

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

Classification and coding of medical and pharmaceutical products. Characteristics of groups of medical and pharmaceutical products. Trade information tools. General requirements, characteristics. Bar coding of medical goods.

#### **Lecture № 2**

Discipline: medical and pharmaceutical commodity science
3 course, 5 semester
Volgograd -2022

# Lecture plan

- 1. Classification and coding of medical and pharmaceutical products. Basic definitions. The purpose of the classification.
- 2. The concept and methods of classification of goods. System and rules of classification.
- 3. Hierarchical and faceted methods.
- 4. Types of classification in commodity science. Classifiers of products and goods.
- 5. Trade classification of goods. Commodity classification of medical and pharmaceutical goods.
- 6. Features of the classification of medical devices. Classification coding methods.
- 7. Characteristics of groups of medical and pharmaceutical products.
- 8. Trade information tools. General requirements, characteristics. Bar coding of medical goods.

Classification and coding of medical and pharmaceutical products. Basic definitions. Purpose of classification, signs.

## **BASIC DEFINITIONS, CONCEPTS**

Classification (from lat. classis - category and lat. facere - do) in general terms is the distribution of a set of objects, for example, pharmaceutical products, into classes, groups and other structures according to a certain characteristic common to each of them. At the same time, all structures of the distributed set constitute a single system in which all parts are interconnected in a certain way, and each part of this system is a collection of similar objects that have at least one common feature.

## **BASIC DEFINITIONS, CONCEPTS**

The object of classification is an element of the classified set. In merchandising, this element is the commodity.

From the set of all goods on the basis of destination, consumer goods are distinguished for individual consumers, and for product manufacturers and / or service providers - industrial goods and goods for management activities (office equipment).

A sign of classification is a property or characteristic of an object by which classification is made .

# Classification is necessary for:

study of consumer qualities and properties of goods; planning and accounting of trade turnover: compiling catalogs, price lists; improvement of the standardization system; product certification and licensing placement of goods for storage; conducting marketing research.

#### PURPOSE OF CLASSIFICATION IN PHARMACEUTICAL COMMODITY

The purpose of the classification is to facilitate the implementation of various commodity research operations, including the study of consumer properties, quality and range of goods, which makes it possible to manage the above operations.

The purpose of classification is to systematize, as well as identify and predict the properties of goods.

#### The classification allows:

- \*explore the consumer properties of homogeneous groups of goods,
- ❖ set the optimum level of these properties,
- to develop group methods for research and evaluation of the level of quality of goods.

❖ Classification makes it possible to evaluate the range of specific product groups and its compliance with needs, to develop directions for the development of the range.

- ❖The grouping of goods according to the commonality of properties is the basis for the development of conditions for storage, transportation, methods of packaging goods.
- \*When providing medical and pharmaceutical care to the population, the classification serves the purpose of rationalizing and accelerating trade and operational processes.

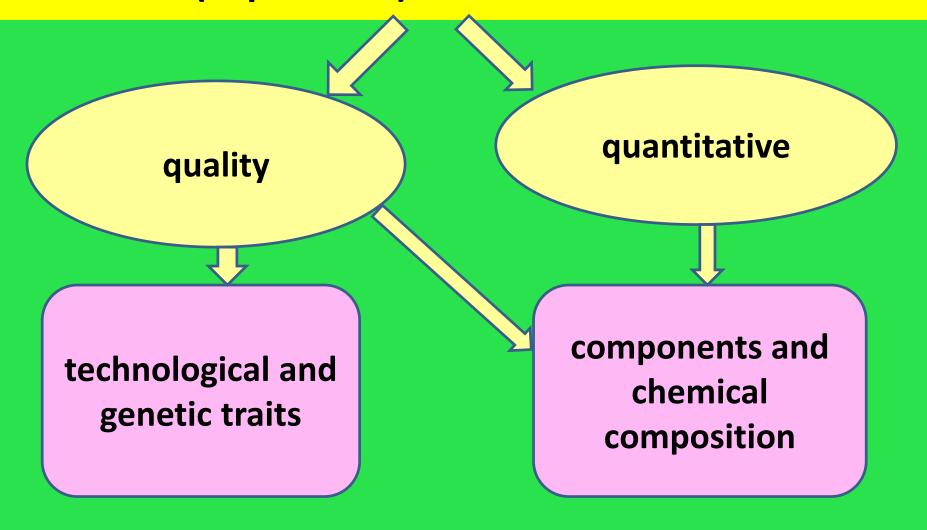
It is used in planning turnover for groups of services or goods, compiling price lists, applications, orders, studying demand, determining the type of warehouses, bases and trade establishments.

## Types of classification features

## Classification signs are divided into:

- teleological (appointment and application),
- \* genetic (source materials, raw materials, main components of the chemical composition),
- \* technological (design, recipe, production processes, methods of finishing or design)

## Value (expression) of a classification feature



### The classification will be applied for the purpose of systematization

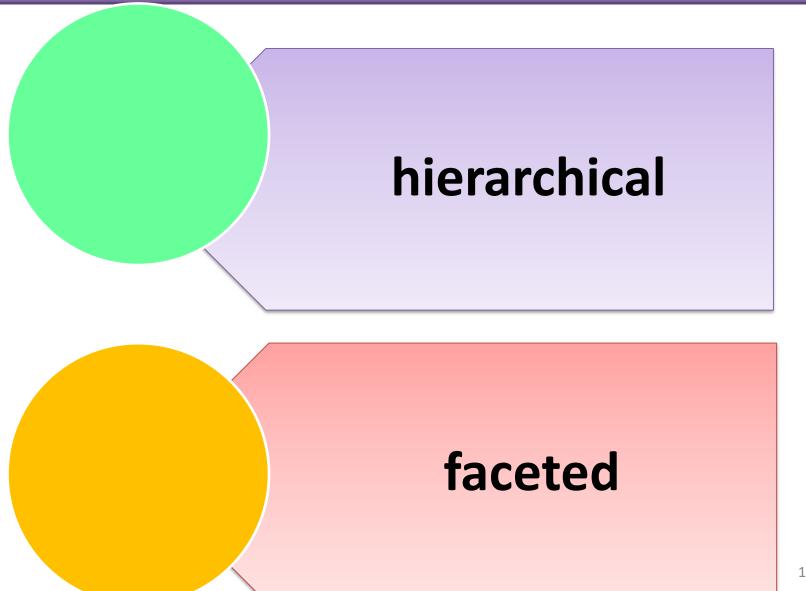
Systematization is achieved by establishing the sequence and relationships of certain classification groups obtained by a specific classification method.

Identification as the establishment of the identity of the most significant features is possible only when these features are identified, characteristic of groupings or objects of classification.

As a result of dividing the set into subsets, classification groupings are created that may have common and different features, and may also be interdependent or independent.

System and rules of classification. Hierarchical and faceted methods.

## Varieties of the classification method:



# CLASSIFICATION SYSTEM. GENERAL RULE FOR HIERARCHICAL AND FACETED METHODS

**Classification system** - a set of methods, rules and classification results.

Classification rules are designed to select varieties of the method and features, according to which the division of the set into subsets is carried out.

General rule for hierarchical and faceted methods is the choice of a type of classification method depending on its intended purpose.

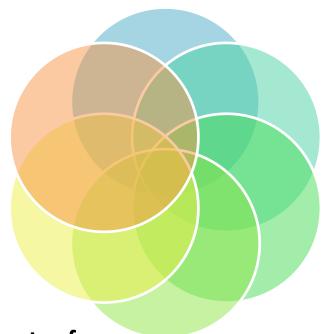
Hierarchical and faceted classification methods are widely used in commodity science when dividing many goods into system categories: genera, classes, groups, etc.

Classification methods and rules can be applied both independently of each other and jointly.

# SPECIFIC RULES FOR CLASSIFICATION UNDER THE HIERARCHICAL METHOD

1) the priority of the most common features when dividing the set into subsets;

5) the need to establish the optimal number of signs and steps, as well as depth.



2) the use at each stage of only one feature that is of fundamental importance for this stage;

4) selection from a set of features of the same degree of generality of the most significant;

3) division of objects sequentially - from larger to smaller, from general to particular;

# **Specific Rules of the Faceted Method**

1) approximately the same significance and independence of the used classification features;

3) the possibility of supplementing the number of features.

2) lack of commonality of classification features;

# Hierarchical classification method (1)

The hierarchical method of classification is the sequential division of a set of objects into subordinate classification groups.

A feature of the hierarchical classification method is the close connection between individual classification groups, revealed through the commonality and differences in fundamental features.

The basis for dividing the set into subsets according to the feature fundamental for this stage is the stage of classification.

Classification stage - the stage of classification in the hierarchical method, which results in a set of classification groups.

# Hierarchical classification method (2)

Each stage and grouping is distinguished by its fundamental feature.

The differences between the groupings are in different signs.

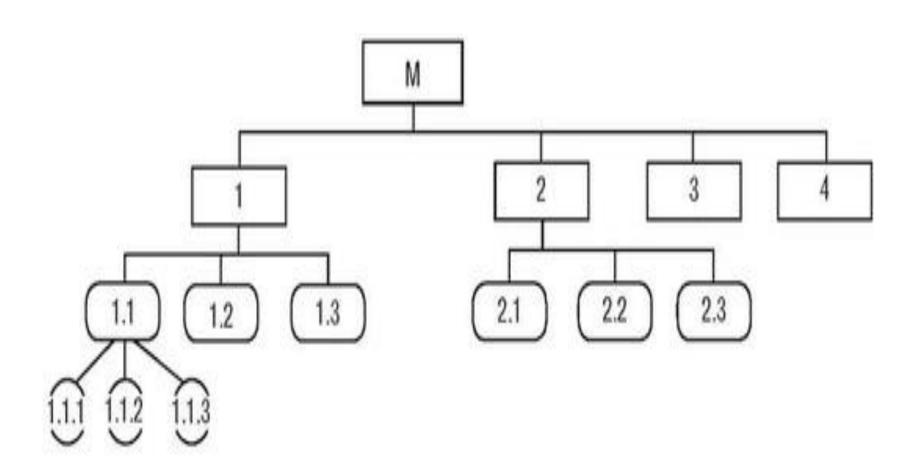
That is why the choice of fundamental features is a responsible operation of dividing the set, on which the final result largely depends.

This choice should be based on the intended purpose of the classification.

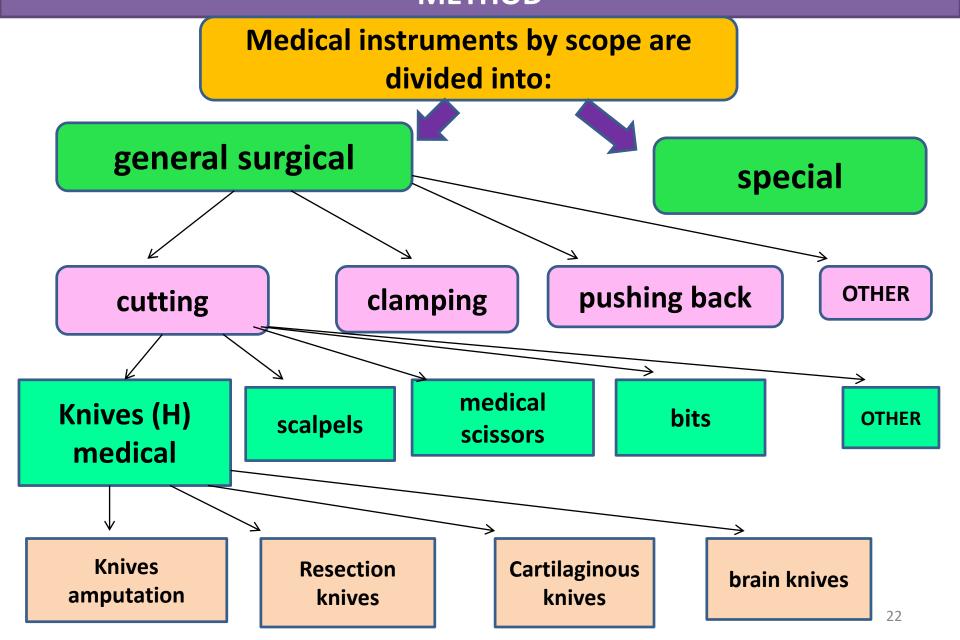
The number of signs and steps determines the depth of classification.

## Hierarchical classification method (3)

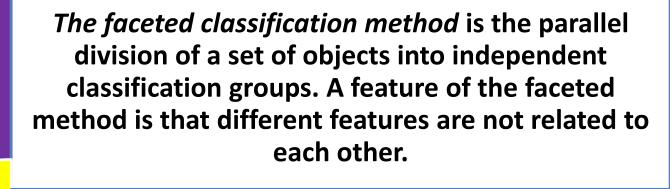
(In the diagram below, the depth of classification by the hierarchical method is 4)



# EXAMPLE OF APPLICATION OF THE HIERARCHICAL CLASSIFICATION METHOD



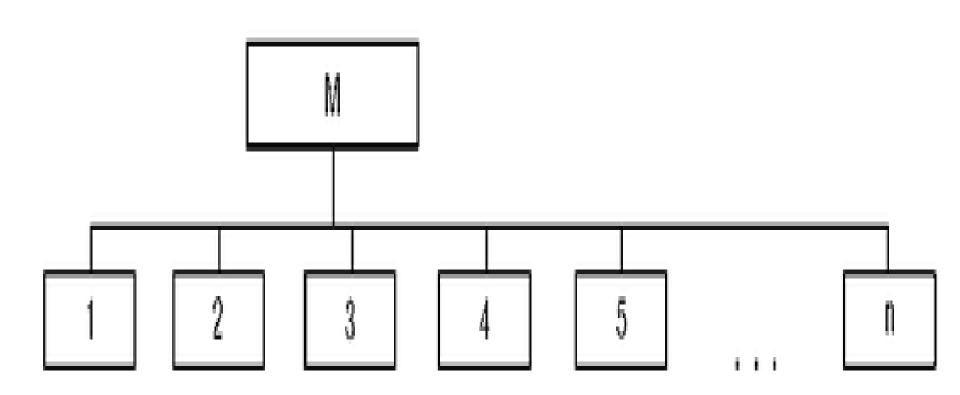
## **Faceted classification method**



The name of the method comes from the French word facette - the edge of a polished stone.

Just as each facet of a stone exists independently of the other faces, so the different classification groups in the facet method are independent and do not obey each other.

# Faceted classification method (2)



# Advantages and disadvantages of hierarchical and faceted classification methods

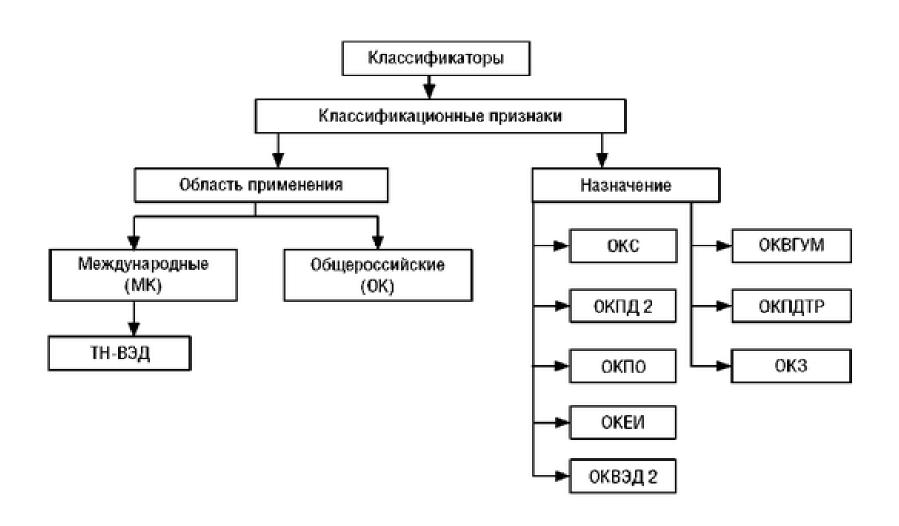
**Flaws** 

**Advantages** 

**Method** 

Hierarchical	of features of objects at the same and different levels. High information saturation	With great depth: excessive bulkiness, high costs, sometimes unreasonable, difficult to use.  At a shallow depth: information insufficiency, incomplete coverage of objects and features
Faceted	system, ease of use, the ability to limit the number of features without losing the sufficiency of	The impossibility of highlighting the commonality and differences between objects in different classification groups

### **CLASSIFIERS USED IN COMMODITY ACTIVITIES**



# BUSINESS

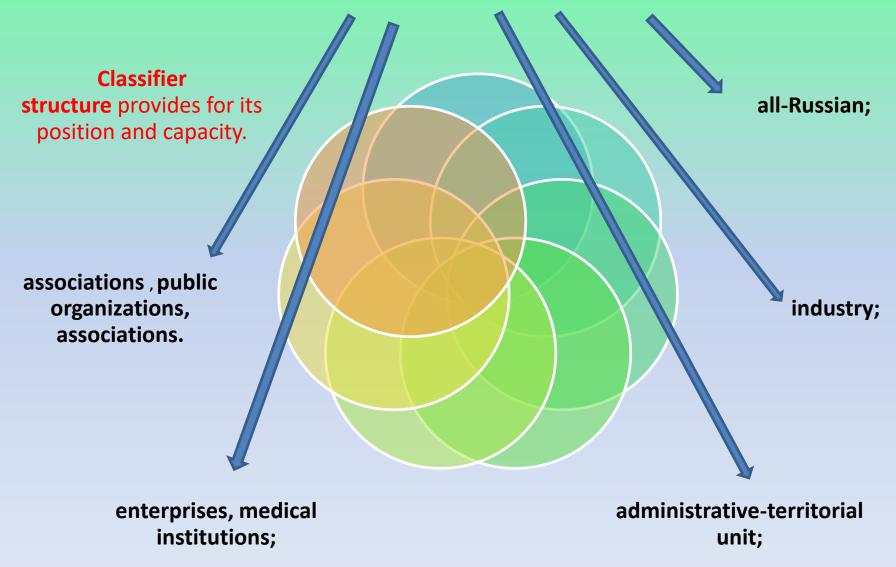
(THE MOST APPLICABLE)

**Statewide** 

**Trading** 

Educatio nal

Depending on the level of approval and scope, classifiers of the following categories are developed and implemented:



# National classification of goods

## Carried out in accordance with:

"Regulations on the development, adoption, implementation, maintenance and application of all-Russian classifiers of technical, economic and social information in the socio-economic area", approved by Decree of the Government of the Russian Federation of November 10, 2003 No. 677 "On all-Russian classifiers of technical, economic and social information in socio-economic area".

# National classification of goods

The development of all-Russian classifiers is provided by the federal executive authorities.

#### **Carried out in agreement with:**

- Federal Agency for Technical Regulation and Metrology,

- Ministry of Industry and Trade of Russia,

- Goskomstat of Russia .

## New edition of classifiers

The new edition of the classifiers (developed by the Ministry of Economic Development of Russia and put into effect by order of the Federal Agency for Technical Regulation and Metrology dated January 31, 2014 No. 14-st.), Which adopted:

- All-Russian classifier of types of economic activity (OKVED 2);

- All-Russian classifier of products by type of economic activity (OKPD 2)

## New edition of classifiers

By order of the Federal Agency for Technical Regulation and Metrology dated January 31, 2014 No. 14-st, they were canceled from January 1, 2015. action of a number of classifiers, including:

- All-Russian classifier of economic activities, products and services (OKDP) OK 004-93,
- All-Russian classifier of products by type of economic activity (OKPD) OK 034-2007,
- All-Russian classifier of services to the population (OKUN),

All-Russian classifier of products (OKP).

# Trade classification of goods (1)

According to the purpose, all goods are divided into genera:

### office supplies

(office goods) -

designed to improve the organization of administrative and managerial activities.

### consumer goods

intended for individual consumers for personal use;

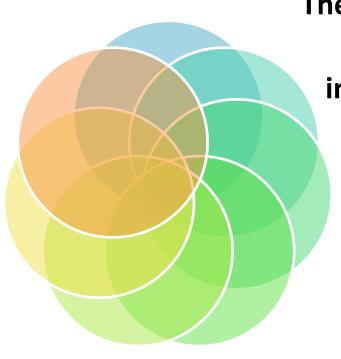
### industrial goods -

goods intended for the production of other goods and creating its raw material and technological support;

## Trade classification of goods (2)

Each kind of goods is subdivided into subgenuses and classes.

Goods class is a set of goods that satisfy generalized groups of needs.



The type of consumer goods is divided

into three classes:

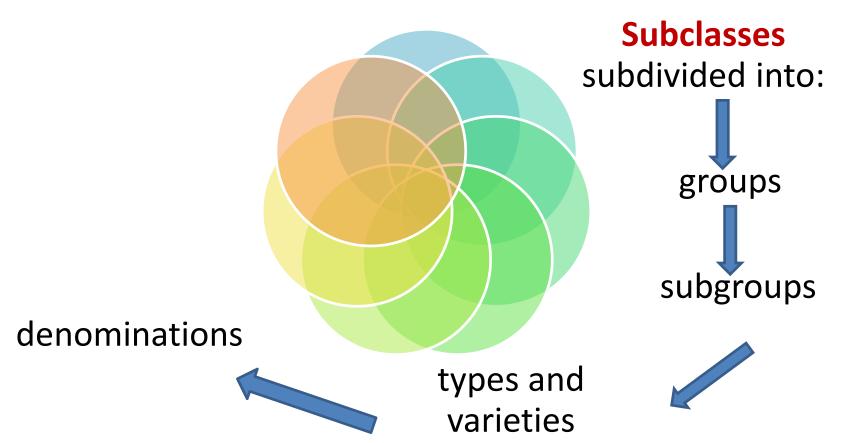
1. Food

2. Non-food

3. medical products

## Trade classification of goods (3)

classes are subdivided into subclasses depending on the raw materials used, purpose and other features.

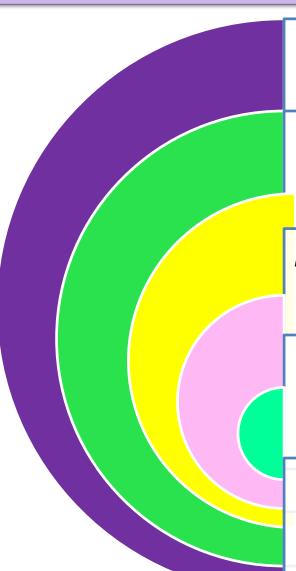


## Trade classification of goods (4)



Classes, subclasses and groups constitute the general commodity classification of consumer goods

# Trade classification of goods (5)



**Goods subclass** - this is a set of goods that satisfy similar groups of needs that have certain differences.

**Group of homogeneous goods** - these are subsets of goods that satisfy specific groups of needs, which is due to the characteristics of the materials used, their finish, etc.

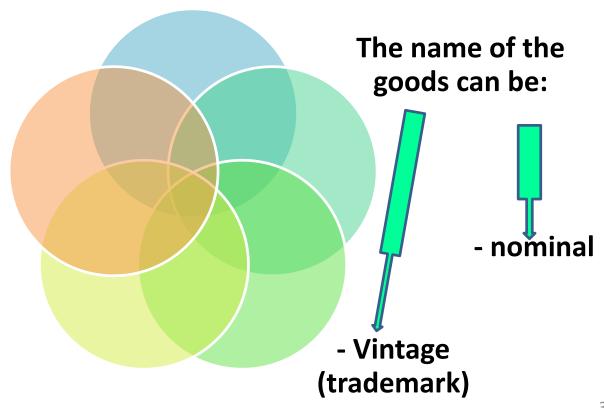
**Product subgroup** - this is a set of goods that have a common main purpose with the group, but differ from the goods of other subgroups only in their inherent characteristics.

**Type of goods** - this is a set of goods that differ in individual purpose and identification features .

**Variety of goods** - a set of goods of the same type, differing in a number of particular characteristics.

# Trade classification of goods (6)

**Description of goods** - this is a set of goods of a certain type, differing from goods of the same type by their own name and individual characteristics, which are due to the selection of raw materials, materials, as well as design, technology.



# Trade classification of goods (7)

**Nominal name** - nominal generalized name of the goods produced by different manufacturers.

For example, " <u>Acetylsalicylic acid</u> tab. 0.5 g, pack . contour . cell . 10", " <u>Multivitamins</u> in dragee", etc.

**Brand name or trade mark** - an individual name of a product produced by a certain manufacturer (often a patent is issued for this name, which provides copyright protection for the brand name).

For example, "Trombo ASS \* ", "Pikovit \* ".

#### Classification of goods used in international trade

In the international trade system, the classification approach is becoming more widespread, the basis of which is formed by the following classes of goods:

single product: characterizes goods for both personal demand and industrial purposes;

commodity-object: the need to develop a systematic approach to the production and sale of products requires the concentration of huge material and labor resources under a single financial, technological and administrative control;

product-program: predominantly an intellectual product created in the field of aerospace business, automated control systems, robotics, intellectual and bioengineering technologies.

# Similarities and differences between pharmaceuticals and other consumer goods:

#### Similarity:

Participate in free sale and purchase according to the scheme:

Consumer (sick)

#### **Pharmacy**

- The consumer himself purchases the goods, guided by his own experience, advertising, advice from relatives.
- For example: some medicines, perfumes and cosmetics; mineral waters, hygiene and sanitation items, etc.

#### Difference:

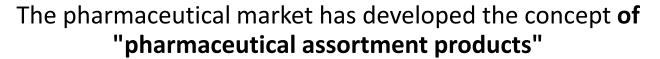
- Sold only by prescription;
- Consumption (operation) is carried out only according to the instructions of medical workers.
- For example: most of the drugs, medical equipment, medical products, etc.

**Doctor Pharmacy** 

Consumer (sick)







summarizing the groups of goods sold through retail and wholesale pharmacy organizations. First of all, these are medicines, medicines, including homeopathic and medical products.

Medicinal products - substances or their combinations that come into contact with the human or animal body, penetrate the organs, tissues of the human or animal body, used for prevention, diagnosis (with the exception of substances or their combinations that are not in contact with the human or animal body), treatment diseases, rehabilitation, for the preservation, prevention or termination of pregnancy and obtained from blood, blood plasma, organs, tissues of the human or animal body, plants, minerals by synthesis methods or using biological technologies. Medicinal products include pharmaceutical substances and drugs.

**Medicinal products** - medicinal products in the form of dosage forms used for the prevention, diagnosis, treatment of a disease, rehabilitation, maintenance, prevention or interruption. Goods of the "main" assortment, which are traditionally sold from pharmacies and form the basis of the Lists of mandatory assortment, vital and essential drugs, drugs dispensed free of charge and on preferential terms. Most of this range is sold only from pharmacies, so these products can be conditionally called *pharmaceutical products*.

In connection with the expansion of the product range of pharmacy organizations, a significant number of products, "additional" assortment or *parapharmaceutical products have appeared in them*. For example, abroad this group includes mainly cosmetics and sanitary and hygienic products.

In our country, there is currently no clear idea of what should be considered parapharmaceutical products. And the interpretation of this term ranges from "reagent kits for radioimmunoassay, isotopes used in medical practice, approved for use for diagnostic purposes" to lists of product groups that can be sold from pharmaceutical organizations, including everything except drugs.

Parapharmaceutical products these are goods of an additional pharmacy assortment, accompanying medicines and medical products, intended for the prevention, treatment of diseases, alleviating a person's condition, caring for body parts, sold from pharmacies serving the population.

#### FEATURES OF THE CLASSIFICATION OF MEDICAL DEVICES

The Uniform Sanitary-Epidemiological and Hygienic Requirements for Goods Subject to Sanitary-Epidemiological Supervision (Control) provide the following basic definitions:

Medical products - products intended for use in medical practice, including devices, dressings and sutures, products made of polymer, rubber and other materials that are used for medical purposes individually or in combination with each other and which are intended: for the prevention, diagnosis, treatment of diseases, rehabilitation, medical procedures, medical research, replacement or modification of parts of tissues, organs and the human body, restoration or compensation of impaired or lost physiological functions, control over conception; effects on the human body in such a way that their functional purpose is not realized through chemical, pharmacological, immunological or metabolic interactions with the human body.

Medical equipment products - devices, devices, tools, devices, complexes, systems with program control, equipment intended for use on a person for the purpose of: research, diagnosis, observation, treatment, prevention, alleviation of a disease, compensation for injury or disability and maintenance of physiological functions.

#### FEATURES OF THE CLASSIFICATION OF MEDICAL DEVICES (2)

Medical devices - medical devices and medical equipment any instruments, devices, devices, devices, materials or other products used individually or in combination with each other, including the software necessary for their intended use, which are intended by the manufacturer for use in to a person for the purpose of: diagnosing, preventing, monitoring, treating or alleviating a disease; diagnosing, monitoring, treating, alleviating or compensating for an injury or disability; research, replacement or modification of the anatomy or maintenance of physiological functions; conception management; provided that their principal effect is not based on the pharmacological, immunological or metabolic effect of the application, but which may contribute to the introduction into the body or delivery to the surface of the human body of agents that cause the above effects.

# FEATURES OF THE CLASSIFICATION OF MEDICAL DEVICES. Detailed definitions of a number of categories of pharmaceutical merchandising.

medical devices - medical equipment products designed to receive, accumulate and / or analyze, as well as display measuring information about the state of the human body for diagnostic or prophylactic purposes.

Thus, a medical device is a generalizing concept.

medical devices - products of medical equipment intended for therapeutic or prophylactic effects on the human body or for replacing or correcting the functions of organs and systems of the body.

Medical complexes - a set of medical equipment products, each of which performs a certain particular function in the system of a complex diagnostic, therapeutic or preventive measure.

Medical equipment - products of medical equipment designed to provide the necessary conditions for the patient and medical personnel during diagnostic, therapeutic and preventive measures, as well as when caring for patients.

#### WORLDWIDE MEDICAL DEVICE NOMENCLATURE

One of the key issues of harmonization (mutual agreement, integration into a system, unification) in the field of medicine is the creation of a unified range of medical devices.

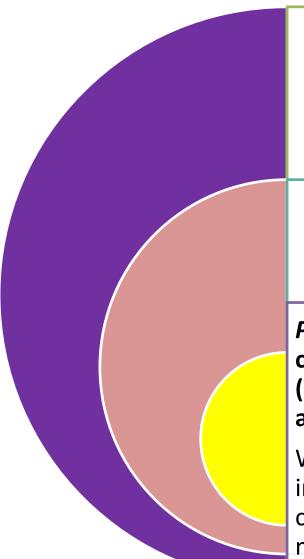
The main task of the created World Nomenclature of Medical Devices (Global Medical device Nomenclature, GMDN) is to provide all structures involved in the circulation of medical devices with a system of unambiguous definition and name of a medical device.

Currently, GMDN unites more than 20,000 positions. At the same time, all positions of the considered nomenclature are united by the concept of "medical device".

However, the category of "medical products" includes products that are not medical devices from the point of view of domestic legislation, such as batteries or personal computers.

# CODING OF GOODS: CONCEPT, STRUCTURE, CODING METHODS

#### **CODING OF GOODS: CONCEPT, STRUCTURE, CODING METHODS**



Goods coding is the formation or assignment of a code to a classification group or object of classification.

A code is a sign or a set of signs used to designate a classification grouping and/or an object of classification.

Purpose of coding is the systematization of objects by classifying, identifying, ranking and assigning a symbol (code), by which you can find and recognize any product among many others.

With the introduction of computer technology, the need and importance of coding has increased. The assignment of codes is carried out on the basis of certain rules and methods.

#### **ENCODING RULES**

#### **Encoding rules:**

3. The code should contribute to the ordering of objects.



2. the code must be expressed using various, predetermined signs;

1. the code must have a certain construction structure;

#### **CODE STRUCTURE**

The structure of a code is a conventional designation of the composition and sequence of characters in it. The code structure consists of the following elements:

- alphabet,
- base,
- category
- length.



# **CODE ALPHABET**

Code alphabet - a system of signs adopted to form a code.

The most commonly used alphabet for codes is:

numbers,

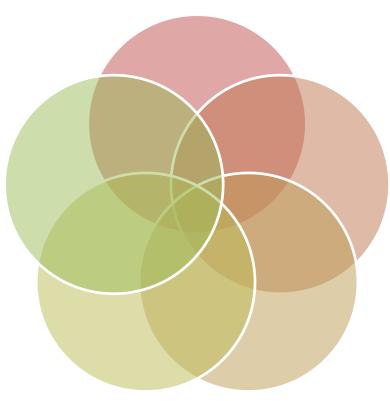
letters or their combinations, dashes and spaces.

#### **TYPES OF ALPHABET CODE**

### **Distinguish:**

bar code alphabet - a code alphabet whose characters are strokes and spaces, the width of which is read by scanners in the form of numbers.

alphanumeric - the alphabet of the code, the characters of which are letters of alphabets and numbers,



numeric - the alphabet of the code, the characters of which are numbers;

alphabetic - the alphabet of the code, the signs of which are the letters of the alphabets of natural languages;

### **GROUND CODE DISCHARGE**

The base of a code is the total number of characters in its alphabet.

The sequence of characters in the code is determined by its rank.

Code digit - the position of characters in the code.

Since each sign characterizes some predetermined attribute of the product, the code category carries a certain semantic load.

#### **EXAMPLE OF CODING ACCORDING TO OKPD 2**

For example, according to OKDP 2, preparations of salicylic acid and its salts have the code 21.10.10.110.

The digit of the code, indicated by the numbers 21 (first position), means that this is a drug belonging to the group "Medicines and materials used for medical purposes."

The dot is the separator between characters. In the example above, the dot separates:

- 21 "Medications and materials used for medical purposes";
- 10 "Pharmaceutical substances";
- 10 "Salicylic acid, O-acetylsalicylic acid, their salts and complex esters";
- 110 "Salicylic acid and its salts."

The code is also characterized by its length.

**Code length** - the number of characters in the code without dots.

For example, the above code 21.10.10.110 has length 9 and base 12.

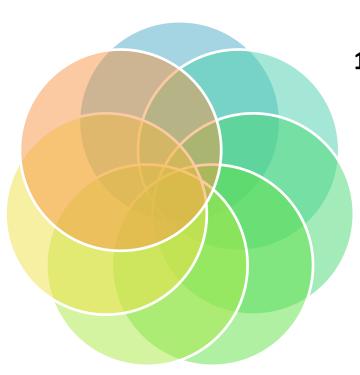
Thus, the length of the code (  $D_k$  ) differs from its base (  $O_k$  ) by the number of points (  $T_k$  ), or

$$D_{to} \setminus u003d O_{to} - T_{to}$$
.

#### **VARIETIES OF THE CODING METHOD**

Coding of goods and other objects is carried out in several ways, which are varieties of the coding method.

The last two coding methods (3,4) are closely related to varieties of the classification method.



These include:

1. Ordinal

2. Serial ordinal

3. Consistent way

4. Parallel way .

## Varieties (methods) of coding methods

**Ordinal coding method.** This is the simplest and most common coding method that does not require specific knowledge in this area. It allows you to encode objects classified according to one or more conditional or random features. For example, medicines on the consignment note are coded alphabetically by name; other signs (dosage form, dosage, storage conditions, etc.) are random.

**Serial-ordinal coding method** - the formation and assignment of a code from the numbers of the natural series, the assignment of individual series and ranges of these numbers to an object of classification with certain characteristics.

An example is the coding used in the Anatomical Therapeutic Chemical Classification (ATC) (Anatomical Therapeutic Chemical - ATC). So, drugs used to treat blood diseases receive an index B, and then a certain serial number: for example, anticoagulants - B01, heparin and its derivatives - B01AB.

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## Varieties (methods) of coding methods (2)

**Sequential encoding method** - formation and assignment of a code of a classification grouping and/or an object of classification using codes of sequentially located subordinate groups obtained using a hierarchical classification method. This method is characterized by all the advantages and disadvantages of the hierarchical classification method. Its main advantages are a high degree of ordering and the ability to identify general and particular features .

**EXAMPLE** of a sequential coding method: a fragment **from OKPD 2**, in which the classification of the product group "Equipment for irradiation, electrical diagnostic and therapeutic, used for medical purposes" is partially given, which is divided into subclasses (XX.X), groups (XX.XX), subgroups (XX.XX.XX), type (XX.XX.XX), category (XX.XX.XXX) and subcategory (XX.XX.XXX) according to interrelated features.

# EXAMPLE of a sequential encoding method: fragment from OKPD 2

- Code Description
- 26.6 Irradiation equipment, electrical, diagnostic and therapeutic, for medical purposes
- ❖ 26.60 Irradiation equipment, electrical, diagnostic and therapeutic, for medical purposes
- **26.60.1** Equipment and apparatus for irradiation, rehabilitation, electrical diagnostic and therapeutic, used for medical purposes
- ❖ 26.60.11 Apparatus based on the use of x-rays or alpha, beta or gamma radiation, used for medical purposes
- ❖ 26.60.11.110 X-ray devices used for medical purposes, including surgery, dentistry, veterinary medicine
- 26.60.11.111 Computer tomographs
- ❖ 26.60.11.112 X-ray apparatus (fluoroscopic)
- **26.60.11.113** X-ray apparatus
- **❖ 26.60.11.114** Apparatus for use in dentistry and veterinary medicine

## Varieties (methods) of coding methods (3)

Parallel coding method - formation and assignment of a code of a classification group and/or an object of classification using codes of independent groupings obtained using the faceted classification method. With a sufficiently high degree of ordering, the independence of groupings does not allow us to fully reveal the commonality and differences in features. However, for this coding method, any predetermined capacity of classified objects and positions is possible.

An example of a parallel coding method is ATC - a system for dividing drugs into groups depending on their effect on a specific anatomical organ or system, as well as on their chemical, pharmacological and therapeutic properties.

Each coding method has certain advantages and disadvantages.

In general, the set of methods and rules for encoding classification groups and classification objects of a given set is called a coding system.

# Characteristics of various coding methods

highlighting the commonality and

to certain characteristics is required

sequentially encoded features. The

complexity of changing the code to

introduce new features

individual groupings

Additional distribution by objects according

Rigidity of the code due to strict fixation of

Insufficient communication between

63

difference between objects

Encoding method	Advantages	Flaws
Ordinal	Face of assigning codes	Lack of additional information of

Ease of assigning codes. Uruman Economical use of 9999 codes objects. The impossibility of

Organize objects by series, resulting in

With a small code length, a large

Good machinability, code flexibility

makes it easy to make necessary

accepted in classifiers

additional information

information capacity

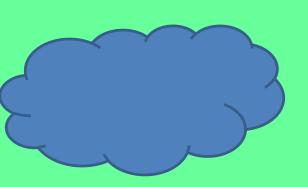
changes to the facet

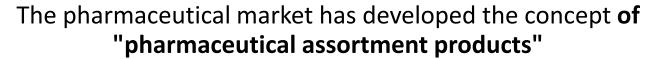
Lack of additional information about

Serial ordinal

Consistent

Parallel





summarizing the groups of goods sold through retail and wholesale pharmacy organizations. First of all, these are medicines, medicines, including homeopathic and medical products.

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#### FEATURES OF THE CLASSIFICATION OF MEDICAL DEVICES

The Uniform Sanitary-Epidemiological and Hygienic Requirements for Goods Subject to Sanitary-Epidemiological Supervision (Control) provide the following basic definitions:

Medical products - products intended for use in medical practice, including devices, dressings and sutures, products made of polymer, rubber and other materials that are used for medical purposes individually or in combination with each other and which are intended: for the prevention, diagnosis, treatment of diseases, rehabilitation, medical procedures, medical research, replacement or modification of parts of tissues, organs and the human body, restoration or compensation of impaired or lost physiological functions, control over conception; effects on the human body in such a way that their functional purpose is not realized through chemical, pharmacological, immunological or metabolic interactions with the human body.

Medical equipment products - devices, devices, tools, devices, complexes, systems with program control, equipment intended for use on a person for the purpose of: research, diagnosis, observation, treatment, prevention, alleviation of a disease, compensation for injury or disability and maintenance of physiological functions.

#### FEATURES OF THE CLASSIFICATION OF MEDICAL DEVICES (2)

**Medical devices** - medical devices and medical equipment any instruments, devices, devices, devices, materials or other products used individually or in combination with each other, including the software necessary for their intended use, which are intended by the manufacturer for use in to a person for the purpose of: diagnosing, preventing, monitoring, treating or alleviating a disease; diagnosing, monitoring, treating, alleviating or compensating for an injury or disability; research, replacement or modification of the anatomy or maintenance of physiological functions; conception management; provided that their principal effect is not based on the pharmacological, immunological or metabolic effect of the application, but which may contribute to the introduction into the body or delivery to the surface of the human body of agents that cause the above effects.

# FEATURES OF THE CLASSIFICATION OF MEDICAL DEVICES. Detailed definitions of a number of categories of pharmaceutical merchandising.

medical devices - medical equipment products designed to receive, accumulate and / or analyze, as well as display measuring information about the state of the human body for diagnostic or prophylactic purposes.

Thus, a medical device is a generalizing concept.

medical devices - products of medical equipment intended for therapeutic or prophylactic effects on the human body or for replacing or correcting the functions of organs and systems of the body.

Medical complexes - a set of medical equipment products, each of which performs a certain particular function in the system of a complex diagnostic, therapeutic or preventive measure.

Medical equipment - products of medical equipment designed to provide the necessary conditions for the patient and medical personnel during diagnostic, therapeutic and preventive measures, as well as when caring for patients.

#### WORLDWIDE MEDICAL DEVICE NOMENCLATURE

One of the key issues of harmonization (mutual agreement, integration into a system, unification) in the field of medicine is the creation of a unified range of medical devices.

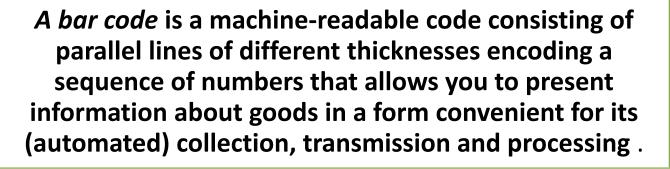
The main task of the created World Nomenclature of Medical Devices (Global Medical device Nomenclature, GMDN) is to provide all structures involved in the circulation of medical devices with a system of unambiguous definition and name of a medical device.

Currently, GMDN unites more than 20,000 positions. At the same time, all positions of the considered nomenclature are united by the concept of "medical device".

However, the category of "medical products" includes products that are not medical devices from the point of view of domestic legislation, such as batteries or personal computers.

# BAR CODING OF GOODS

#### **BAR CODING**



The need to introduce bar coding arose in connection with the development of information technology, the widespread introduction of computer technology in the production and sale of pharmaceutical products.

There are several major bar coding systems currently in use around the world.

#### **Benefits of barcoding:**

for manufacturers - automation of accounting for the quantity of manufactured products, their sorting and warehousing, the formation of orders;

for wholesale intermediaries - acceptance of goods by quantity and names, accounting and control of commodity stocks in a warehouse, shipment to retail trade;

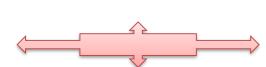
for transport organizations - acceptance and delivery of goods;

for retailers - acceptance of goods by quantity and names, placement in a warehouse, accounting and control of commodity stocks, control over safety, ensuring the rhythmic replenishment of the stock of goods as they are sold.

#### **European EAN system (European Article Numbering)**

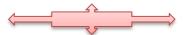
4. Code EAN-8 is for small packages where a longer code cannot be placed.

EAN-8 consists of a country code, a manufacturer's code and a control number (sometimes the product registration number instead of the manufacturer's code).



3. Each digit (or digit) consists of two strokes and two spaces.

1. Two EAN codes are most widely used:



- 8-bit

- 13-bit digital codes,

which are a combination of strokes and spaces of different widths.



2. The narrowest stroke is taken as one.

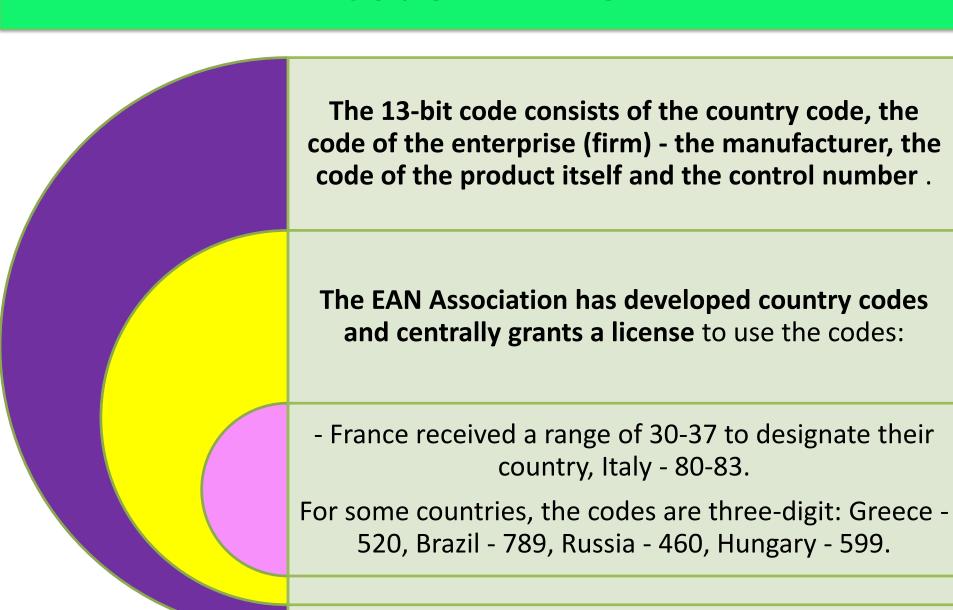
#### **Appearance of the 8-bit EAN code**



#### **Appearance of the 13-bit EAN code**



#### Code EAN-13



EAN	codes of t	ne mai	in countr	ies of tr	ne world
Code of the country	Country	Code of the country	•	Code of the country	Country
93	Australia	539	Ireland	888	Singapore
90-91	Austria	569	Iceland	383	Slovenia
779	Argentina	84	Spain	00-09	USA and Canada
54	Belgium and Luxembourg	80-83	Italy	869	Turkey
380	Bulgaria	529	Cyprus	64	Finland

China

Cuba

Mexico

Norway

**Poland** 

**Portugal** 

Russia

**Netherlands** 

**New Zealand** 

690

850

**750** 

**87** 

94

**70** 

**590** 

**560** 

460-469

France

Czech

Chile

Sweden

**Switzerland** 

Yugoslavia

**South Korea** 

79

Japan

30-37

859

**780** 

**73** 

**76** 

860

880

45-49

**789** 

fifty

**599** 

**759** 

489

**520** 

**57** 

729

400-440

**Brazil** 

**Great Britain** 

Hungary

Venezuela

Germany

Greece

**Israel** 

Denmark

**Hong Kong** 

## European EAN system (European Article Numbering) (2)

The manufacturer's code is compiled in each country by the appropriate national authority. It consists of five digits following the country code.

In Russia, bar coding is handled by the Foreign Economic Association for Automatic Identification Problems (UNISCAN / GS1 RUS), whose task is to introduce global standards and solutions aimed at improving the efficiency and transparency of supply chains in all economic sectors of the country.

## European EAN system (European Article Numbering) (3)

The product code is compiled directly by the manufacturer (five digits).

The decoding of the code is not standard, it may reflect certain characteristics (features) of the product itself or it represents the registration number of the product, known only to this enterprise. The check digit is intended to establish the correctness of the code reading by the scanner according to the EAN algorithm.

Both a proportional increase in the EAN-13 symbol up to 200% of the nominal dimensions, and a decrease up to 80% are allowed. Height truncation of the barcode is not allowed. Reducing the height of a symbol while maintaining its horizontal size (truncation) interferes with the normal operation of multi-beam scanners, which are widely used in pharmaceutical organizations.

## American UPC system (Universal product code). Appearance of the UPC code

- American UPC system (Universal product code). It was developed in North America in 1973 for the retail needs of the United States and Canada, where it is still used today. The length of the code is represented by 12 digits, since the country prefix in this system always consists of two digits.
- Each code position is formed by two dark and two light strokes. The UPC code symbol consists of two parts left and right. Each part is in the shape of a rectangle. The elements on the left side are a mirror image of the right side. The light bar means zero, the dark bar means one.



#### American UPC system (Universal product code)

#### There are three types of UPC code:

**UPC-A** - contains **11** informational and 1 control character; designed for coding food and non-food products sold through supermarkets;

**UPC-D** - designed for coding non-food products;

**UPC-E** - has 6 characters and is a truncated version of UPC. Any information is encoded.

#### West German BAN system (Bundes Ainheitliche Artikelnummer)

In Germany, the BAN code system was introduced in 1968.

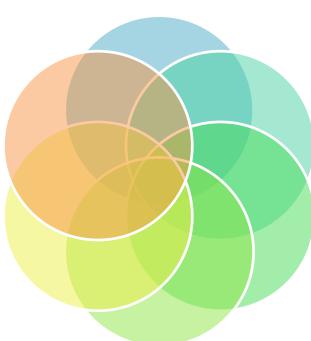
The code symbol consists of 8 digits: the first and second digits contain information about the type of goods; the third - the number of the product group; the fourth - the number of the assortment group; fifth, sixth and seventh - the serial number of the goods; the eighth is the sample number.

BAN applies only to the designation of consumer goods.

#### Japanese CALRA-CODE system

### Introduced in Japan in 1987, it is a graphic coding system.

4. Hatching of the corresponding fields creates the possibility of obtaining a large number of combinations on 10 large squares and allows you to encode a billion alphanumeric combinations.



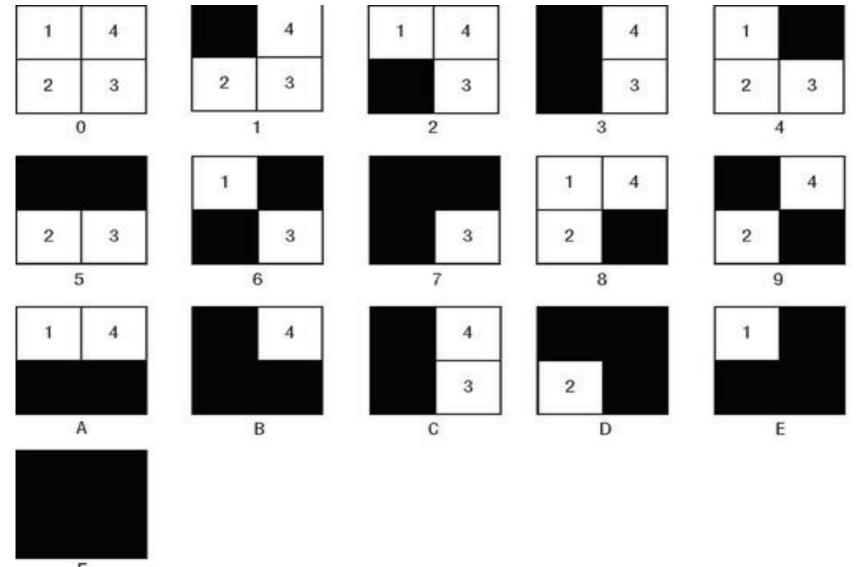
1. It consists of 10 large squares, each of which is divided into smaller squares of the same size.

They are assigned specific numbers: 1, 2, 4, 8.

3. Accordingly, each square is assigned a certain, invariably one and the same figure.

2. Hatching options for a small square in relation to the main one allow coding the corresponding goods.

#### Alphanumeric coding options in the CALRA-CODE system



#### **Comparative evaluation of CALRA-CODE and EAN systems**

CALRA-CODE is easier to use, contains a larger amount of information, and a device for reading and decoding it is cheaper and much more efficient even with a fuzzy font print.

Reading the code is possible even if the square is distorted up to 1 mm.

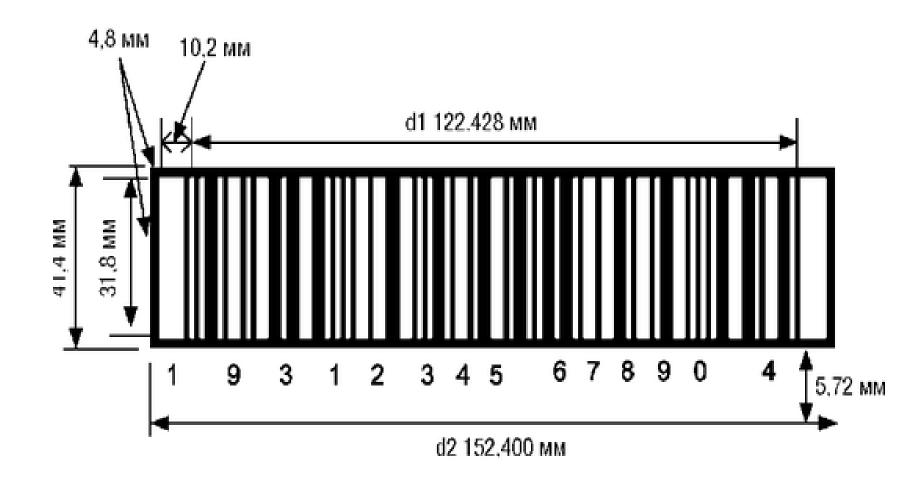
Despite its advantages, the CALRA-CODE system is now used only in Japan and has not been adopted in other countries.

#### Transport packaging bar coding system

A 14-digit EAN/UCC-14 number is applied to the shipping packaging as a barcode.

This uses the graphic symbolism "2 of 5 interleaved" (Interleaved Two of Five - ITF), which is why the barcode is also abbreviated as ITF-14.

#### Appearance and dimensions of the ITF-14 barcode



#### Comparative evaluation of EAN systems and ITF symbols

- Compared to EAN codes, the ITF symbology is characterized by significantly larger barcode image sizes (width - 152.4 mm, height - 41.4 mm) and less stringent surface specifications.
- Thus, the ITF-14 bar code can be printed not only on labels, but also directly on the walls of cardboard boxes.
- Even in this case, it will be successfully read by scanners.
- The code includes 12 EAN/UCC-13 information bits (except for the control one), which determine the main characteristics of the packaged products.
- The information content of the ITF-14 barcode is presented in the table (slide)

## The information content of the ITF-14 barcode. Barcode structure 1407009520084 (example)

#### Barcode structure 1407009520084 (example)

one	460	700952	008	four
	EAN/UCC-13 v			
Logistic variant - different shipping packages with the same contents (EAN/UCC-13) differ in the rank of the logistic variant. Valid numbering - from 1 to 8	prefix - UNISCAN/GS1 Russia	Company registration number - generated when registering a company with UNISCAN/GS1 Russia	individual type of product (single package) corresponds to a	Control 14th category - calculated from the values of the previous 13 bits
				91

## The information content of the ITF-14 barcode. *Barcode* structure 1407009520084 (example)

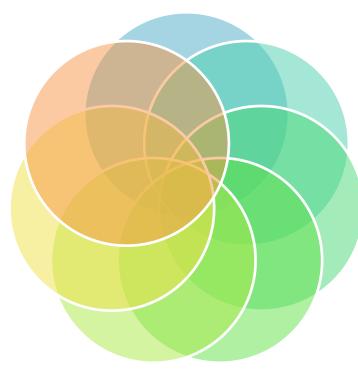
- The authenticity of the goods can be determined after calculating the check digit of the bar code. Let's assume that we have an ITF-14 barcode -7290000494616.
- The calculation is made as follows:
- 1. Add the numbers of the bar code in even places : 2 + 0 + 0 + 4 + 4 + 1 = 11.
- 2. Multiply the resulting amount by 3:  $11 \times 3 = 33$ .
- 3. Add the numbers in odd places without a control
- **digits**: 7 + 9 + 0 + 0 + 9 + 6 = 31.
- 4. Add the numbers calculated in paragraphs 2 and 3: 33 + 31 = 64.
- 5. Discard tens from the amount received: it turns out 4.
- 6. From 10 subtract the figure obtained in paragraph 5: 10 4 = 6.
- If the figure obtained as a result of the calculation (see point 6) does not match the check digit in the barcode, this means that the product was produced illegally and its quality is not guaranteed. Since January 1993, the bar code must be applied to all goods entering Europe. The price of a product released to the market without a bar code is reduced by 3-15% of its value.

#### **INTERNAL BARCODING IN A PHARMACY**

## It is possible to produce internal barcoding in a pharmacy.

4) when the product has a unique subordinate code - serial number, series, inventory number, etc.

3) when it is convenient to take into account the goods not in basic units, but in packages for the receipt of goods or inventory;



This is necessary in the following cases:

1) when there is no barcode at all;

2) when a product of the same type has a barcode, but at the same time the product has different characteristics that are important for accounting, for example, packing size, dosage, etc.;

#### INTERNAL BARCODING IN A PHARMACY

 To create internal barcodes, barcode printers are used, designed to label goods with barcodes with minimal labor costs for pharmaceutical personnel.

#### Barcode printers provide:

- automatic generation of a bar code in accordance with standard international standard sizes;
- automatic printing of a set number of specified labels;
- work offline and under computer control;
- input of initial data from the keyboard of the device or automatically via communication lines from a computer;
- control of the formation and printing of machine and visually readable information with the issuance of error messages;
- correction of erroneous information;
- design and cutting labels of the required sizes.

#### **Appearance of a thermal barcode printer**



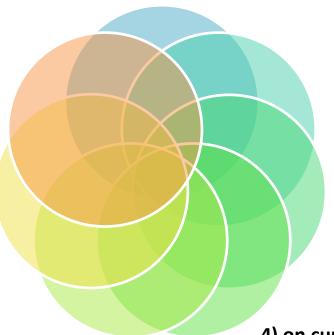
#### Appearance of a thermal transfer barcode



## Requirements for applying a barcode on packaging, established by international rules:

6) the background must be light, without drawings and perforations, text, white, yellow, orange or light brown.

5) bar code printing in black, blue, dark green or dark brown; light brown and yellow are not used, since the optical reader does not distinguish between them; 1) there must be one EAN barcode on the package;



2) the size of the code applied to the packaging must be from 80 to 200% of the original - base image;

3) the bar code is placed on the back of the package in the lower right corner at a distance of at least 20 mm from the edges, if this is not possible, then the bar code is applied on the right side of the front side;

4) on curved surfaces, the bar code is placed vertically; on plastic packages and packages, the barcode is applied to a more even surface;

# Thank you for your attention