# RULES OF STORAGE OF MEDICINES Premises for storing medicines in a pharmacy. General requirements for their design and operation

Lecture for students
3 year 5 semester

Management and economy in Pharmacy

#### The main document

- Order of the Ministry of Health of the S.R. of the Russian Federation of 23.08.2010 No. 706-n "On approval of the rules for the storage of medicines" establishes the Rules for the storage of medicinal products, including:
- requirements for premises for the storage of medicinal products for medical use (hereinafter - medicinal products - medicinal products),
- regulate the storage conditions of medicinal products and apply to manufacturers of medicinal products, organizations of wholesale trade of medicinal products, pharmacy organizations, medical and other organizations operating in the circulation of medicines, individual entrepreneurs who have a license for pharmaceutical activity or a license for medical activity (hereinafter, respectively, organizations, sole proprietors).

# General requirements for their design and operation

- The device, composition, dimensions, operation and equipment of drug storage facilities hould ensure the safety of pharmacy products.
- Устройство, состав, размеры площадей (для <u>организаций оптовой торговли</u> ЛС), эксплуатация и оборудование помещений для хранения ЛС должны обеспечивать <u>их сохранность</u>.

- Certain temperature and humidity of the air must be maintained in the premises for the storage of LP. This makes it possible to ensure the storage of LP in accordance with the requirements of the manufacturers of drugs. These requirements are indicated by the manufacturer on the primary and secondary (consumer) packaging of the medicine.
- В помещениях для хранения ЛС должны поддерживаться определенные <u>температура и влажность воздуха</u>, позволяющие обеспечить хранение ЛС в соответствии с указанными на <u>первичной и вторичной</u> (потребительской) упаковке <u>требованиями производителей</u> ЛС.

# General requirements for their design and operation (2)

- Air conditioners and equipment for air exchange in the room for the storage of medicines ensure the correct storage of medicines. In addition, it is recommended to equip the windows of the storage room with panes, transoms, and to equip the doors with second lattice doors.
- Помещения для хранения ЛС должны быть оборудованы кондиционерами и другим оборудованием, позволяющим обеспечить хранение ЛС в соответствии с указанными на первичной и вторичной (потребительской) упаковке требованиями производителей ЛС, либо помещения рекомендуется оборудовать форточками, фрамугами, вторыми решетчатыми дверьми.

Racks, cabinets, pallets and accessories should be in the room. They are necessary for storing LP. Помещения для хранения ЛС должны быть обеспечены стеллажами, шкафами, поддонами, подтоварниками.

The decoration of the premises for the storage of medicines (the inner surfaces of walls, ceilings) should be smooth. This is necessary to perform wet cleaning in the room. Отделка помещений для хранения лекарственных средств (внутренние поверхности стен,

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# Equipment and equipment of premises for storage of medicines.

Оснащение и оборудование помещений для хранения ЛС.

- Devices for recording air parameters: thermometers, hygrometers electronic hygrometers or psychrometers are necessary in rooms for storing MP.
- Помещения для хранения лекарственных средств должны быть оснащены приборами для регистрации параметров воздуха (термометрами, гигрометрами (электронными гигрометрами) или психрометрами).

- The measuring parts of these devices should be placed at a distance of at least 3 m from doors, windows and heating devices. The devices should be located in a place accessible to personnel at a height of 1.5 1.7 m from the floor.
- Измерительные части этих приборов должны размещаться на расстоянии не менее 3 м от дверей, окон и отопительных приборов. Приборы и (или) части приборов, с которых производится визуальное считывание показаний, должны располагаться в доступном для персонала месте на высоте 1,5 1,7 м от пола.

The readings of these devices are recorded daily in a special log (map). This journal is kept by a responsible pharmacist.

# <u>Fquipment and equipment of premises</u> <u>for storage of medicines (2)</u>

- The log (map) of temperature and humidity accounting is stored for one year, not counting the current one.
- · Журнал (карта) регистрации хранится **в течение одного года**, не считая текущего.

- All these devices must be certified, calibrated and verified once a year.
- Контролирующие приборы должны быть **сертифицированы, калиброваны и подвергаться поверке ежегодно** в установленном порядке.

- Racks (cabinets) for storing medicines in the premises should be installed so as to ensure:
- access to personal data.

# Drugs are placed

- In the premises for the storage of drugs, they are placed in accordance with the requirements of the regulatory documentation indicated on the packaging of the drug, taking into account:
- physico-chemical properties of medicines;
- pharmacological groups (for pharmacy and medical organizations);
- method of application (internal, external);
- the aggregate state of pharmaceutical substances (liquid, bulk, gaseous).
- according to the alphabetical principle, by codes, when computer technologies are used in the placement of drugs.
- drugs under control are stored in technically fortified premises (separately) in accordance with international legal norms:

# The drugs in the pharmacy must be identified

- The drugs in the pharmacy must also be identified using a shelving card. It contains the following information about the stored L P
- name,
- release form and dosage,
- serial number,
- expiration date,
- LP manufacturer
- · Хранящиеся ЛС должны быть также **идентифицированы** с помощью <u>стеллажной карты</u>, содержащей информацию о хранящемся ЛП
- . наименование,
- . форма выпуска и дозировка,

# a limited shelf life of drugs

- In organizations and sole proprietors, it is necessary to keep records of medicines with a limited shelf life on paper or in electronic form with archiving.
- В организациях и у ИП необходимо вести учет ЛС с **ограниченным сроком годности** на бумажном носителе или в электронном виде с архивацией.

- Control over the timely implementation of a limited shelf life LP should be carried out using various methods:
- computer technology,
- shelving cards indicating the name of the LP, series, expiration date
- expiration date logs.
- Контроль за своевременной реализацией ЛП с <u>ограниченным сроком</u> <u>годности</u> должен осуществляться с использованием разных способов:
- компьютерных технологий,

# Storage of pharmacy assortment goods.

Хранение товаров аптечного ассортимента.

- Storage of goods is carried out at all stages of commodity movement from the release of finished products to consumption or disposal.
- this is the process of placing goods in warehouses, maintaining and caring for them in order to ensure their quality and quantity. The main task of storage is to ensure the stability of the initial properties of goods.
- Basic conditions for the organization of storage of goods:
  - Availability of appropriate storage facilities.
  - Creation of the required storage mode.
  - Organization of the placement of goods during storage.
- Хранение товаров осуществляется на всех этапах товародвижения от выпуска готовой продукции до потребления или утилизации.
- это процесс размещения товаров в складских помещениях, содержание и уход за ними с целью обеспечения их качества и количества. Основная задача *хранения* обеспечение стабильности исходных свойств товаров.
- Основные условия организации хранения товаров:

#### The main documents

- To unify the requirements for the storage of goods of the pharmacy assortment of the Ministry of Health of the Russian Federation, the following ND has been issued:
- Order of the Ministry of Health of the Russian Federation No. 377
  of 13.11.96 "On approval of instructions for the organization of
  storage in a /u of various groups of drugs and medical devices".- only
  IMN, BMI.
- RF PP No. 1148 dated 31.12.2009 "On the storage of n.cf. and ps.substances" - established requirements for the premises and quantities of storage of n.cf. and ps.v-v.
- Order of the Ministry of Health of the S.R. of the Russian Federation dated 23.08.2010. No. 706-n "On approval of the rules for the storage of medicines".
- In accordance with Federal Law No. 61-FZ "On the circulation of drugs" Article 58 "Storage of drugs" in Chapter 10 "Pharmaceutical

- General requirements for the design and operation of premises
- General requirements for drug storage facilities and organization of their storage
- Requirements for premises for the storage of flammable and explosive drugs and the organization of their storage
- Features of the organization of storage of medicines in warehouses
- Features of storage of individual groups of drugs depending on physical and physico-chemical properties, the impact of various environmental factors on them:
- protection from the action of light
- protection from moisture
- protection against volatilization and drying
- protection from exposure to elevated temperature

• Storage conditions for specific groups of drugs:

a) odorous and coloring medicines

- b) disinfecting medicines
- c) LP for medical use
- d) medicinal plant raw materials
- e) medical leeches
- f) flammable and explosive medicines
- g) narcotic and psychotropic drugs
- h) potent and poisonous medicines,
- medicines subject to PKU.

# climatic and sanitary and hygienic requirements

• Storage mode is a combination of climatic (temperature, relative humidity, air exchange, gas composition of the air and illumination) and sanitary and hygienic requirements (a set of cleanliness indicators — the presence of contamination on the product and in the environment, not exceeding the established norms). Режим хранения — совокупность климатических (температура, относительная влажность воздуха, воздухообмен, газовый состав воздуха и освещенность) и санитарно- гигиенических требований ( комплекс показателей чистоты- наличие загрязнений на товаре и в окружающей среде, не превышающие установленные нормы).

- Special requirements for the storage mode are imposed on the drug and MIBP.
- Improper storage of drugs, in addition to material damage, can harm the patient. The fact is that spoiled drugs are not easy to visually identify, and in many cases they cannot be distinguished from benign ones, since the so-called hidden 6rak is detected only at the stage of LP consumption.
- Особые требования к режиму хранения предъявляются к ЛС и МИБП.
- Неправильное хранение **ЛС,** помимо материального ущерба, может нанести вред больному. Дело в том, что

# Factors affecting the storage regime of pharmacy assortment goods.

- In this regard, the pharmacist must know the factors affecting the stored goods of the pharmacy assortment, understand the mechanism of this influence, in order to take measures to organize proper storage.
- Factors affecting the storage regime of pharmacy assortment goods.
- physical (air temperature and humidity, light)
- 2. chemical (oxygen, ozone, carbon dioxide, hydrogen sulfide, sulfur dioxide and other air components)
- 3. biological (microorganisms, insects and rodents)
- 4. mechanical (concussions, vibration, compression, stretching, impact, etc.)
- В этой *связи,* провизор должен знать факторы, влияющие на хранимые товары аптечного ассортимента, понимать механизм этого влияния, для принятия мер по организации правильного хранения.
- Факторы, влияющие на режим хранения товаров аптечного ассортимента.
- физические (температура и влажность воздуха, свет)

#### the time factor

- Since the influence of these factors occurs over a period of time, it is necessary to take into account the time factor.
- At the same time, with proper storage, for example, of antibiotics, organopreparations and other groups of pharmaceutical products, their quality deteriorates as a result of long-term storage.
- In this regard, expiration dates are established, during which the main consumer properties are preserved.

- Поскольку влияние перечисленных факторов происходит в течение какого-то промежутка времени, то обязательно нужно учитывать и фактор времени.
- В то же время при правильном хранении, например, антибиотиков, органопрепаратов и других групп фармтоваров, качество их ухудшается в результате длительного хранения.

# requirements for the temperature regime

GF XIV edition establishes requirements for the temperature regime and storage conditions of LP.

Temperature.

**Deep cooling Below** 

-15 degrees. C

In the refrigerator

From + 2 to +8 degrees. C

In a cold or cool place

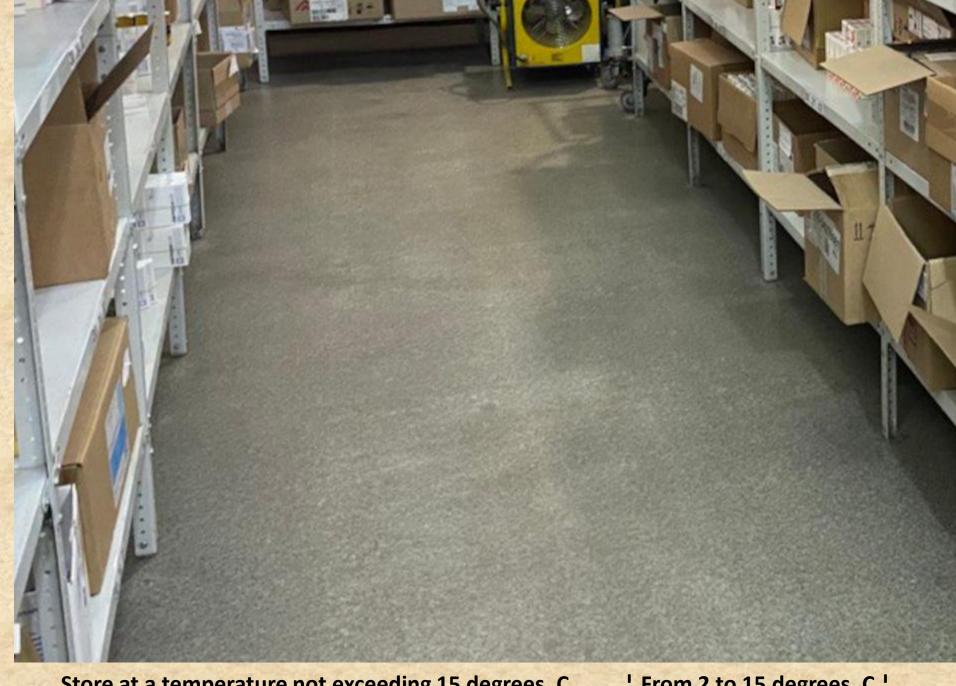
From +8 to +15 degrees. C

At room temperature

From +15 to +25 deg. C

In addition to the exacific indication of towns returns the following towns are also





Store at a temperature not exceeding 15 degrees. C

# Rules for storing various groups of medicines in a warehouse Rules for storing various groups of medicines in a warehouse Rules for storing various groups of medicines in a warehouse

In warehouses, all medical preparations are stored on pallets in racks. It is forbidden to leave them on the floor in a packaging container (box or container). The height of the cabinets depends on the type of loading and unloading operations being carried out. If mechanized equipment is used, the space can be filled in several tiers, for the manual method, the maximum lift is no more than 1.5 m.

#### Правила хранения различных групп лекарственных средств на складе

В складских помещениях все медицинские препараты содержатся на поддонах в стеллажах. Оставлять их на полу в упаковочной таре (коробке или контейнере) запрещается. Высота шкафов зависит от вида реализуемых погрузочноразгрузочных работ. Если применяется механизированная техника, пространство можно заполнять в несколько ярусов, для ручного способа максимальный подъем составляет не более 1,5 м.

#### Principles of placement of individual categories

Some substances are more sensitive to changes in the climatic regime than others. Their chemical and physical properties may be lost, and their appearance may change if there are problems with maintaining the same temperature or humidity in the room. Moreover, the processes occurring in substances often make such products dangerous to the life of the end user. The list of medicines requiring special storage conditions includes vital parcetic poisonous medicines



- How to place to protectofstom moisture.
- Mandatory requirements are: cool air (no higher than +15 degrees) and special equipment. The packages are placed in a separate container with high water-repellent properties. In addition, it should not miss pairs. For these purposes, glass, various metals and thick plastic are most often chosen. The use of primary and secondary packaging of the supplier and manufacturer is also allowed if it meets the requirements. Ensure tightness with the help of paraffin or other materials that seal the holes.

#### Как размещать, чтобы защититься от влаги

Обязательными требованиями являются: прохладный воздух (не выше +15 градусов) и особое оснащение. Упаковки помещают в отдельную тару, обладающую высокими водоотталкивающими свойствами. Кроме того, она не должна пропускать и пары. Для этих целей чаще всего выбирают стекло, различные металлы и толстый пластик. Использование первичной и вторичной тары поставщика и производителя тоже допускается, если она соответствует требованиям. Обеспечивают герметичность с помощью парафина или других материалов, которым закупориваются отверстия.

#### Prone to volatilization and drying out

This group includes substances based on a volatile solvent, namely alcohol, as well as products made with the use of essential oils containing crystal hydrates and some other products. The rules of storage and use of medicines and products

# Protection against exposure to elevated temperatures

Protection against exposure to elevated temperatures

- All permissible temperature conditions are indicated on the primary and secondary packaging, in the instructions, as well as accompanying documents.
- Protection from exposure to elevated temperatures is necessary for
- enzyme preparations,
- medical immunobiological preparations (serums, vaccines, toxoids, allergens, immunoglobulins),
- . some ointments,
- · suppositories,
- antibiotics and other drugs.
- This information is taken into account by pharmacy employees, already at the time of acceptance control when drugs are received at the pharmacy.

# The task of pharmacy employees

- Placement of plant raw materials for the manufacture of medicines
- Unpacked substances are stored in securely closed containers that protect them from foreign debris, excessive humidity and other negative influences.
- Размещение растительного сырья для изготовления лекарств
- Не расфасованные вещества хранятся в надежно закрытой таре, защищающей их от попадания постороннего мусора, излишней влажности и других негативных воздействий.

- The task of pharmacy employees: to conduct regular inspections of products in order to detect their spoilage, moldy, insect infestation.
- The detected defect is immediately placed in the quarantine zone, so as not to harm all other medicines sold at the point of sale. If there are strong poisons among the raw materials, they are placed in a separate room or at least in a closet (with a lack of free space). The responsible person is responsible for their safety and security for others.

# Location of narcotic and psychotropic drugs

Location of narcotic and psychotropic drugs

- This group of medicines requires a separate isolated room equipped with a reliable security system.
- Their movement is recorded in a special journal, and the implementation is carried out with the verification of permits (prescription).
- Placement of drugs in a place of temporary storage is allowed, but in compliance with the requirements of a separate resolution.
- The inspection organizations monitor compliance with the requirements and, in case of detection of a violation, apply strict sanctions.

- Расположение наркотических и психотропных ЛС
- Эта группа медикаментов требует отдельного изолированного помещения, оборудованного надежной системой охраны. Их перемещение фиксируется в специальном журнале, а реализация осуществляется с проверкой разрешительных документов (рецепта). Размещение препаратов в месте временного хранения допускается, но с соблюдением требований отдельного

# The location of potent and poisonous drugs in the pharmacy

- The location of potent and poisonous drugs in the pharmacy
- The group includes medical products included in the corresponding list prepared by the Government of the country.
- Their placement fully complies with the norms applicable to narcotic and psychotropic drugs.
- Often, one room equipped with a security system is even used for this. At the same time, the packages occupy different cabinets or at least shelves, if we are talking about small stocks.
- . The control of strong poisons is also carried out using international standards.

- Расположение в аптеке сильнодействующих и ядовитых ЛС
- В группу относятся медицинские средства, входящие в соответствующий список, подготовленный правительством страны. Их размещение полностью соответствует нормам, применяемым в отношении наркотических и

# Premises for the storage of narcotic and psychotropic drugs

- Premises for the storage of narcotic and psychotropic drugs
- Narcotic and psychotropic drugs are stored in organizations in compliance with the requirements according to the Rules for the storage of narcotic drugs and psychotropic substances established by the Decree of the Government of the Russian Federation of December 31, 2009 N 1148:
- in isolated premises specially equipped with engineering and technical means of protection,
  - in places of temporary storage.
- The premises are divided into 4 categories. In relation to the premises of each of the categories, basic requirements are established for their equipment with engineering and technical means of protection, as well as for the conditions of storage of narcotic drugs and psychotropic substances in them.

Помещения для хранения наркотических и психотропных лекарственных средств

- в изолированных помещениях, специально оборудованных инженерными и техническими средствами охраны,

# The 1st category

- The 1st category includes premises of manufacturers and manufacturers (with the exception of pharmacies) of narcotic drugs and psychotropic substances, as well as premises of organizations engaged in wholesale trade or processing of narcotic drugs and psychotropic substances.
- К 1-й категории относятся помещения производителей и изготовителей (за исключением аптечных учреждений) наркотических средств и психотропных веществ, а также помещения организаций, осуществляющих оптовую торговлю или переработку наркотических средств и психотропных веществ,

- The 2nd category includes the premises of pharmacies intended for storing a monthly supply of narcotic drugs and psychotropic substances used for medical purposes.
- **Ко 2-й категории** относятся помещения **аптечных учреждений**, предназначенные для хранения **месячного запаса** наркотических средств и психотропных веществ, используемых в медицинских целях.

# the 2nd category

- The room belonging to the 2nd category is equipped with security alarm systems consisting of at least 2 protection lines, and an alarm system with the output of signals to the central monitoring console of the police unit of the private security at the internal affairs body of the Russian Federation, and in the absence of the possibility of such connection with the output of a signal to the guard post.
- Narcotic drugs and psychotropic substances are stored in lockable safes not lower than the 4th class of burglary resistance or metal cabinets.

- . 1. The entrance door to the room can be:
- metal, wooden (reinforced with padding on 2 sides with sheet iron or metal linings) or of other material that provides a class of protection against destructive influences not lower than the 3rd.
- must have at least 2 locking devices of the 3rd class of protection against destruction.







# the 2nd category

- Window structures must have a class of protection against destruction not lower than the 3rd.
- On the window structures of the 1st and last floors, metal grilles made of steel rods or blinds equivalent in strength to metal grilles are installed on the inside or between the frames.
- Оконные конструкции должны обладать классом защиты от разрушения не ниже 3-го.
- На оконные конструкции **1-го и последнего этажей** с внутренней стороны или между рамами устанавливаются **металлические решетки**, изготовленные из стальных прутьев, либо жалюзи, эквивалентные по прочности металлическим решеткам. Наркотические средства и психотропные вещества хранятся **в запирающихся сейфах не** ниже 4-го класса устойчивости к взлому или металлических шкафах.

# the 3nd category

- The 3rd category includes premises of MO institutions intended for storage of:
- 5-day and (or) 3-day stocks of narcotic drugs and psychotropic substances;
- narcotic drugs and psychotropic substances donated by relatives of deceased patients,
- premises of legal entities intended for the storage of narcotic drugs and psychotropic substances used for veterinary, scientific, educational and expert purposes.

К 3-й категории относятся помещения учреждений МО, предназначенные для хранения :

- **5-дневного и (или) 3-дневного запаса** наркотических средств и психотропных веществ;
- наркотических средств и психотропных веществ, сданных родственниками умерших больных,
- помещения юридических лиц, предназначенные для хранения наркотических средств и психотропных веществ, используемых в ветеринарных, научных, учебных и экспертных целях.

The 4th category includes premises of ZO institutions for the storage of a daily supply of narcotic drugs and psychotropic substances, as well as places of temporary storage of narcotic drugs and psychotropic substances used for

# the 4th category

- In a room of the 4th category, narcotic drugs and psychotropic substances are stored in lockable bulk or attached to the floor (wall) safes not lower than the 3rd class of burglary resistance.
- The safe weighing less than 1000 kilograms is attached to the floor or wall or is built into the wall using an anchor attachment.
- In other places of temporary storage, narcotic drugs and psychotropic substances are stored in lockable safes at least
- of the 1st class of burglary resistance or metal or containers made of other highstrength materials.

- В помещении **4-й категории**, наркотические средства и психотропные вещества <u>хранятся</u> в запирающихся насыпных или прикрепленных к полу (стене) **сейфах** не ниже **3-го класса** устойчивости к взлому.
- Сейф массой **менее 1000 килограммов** прикрепляется **к полу или стене** либо <u>встраивается</u> в стену с помощью <u>анкерного крепления.</u>

<u>В иных местах</u> временного хранения наркотические средства и психотропные вещества хранятся в запирающихся сейфах не ниже

1-го класса устойчивости к взлому или металлических либо изготовленных из других высокопрочных материалов контейнерах.

# medicines subject to PKU

- Requirements for premises for the storage of potent and poisonous medicines, medicines subject to PKU.
- The storage of potent and poisonous medicines under control in accordance with international legal norms (hereinafter referred to as potent and poisonous medicines under international control) is carried out in premises equipped with engineering and technical means of protection similar to those provided for the storage of narcotic and psychotropic medicines.
- Storage of potent and poisonous medicines that are not under international control is carried out in a material room in metal cabinets sealed or sealed at the end of the working day.

- Требования к помещениям для хранения сильнодействующих и ядовитых лекарственных средств, лекарственных средств, подлежащих ПКУ.
- Хранение сильнодействующих и ядовитых лекарственных средств, находящихся под контролем в соответствии с международными правовыми нормами (далее - сильнодействующие и ядовитые

### **Drugs subject to PCU**

- Drugs subject to PCU in accordance with the Order of the Ministry of Health of the Russian Federation dated 22.04. 2014 N 183n "On approval of the list of medicines for medical use subject to quantitative accounting" with the exception of narcotic, psychotropic, potent and poisonous medicines,
- they are stored in the material room in metal or wooden cabinets, sealed or sealed at the end of the working day.

- **ЛС, подлежащие ПКУ** в соответствии с Приказом МЗ РФ от 22,04. 2014 г. N 183н " Об утверждении перечня лекарственных средств для медицинского применения, подлежащих предметно-количественному учету" <u>за исключением</u> наркотических, психотропных, сильнодействующих и ядовитых лекарственных средств,
- хранятся <u>в **материальной** комнате</u> в <u>металлических или деревянных шкафах</u>, опечатываемых или пломбируемых в конце рабочего дня.