.
- 10.Price.
- 11. Rules for dispensing from a pharmacy.

Algorithm for the acceptance of medicines in pharmacies in connection with the entry into force on November 29, 2019 of a **new procedure for introducing medicines into civil circulation**

1. In connection with the new rules for introducing medicinal products for medical use into civil circulation, **series (batches) of medicinal products entering civil circulation after November 29, 2019 are not accompanied by documents containing information on registered declarations of conformity and issued certificates of conformity.**

Algorithm for the acceptance of medicines in pharmacies (2)

2. The supply of medicinal products (with the exception of immunobiological medicinal products: vaccines, sera, immunoglobulins, toxins and antitoxins) may be accompanied by the following documents:

- **a certificate (passport) of the manufacturer on the compliance of the series (batch) of the medicinal product with the requirements of regulatory documentation** ;

– **confirmation by the authorized person of the medicinal product manufacturer** (for drugs manufactured at domestic production sites) **or the responsible person of the organization importing the medicinal product into the Russian Federation and authorized by the foreign manufacturer of medicinal products, that the imported medicinal product complies with the requirements established during its state registration;**

Algorithm for the acceptance of medicines in pharmacies (3)

3. **The supply of immunobiological medicinal products** (vaccines, sera, immunoglobulins, toxins and toxoids) **may be accompanied by a copy of the Roszdravnadzor's permission to put into civil circulation, certified by an electronic digital signature.**

Algorithm for the acceptance of drugs in pharmacies (4)

4. The legality of finding a series (batch) of a medicinal product **is checked through the official website of Roszdravnadzor www.roszdravnadzor.ru.**

To do this, on the website of Roszdravnadzor **, you need to go to the section "Medications" and in the heading "Electronic Services" find the service: "Information about drugs that entered the civil circulation in the Russian Federation."**

Algorithm for the acceptance of drugs in pharmacies (5)

Search is possible by several details, including trade name, series number, manufacturer, country of production.

Information about Roszdravnadzor's permissions to enter the civil circulation of a series (batch) of **an immunobiological medicinal product is also posted on the Roszdravnadzor website under the heading "Electronic Services" / "Information about drugs entered into civil circulation in the Russian Federation".**

Information from the website of Roszdravnadzor is possible for printing after uploading to an Excel file.

Algorithm for the acceptance of drugs in pharmacies (6)

5. In accordance with Part 10 of Article 52.1 of Federal Law No. 61-FZ dated April 12, 2010 “On the Circulation of Medicines”, **if a series or batch of a medicinal product is detected in civil circulation, documents and information about which are not submitted to Roszdravnadzor, or series or batches immunobiological medicinal product that do not have permission to enter into civil circulation, Roszdravnadzor makes a decision to terminate the civil circulation of such a series or batch before the submission of the specified documents and information or receipt of the specified permission.**

Algorithm for the acceptance of medicines in pharmacies (7)

Thus, in the absence of information on the Roszdravnadzor website on the introduction of a series (batch) of a medicinal product into civil circulation, you should contact the territorial body of Roszdravnadzor to consider the need for control measures.

Contact details of the Territorial Bodies of Roszdravnadzor are publicly available on the Roszdravnadzor website http://roszdravnadzor.ru/about/structure/territorial (Section "About the Service" / "Structure" / "Territorial Bodies").

Merchandising, sales, contracts, special conditions for the supply of medical products

DEFINITIONS OF SOME BASIC TERMS

Merchandising is the movement of goods from the producer to the consumer.

A distribution channel *is* a set of firms or individuals who successively acquire ownership of a drug on its way from manufacturer to consumer. Inside the distribution channel, a drug constantly changes its owner.

Marketing is the movement of goods from the producer to the consumer.

A distribution channel is a collection of organizations or individuals that assume or help transfer ownership of a particular good or service to another along the way from producer to consumer.

DEFINITIONS OF SOME BASIC TERMS (2)

The channel of sale (distribution) ***is*** the path along which goods move from the producer to the consumer, the selected channels directly affect the speed, time, efficiency of movement and the safety of products when they are delivered from the producer to the final consumer.

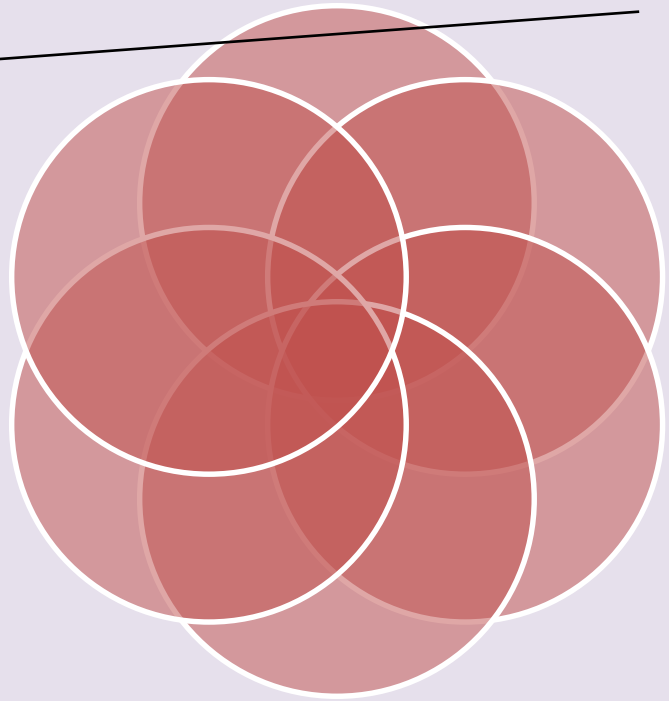
The channel level **is** the intermediary that does the work of bringing the product and ownership closer to the end consumer .

Distribution network **-** a system of interconnected organizations or individuals that move goods from producer to consumer.

COMMODITY MOVEMENT

Merchandising is the movement of goods from producer to consumer .

Channel commodity circulation



In order for goods from the manufacturer to reach the final consumers, there are distribution channels .

In order for a drug to be sold, **the distribution channel must act as an interconnected and coordinated system** of all firms involved in the distribution of goods.

SALES POLICY

STAGES of the marketing policy (***promotion of goods from the manufacturer to the consumer)*** :

1. preparatory stage **,** which immediately precedes the distribution of goods and the sale of goods to end customers. At this stage, planning and development of a strategy for the implementation of the marketing policy are carried out.

2. the stage of specific activities to organize a system for the physical movement of goods (distribution *) from the manufacturer to destinations (wholesale seller's warehouses, retail outlets, end buyers.*

3. stage of sales strategy, analysis, ***building a sales*** *network.*

ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS

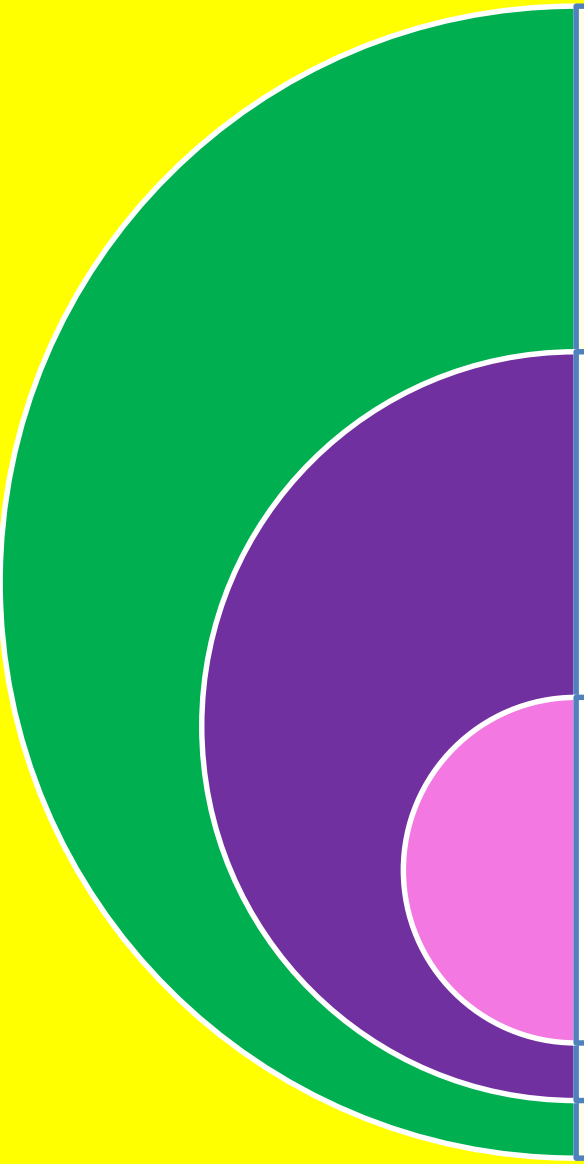
Marketing includes all activities necessary to deliver the product from the producer to the consumer *, incl.*

- wholesale and retail trade,

- warehousing and transportation.

The organization of marketing activities occupies one of the central places in logistics and in the marketing system : **the increase in sales, cost reduction, and profit growth depend to a decisive extent on its level.**

ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS (2)



The main objective of marketing activities is **the sale of products at a profit.**

To successfully solve this problem, various marketing methods are used.

The choice of a specific method of distribution underlies the organization of the sales network.

ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS (3)

Classification of marketing methods :

4) By type of sales marketing systems.

1) Depending on the type of distribution channel (distribution channel)

2) Depending on the degree of sales intensity

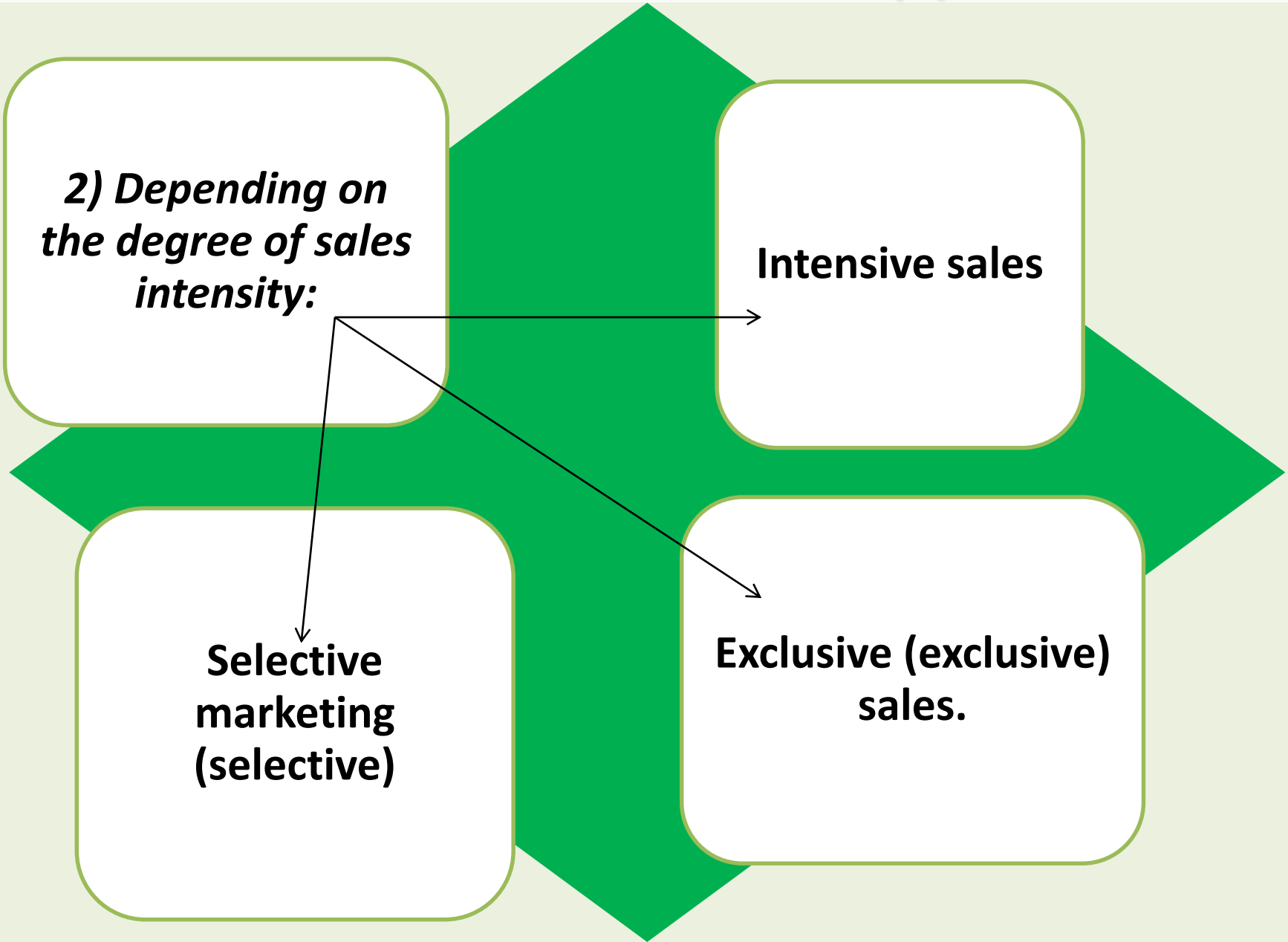
3) By consumer orientation

ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS (4)

1) Depending on the type of distribution channel (distribution channel):

- **Direct or direct method**
- **indirect method**
- **Combined, mixed sales.**

ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS (5)



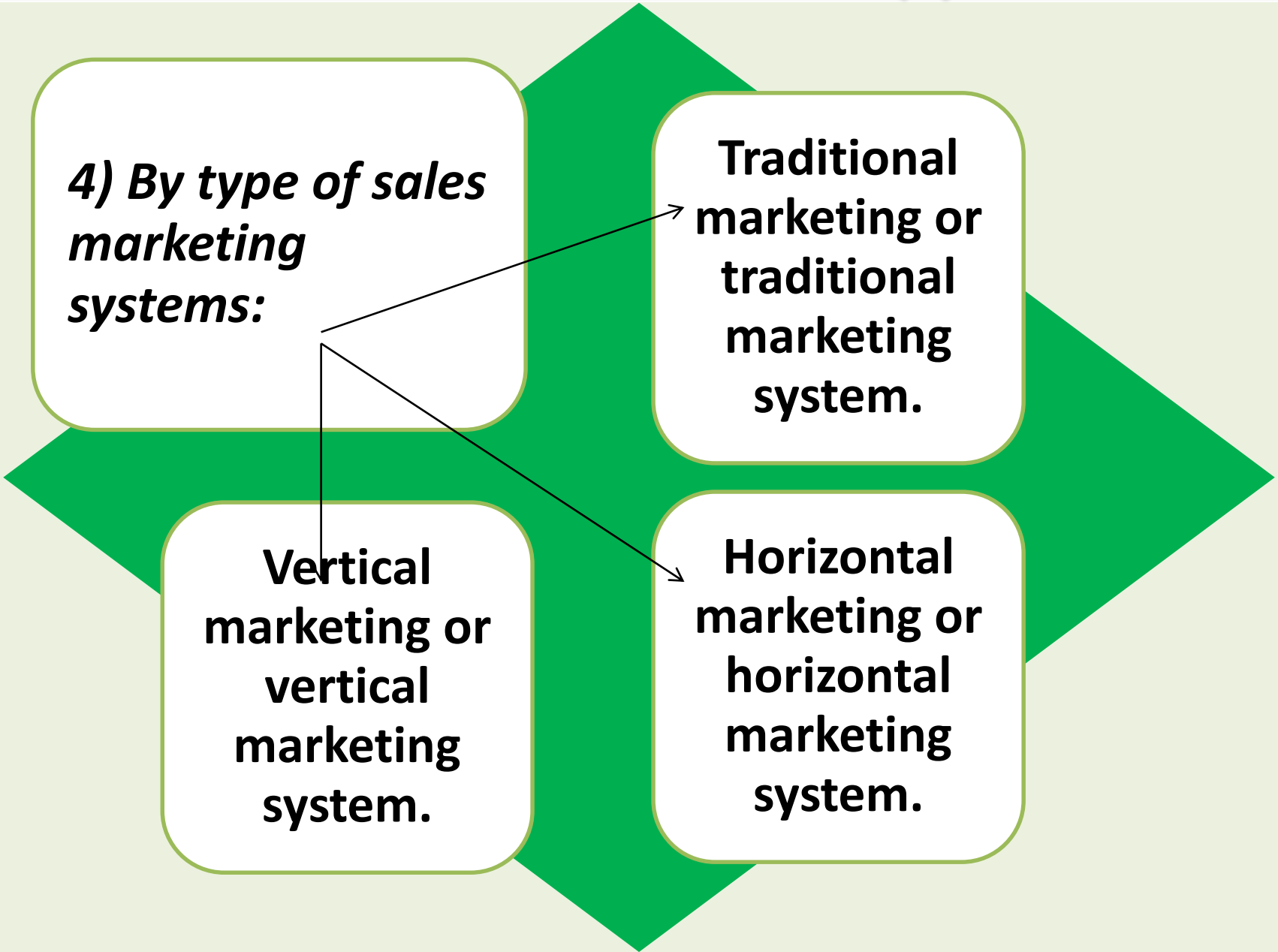
ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS (6)

3) By consumer orientation:

targeted sales

Untargeted sales

ORGANIZATION OF SALES ACTIVITIES. CLASSIFICATION OF MARKETING METHODS (7)



SUMMARY OF MARKETING METHODS (1)

1.1. Direct, or direct method - ***the manufacturer of the product enters into direct relations with its consumers and does not resort to the services of independent intermediaries*** .

For example, a chemical-pharmaceutical plant is a pharmacy.

Advantages of the method: the direct method ***allows the pharmaceutical manufacturer to maintain full control over the conduct of sales operations and close contact with consumers,*** such organizations have limited target markets.

SUMMARY OF MARKETING METHODS (2)

1.2. Indirect method - to organize the sale of their goods, the manufacturer uses the services of independent intermediaries.

Advantages of the method : the ***intermediary link in the marketing activities of a pharmaceutical organization increases the efficiency of marketing operations*** , since the high professionalism of the intermediary in the marketing and commercial areas allows you to accelerate cost recovery and turnover of funds, creates convenience for end customers, saves money and time on a smaller number of business relationships.

SUMMARY OF MARKETING METHODS (3)

1.3. Combined, mixed sales - in this case, the manufacturer either goes to the buyer or to the intermediary, and the capital of the manufacturer and the intermediary participates in the intermediary link.

SUMMARY OF MARKETING METHODS (4)

2.1. Intensive sales - ***sale through the maximum possible number of sales organizations in a particular market, regardless of the form of their activity*** . For example, the sale of medicines through all possible specialized points: pharmacies, pharmacy kiosks, pharmacy points, etc. The intensity of sales depends largely on the type of product. For example, kiosks provide intensive sales for medicines.

2.2. Selective marketing (selective) - ***it provides for limiting the number of sales organizations.*** It is typical for the sale of goods that require special services and a high level of personnel training (for example, higher and secondary pharmaceutical education for the sale of medicines).

2.3. Exclusive (exclusive) sales - ***sale through an extremely small number (1-2) sales organizations in a particular market*** . For example, many large pharmaceutical organizations take the exclusive right to sell specific drugs from manufacturers.

SUMMARY OF MARKETING METHODS (5)

3.1. Targeted sales - the sale of goods (including medicines) to a specific group of consumers. For example, oral contraceptives are intended for women of reproductive age, anti-tuberculosis drugs - for a tuberculosis dispensary, cardiovascular drugs - for a cardiological center, antipsychotics, sedatives - for a psychiatric hospital, etc.

3.2. Non- targeted sales - the sale of goods for the entire market without restriction. This type of marketing requires high advertising costs and is recommended for consumer goods. It is possible to use non- targeted marketing for the sale of drugs. For example, the sale of vitamin preparations.

SUMMARY OF MARKETING METHODS (6)

4.1. Traditional marketing or traditional marketing system - ***with this method of selling, independent independent organizations of manufacturers, wholesalers and retailers are not controlled by each other.*** They pursue the goal of maximizing profits only on their site, not caring about profits in the marketing system as a whole.

4.2. Vertical marketing or vertical marketing system - ***acts as a single system, since it includes a manufacturer, wholesalers and retailers pursuing common goals and operating under joint control*** , was the most common in the pharmacy system of the former USSR.

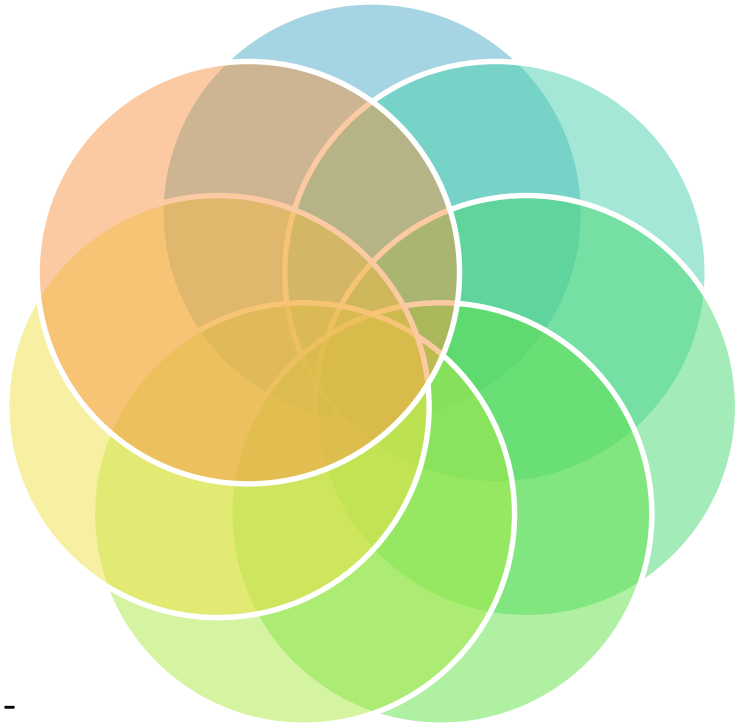
4.3. Horizontal marketing or a horizontal marketing system is ***an association of several pharmaceutical organizations for the joint development of a specific market.*** It is created when one organization lacks the means, capacity or knowledge to organize marketing activities. It is possible to use such a distribution system in the pharmacy system (for example, the association of pharmacies in a particular region to conduct a wide advertising campaign and increase the sales of their products).

Organization of the sales network. Stages of organizing a distribution network

Stages of organizing a sales network, incl. pharmacy:

1st stage. ***Selection of the type and level of sales for each group of goods and market segments.*** The pharmacy distribution network is characterized by indirect one-, two-, and three-level channels.

2nd stage. ***Determining the width of the distribution channel, i.e. the number of independent participants at each stage of marketing*** (the number of pharmacy warehouses or wholesale pharmaceutical organizations and the number of pharmacies selling products of a particular manufacturer).



3rd stage . ***Determining the level of sales intensity*** (intensive, selective, exclusive) and its focus (targeted and non-targeted).

4th stage . ***The choice of a management system for the sales network and the form of establishing legal and organizational relations*** (traditional, vertical, horizontal).

Main types of distribution network (1)

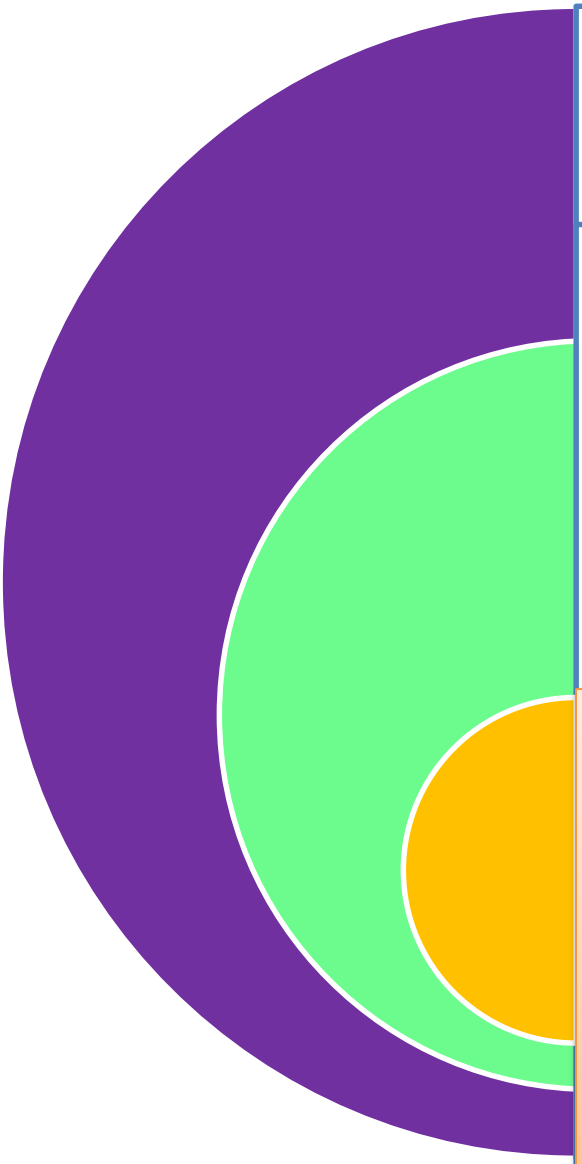
The organization of the distribution network depends on three main factors:

- Product type.
- Geographical extent of the market.
- The nature of the consumer.

In accordance with them, there are three main types of distribution network:

- ***By type of product.***
- ***By regions.***
- ***By the nature of the consumer.***

Main types of distribution network (2)

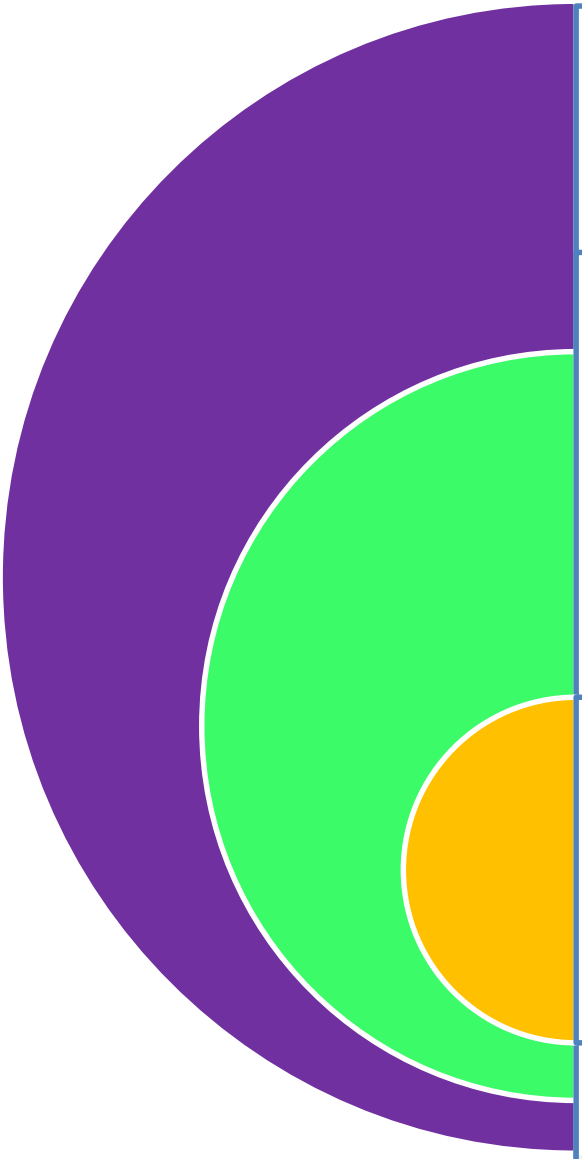


1. Sales network by product type:

When organizing sales by type of product, separate divisions are formed that specialize in one or more types of goods. Such a distribution network is preferred when the range of products varies greatly in terms of assortment and requires special knowledge .

Thus, the nomenclature of pharmaceutical products is represented by significantly different assortment groups: medicines and chemical products; dressings and patient care items; medical equipment, optics, etc. In this regard, specialized divisions are formed in the pharmacy network for the sale of specific groups of goods (for example, for medical equipment - " Medtekhnika " stores; for the sale of glasses, frames, lenses - "Optics", etc.) .

Main types of distribution network (3)



2. Sales network by regions

When organizing sales by regions **, regional sales divisions are formed** . For example, for the regional marketing of medicines and medical products, a pharmacy network has been formed in the regions of the Russian Federation.

An independent type of marketing activity, organized both by type of product and by region (country), is export - sales of products on a foreign market.

Main types of distribution network (4)

4. Sales network by the nature of the consumer:

When organizing sales by the nature (type) of the consumer, separate divisions are formed that specialize in serving one or more types of consumers . For example, for the sale of medicines and medical supplies, the following are organized:

- pharmacies serving only the population;

- pharmacies serving one medical institution (hospital);

- pharmacies supplying several medical institutions and other organizations.

A rationally formed sales network contributes to the most complete satisfaction of consumer needs, since it ensures optimal promotion of goods in the pharmacy system.

Pharmaceutical and logistics system of the distributor

Distributor **-** a legal entity acting as an intermediary between the manufacturer and the buyer on behalf of the manufacturer. The distributor may or may not be the owner of the product .

The purpose of the pharmaceutical and logistics system is to deliver goods in the required quantity and assortment at a given time, to the maximum extent possible, prepared for consumption at a given level of costs and service.

Pharmaceutical and logistics system of the distributor

As a result, the logistics functions of the pharmaceutical and logistics system of the distributor are performed:

- organization of supply processes,
- Inventory Management,
- transportation,
- coordination of information flows.

CHARACTERISTICS OF DISTRIBUTION CHANNELS (1)

primary goal *logistics distribution system* - **deliver goods to the right place and at the right time with minimal cost** using organized distribution channels.

The use of distribution channels brings certain benefits to manufacturers:

financial savings on the distribution of products;

the possibility of investing the saved funds in the main production;

selling products in more efficient ways, high efficiency in ensuring the wide availability of goods and bringing it to target markets;

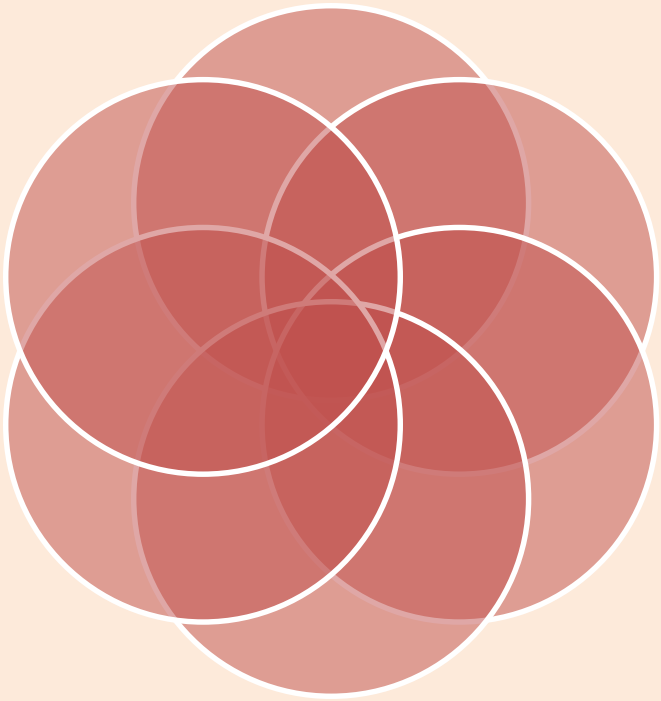
reduction in the volume of work on the distribution of products.

Thus, the decision on the choice of distribution channels is one of the most important, which must be taken by the management of the organization.

CHARACTERISTICS OF DISTRIBUTION CHANNELS (2)

The most important channels for the sale of goods are trade organizations:

- auctions
- trades
- brokerage
- exchanges
- wholesale
- retail
- imported
- Commission
- consignment
- agency



CHARACTERISTICS OF DISTRIBUTION CHANNELS (3)

Functions of the organizations or individuals that make up the channel :

carry out research work to collect information necessary for planning the distribution of products and services;

stimulate sales by creating and disseminating product information;

establish contacts with potential buyers;

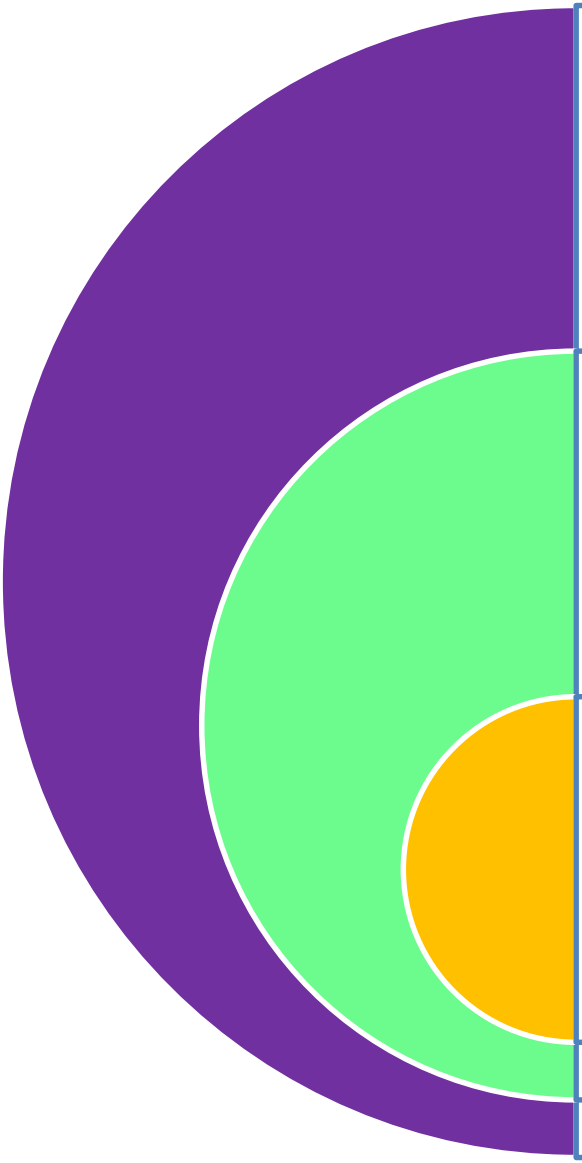
adapt the goods to the requirements of buyers ;

conduct negotiations with potential consumers of products ;

organize goods circulation (transportation and warehousing); finance the movement of goods through the distribution channel;

assume the risks associated with the operation of the channel.

Wholesale intermediaries: tasks, functions, classification (1)



The choice of one or another method of organizing marketing activities and a pharmaceutical organization **depends on the specific market conditions, sales and strategy of the organization itself** .

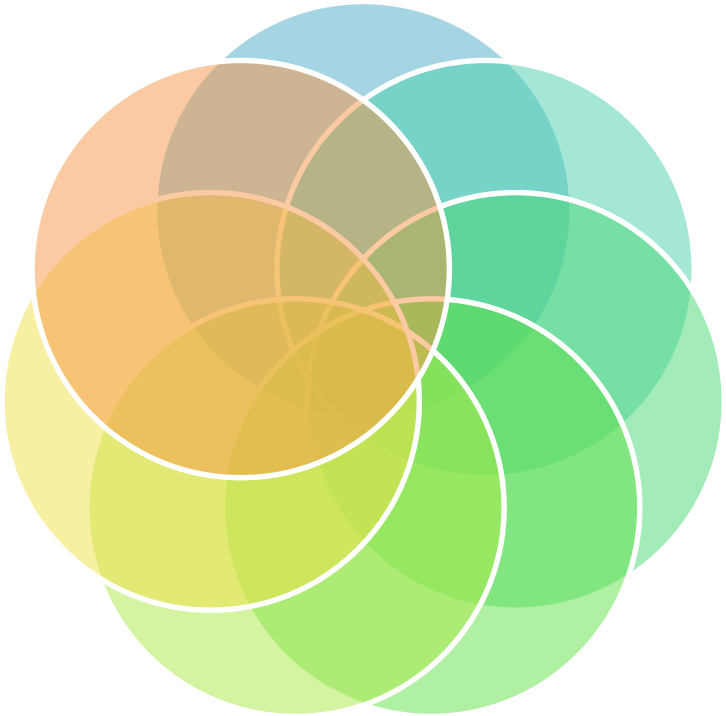
Often **a pharmaceutical organization** , especially ***a large one, prefers to work*** by **combining all available types of distribution network organization by market and product.**

The use of the services of intermediaries in a number of cases ***turns out to be the only possible method of sale due to the customs and traditions established in this market.***

Wholesale reseller functions (2)

Sales and promotion.

Marketing. Wholesalers conduct a comprehensive market research on the implementation of product policy, pricing policy, etc.



Reception, storage of goods and inventory management.

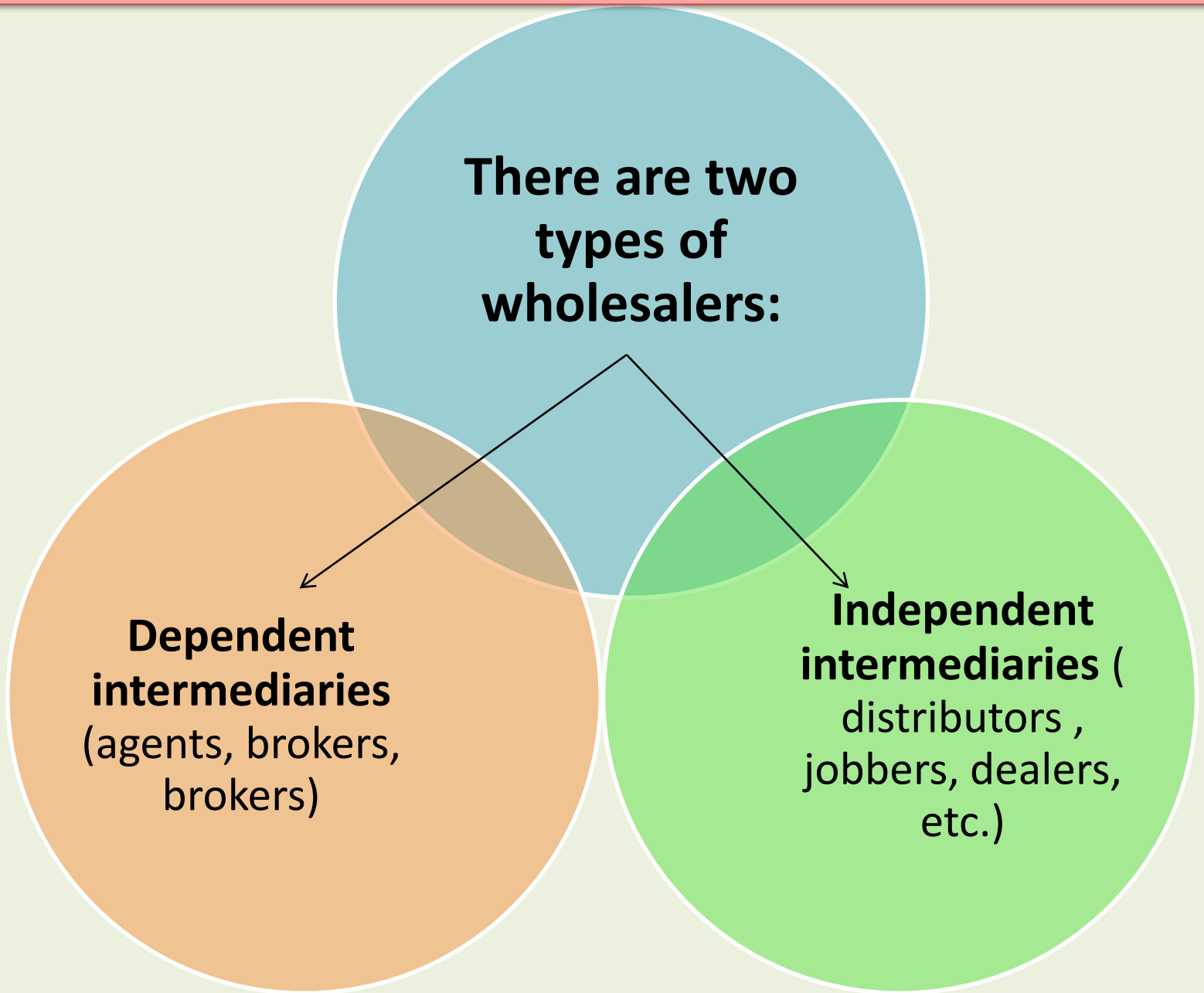
Informational. The wholesaler provides suppliers and retailers with the information they need (catalogs, exhibitions, fairs, advertising, brochures).

Transportation of goods.

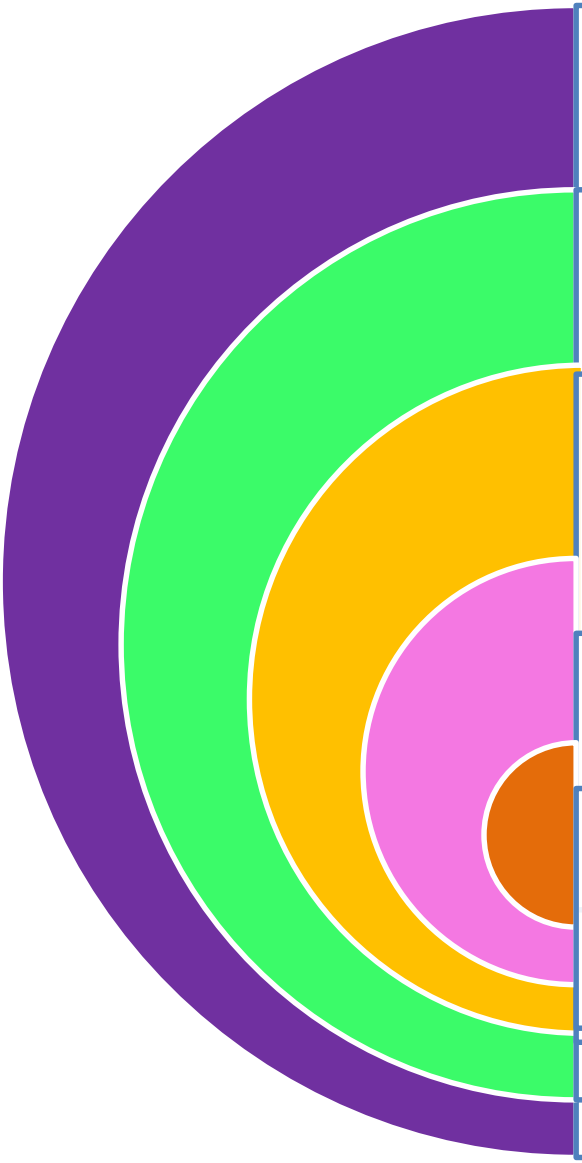
Crediting (consignment) of its clients. A wholesaler can offer retailers the sale of goods on credit, without prepayment.

Redistribution of risk by unplanned expenses . By acquiring the right of ownership of the goods, wholesalers release manufacturers from a certain risk associated with damage or theft of goods, falling prices for it.

CLASSIFICATION OF WHOLESALERS (3)



CLASSIFICATION OF WHOLESALERS (4)



Independent intermediaries or wholesalers (merchant wholesalers) are businesses that:

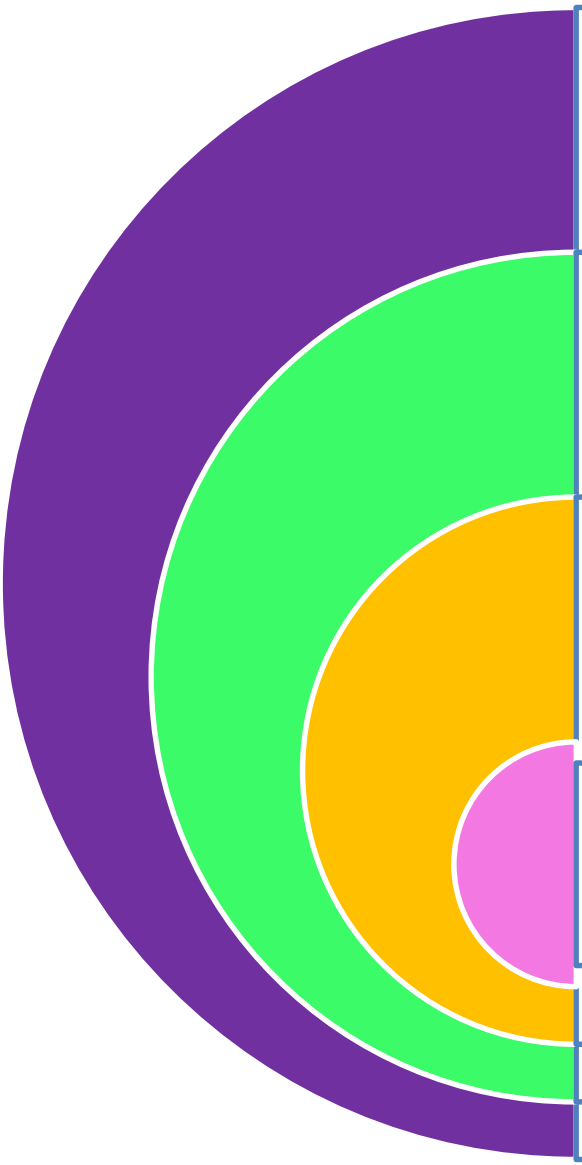
- ***acquire ownership of the goods with which they deal.*** That is, they buy goods from suppliers, and then sell them to retail pharmacies;

- ***carry out all or some of the functions characteristic of wholesale intermediaries*** (realization, storage, transportation of goods, lending to buyers, redistribution of risk, information, marketing);

- receive remuneration from the profit from the sale.

The amount of remuneration covers the costs of the wholesaler and provides him with a profit. The remuneration to the wholesaler is paid by the consumer (from 5% to 25% commission).

CLASSIFICATION OF WHOLESALERS (5)



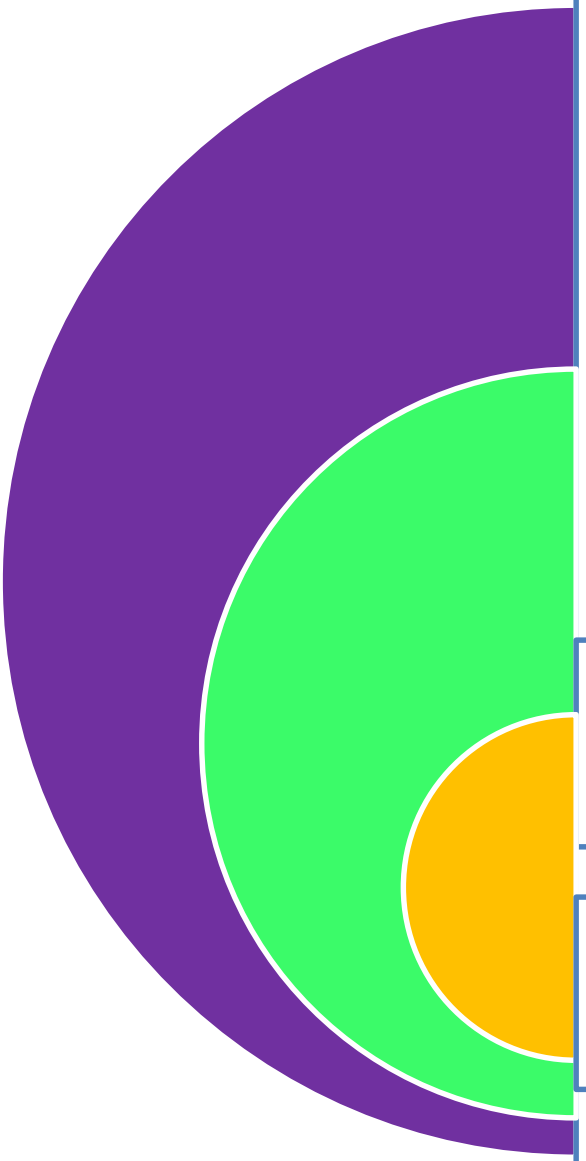
Dependent intermediaries (*agents and brokers)* are organizations or individual entrepreneurs who:

- do not take ownership of the goods , i.e. do not buy goods and do not directly participate in the sale;

- ***perform the following functions: facilitating the sale or sale*** , i.e. bring sellers and buyers together; ***carry out information and marketing functions*** ;

- receive remuneration at the expense of commissions (from 2 to 10% of the sale price). The agent who hires him pays.

BRIEF DESCRIPTION OF SOME TYPES OF INTERMEDIARY (independent)



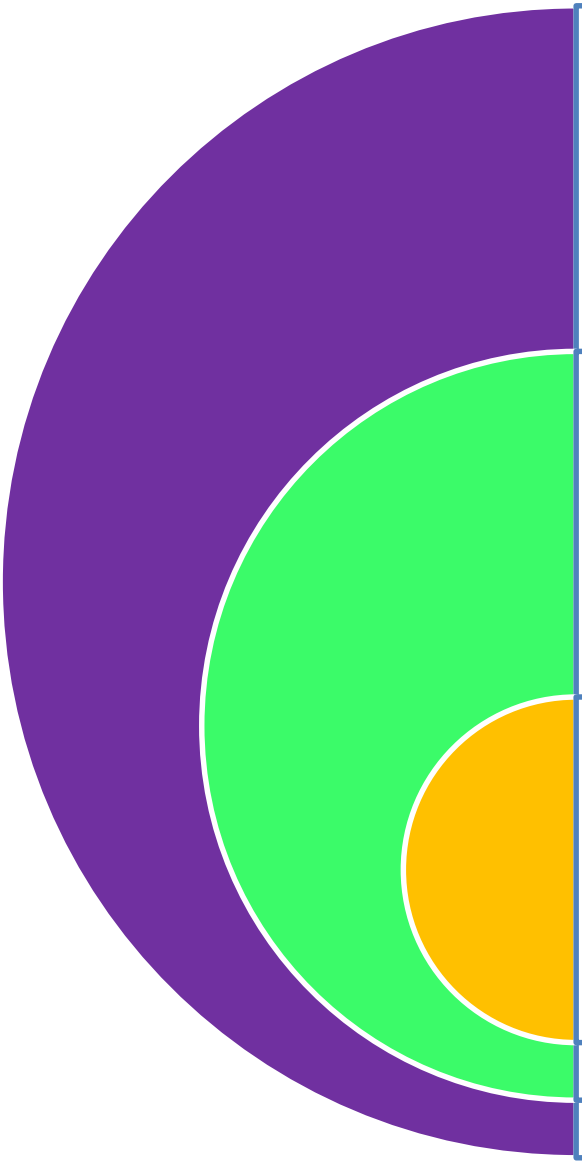
Distributors are wholesalers and retailers who operate on behalf of the manufacturer and at their own expense. As a rule, the manufacturer grants the distributor the right to sell his products in a certain territory and for a certain period of time. Thus, the distributor is not the owner of the product. Under the contract, they acquire the right to sell products.

The distributor may act on his own behalf. In this case, within the framework of the contract for granting the right to sell, a supply contract is concluded between the manufacturer and dealers.

Jobbers are organizations that buy individual large or small lots of goods for quick resale .

Commission agents are wholesale and retail intermediaries who conduct operations on their own behalf and at the expense of the manufacturer.

BRIEF DESCRIPTION OF SOME TYPES OF INTERMEDIARY (dependent)



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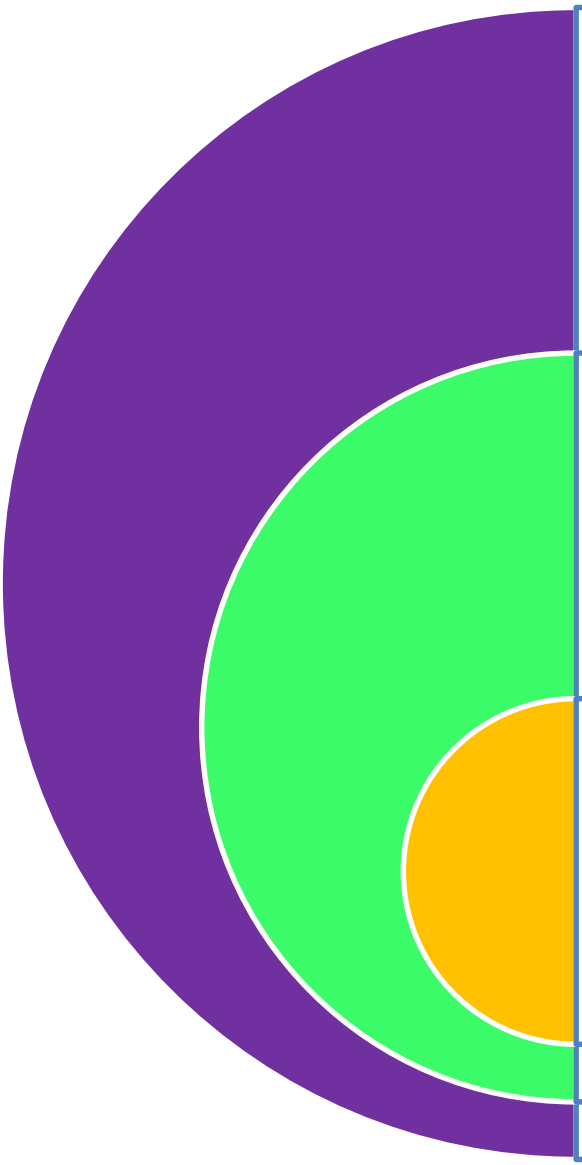

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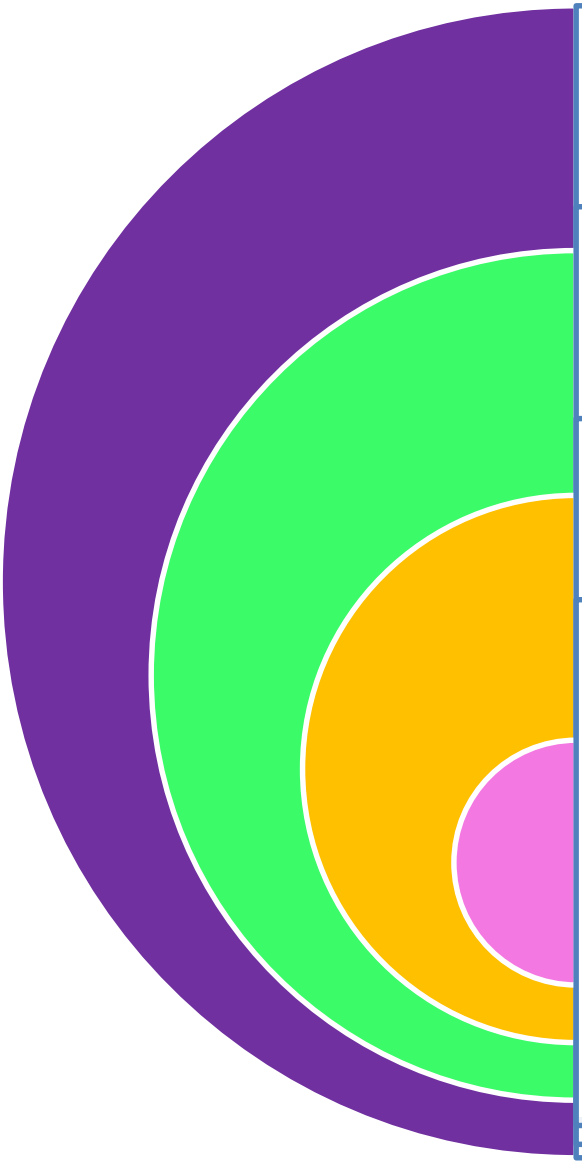

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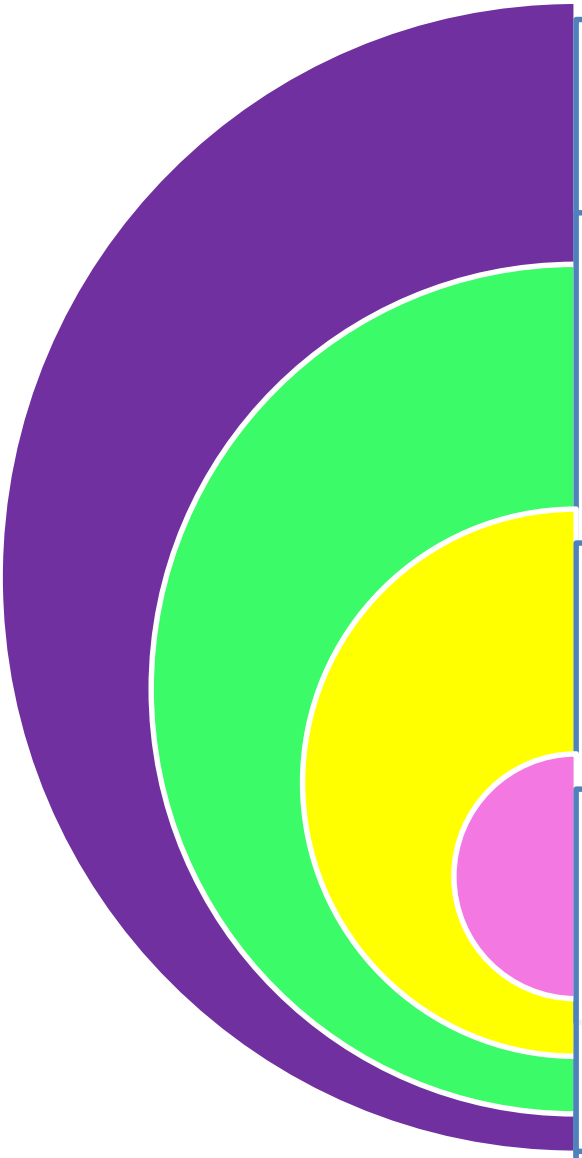

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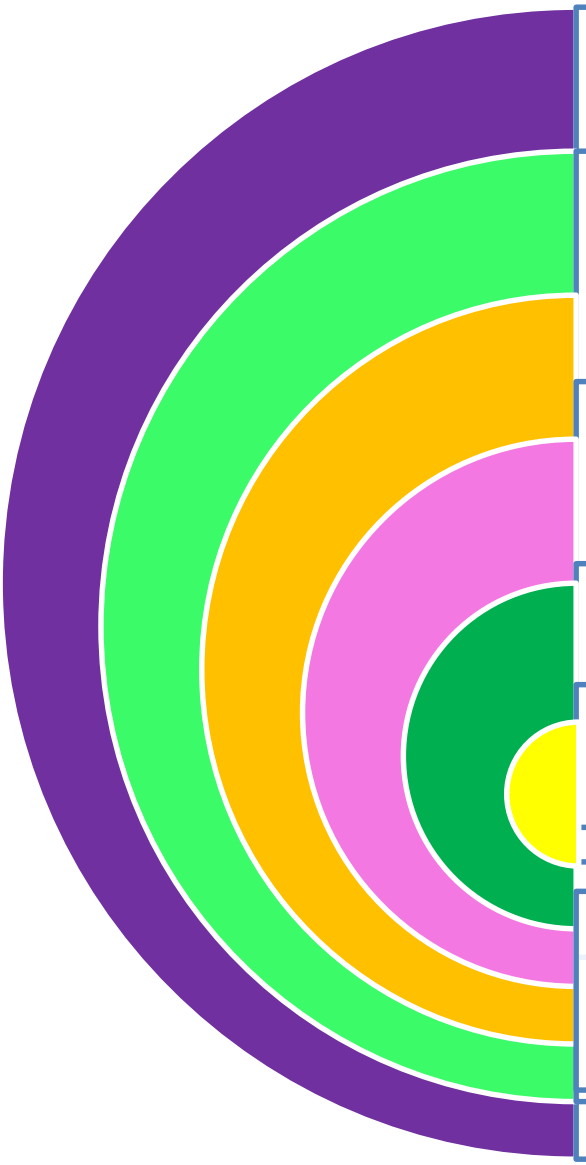

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Purchasing is the management of material flows in the process of providing a pharmaceutical organization with material resources .

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purchase of the desired product at the lowest purchase price;

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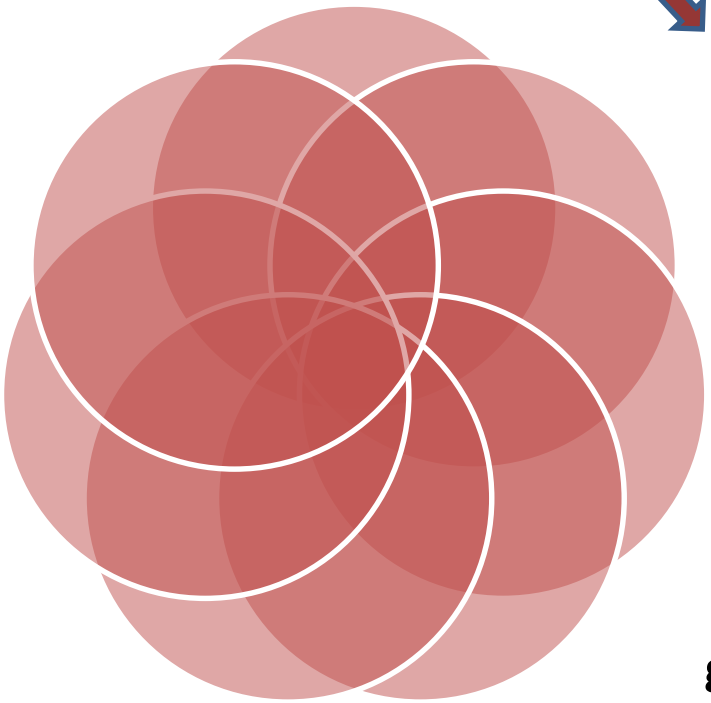

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SELECTION AND EVALUATION OF SUPPLIERS

The supplier selection procedure is the main component of the procurement activity and includes several stages:

1) collection of information about existing and potential suppliers of pharmaceutical products;

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3) evaluation of suppliers according to selected criteria ;

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In order to evaluate suppliers, it is important to make the most of all available information. Knowledge of the sources of supply is the basis of the qualifications of any effective purchasing specialist .

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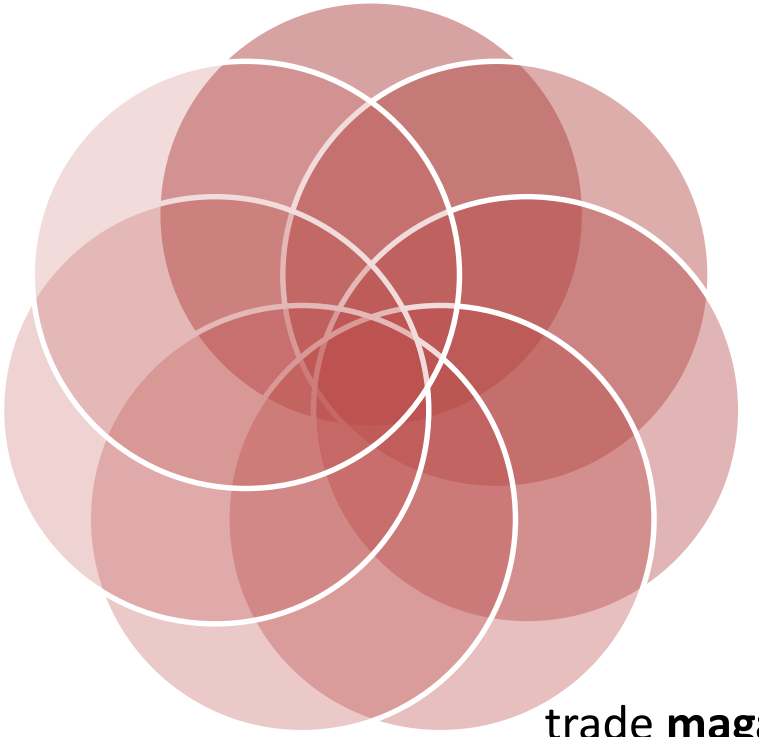

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Stage 2 - narrowing the list of existing suppliers to the list of the most likely sources of supply.

When reducing the number of potential suppliers or when choosing a new supplier , the capabilities of each supplier **should** be **studied accordingly.**

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Supplier evaluation **is an ongoing process:**

- it is necessary to **monitor the activities of currently existing** suppliers in **order to know whether their performance meets expectations** ;

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- Both groups are constantly evaluated from both formal and informal positions.
- *An informal assessment* includes an assessment of personal contacts between the supplier and specialists from all departments of the pharmaceutical organization (buyer). In fact, in most small pharmaceutical organizations, almost all evaluation of currently available sources of supply is done informally.
- *Formal evaluation and certification of the supplier.* The most formal supplier evaluation schemes analyze supplier performance in terms of quality, delivery, price, service, and terms of payment.

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Regardless of the method used, the evaluation procedure should be carried out in an amount corresponding to the needs of the procurement activities of a particular pharmaceutical organization.

The method of rating estimates **is based on the evaluation of suppliers according to certain criteria, which have different significance** . *The significance of the criterion is determined by an expert by the procurement service employees or involved experts.*

The cost estimation method is **sometimes referred to as the "mission method". It lies in the fact that the entire supply process under study is divided into several possible options (missions) and all expenses and incomes are carefully calculated for each.** As a result, data is obtained for comparing and selecting solutions (missions). This method is interesting from the point of view of valuation and allows you to determine the "cost" of choosing a supplier. The disadvantage of the method is that it requires a large amount of information for each supplier.

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The method of dominant characteristics **consists in focusing on one selected parameter (criteria).** This parameter can be the lowest price, the best quality, the delivery schedule that inspires the most confidence, etc. The advantage of this method is in simplicity, and the disadvantage is in ignoring other factors - selection criteria.

preference category method, in which **the assessment of the supplier** , including the choice of how to evaluate it **, depends on information received from many departments of the organization.**

Evaluation of individual product samples considered to be a fairly common method. The supplier organization supplies samples of its products, which are subjected to careful control, analysis, and on their basis, appropriate conclusions are made about all products.

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Vendor reputation method **is based on a study of the characteristics that reflect its reputation:**

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Group *of quantitative methods for evaluating suppliers:*

- *calculation of the values of individual performance indicators* (delivery reliability indicator, quality indicator, supply fragmentation indicator, etc.);

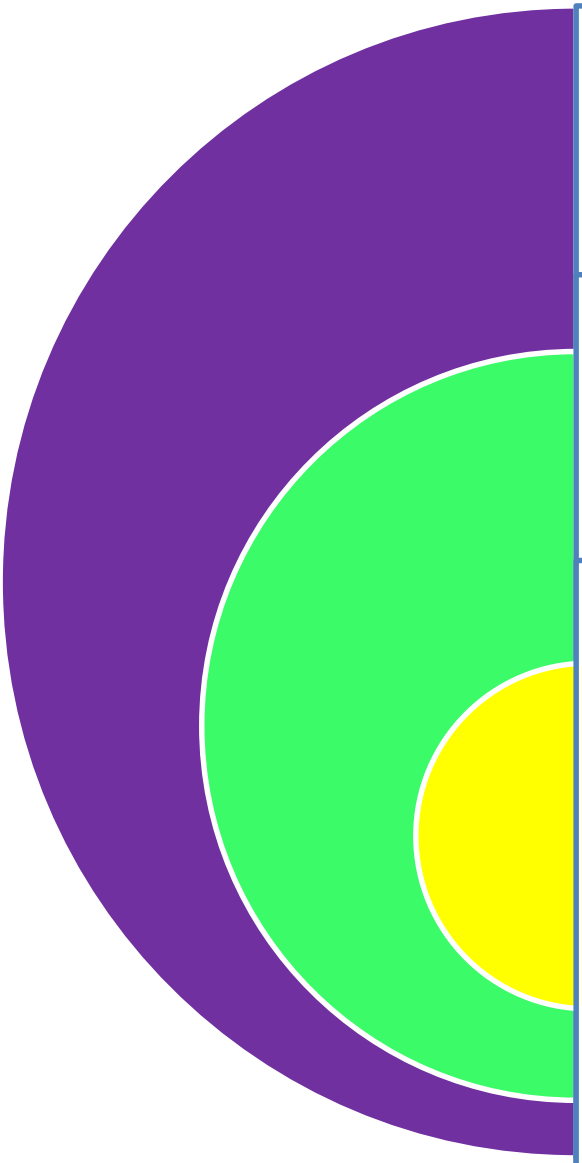
- *methods for a comprehensive quantitative assessment of suppliers (for example, A.* Robertson 's method).

Quantifying supplier performance

When quantitatively assessing the performance indicators of suppliers, to calculate the rating ***for each indicator , the*** product of the obtained value of the growth rate by weight is calculated. The sum of the products will make the rating of suppliers.

Method for evaluating supplier capabilities according to A. Robertson involves taking into account such components of the supply as quality, price, timeliness of delivery and the service provided by the supplier.

SUPPLIER ASSESSMENT



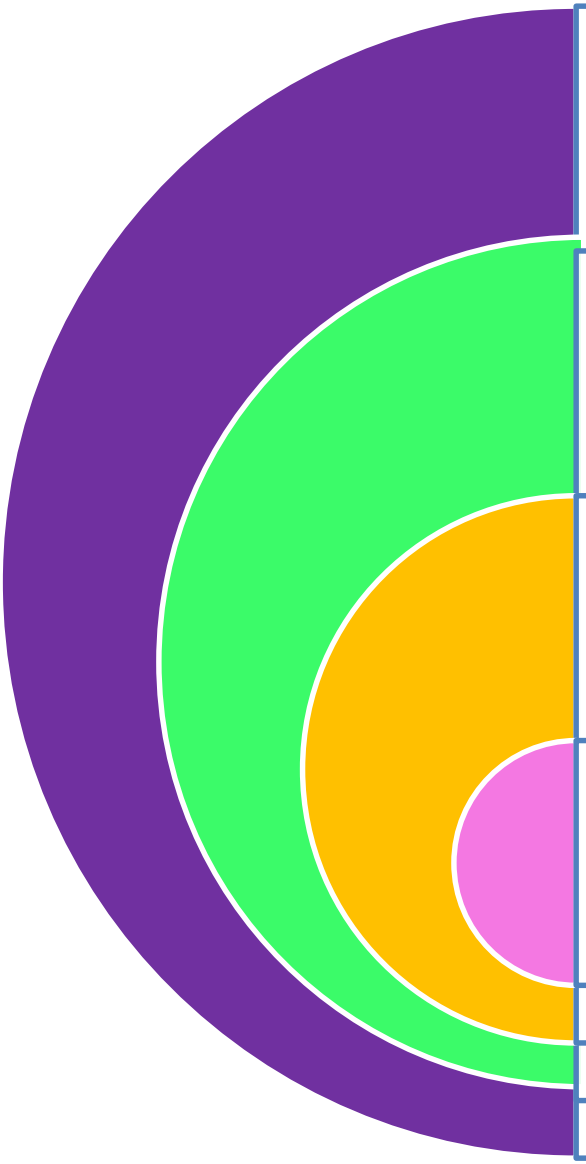
The result of supplier evaluation activity is the identification of one or more sources of supply .

Logistic distribution channels for pharmaceutical and medical products **consist of market intermediaries that bring the product from the manufacturer to the final consumer.**

There are **two main types of logistics distribution channels: direct and indirect** . ***The number of intermediaries determines the channel level.***

Direct channels do not have intermediaries, they are called ***zero-level channels*** **.** This type of logistics channels is not typical for the pharmaceutical market due to the presence of a wide range of products, seasonality of sales, increased requirements for storage conditions for goods and the geographical dispersal of market entities.

APPROACHES TO PROCUREMENT OF GOODS FROM SUPPLIERS



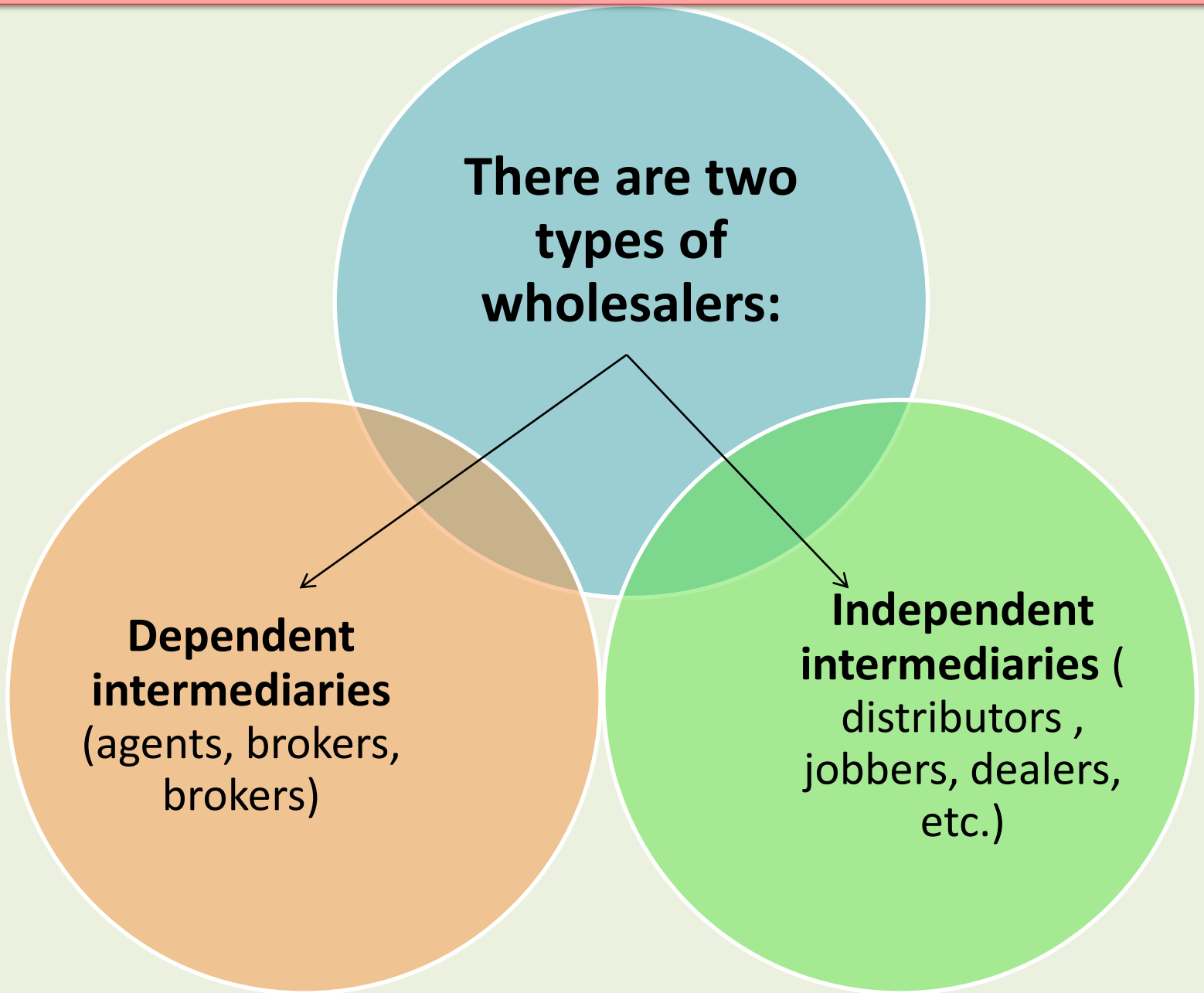
In the practice of procurement, the rule is used to limit the volume of purchases from one supplier within 20-30% of the total volume of purchases.

If a pharmaceutical organization **uses the practice of sharing an order among several suppliers** , then several approaches can be used, including:

One **approach is to split the order evenly,**

another **approach is to place most of the order with the preferred supplier and the rest with one or more supply sources.**

CLASSIFICATION OF WHOLESALERS (3)



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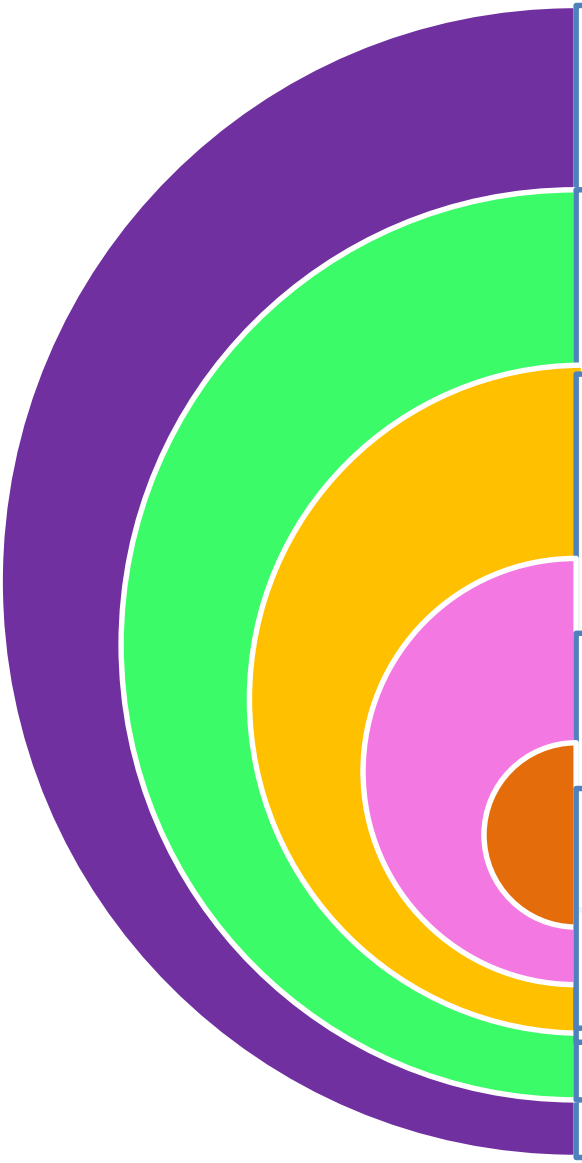

Independent intermediaries or wholesalers (merchant wholesalers) are businesses that:

- ***acquire ownership of the goods with which they deal.*** That is, they buy goods from suppliers, and then sell them to retail pharmacies;

- ***carry out all or some of the functions characteristic of wholesale intermediaries*** (realization, storage, transportation of goods, lending to buyers, redistribution of risk, information, marketing);

- receive remuneration from the profit from the sale.

The amount of remuneration covers the costs of the wholesaler and provides him with a profit. The remuneration to the wholesaler is paid by the consumer (from 5% to 25% commission).

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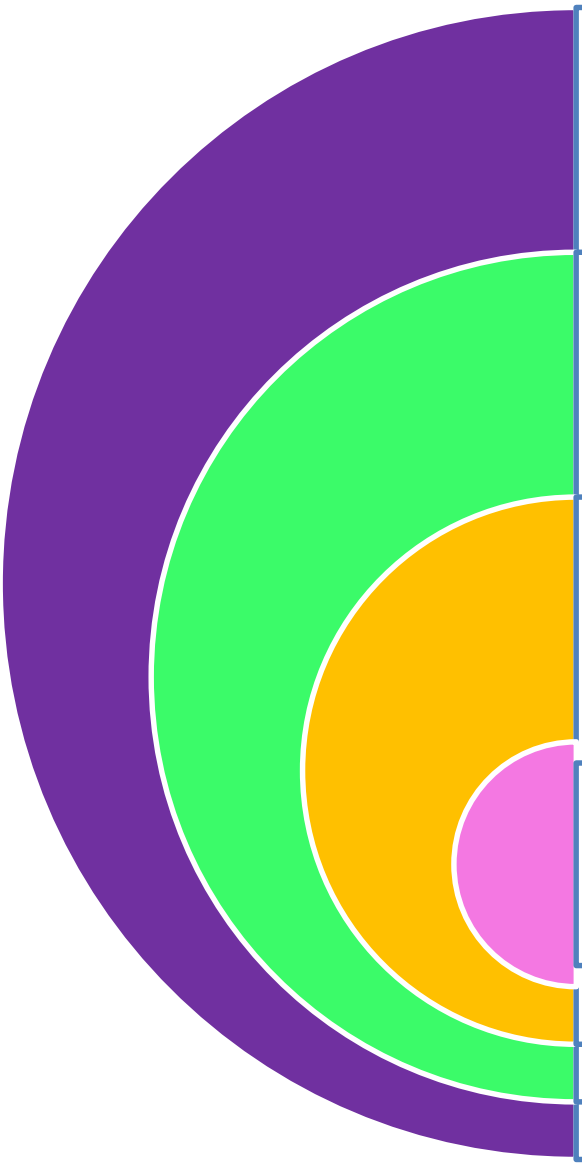

Dependent intermediaries (*agents and brokers)* are organizations or individual entrepreneurs who:

- do not take ownership of the goods , i.e. do not buy goods and do not directly participate in the sale;

- ***perform the following functions: facilitating the sale or sale*** , i.e. bring sellers and buyers together; ***carry out information and marketing functions*** ;

- receive remuneration at the expense of commissions (from 2 to 10% of the sale price). The agent who hires him pays.

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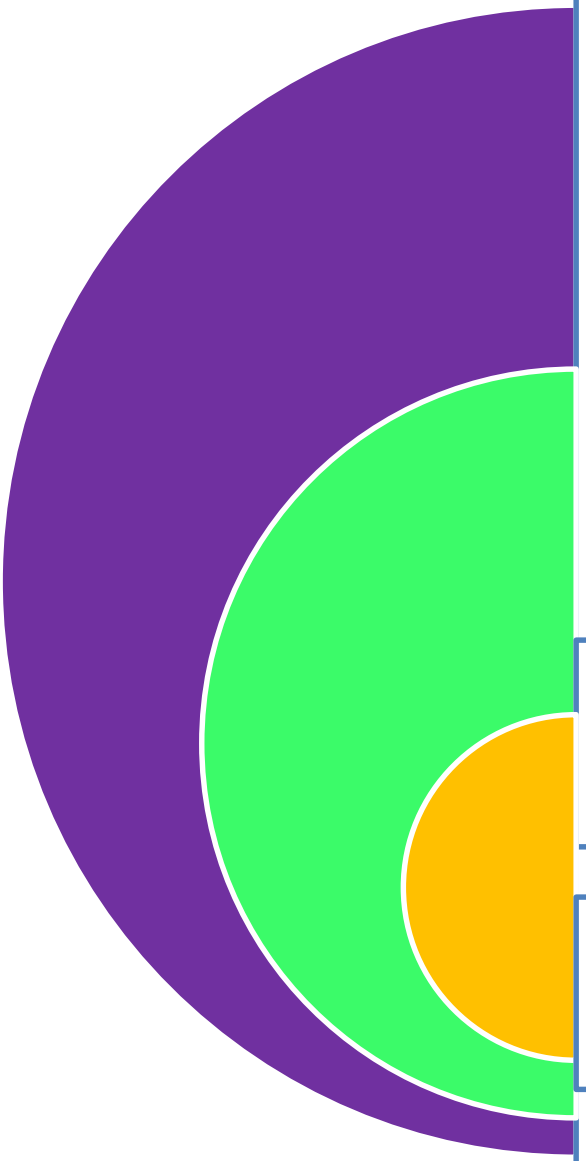

Distributors are wholesalers and retailers who operate on behalf of the manufacturer and at their own expense. As a rule, the manufacturer grants the distributor the right to sell his products in a certain territory and for a certain period of time. Thus, the distributor is not the owner of the product. Under the contract, they acquire the right to sell products.

The distributor may act on his own behalf. In this case, within the framework of the contract for granting the right to sell, a supply contract is concluded between the manufacturer and dealers.

Jobbers are organizations that buy individual large or small lots of goods for quick resale .

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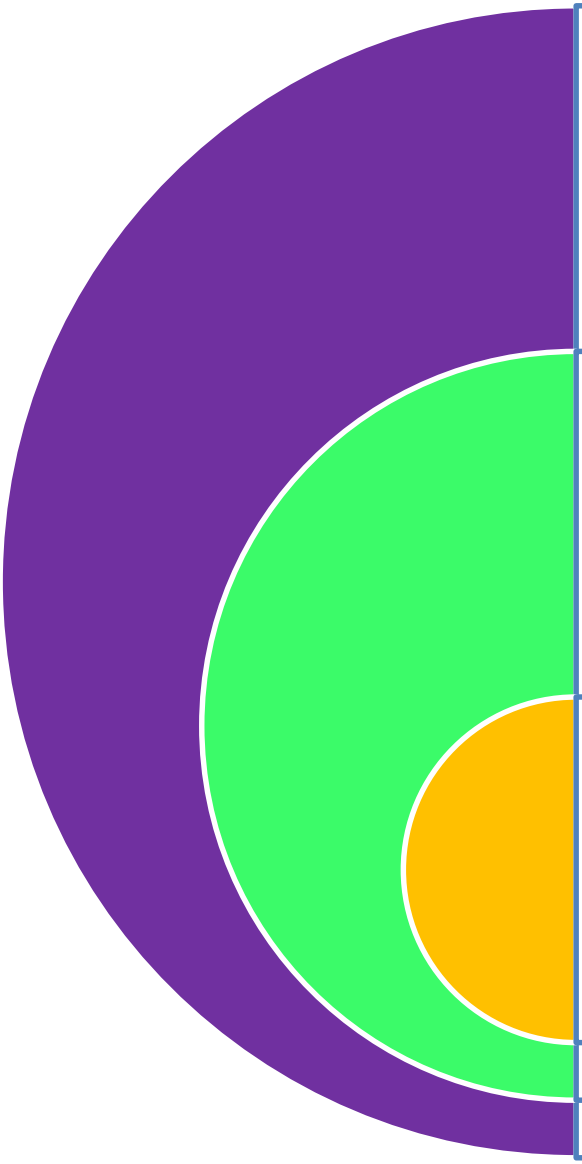

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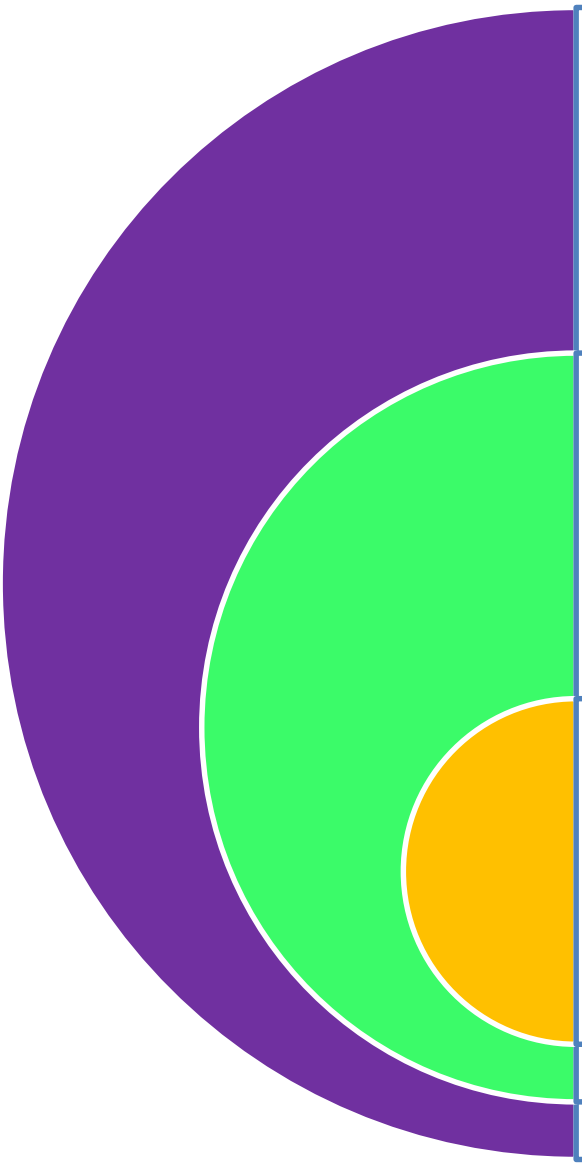

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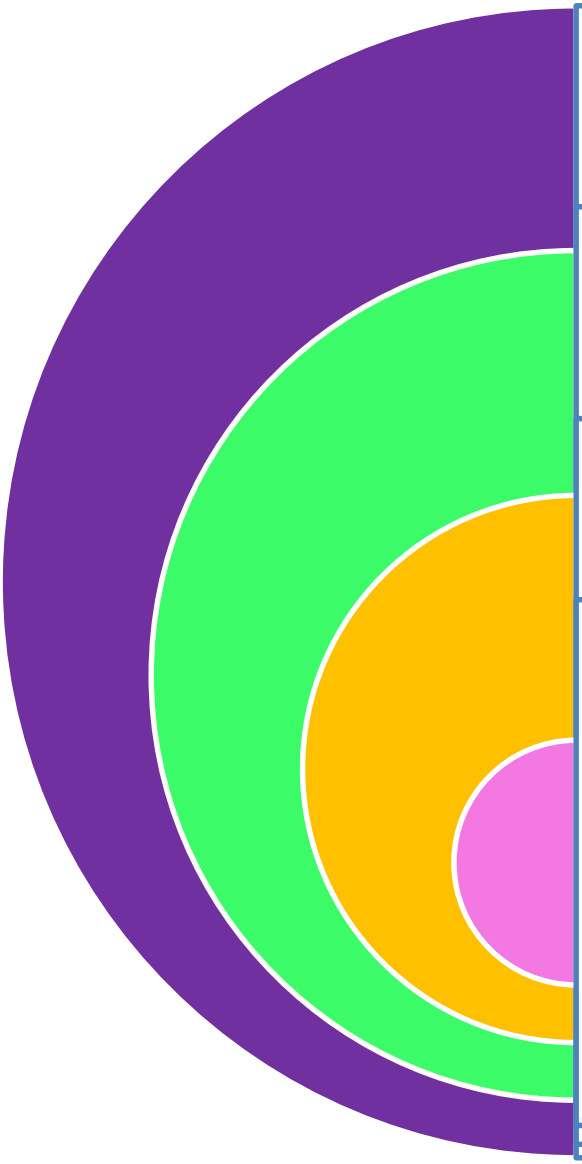

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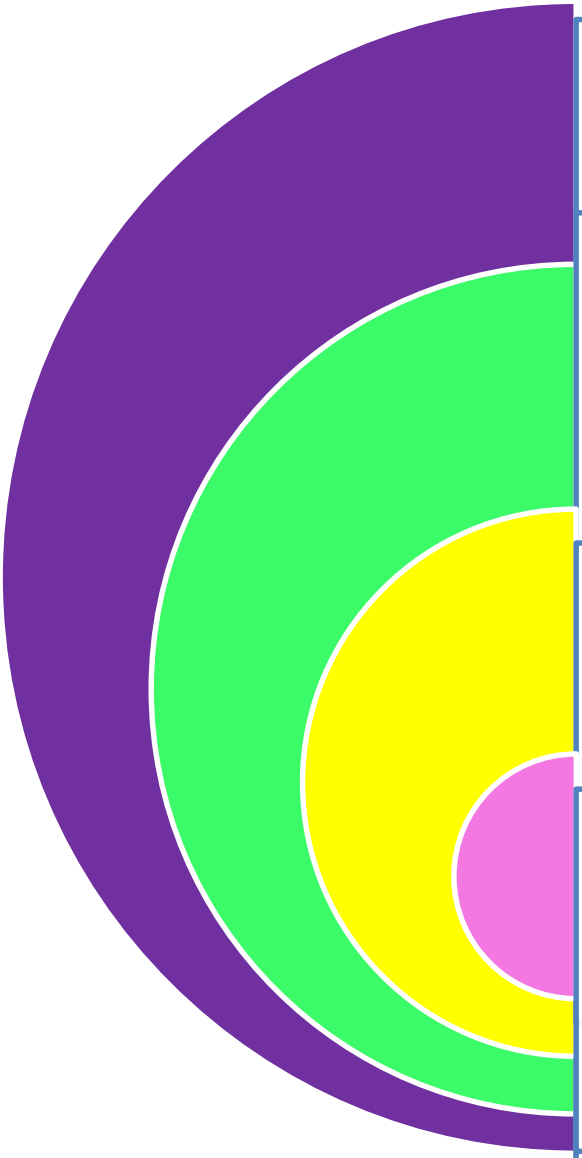

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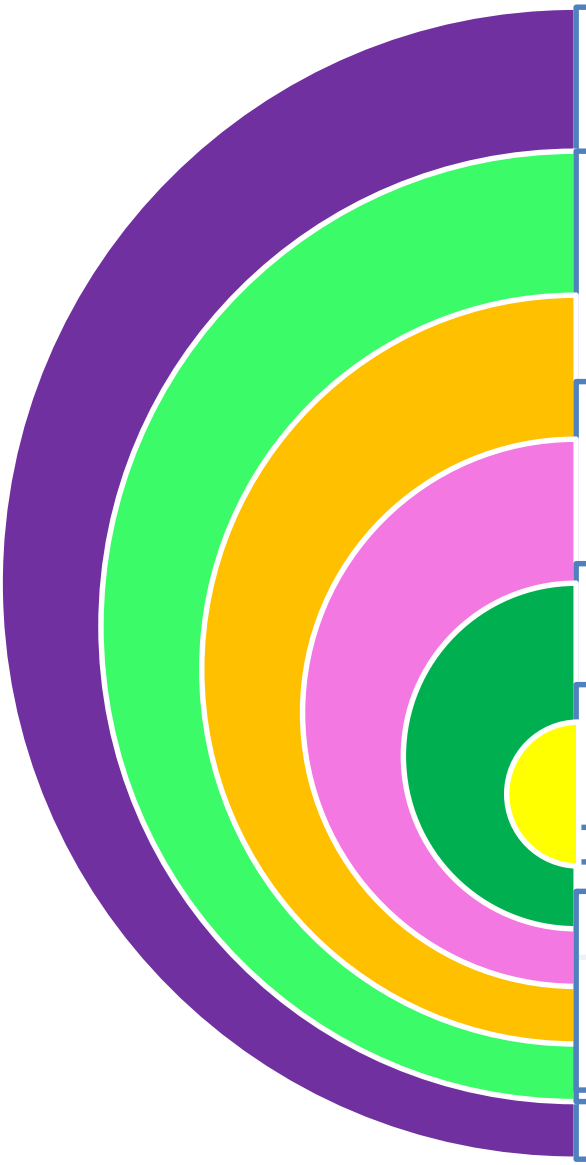

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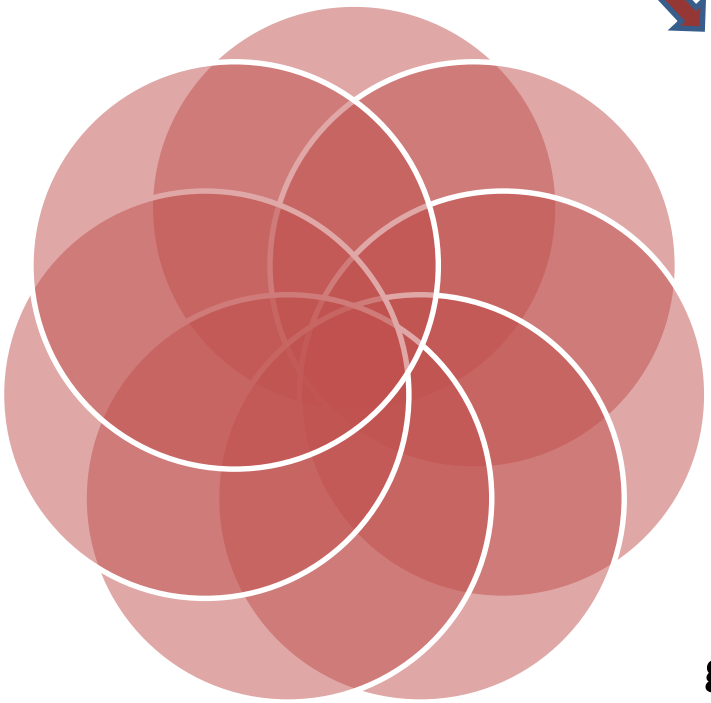

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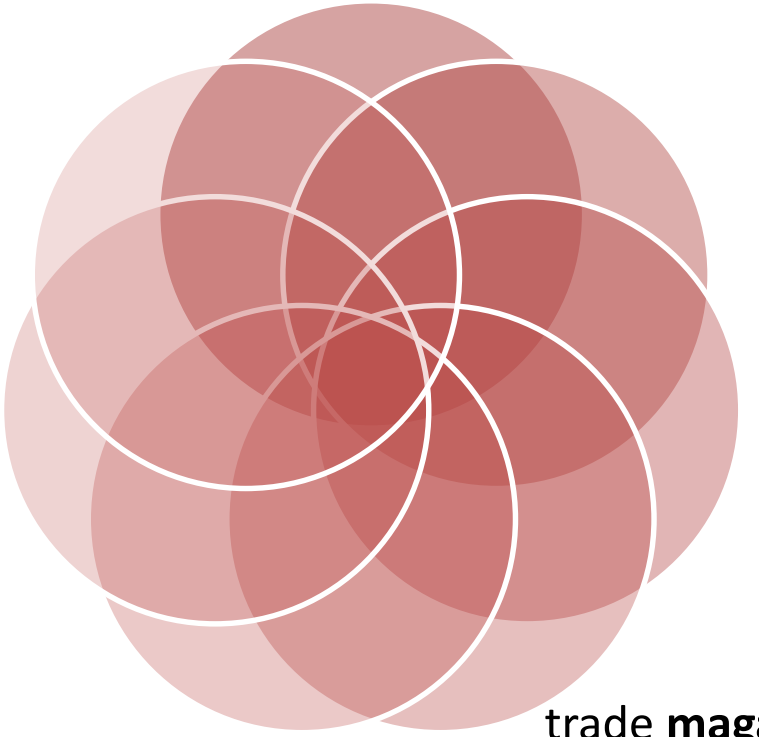

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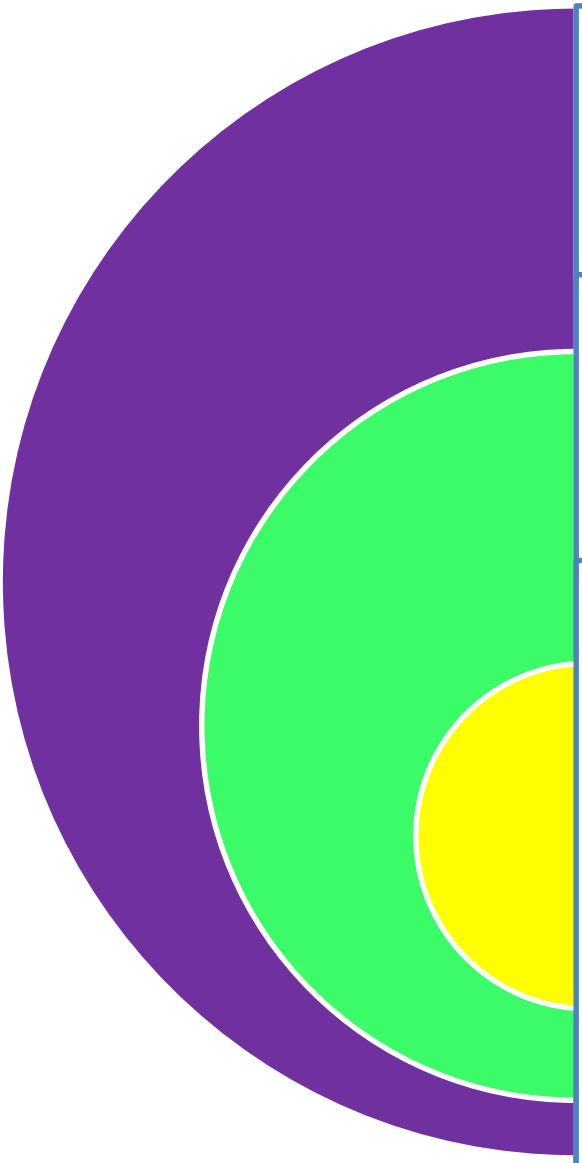
Method for evaluating supplier capabilities according to A. Robertson involves taking into account such components of the supply as quality, price, timeliness of delivery and the service provided by the supplier.

SUPPLIER ASSESSMENT



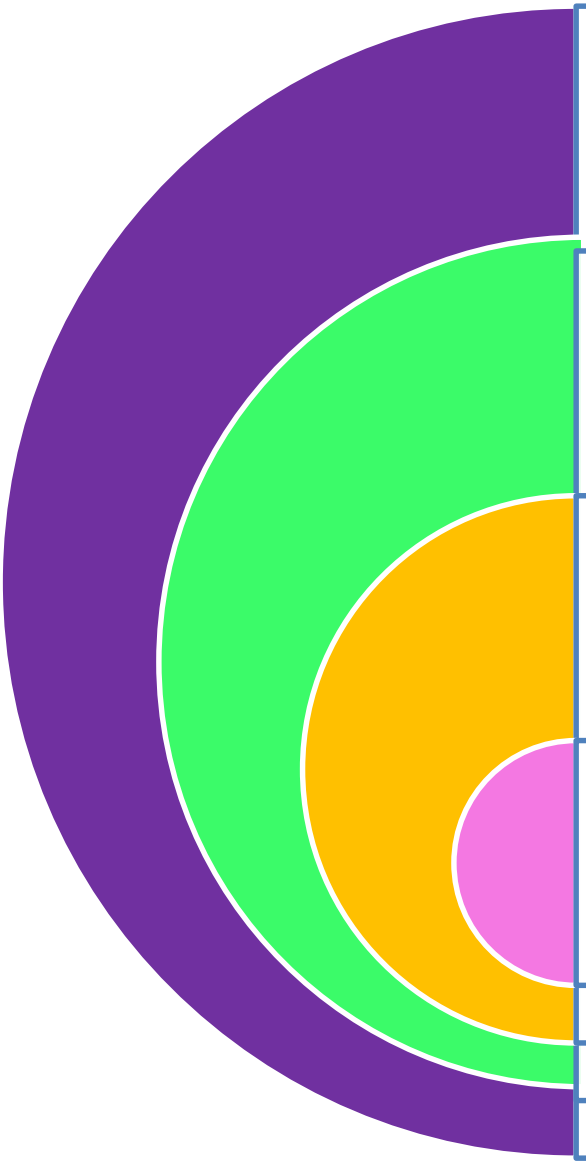
The result of supplier evaluation activity is the identification of one or more sources of supply .

Logistic distribution channels for pharmaceutical and medical products **consist of market intermediaries that bring the product from the manufacturer to the final consumer.**

There are **two main types of logistics distribution channels: direct and indirect** . ***The number of intermediaries determines the channel level.***

Direct channels do not have intermediaries, they are called ***zero-level channels*** **.** This type of logistics channels is not typical for the pharmaceutical market due to the presence of a wide range of products, seasonality of sales, increased requirements for storage conditions for goods and the geographical dispersal of market entities.

APPROACHES TO PROCUREMENT OF GOODS FROM SUPPLIERS



In the practice of procurement, the rule is used to limit the volume of purchases from one supplier within 20-30% of the total volume of purchases.

If a pharmaceutical organization **uses the practice of sharing an order among several suppliers** , then several approaches can be used, including:

One **approach is to split the order evenly,**

another **approach is to place most of the order with the preferred supplier and the rest with one or more supply sources.**

PROCEDURE FOR FORMULATION AND CONCLUSION OF AGREEMENTS AND CONTRACTS WITH SUPPLIERS

PROCEDURE FOR FORMULATION AND CONCLUSION OF AGREEMENTS AND CONTRACTS WITH SUPPLIERS

An agreement is an agreement between two or more persons on the establishment, change or termination of civil rights and obligations .

The contract is a way of concluding bilateral and multilateral transactions.

Any individual or legal entity is free to conclude contracts; ***when concluding a contract for the supply of pharmaceutical products, it is necessary to pay attention to the availability of an appropriate license giving the right to carry out pharmaceutical activities.***

Lack of a license can become a limitation for concluding an agreement.

PROCEDURE FOR FORMULATION AND CONCLUSION OF AGREEMENTS AND CONTRACTS WITH SUPPLIERS

The agreement performs the following functions:

- concretization and clarification between the parties to the agreement of the conditions for joint activities;

- implementation of mutual control over the fulfillment of obligations.

In terms of content, a contract is a list of the rights and obligations of the parties defined in its terms. **The terms of the contract are divided into:**

essential - the conditions necessary for the recognition of the contract as concluded; in the absence of an agreement on at least one of the essential conditions or in the absence of an essential condition, the contract is not considered concluded;

***usual* e** - conditions that do not affect the fact of concluding a contract;

random - conditions that acquire legal force only after they are included in the contract; as a rule, they are not defined by law, but are determined by the parties when making a transaction

CLASSIFICATION OF CONTRACTS (1)

Oral and written. An agreement in writing can be concluded by drawing up one document signed by the parties, as well as by exchanging letters, telegrams, telefaxes and other documents, including electronic documents transmitted via communication channels, which make it possible to reliably establish that the document comes from a party under the agreement .

Compensatory. A contract under which a party is required to receive payment or other consideration for the performance of its obligations.

Free. A contract is recognized as gratuitous, under which one party undertakes to provide something to the other party without receiving payment from it or other counter provision .

Public. A contract is recognized as public, subject to conclusion by a commercial organization or an individual entrepreneur with everyone who applies for the goods alienated by them, works performed or services rendered. A commercial organization has no right to refuse to conclude such an agreement.

CLASSIFICATION OF CONTRACTS (2)

Preliminary. Under the preliminary agreement, the parties undertake to conclude in the future an agreement on the transfer of goods, performance of work or provision of services on the terms stipulated by the preliminary agreement. The preliminary contract indicates the period in which the parties undertake to conclude the main contract. If such a period is not specified in the preliminary agreement, the main agreement is subject to conclusion within a year from the date of conclusion of the preliminary agreement.

Framework agreement (contract with open conditions). An agreement that defines the general terms of the obligations of the parties, which can be ;ified and specified by the parties by concluding separate agreements.

Unilateral . To conclude a transaction executed by this type of contract, it is enough to express the will of one party .

Bilateral, multilateral . Their conclusion requires the expression of the agreed will of two parties or more.

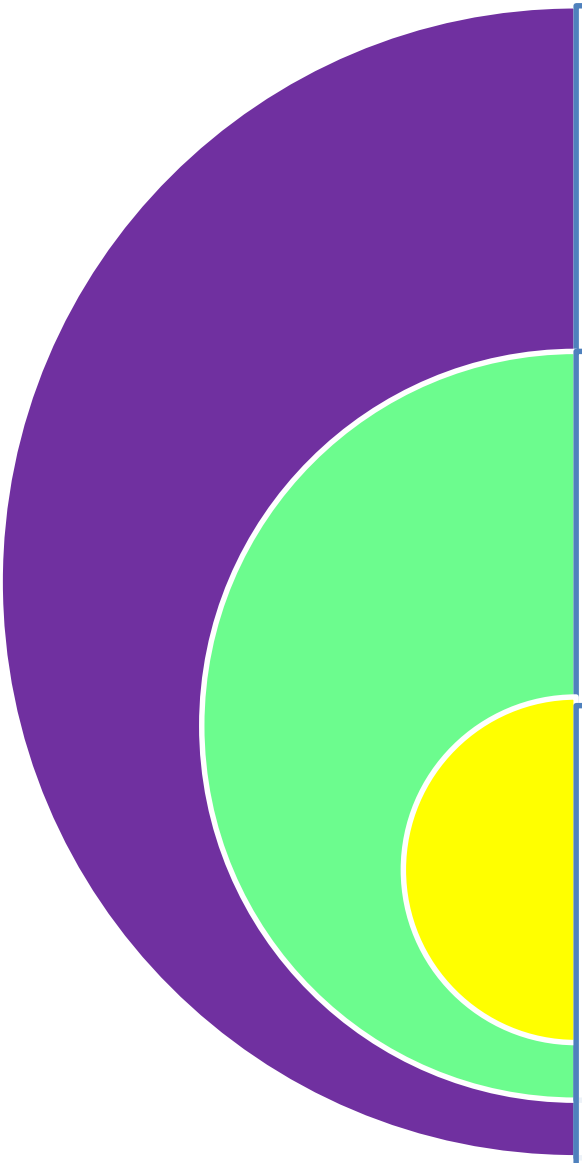
Unconditional and committed under any condition .

PROCEDURE FOR CONCLUDING CONTRACTS (1)

- **Also, the classification of contracts can be based on various initial criteria, for example, the object (subject) of the transaction, the validity period (execution) of the transactions being concluded, and so on.**
- **Contracts are concluded by *sending an offer (offer to conclude a contract) by one of the parties and its acceptance (acceptance of the offer) by the other party.* The contract is recognized as concluded at the moment the person who sent the offer receives its acceptance.**

- **The parties may conclude an agreement on the procedure for conducting negotiations. Such an agreement may specify the requirements for good faith negotiation, establish the procedure for distributing the costs of negotiating, and other similar rights and obligations.**

PROCEDURE FOR CONCLUDING CONTRACTS (2)



An offer **is an offer addressed to one or more specific persons, which is quite specific and expresses the intention of the person who made the offer to consider himself as having entered into an agreement with the addressee who will accept the offer** . The offer must contain the essential terms of the contract.

The offer may be withdrawn by the person who sent it earlier. If the notice of withdrawal of the offer was received earlier or simultaneously with the offer itself, the offer shall be deemed not received. The offer received by the addressee cannot be withdrawn within the period established for its acceptance, unless otherwise stipulated in the offer itself .

Advertising and other offers addressed to an indefinite circle of persons are considered as an invitation to make offers, unless otherwise expressly stated in the offer. An offer containing all the essential terms of the contract, from which the will of the person making the offer is seen to conclude an agreement on the conditions specified in the offer with anyone who responds, is recognized as an offer (public offer).

PROCEDURE FOR CONCLUDING CONTRACTS (3)

- ***An acceptance*** **is the response of the person to whom the offer is addressed about its acceptance** . The acceptance must be complete and unconditional. However, silence is not an acceptance.
- **Like an offer, an acceptance can be withdrawn** , and in this case, if the notice of withdrawal of the acceptance was received by the person who sent the offer before the acceptance or simultaneously with it, the acceptance is considered not received.
- **When the period for acceptance is specified in the offer, the contract is considered concluded if the acceptance is received by the person who sent the offer within the period specified in it.** In the event that the written offer does not specify a time limit for acceptance, the contract is considered concluded within the time normally required for this. **When an offer is made orally without specifying a deadline for acceptance, the contract is considered concluded if the other party immediately declared its acceptance.**
- **The answer about the consent to conclude a contract on other terms than those proposed in the offer is not an acceptance. Such a response is recognized as a refusal of acceptance and at the same time a new offer (counter-offer).**

PROCEDURE FOR CONCLUDING CONTRACTS (4)

The contract comes into force and becomes binding on the parties from the moment of its conclusion . The agreement may provide that the expiration of the term of the agreement entails the termination of the obligations of the parties under the agreement. An agreement in which there is no such condition is recognized as valid until the moment of completion of the fulfillment of obligations by the parties specified in it. At the same time, the expiration of the term of the contract does not relieve the parties from liability for its violation.

By agreement of the parties, changes and termination of the contract are possible. A multilateral agreement may provide for the possibility of amending or terminating such an agreement by agreement of both all and the majority of the persons participating in the said agreement. In this case, the agreement may provide for the procedure for determining such a majority.

PROCEDURE FOR CONCLUDING CONTRACTS (5)

The decision to change or terminate the contract at the request of one of the parties may be taken by the court only in case of a material breach of the contract by the other party . Violation of the contract by one of the parties is recognized as essential, which entails such damage for the other party that it is largely deprived of what it was entitled to count on when concluding the contract. In addition, the grounds for amendment or termination may be a significant change in the circumstances from which the parties proceeded when concluding the contract. A change in circumstances is recognized as significant when they have changed so much that, if the parties could reasonably foresee this, the contract would not have been concluded by them at all or would have been concluded on significantly different terms.

Also, one of the parties has the right to send a notice to the other party about the refusal of the contract (performance of the contract) . In this case, the contract is terminated from the moment of receipt of this notice. In case of unilateral refusal of the contract (performance of the contract) in whole or in part, if such a refusal is allowed, the contract is considered terminated or amended. For example, if one of the parties to the contract does not have a license to carry out pharmaceutical activities necessary to fulfill an obligation under the contract, the other party has the right to refuse the contract (execution of the contract) and demand compensation for losses.

An agreement to amend or terminate a contract is made in the same form as the contract.

STRUCTURE OF THE CONTRACT

The main elements that are found in any type of contract are:

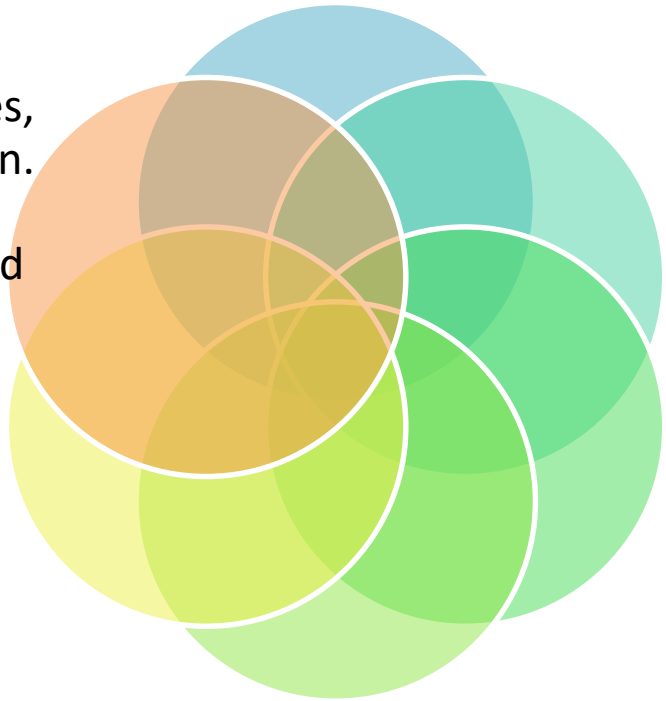
1. contract details - the element includes information about the number of the contract, the date and place of its conclusion;

2. preamble to the treaty - the element contains information about the names of the parties and authorized persons;

3. subject of the contract - an element that describes an action or a set of actions that determine the type and nature of the conditions of the transaction being concluded;

4. responsibility of the parties ;

5. details of the parties - the element includes information about the details of the parties, addresses, contact information. In this element, the fact of agreeing on the conditions and concluding an agreement is recorded by signing and fixing the signature with the seal of the party .



STRUCTURE OF THE CONTRACT

The structure of the contract is determined by the parties to the relationship established in it. As a rule, the structure of the contract depends on the subject of the transaction.

An example of the structure of a sales contract

Details of the contract	Number, date and place of detention
Preamble	In a bilateral agreement, the parties are named - for example, the Buyer, the Seller. Full name is indicated. persons authorized to conclude an agreement on behalf of the parties, indicating the document granting these powers
Subject of the contract	The Seller undertakes to transfer the goods to the Buyer in the quantity and assortment specified in the same section of the contract, or in the "Specification" to the contract, if the list of goods is large enough to be included in the text of the contract. The buyer undertakes to accept the goods and pay the price for it in the amount and in the manner prescribed by the contract
Rights and obligations of the parties	**The obligations of the Seller are indicated:** - to transfer to the Buyer the goods of proper quality and in proper packaging in the manner and within the time stipulated by the contract, as well as the relevant accessories and documents. Buyer Responsibilities: - accept the goods and pay for it in the manner and within the time limits stipulated by this agreement
Price and calculation procedure	**The following are determined:** 1) the price of the goods; 2) the price of the contract; 3) method of payment; 4) terms of settlements

An example of the structure of a sales contract (continued)

Details of the contract	Number, date and place of detention
Product quality	Defined: 1) a list of documents on the basis of which the quality of goods is confirmed; 2) the procedure for confirming the appropriate level of quality of the goods by the Buyer, including documents confirming the quality check carried out; 3) the rights of the Buyer in case of detection of defective goods
Transfer and acceptance of goods	Defined: 1) address of delivery of goods; 2) terms of delivery (by whose forces and means); delivery terms; 3) the procedure for acceptance of goods in terms of quantity and quality; 4) facts confirming the transfer and acceptance of goods
Responsibility of the parties	The amount of penalty for non-fulfillment of the terms of the contract is established, such as: - violation of the deadline for payment of the contract price for each day of delay; - violation of the deadline for the transfer of goods for each day of delay. For violation of other terms of this agreement, the parties are liable under the current legislation of the Russian Federation

An example of the structure of a sales contract (end)

Dispute Resolution	A pre-trial procedure for settling disputes is being established. If disputes are not resolved during the negotiation process, disputes are resolved in court in the manner established by the current legislation of the Russian Federation
Final provisions	Defined: 1) date of entry into force and duration of the contracts; 2) the procedure for making changes, additions and termination of the contract; 3) the number of copies of the agreement; 4) a list of annexes to the contract, which are its integral part, for example: *The act of acceptance and transfer of goods (Appendix No. _).* *The requirement (claim) for the replacement of a low-quality product, the properties of which do not allow to eliminate its shortcomings,* *good quality goods (Appendix No. _).* *Application (claim) for refusal of the goods and compensation for damages caused due to the seller's failure to transfer accessories and documents related to the goods within the prescribed period (Appendix No. ___)*
Details and signatures	Due to the fact that the sale and purchase agreement is paid, in addition to general information, the bank details of the parties are indicated.

Thank you for your attention