Seminar 15.

Acceptance of medical and pharmaceutical goods: general provisions

Questions:

1. Goods movement, definition of the concept. Merchandising channels.
2. Classification of commodity operations in the pharmacy network.
3. The structure of the contract for the supply of goods. Organization of supplies of pharmaceutical products.
4. Documents attached to the medicinal product during the supply of goods.
5. Organization of acceptance of goods in terms of quantity and quality.
6. Pre-trial procedure for settling disputes. Claims rules.

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

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

Marketing is the movement of a product from the producer to the consumer.

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

Channel of sale (distribution) - this is the path along which goods move from from the manufacturer 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 manufacturer to the final consumer.

The channel layer is the intermediary that does the work of approximating goods and ownership of it to the end consumer .

Distribution network - a system of interrelated organizations or individuals, moving goods from producer to consumer.

Product distribution in marketing is a set of activities, aimed at ensuring the delivery of goods necessary for the consumer to the points of sale at a certain time (including transportation, storage, transactions) with the highest possible level of service and municipal costs.

2. Classification of commodity operations in the pharmacy network.

Merchandising operations are a set of activities related to goods movement and provision of conditions for the acceptance, storage, release and write-off of goods.

They can be classified according to the following groups:

- Merchandising operations (control over the physical movement of products from places of production to places of sale).
- Operations for the acceptance of goods (delivery from the supplier, unloading of goods, checking the quantity and quality, completeness and compliance with the data noted in the accompanying documents, streamlining acceptance certificates, registers, processing claims).
- Operations related to the storage of goods (acceptance to storage departments, distribution of goods into groups according to storage conditions, placement of goods in storage places in accordance with the requirements of the NTD, control of expiration dates

and quality condition of the goods, etc., organization of measures that ensure the integrity of the goods) .

- Operations related to the release of goods (selection of goods by order of the sales department , packaging in shipping containers and sending to the pharmacy network, release of goods to the consumer).
- Operations related to the write-off of goods (drawing up acts and destruction of goods).

Classification of marketing methods:

1) Depending on the type of distribution channel (channel of distribution)
    a. Direct or direct method
    b. indirect method
    c. Combined, mixed sales.
2) Depending on the degree of sales intensity
    a. Intensive sales
    b. Selective marketing (selective)
    c. Exclusive (exclusive) sales.
3) By consumer orientation
    a. targeted sales
    b. Untargeted sales
4) By type of sales marketing systems.
    a. Traditional marketing or traditional marketing system
    b. Vertical marketing or vertical marketing system
    c. Horizontal marketing or horizontal marketing system

1. a . Direct, or immediate 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 enables the manufacturer pharmaceuticals to maintain full control over the conduct of trade operations and close contact with consumers, such organizations have limited target markets.

1. b . Indirect method - to organize the marketing of their goods, the manufacturer uses the services of independent intermediaries.

Advantages of the method: an intermediary link in marketing activities Pharmaceutical organization improves the efficiency of marketing operations, as 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 fewer business relationships.

1.c. _ _ Combined, mixed marketing - in this case, the manufacturer either goes to the buyer, or to the intermediary, and the capital of the producer and the intermediary participates in the intermediary link.

2.a. _ _ Intensive sales - selling through the maximum possible on a specific market , the number of sales organizations, regardless of the form of their activities. For example, the sale of medicines through all possible specialized points: pharmacies, pharmacy kiosks, drugstores, etc. The intensity of sales depends largely on the type of product. For example, kiosks provide intensive sales for medicines.

2.b. _ _ Selective marketing (selective) - it provides for limiting the number marketing 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.c. _ _ Exclusive (exclusive) sale - sale through the maximum

a 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.

3.a. _ _ Targeted marketing - sale of goods (including medicines) 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.b. _ _ 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.

4.a. _ _ Traditional marketing or traditional marketing system - with this method sales 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.

4b . _ Vertical marketing or vertical marketing system - acts as a single system, since it includes a manufacturer, wholesalers and retailers pursuing common goals and functioning under joint control, was the most common in the pharmacy system of the former USSR.

4.c. _ _ Horizontal marketing or horizontal marketing system - represents 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).

3. The structure of the contract for the supply of goods . About the organization of the supply of pharmaceutical products.

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

1. **Details of the contract** - the element includes information about the number of the contract, the date and place of its conclusion;
2. **Preamble of the agreement** - the element contains information about the names of the parties and authorized persons;
3. **Subject of the contract** - an element that describes the 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 securing the signature with the seal of the party.

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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) contract price; 3) method of payment; 4) terms of settlements
Product quality	**Defined:** a list of documents on the basis of which the quality of goods is confirmed; the procedure for confirming the appropriate level of quality of the goods by the Buyer, including documents confirming the quality check carried out; Buyer's rights in case 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
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 contract; 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 contract of sale is paid, in addition to general information, the bank details of the parties are indicated.

4. Documents attached to the medicinal product during the supply of goods.

An accompanying document is issued on the LS containing information:

- on the date of issuance of the accompanying document;
- on the name of the medicinal product (international non-proprietary name of the medicinal product and trade name of the medicinal product), expiration date and batch number;
- about the manufacturer of the medicinal product, indicating the name and location of the manufacturer;
- on the number of packages;
- about the supplier (taxpayer identification number, full name of the supplier, its location);
- about the buyer (taxpayer identification number, full name of the buyer, its location);
- about the official who compiled the accompanying document (position, full name).
- The document is certified by the signature of the official who prepared the accompanying document, the seal of the organization or information barcode and seal of the organization.

Waybill form TORG-12 (OKUD 0330212), used for the transfer inventory from the supplier to the buyer. Such waybills can be generated and stored both in paper and in electronic form.

Bill of lading. If the provider uses the services by a third-party transport organization for the delivery of goods to the buyer, then upon delivery of the goods, a consignment note must also be issued . To issue a bill of lading, a unified form 1-T (OKUD 0345009) is used.

Invoice . If the organization is a VAT payer, then it is necessary request from the supplier an invoice for the delivered goods. The invoice is used to maintain VAT tax records. The invoice has a strictly defined format, approved by Decree of the Government of the Russian Federation of December 26, 2011 No. 1137. The main requirements for filling out an invoice are specified in Article 169 of the Tax Code of the Russian Federation.

Price negotiation protocol . When supplying medicines, included in the Vital and Essential Drugs List, the wholesale trade organization is obliged to provide the buyer with a protocol for agreeing the price for such medicines. According to clause 6 of the Rules for establishing the maximum wholesale and maximum retail markups to the actual selling prices of manufacturers for medicines included in the list of Vital and Essential Drugs in the constituent entities of the Russian Federation (approved by Decree of the Government of the Russian Federation of October 29, 2010 N 865), the sale of medicines by wholesalers is carried out with the obligatory execution of a protocol for agreeing on prices for the supply of vital and essential drugs in the form approved by Decree of the Government of the Russian Federation of 08.08.2009 N 654 “On improving state regulation of prices for vital and essential medicines”.

Check. If payment to the supplier will be made on his calculated invoice, you must also request an invoice from the supplier. The invoice must contain basic information on the concluded transaction, as well as comprehensive details for which non-cash payment for the goods should be made.

Documents confirming the quality . When supplying pharmaceutical products assortment by virtue of paragraph 4 of the Regulations on the Certification System for Medicinal Products (approved by the Decree of the State Standard of the Russian Federation of 02.12.2002 N 121), the seller is obliged to bring to the attention of the buyer reliable information about the quality of the goods supplied. As a document confirming the quality, one of the following documents must be submitted :

- Certificate (declaration) of conformity or certificate of quality and safety (for dietary supplements);
- A copy of the certificate (declaration) of conformity or a certificate of quality and safety (for dietary supplements), certified by the holder of the original document, a notary or a certification body that issued the document;
- Shipping documents (attachment to the invoice) issued by the manufacturer or supplier, containing information on each name of the medicinal product, series of the drug, its quantity, number of the certificate (declaration) of conformity, their validity period, name of the authority that issued the document and its registration . room).

This document must be certified by the signature and seal of the manufacturer or supplier, seller, indicating his address and telephone number.

5. Organization of the receipt of goods in terms of quantity and quality.

Acceptance of goods - checking the conformity of quality, quantity and completeness goods to its characteristics and technical conditions. According to the evaluated categories, the acceptance of goods is distinguished by quantity and quality.

1. The order of acceptance of goods by quantity consists in recalculation (measurement,

weighing) t of goods received by the recipient organization, and assessing the conformity of the results obtained with the data specified in transport and accompanying documents of the sender (invoice, specifications, inventory, packing labels , wagon lists , etc.).

The absence of these documents or some of them does not suspend product acceptance . In this case, it is drawn up on the actual availability of products, and the act indicates which documents are missing .

of products received upon acceptance should be determined in the same units of measurement , which are indicated in the accompanying documents. of the public may be allocated to participate in the acceptance , to which a duly executed and certified seal of a one-time certificate signed by the head of the enterprise or his deputy .

Acceptance of goods by quantity is carried out in the following terms:

Products received without containers, in open and / or damaged containers - in the moment of its receipt from the supplier (or from the warehouse of the transport authority) or at the moment of opening the sealed and unsealed vehicles and containers, but not later than the deadlines set for their unloading.

Products received in good packaging, by gross weight and number of places -at the time of its receipt from the supplier or transport authority.

By net weight and number of trade units in each place: upon delivery of products by the supplier or removal by the recipient from the warehouse of the supplier - simultaneously with the opening of the container, but no later than 10 days from the date of receipt of the products ; in all other cases - from the moment of delivery of the goods by the transport authority.

In the regions of the Far North, remote regions and other regions of early delivery, acceptance of industrial consumer goods is carried out no later than 60 days from the moment they arrive at the recipient's warehouse.

Acceptance is considered to be made on time if the verification of the quantity of products is completed on time.

If a shortage is discovered upon acceptance, the recipient must do the following:

Suspend further acceptance, ensure the safety of products, and take measures to prevent its mixing with other homogeneous products.

Simultaneously with the suspension of acceptance, call for participation in the continuation acceptance of products and drawing up a bilateral act of the sender's representative. The sender's representative must have a certificate for the right to participate in the acceptance of products from the recipient.

The results of the acceptance of products by quantity are drawn up by an act on the same day when the shortage is revealed.

The act must be signed by all persons involved in the acceptance of products by quantity.

A person who does not agree with the content of the act is obliged to sign the act with a reservation about disagree and express your opinion

In the act, before the signature of the persons participating in the acceptance, it must be indicated that these persons are warned that they are responsible for signing the act containing data that does not correspond to reality.

The acceptance certificate is approved by the head or deputy head of the recipient enterprise no later than the next day after the act is drawn up.

2. During the acceptance of products for quality, they check the conformity of the products requirements of standards , technical conditions , main special conditions of delivery, other mandatory DL | parties to the rules, as well as accompanying documents (technical passport, certificate, quality certificate , invoice, specification , etc.).

Simultaneously with acceptance products are checked for quality completeness of products, compliance of containers, packaging, labeling with the

requirements of NTD and other mandatory rules and contracts . ***Acceptance of products in terms of quality and completeness is carried out at the recipient's warehouse in the following terms:***

- ✓ For out-of-town delivery - no later than 20 days after the issuance of the products by the transport authority or receipt at the recipient's warehouse upon delivery by the supplier or removal by the recipient.
- ✓ In case of single delivery - no later than 10 days after receipt of products at the consignee's warehouse.
- ✓ In the regions of the Far North, remote regions and other regions of early delivery, acceptance of industrial consumer goods is carried out no later than 60 days after they arrive at the recipient's warehouse.
- ✓ The quality and completeness of the products received in containers are checked upon opening the container, but no later than the above deadlines , unless other terms are provided for in the contract due to the specifics of the products (goods) supplied.
- ✓ Machinery, equipment, instruments and other products received in containers and having a warranty period of service or storage are checked for quality and completeness when the container is opened, but no later than the established warranty periods.

Acceptance of products in terms of quality and completeness at the supplier's warehouse produced in the cases stipulated in the contract.

Trade organizations have the right, regardless of the quality control of goods Activate manufacturing defects if they are discovered during the preparation of goods for retail sale or during retail sale within 4 months after receipt of the goods.

Hidden shortcomings are those shortcomings that could not be detected during the usual inspection for this type of product and are detected only during processing, preparation for installation, during installation, testing, use and storage of products.

Deadlines for drawing up an act on hidden shortcomings :

Within 5 days after the discovery of deficiencies, however, no later than 4 months from the date of receipt of the products at the warehouse of the recipient who discovered hidden deficiencies, unless other terms are established by the rules binding on the parties.

If hidden flaws are found in products with a warranty period of service or storage - within 5 days from the date of discovery of flaws, but within the established limits . warranty period

If the warranty period for goods is calculated from the moment of their retail sale, the act can also be drawn up during the period of storage before sale, regardless of the time of receipt of the goods.

Acceptance is considered to be made in a timely manner if the quality and completeness of the products are checked on time.

If a discrepancy is found in quality , to completeness , marking of received products , t ary or packaging to the requirements of the NTD, the recipient and the manufacturer (sender) are obliged to fulfill the following.

The recipient must:

Suspend further acceptance of products and draw up an act that indicates the number of inspected products and the nature of the defects identified during acceptance

Ensure the storage of products of inadequate quality or incomplete products in conditions that prevent deterioration of its quality and mixing with other homogeneous products.

Call for participation in the continuation and acceptance of products and drawing up a bilateral act of a representative of a non-resident manufacturer (or sender), if this is provided for in the mandatory rules or contract.

Actions of the manufacturer (sender):

The non-resident manufacturer (sender) is obliged, no later than the next day after receiving

the recipient's call, to inform by telegram or telephone message whether a representative will be sent to participate in the product quality check.

In case of a homogeneous delivery, the call of the manufacturer's representative (o consignor) and his presence to participate in checking the quality and completeness of the products and drawing up an act are mandatory (the representative of the manufacturer (sender) must have a certificate for the right to participate in determining the quality and completeness of the products received by the recipient)

The manufacturer (sender) may authorize an enterprise located at the place of receipt of the products to participate in the acceptance by the recipient of the products.

- In this case, the certificate to the representative is issued by the enterprise that singled him out .
- The certificate must contain a reference to the document to which the manufacturer (sender) authorized this enterprise to participate in the acceptance of products.

If the representative of the manufacturer (the sender) does not appear, I will call the recipient

(buyer) within the stipulated time quality check products are manufactured by a representative of the relevant industry inspections for the quality of products, and checking the quality of goods - an expert of the Bureau of Commodity Expertise or a representative of the relevant quality inspectorate .

In the absence of an appropriate quality inspection or commodity bureau examination at the location of the recipient , in case of their refusal to allocate a representative or his failure to appear on the call of the recipient, the check is carried out:

- With the participation of a competent representative of another enterprise, appointed by the head or deputy head of this enterprise
- Either with the participation of a competent member of the public of the recipient enterprise, appointed by the head of the enterprise from among persons approved by the decision of the factory, plant or local trade union committee of this enterprise
- Or unilaterally by the recipient enterprise, if the manufacturer (sender) has agreed to unilateral acceptance of products.

To participate in the acceptance of products should be allocated persons competent e (by type work, education , work experience) in matters of determining the quality of the completeness of the products to be accepted . In all cases when the NTD and other mandatory rules or the contract provides for the selection of samples (samples), persons participating in the acceptance of products for quality are obliged to select samples (samples) of this product .

According to the results of acceptance of products in terms of quality and completeness

an act is drawn up on the actual quality and completeness of the products received.

The act must be drawn up on the day of the end of the acceptance of products in terms of quality and completeness.

An act establishing inadequate quality or incompleteness of products, drawn up with the participation of representatives of enterprises, is approved by the head of the recipient enterprise or his deputy no later than three days after the act is drawn up.

The acts drawn up by the Bureau of Commodity Examinations or the Product Quality Inspectorate are approved in the manner prescribed by the relevant regulations on inspections and the Bureau of Commodity Examinations.

With regard to goods whose quality is inadequate discovered by the consumer after purchasing them in stores, the recipient, instead of the act of actual quality of the completeness of the received products, must provide the manufacturer (sender) with the following documents:

Application of the consumer for the exchange of goods and the conclusion of the retail trade organization indicating the name of the goods, its manufacturer (sender) and supplier, the

price of the goods, the nature of the defects and the reasons for their occurrence, the time of sale, exchange, repair of goods or the return of their cost.
Documents stipulated by the Rules for the exchange of industrial goods purchased in a retail trade network, confirming the inadequate quality of goods.
Receipt of the consumer for the exchange of goods or for the receipt of its value.
The manufacturer (sender, supplier) has the right to recheck the quality of products rejected and returned by the recipient.

6. Pre-trial procedure for settling disputes. Claims rules.

Claim (or other pre-trial) procedure for resolving a dispute is about
one of the forms of protection of civil rights, which consists in an attempt to resolve disputes on the fulfillment of obligations directly between the parties to the contract before the case is referred to the arbitration court.
The claim procedure for pre-trial settlement of a dispute is
binding on the parties and is considered as an additional guarantee of state protection of rights , allowing voluntarily, without additional costs and in a short time, to restore violated rights and legitimate interests.
According to Ch . 5 st. 4 of the Arbitration Procedure Code of the Russian Federation , civil legal disputes on the recovery of funds under claims arising from agreements may be referred to arbitration court only after the parties have taken measures for pre-trial settlement within 30 calendar days from the date the claim (claim) was sent .
The parties cannot exclude the claim procedure by means of an agreement (contract), however , they have the right to change the term and procedure for pre-trial settlement of the dispute (the 30-day period can be either reduced or extended by fixing the relevant condition in the contract).
Claim - main . document confirming the fact of the pre-trial
dispute resolution. It is drawn up in any form, but it must contain the necessary information:
copies of documents confirming the requirements, or extracts from them