Lesson No. 6.
Features of trade and production activities of a pharmaceutical organization

From the perspective of Civil and Tax legislation, pharmaceutical activities are considered as trading activities.

Trading activity is understood as a type of business activity associated with the purchase and sale of goods and the provision of services to buyers. In the process of trading activities, part-time work, sorting and packaging of goods can be carried out.

Some pharmacies, along with purchase and sale, provide services: for the manufacture of drugs according to individual prescriptions; production of concentrates and semi-finished products, production of purified water (Chapter 21, Article 149, paragraph 2, paragraph 24 of the Tax Code of the Russian Federation).

Since pharmacies sell medicines for the treatment of patients as goods, this gives a social character to the activities of pharmacies.

When carrying out trading activities, pharmaceutical organizations can carry out wholesale or retail trade in pharmaceutical products , the result of which is wholesale or retail turnover.

Trading activity (trade): A type of business activity associated with the acquisition and sale of goods.

Wholesale trade: A type of trading activity associated with the acquisition and sale of goods for use in business activities, including for resale, or for other purposes not related to personal, family, household and other similar use.

Retail trade: A type of trading activity associated with the acquisition and sale of goods for use for personal, family, household and other purposes not related to business activities.

"GOST R 51303-2023. National standard of the Russian Federation. Trade. Terms and definitions" (approved by Order of Rosstandart dated June 30, 2023 N 469-st)

Order of the Ministry of Health of Russia dated August 31, 2016 N 647n “On approval of the Rules of Good Pharmacy Practice for Medicinal Products for Medical Use”

Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 N 80 "On approval of the Rules of Good Distribution Practice within the Eurasian Economic Union"

Goods are part of inventories acquired or received from other legal entities or individuals and intended for sale.

Goods are part of the working capital that supports the economic activities of a pharmaceutical organization, purchased or received from a supplier and intended for sale.

Product distribution is the activity of moving goods from producer to consumer.

Accounting is based on the inventory balance formula:

balance at the beginning of the reporting period + income =
expense + balance at the end of the reporting period

The product distribution process is preceded by several stages:

1) preparatory (analysis of the pharmaceutical market, study of supply and demand, selection of suppliers);

2) contractual (coordination and signing of a supply agreement - form of payment, terms, prices);

3) building a system for accounting for goods in a pharmacy.

The accounting of goods of a pharmaceutical trade organization is based on several principles:

1. Organization of accounting for each financially responsible person. If this principle is violated, the administration cannot bring a valid claim against those responsible for product losses.

2. Selecting a goods accounting scheme that is most appropriate in the operating conditions of a given pharmaceutical enterprise. It is possible to use schemes such as:

• individual (item-by-item) - records the movement of each unit of goods (provided by a bar coding system and automation of the procedure for recording the movement of commodity units);

• natural value - records the movement of goods by individual items in natural and value meters (subject-quantitative accounting);

• batch - records the movement of a separate batch of goods (typical for pharmaceutical wholesale organizations);

• cost - fixes the total volume of commodity mass.

3. Unity of valuation of goods upon their receipt and disposal.

4. Reporting on the availability and movement of goods by financially responsible persons in a timely manner.

5. Periodic inspection by conducting an inventory.

The process of supplying a pharmaceutical organization with goods consists of the following operations:

- analysis and determination of demand for pharmaceutical products, selection of suppliers and registration of contractual relations;
- delivery of goods and its acceptance;
- payment for goods and transportation costs for its delivery.

Supplier selection criteria:

- compliance of the supplier with the requirements of the current legislation of the Russian Federation on licensing of certain types of activities;
- business reputation of the supplier in the pharmaceutical market;
- compliance of the quality of pharmaceutical products with the requirements of the legislation of the Russian Federation;
- compliance by the supplier with documentation requirements;
- compliance by the supplier with temperature conditions during transportation of thermolabile drugs, including immunobiological drugs;
- competitiveness of the contract terms offered by the supplier;
- economic feasibility of the terms of delivery of goods proposed by the supplier (multiplicity of packages supplied, minimum delivery amount, compliance of delivery time with the working hours of the retail trade entity);
- possibility of supplying a wide range.

Intercity delivery:

In the case of intercity delivery for a wholesale pharmaceutical organization, the cargo is accepted at railway, water stations or air terminals.

Acceptance is carried out according to the number of pieces and gross weight based on:

• **cargo receipt (railway bill)** - when cargo travels by rail or air;

• **bill of lading** - for delivery by water;

• **invoices** .

In the absence of accompanying documents, **a "Act on the actual availability of goods" is drawn up,** which indicates the absence of accompanying documents. If a shortage or damage to the cargo is detected, the commission draws up **a "Commercial Act".** The commission must include a representative of the transport organization.

The accepted goods are registered in the primary accounting documents:

• "Logbook of incoming cargo", "Part card", "Report on the movement of inventory items in storage areas";

• "Journal of registration of acceptance control results."

One-city delivery:

- The pharmacy management itself establishes the organization of acceptance, verification, registration, payment of incoming customers in accordance with the requirements of the legislation of the Russian Federation (**Order of the Ministry of Health of the Russian Federation dated August 31, 2016 No. 647n** , Order of the Ministry of Health of Russia dated October 26, 2015 No. 751n), in addition, the procedure for acceptance provided for in the contract with the supplier. Determines the persons responsible for acceptance of goods. Acceptance of pharmaceutical products is carried out by a financially responsible person.
- The procedure and place of acceptance of goods depend on the method of receipt.
- If goods are delivered by the supplier's transport, then acceptance of the quantity and quality of goods is carried out directly at the pharmacy. If pharmaceutical products are in transport containers without damage, then acceptance can be carried out by the number of places or by the number of product units and markings on the container. If the actual availability of pharmaceutical goods in containers is not checked, then it is necessary to make a note about this in the accompanying document.
- If a pharmacy representative himself comes to the supplier to pick up the goods, then full acceptance with quantity and quality checks is carried out at the supplier's warehouse.

Accompanying documents:

- The goods arrive with **a package of accompanying documents** , which the supplier issues to the pharmacy organization upon shipment of the goods:
- settlement documents– **invoices, payment requests** ;
- commodity documents– **waybills, waybills** ;
- **protocol for agreeing the price of vital drugs** ;
- tax documents– **invoices** ;
- **packaging insert** (included in the transport container).
- The quantity of goods received upon acceptance within the organization is recorded in the same units that were indicated in the accompanying documents.

RESOLUTION of November 26, 2019 N 1510 ON THE PROCEDURE FOR INTRODUCING MEDICINES FOR MEDICAL USE INTO CIVIL CIRCULATION

- If drugs were put into civil circulation before November 29, 2019, then they are accompanied by a register of quality documents (certificates of conformity and other documents confirming quality).
- If medicines, with the exception of immunobiological medicines, are put into civil circulation after November 29, 2019, they will not be accompanied by documents containing information about registered declarations of conformity and issued certificates of conformity.
- The supply of such drugs may be accompanied by the following documents:
- – manufacturer's passport (certificate) on compliance of the series (batch) of the medicinal product with the requirements of regulatory documentation;
- – confirmation of the authorized person of the manufacturer of medicines (for drugs produced at domestic production sites) or the responsible person of the organization importing the medicine into the Russian Federation and authorized by the foreign manufacturer

of medicines, the compliance of the imported medicine with the requirements established during its state registration.

- **The legality of the presence of a series (batch) of a medicinal product is verified through the official website of Roszdravnadzor www.roszdravnadzor.ru .**
- The supply **of immunobiological medicinal products** (vaccines, serums, immunoglobulins, toxins and toxoids) may be accompanied **by a copy of Roszdravnadzor's permission to enter into civil circulation** , certified by an electronic digital signature.
- from July 1, 2020, quality is confirmed by the state information system (GIS) monitoring "Honest Sign" using a unique two-dimensional bar code Data Matrix

Acceptance control

consists of checking incoming medicinal products by assessing:

a) appearance, color, smell;

b) integrity of the packaging;

c) compliance of the labeling of medicinal products with the requirements established by the legislation on the circulation of medicinal products;

d) correct execution of accompanying documents;

Acceptance of the goods is confirmed **by the financially responsible person** .

On one of the copies of the consignment note accompanying the cargo, the seal of the pharmaceutical organization is affixed, the number of accepted items, the amount of goods according to the consignment notes, the date of acceptance and the signature of the financially responsible person and the acceptance stamp are indicated. (Order of the Ministry of Health of the Russian Federation dated August 31, 2016 No. 647n).

Registration of received goods:

By location and storage, goods received for each document are recorded in chronological order:

- **"Logbook" on out - of-stock goods "**
- **"Journal of registration of acceptance control results** ."
- Besides:
- Medicines subject to subject-quantitative accounting in pharmacies in accordance with the list established by Order of the Ministry of Health of Russia dated April 22, 2014 N 183n (as amended on July 27, 2018) "On approval of the list of medicines for medical use subject to subject-quantitative accounting" are additionally registered :
- Narcotic drugs and psychotropic substances in a special **"Logbook of registration of operations related to the circulation of narcotic drugs and psychotropic substances, as a result of which the quantity and condition of narcotic drugs and psychotropic substances change** ."
- Precursors of narcotic drugs and psychotropic substances in a special **"Logbook of registration of transactions in which the amount of precursors of narcotic drugs and psychotropic substances changes."**
- All other drugs subject to PCU in the **" Logbook of transactions related to the circulation of medicines for medical use ."**
- **"Logbook of movement of immunobiological preparations"** ,
- Medicines with a limited shelf life (up to 2 years) are registered (by name) in the **"Registration Journal of Medicines with a Limited Shelf Life"**
- receipt part of **the "Commodity report"**
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Cases of non-compliance of goods with the terms of the contract:

- If the goods arrived without accompanying documents, the MOL draws up **an "ACT of acceptance of goods without a supplier's invoice"** . In the future, measures are taken to obtain the required accompanying documents.
- If a discrepancy with the supplier's documents is detected, acceptance is suspended and conditions are created for the safety of the accepted goods. The supplier is informed about the discrepancy by telephone and the issue of his representative's departure or the creation of a commission to accept the goods without the supplier's representative is decided. Based on the results of acceptance, **a "Report on the established discrepancies in quantity and quality when accepting inventory items" is drawn up.**

Pre-sale preparation:

- Before being supplied to the sales area, pharmaceutical products must undergo unpacking, sorting and inspection, checking the quality of the product (by external signs) and the availability of the necessary information about the product and its supplier.
- Medical, baby and dietary food products, dietary supplements must be freed from containers, wrapping and binding materials, and metal clips. Trade in medical, baby and dietary food products, biologically active additives is prohibited if the integrity of the packaging is violated. In case of violation of the integrity of the packaging or lack of a complete package of documents, medical, baby and dietary food products, dietary supplements must be returned to the supplier.
- Disinfectants, before being supplied to the sales area or placed at the point of sale, must undergo pre-sale preparation, which includes release from transport containers, sorting, checking the integrity of the packaging (including the functioning of aerosol packaging) and the quality of the product by external signs, the availability of the necessary information about disinfectants products and its manufacturer, instructions for use.

Incoming commodity transactions:

- Receipt of goods from the supplier is the main, but not the only incoming commodity transaction. So, in a retail pharmaceutical organization this type of business operations also includes:
- moving goods from department to department; in this case, an "Internal Movement Invoice" must be issued;
- additional valuation for laboratory and packaging work, as well as charging a tariff for the production of extemporaneous dosage forms and in-pharmacy preparations, purified water (documented on the basis of the "Certificate of additional valuation and markdown for laboratory and packaging work, sales of services");
- revaluation of goods towards an increase in value (based on the "Revaluation Act").

Container accounting:

Containers are a type of inventory intended for packaging, transportation and storage of products, goods and other material assets.

- ***Disposable*** **containers** (paper, cardboard, polyethylene, etc.), as well as paper and polymer bags used for packaging products (goods), as a rule, are included in the cost of packaged products and are not paid separately by the buyer.
- Contracts for the supply of products (goods) may provide for the use of **reusable packaging** , which is subject to mandatory return to suppliers of products (goods) or delivery to container repair organizations (returnable packaging).

- *Reusable containers* under goods and empty are taken into account in subaccount 41-3 “Containers under goods and empty”.
- ***Inventory containers*** *intended* for storing significant volumes of goods are accounted for in subaccount 9 of account 10 “Materials” based on registration in materials accounting cards.

Accounting for the receipt of goods in pharmacy organizations.

1. FINISHED PRODUCTS OF OTHER ORGANIZATIONS PURCHASED BY A PHARMACY FOR RETAIL:
a) goods;
b) raw materials;
c) materials;
d) purchased semi-finished products.

2. PHARMACY ORGANIZATIONS CAN PURCHASE MEDICINES FROM
a) medical equipment stores;
b) drug wholesalers and drug manufacturers
c) pharmacy organizations;
d) laboratories.

3. BUSINESS RELATIONS BETWEEN THE SUPPLIER AND THE BUYER (PHARMACY ORGANIZATION) ARE FORMULATED
a) a letter of credit;
b) an obligation;
c) an agreement;
d) an agreement.

4. FINAL ACCEPTANCE OF GOODS "BY THE NUMBER OF ITEMS AND NET WEIGHT" AND QUALITY IN THE PHARMACY ORGANIZATION CANNOT BE CARRIED OUT
a) financially responsible persons;
b) leader;
c) an accountant;
d) a financially responsible person and a representative of the public of the pharmacy organization.

5. IN THE EVENT OF THE ACTUAL AVAILABILITY OF GOODS OR DEVIATION IN QUALITY WITH THE DATA SPECIFIED IN THE ACCOMPANYING DOCUMENTS, IN THE PHARMACY ORGANIZATION SHOULD BE DONE
a) an act on the established discrepancy in quantity and quality upon acceptance of inventory items;
b) acceptance certificate;
c) reclamation act;
d) an act of acceptance of goods received without a supplier's invoice.

6. IF THE SUPPLIER'S DOCUMENTS ARE NOT AVAILABLE AT THE TIME OF GOODS RECEIPT, THE RECEPTION COMMISSION IS AVAILABLE
a) an act on the established discrepancy in quantity and quality upon acceptance of inventory items;
b) acceptance certificate;
c) reclamation act;
d) an act of acceptance of goods received without a supplier's invoice.

7. THE FINAL ACCEPTANCE OF THE GOODS, EXCEPT FOR THE ISSUANCE OF THE ACCEPTANCE STAMP, CANNOT BE CONFIRMED:
a) the signature of the accountant;
b) the signature of materially responsible persons in the consignment note;
c) the signature of the head of the organization on the consignment note;
d) the seal of the pharmacy organization in the consignment note.

8. THE FORMULA OF THE BALANCE OF COMMODITIES HAS THE FORM
a) Balance at the beginning of the month + Consumption of goods = Arrival of goods + Balance at the end of the month ;
b) Balance at the beginning of the month - Arrival of goods = Consumption of goods + Balance at the end of the month ;

c) Balance at the beginning of the month + Arrival of goods = Consumption of goods + Balance at the end of the month ;
d) Arrival of goods + Consumption of goods = Balance at the end of the month - Balance at the beginning of the month .

9. PRIMARY RECORDING FOR REDUCTION AND ADDITIONAL PRICE OF GOODS FOR LABORATORY AND PACKAGING WORKS IS CARRIED OUT IN
a) recipe register;
b) a register of laboratory and packaging work;
c) a journal of subject-quantitative accounting;
d) cash book.

10. TURNOVER BY OUTPATIENT PRECIPION, OTC DISSOLUTION AND SMALL RETAIL NETWORK ARE INCLUDED IN THE STRUCTURE
a) other documented expense;
b) supplies;
c) wholesale trade;
d) retail trade .

11. FOR LABORATORY AND PACKAGING WORKS
a) an allowance;
b) markdown;
c) revaluation ;
d) retail price.

12. ACCOUNT OF IMMUNOGLOBULIN AGAINST TIC-BASED ENCEPHALITIS 1 ML No. 10 IN AMPOULES
a) a register of medicines with a limited expiration date;
b) a register of transactions related to the circulation of NS and HP , as a result of which the quantity and condition of narcotic drugs and psychotropic substances change ;
c) register of transactions related to the circulation of drugs for medical use;
d) a journal of receipt and consumption of immunobiological preparations.

13. THE PROCEDURE FOR REGISTRATION OF MEDICINES WITH A LIMITED EXPIRY LIFE IN A PHARMACY ORGANIZATION IS ESTABLISHED
a) the head of the organization;
b) the licensing authority;
c) an executive authority of a constituent entity of the Russian Federation;
d) Decree of the Government of the Russian Federation.

14. TRADING IN GOODS AND PROVIDING SERVICES TO BUYERS FOR PERSONAL, FAMILY, HOME USE NOT RELATED TO BUSINESS ACTIVITIES IS
a) pharmaceutical assistance;
b) wholesale trade;
c) pharmaceutical marketing;
d) retail.

15. DEVIATIONS IN QUANTITY AND QUALITY WHEN ACCEPTING GOODS AT THE PHARMACY ARE REFLECTED IN
a) an act of acceptance of goods received without a supplier's invoice;
b) acceptance act;
c) a card for recording claims and shortages;
d) an act on the established discrepancy in quantity and quality upon acceptance of the goods.

16. IN A PHARMACY ORGANIZATION, OPERATIONAL RECORDING OF PRICE DISCOUNTS AND ADDITIONAL EVALUATION FOR LABORATORY AND PACKAGING WORKS DURING A MONTH IS CARRIED OUT IN

a) register of issued invoices;
b) recipe log book;
c) turnover sheet;
d) a register of laboratory and packaging work.

17. TURNOVER BY OUTPATIENT PRECIPION, OTC DISSOLUTION AND SMALL RETAIL NETWORK ARE INCLUDED IN THE STRUCTURE
a) supplies;
b) retail sale;
c) wholesale;
d) product coverage.

18. SUPPLIER SELECTION CRITERIA DOES NOT APPLY
a) organization of supplies and service;
b) the supplier's storage system;
c) business ethics (courtesy, friendly attitude);
d) the range and price of the products offered.

19. ACCORDING TO THE CIVIL CODE OF THE RUSSIAN FEDERATION, THE AGREEMENT
a) retail sale;
b) commissions;
c) deliveries;
d) supply of goods for state needs.

20. THE AGREEMENT OF SALE DOES NOT SPEECH
a) licensing conditions for carrying out activities;
b) price and payment procedure;
c) the quality of goods, as well as claims for quantity and quality;
d) the procedure and terms of delivery and acceptance.

21. SUPPLY CONTRACT IS SIGNED
a) a financially responsible person;
b) chief accountant;
c) deputy head;
d) the head of the organization, or a person who has a power of attorney for the right to conclude an agreement.

22. NAME AND QUANTITY OF GOODS IS A SECTION OF THE CONTRACT
a) order of delivery;
b) the subject of the contract;
c) the order of acceptance;
d) determination of the parties.

23. THE QUALITY OF THE GOODS SUPPLIED AS WELL AS THE RESIDUAL EXPIRATION DATES OF THE GOODS ARE DISCLAIMED IN THE CONTRACT SECTION
a) order of delivery;
b) the order of acceptance;
c) the quality and completeness of the goods;
d) the subject matter of the contract.

24. A LETTER OF CLAIM TO THE SUPPLIER OF GOODS WHEN DIFFERENT FAULTS ARE DISCOVERED IN THE PROCESS OF ACCEPTANCE OF GOODS IN A PHARMACY, YOU CAN SEND TO
a) the terms determined by the terms of the contract;
b) within 20 days for imported or 10 days for domestic;
c) within 15 days for imported or 7 days for domestic;
d) within 6 days for imported and 12 days for domestic.

25. PROBLEMS OF SUPPLY ORGANIZATION AT THE ORDER FORMATION STAGE DO NOT APPLY
a) purchase of unreasonably expensive goods;
b) buying too many items;
c) poor storage conditions;
d) purchase of quantities of goods that do not meet the standard of commodity stocks.

26. THE PROCEDURE FOR PURCHASING AND FORMING A REQUEST FOR MEDICINES IN MEDICAL ORGANIZATIONS IS REGULATED
a) the Civil Code of the Russian Federation;
b) Federal Law of 04/05/13. No. 44-FZ "On the contract system in the field of procurement of goods, works, services to meet state and municipal needs";
c) by order of the chief physician of a medical organization;
d) Federal Law of 01/08/98. No. 3-FZ "On Narcotic Drugs and Psychotropic Substances".

27. THE MAIN CRITERIA FOR THE PERFORMANCE OF PURCHASING, ACCORDING TO Federal Law No. 44-FZ ON THE CONTRACT SYSTEM IN THE SPHERE OF PROCUREMENT OF GOODS, WORKS, SERVICES TO SUPPORT STATE AND MUNICIPAL NEEDS IS
a) the amount of the order for medicines;
b) business reputation of the supplier;
c) the price of the medicinal product;
d) the distance of transportation from the supplier to the pharmacy of the medical organization.

28. A SYSTEM OF RELATED ORGANIZATIONS OR INDIVIDUALS CARRYING OUT THE MOVEMENT OF GOODS FROM MANUFACTURER TO CONSUMER IS DEFINIED AS
a) marketing network;
b) a wholesale trade enterprise;
c) medical organization;
d) a retail business.

29. A PHARMACEUTICAL SUPPLIER'S WRITTEN OFFER TO PROSPECTIVE BUYERS OF ITS PRODUCTS IS
a) an agreement;
b) tender;
c) a contract;
d) offer.

30. TRANSFER OF GOODS FROM A PHARMACY TO A SMALL RETAIL NETWORK IS CARRIED OUT BY
a) prescriptions;
b) write-off act;
c) waybill for the internal movement of materials;
d) requirement .