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 Merchandising

Promotion of over-the-counter and prescription drugs on the pharmaceutical market

Lecture No. 5
Discipline: pharmaceutical marketing
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LECTURE PLAN

- 1. Introduction. Definition of some terms.
- 2. General characteristics of over-the-counter drugs.
- 3. Criteria for classifying a drug as over-the-counter.
- 4. Rules for determining the categories of drugs sold without a prescription and with a prescription.
- 5. Assortment of OTC drugs. Responsible self-medication concept.
- 6. Macromodels for promoting a pharmaceutical product.
- 7. The concept of “7 P ” - megamarketing in pharmacy.
- 8. Legal relations in the field of promotion of medicines.
- 9. Information about a new drug. Work through medical representatives.
- 10. Methods for promoting prescription and over-the-counter drugs.

DEFINITION OF THE TERM. GENERAL PROVISIONS.

Medicines sold without a doctor's prescription are those whose composition and action, when used in therapeutic doses indicated on the packaging and in the instructions for use, which are understandable and followed by the patient, usually do not pose a risk of complications and/or side effects.

Over-the-counter drugs (OTC drugs - from English over the counter) is an extensive group of medications that a patient can buy for self-medication directly at the pharmacy (and some medications not only at the pharmacy) without a doctor’s prescription. They go to the patient directly from the hands of the pharmacist, bypassing the doctor.

Over-the-counter medications are intended for:

- self-help,

- self-prevention ,

- maintaining health and leading a healthy lifestyle.

Their acquisition depends on the influence of various factors on the consumer, including:

- own experience of use,

- opinions of families and advice from friends,

-advice from doctors and pharmacists,

- advertising campaigns of manufacturers of drugs BRO, etc.

According to WHO requirements, medicines sold without a doctor's prescription must meet the following criteria:

- **active and auxiliary substances in the composition must have low toxicity** ;

- active ingredients must be acceptable for use as self-help and self-medication without additional consultation with specialists; minimal number of side effects;

- **no risk of physiological addiction;**

- **absence of mutual inhibition when used with other medications and foods.**

Thus, in accordance with WHO requirements, an over-the-counter drug:

- the drug must be well known	- often used in medical practice	- go into the home medicine cabinet	- do not have a toxic effect on the body.

Safety

Safety is the main property that is considered when deciding whether to transfer a drug previously available only by prescription to the drug group .

All drugs have both beneficial effects and side effects. A certain degree of risk is considered acceptable if it is outweighed by the expected benefit from taking the drug.

However, determining an acceptable level of risk is difficult.

Security (2)

The safety of a BLP depends on its correct use.

- The use of the drug is based on the diagnosis (often erroneous) that the person made for himself.

For example, in most cases, a headache is not a sign of a serious illness, but sometimes it is an early warning sign of a brain hemorrhage or the formation of a brain tumor.

- Similarly, the feeling of severe heartburn can be a symptom of myocardial infarction.

-Ultimately, a person relies on common sense to determine when a symptom or illness is minor and when professional medical attention is required.

In setting the dosages of drugs, manufacturers strive to balance between safety and effectiveness.

Precautionary measures

Common sense is the most important element of self-help. It is important to remember that some people experience adverse drug reactions more often than others.

Medications should be given to young children, the elderly and seriously ill patients with extreme caution, and medical supervision is often required .

Before taking different medications together, you should consult your pharmacist or doctor to avoid dangerous interactions.

Over-the-counter medications are not intended to treat serious illnesses and may make some conditions worse.

An unexpected reaction , such as a skin rash or insomnia , **requires immediate discontinuation of the medication and seeking professional help.**

Children

- a child’s body reacts to medications differently than an adult,

- often a drug is widely used for many years before it becomes known that it poses a danger to children;

For example, it took 5 years before researchers confirmed that Reye's syndrome was associated with aspirin use in children with chickenpox or influenza.

Children

1) choosing the right dose of medicine for a child can be difficult,

2) dosages of medications for children are often focused on age ranges (for example, for children from 2 to 6 years or from 6 to 12 years),

3) children in any age range can differ very significantly in weight and height, and it has not yet been decided how best to determine the dose of a drug: based on weight, height or total body surface.

4) **the easiest dose to use is calculated based on the child's weight** .

Children

If the annotation does not contain information about the dose of the medicine intended for children, parents should not choose it themselves.

If in any doubt, parents should consult a pharmacist or doctor.

These precautions will help prevent your child from receiving a dangerous substance or a dangerously high dose of a needed medication.

CHILDREN:

- Many medications for children are in liquid form. The label contains clear instructions regarding the dose, but sometimes adults dose the drug incorrectly because they use a regular teaspoon

- Such spoons do not allow you to accurately measure the amount of liquid medicine, so it is better to use a special measuring spoon, and it is preferable to administer the medicine into the baby's mouth with a disposable syringe (the tip of the syringe must be removed immediately before use).

- Some medicines for children come in different forms. Adults should read the label carefully each time they bring home a new children's medicine.

Aged people

As we age, the rate and pathways by which drugs are broken down in the body changes. Changes in liver and kidney function that occur naturally with aging can affect drug conversion and elimination. Older people are more likely to experience adverse reactions or drug interactions than younger people. Prescription drug labels often indicate whether dose adjustments are necessary for older adults, but drug labels usually do not include such warnings.

Many BLPs are potentially dangerous for the elderly. The risk increases if medications are taken regularly or at the highest dose. For example, in an elderly person suffering from arthritis, the use of an analgesic or anti-inflammatory drug often leads to serious consequences. Bleeding ulcers, a life-threatening complication for older adults, can develop without warning symptoms.

Aged people

Antihistamines, especially in high doses or in combination with other medications, sometimes cause confusion or delirium in older adults.

In addition, older people are more susceptible to the possible side effects of medications that affect the digestive tract. Thus, antacids containing aluminum salts are more likely to cause constipation, and similar magnesium-based drugs are more likely to cause diarrhea and dehydration. Even taking vitamin C can cause stomach upset or diarrhea.

When visiting a doctor, older adults should disclose any dietary supplements they are taking, including vitamins and mineral supplements. This helps the physician evaluate the drug regimen as a whole and determine whether the LLP may be causing the patient's reported symptoms.

Drug interactions

Many people forget to mention the use of BLP when talking to their doctor or pharmacist.

At the same time, many drugs can interact unfavorably with a wide range of drugs.

For example, one aspirin tablet may reduce the effectiveness of enalapril .

This is also observed with the use of other angiotensin-converting enzyme (ATC) inhibitors.

Taking aspirin with the anticoagulant phenylin or neodicoumarin may increase the risk of bleeding.

People suffering from heart failure do not always know that when taking an antacid containing aluminum or magnesium salts, the absorption of digoxin is reduced.

Drug interactions

Taking a vitamin and mineral supplement may interfere with the action of some medications prescribed by your doctor.

The antibiotic tetracycline may not be effective if it is taken with medications containing calcium, magnesium, or iron.

Criteria for classifying medicines as over-the-counter products

In different countries, there are different approaches to the criteria for classifying medicines as over-the-counter drugs; The list of drugs sold without a doctor's prescription also varies.

Therefore, drugs that are classified as over-the-counter in one country may be available with a prescription in another.

World practice provides for the distribution of drugs into various categories:

For example, in the UK all drugs are divided into three categories:

- Medicines available only with a doctor's prescription;

- over-the-counter drugs permitted for sale through the general distribution network;

- over-the-counter drugs sold only through pharmacies.

In the Czech Republic, drugs are divided into:

- Medicines available only by prescription;

- prescription drugs approved for over-the-counter dispensing;

- Medicines approved for sale outside of pharmacies.

The status of a drug can be influenced by the social aspect:

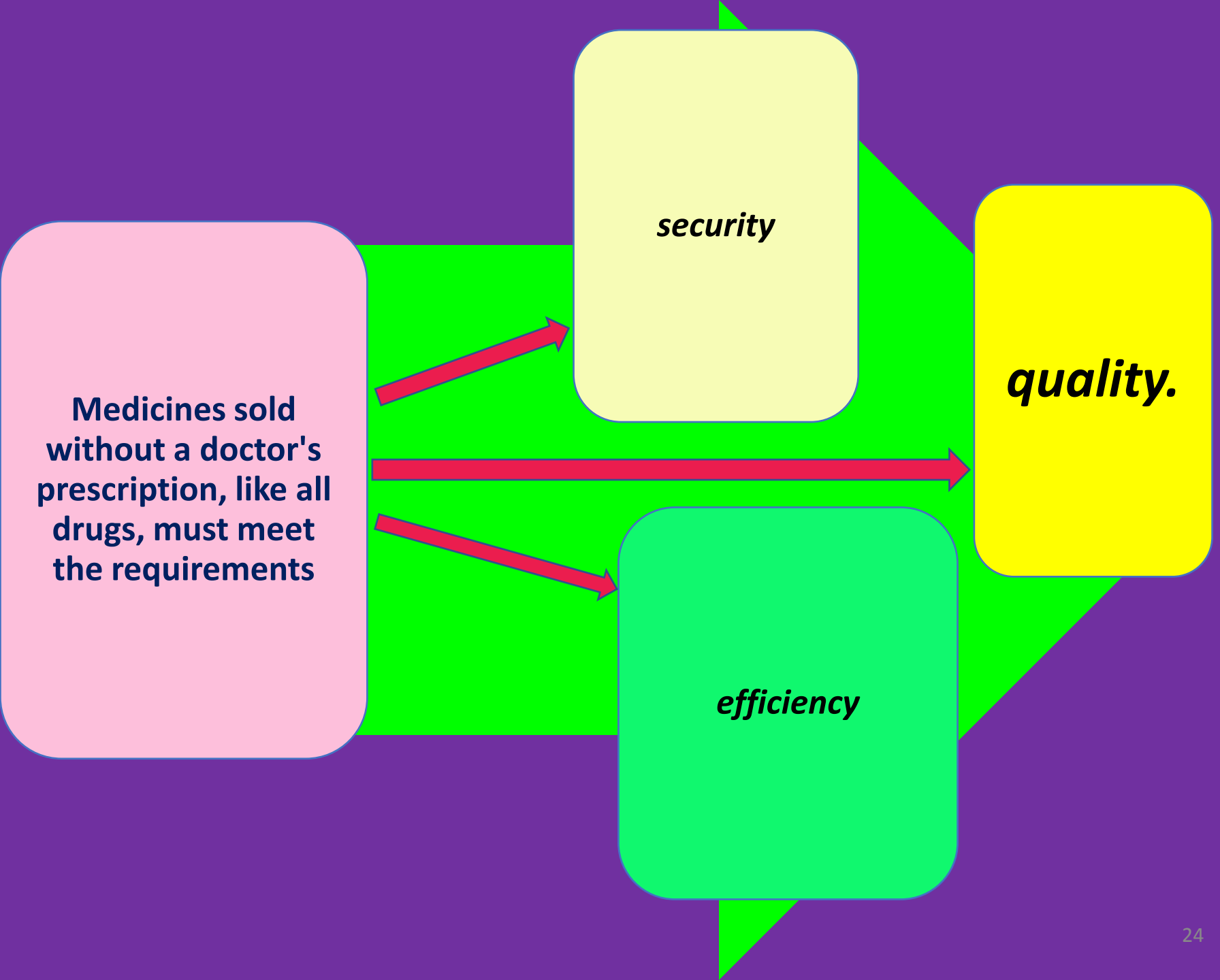
- in countries with a developed medical insurance system, **drugs, which due to their pharmacological properties can be classified as over-the-counter, often have prescription status,** since in this case the patient receives compensation from the insurance fund.

In Spain, drugs are divided into:

- Medicines available only by prescription;

- over-the-counter drugs used exclusively for self-medication; the costs of their acquisition are not reimbursed;

- over-the-counter drugs, which can be sold either with a doctor's prescription or without a prescription.


Medicines sold without a doctor's prescription, like all drugs, must meet the requirements
security
efficiency
quality.

Specific criteria for over-the-counter medicines:

The route of administration of the drug does not require the assistance of medical personnel - ***all dosage forms for injections are*** **prescription drugs.**

There are no restrictions on use for children and the elderly - ***if this medicine cannot be used by children under*** **a certain age, the list should contain appropriate instructions.**

For example, **acetylsalicylic acid - for the treatment of children under 12 years of age (Austria, Ireland), up to 3 years of age (Greece), up to 16 years of age (Spain) - with a doctor's prescription;**

Famotidine (in Ireland) - for the treatment of children over 16 years of age - available without a doctor's prescription.

The drug will not cause much harm to health if used incorrectly or in a small overdose - an **over-the-counter drug should have a wide range of therapeutic action and a wide range of therapeutic concentrations .**

Experience in using the drug (the drug has been used for a long time, in a wide group of people, the side effects of the drug have been studied) - *when determining the duration of* use of the drug, you can use the experience of its use in other countries.

Thus, in world practice, as a rule, all new drugs on the market, despite the availability of safety data, are classified as prescription drugs for the first five years.

The lack of information in the pharmacological characteristics about the cardiotoxic, hepatotoxic, nephrotoxic effects of the drug - ***if*** **these effects can occur with long-term use and in large dosages - the consumer needs to know about this.**

For example, paracetamol - with long-term use in large doses, hepatotoxic effects are possible.

Easily recognizable symptoms of the disease by the patient themselves - symptoms for which an over-the-counter drug is indicated should be able to be correctly assessed by the patient.

A simple regimen for taking the drug - *when using* an over-the-counter drug, the consumer should not have any difficulties associated with calculating the single, daily and course dose.

Difficulties may arise in calculating the dosage of a drug per 1 kg of body weight (for example, mg/kg, µg/kg) or based on the size of the body surface (per 1 m3).

Specific dosage for certain medications:

Some single drugs are sold without a doctor's prescription in a certain dosage, for example, Famotidine - 10 mg (Finland, France, Germany, Ireland, Great Britain, Poland, Russia).

As part of combination drugs - for example, codeine in certain combination drugs at a dosage of 8 mg, 10 mg (Russia), 20 mg (France, Ireland), 15 mg or 15 mg/ml in cough syrups (Netherlands), 20 mg or 1.5% (UK **) and in a certain quantity are sold without a doctor's prescription.**

A specific dosage form of a drug:

For example, Acyclovir - eye ointment, cream for external use, ointment for external use (Russia), ointment (Finland), cream (UK);

Cromoglycate – eye drops (Austria, Bulgaria, Poland), eye ointment (France), eye drops and nasal drops (Ireland, Spain) – available without a doctor’s prescription.

The number of doses when dispensing medicines *is a limitation* on the dispensing of a medicine in the number of doses so that the patient can contact a specialist in a timely manner if necessary.

Lack of information about the use of the drug for a purpose other than the indications for use *- if there is information about* the improper use of the drug, it cannot be classified as over-the-counter, as it can cause significant harm to health.

For example, Diphenhydramine (Diphenhydramine) is available without a prescription in many countries (Austria, Belgium, France, Germany, Greece, Ireland, Italy, Portugal, Spain, UK, Czech Republic, Argentina, Canada, Japan, Korea, Mexico, Singapore, USA).

- **About the Rules for determining the categories of drugs sold without a prescription and with a prescription**
- COLLEGE OF THE EURASIAN ECONOMIC COMMISSION
- SOLUTION
- dated December 29, 2015 N 178
- **About the Rules for determining the categories of drugs sold without a prescription and with a prescription**
- The rules were developed in accordance with the Agreement on uniform principles and rules for the circulation of medicines within the framework of the Eurasian Economic Union dated December 23, 2014 and determine:

the procedure and criteria for classifying a medicinal product into the category of medicines sold without a prescription (over-the-counter drugs) or medicines sold by prescription (prescription drugs);

The classification of a medicinal product as a prescription or over-the-counter medicinal product is carried out upon registration of the medicinal product.

Changing the dispensing category of a medicinal product is possible upon confirmation of registration (re-registration) and making changes that require an examination of the expected benefit versus possible risk in the registration dossier of the medicinal product.

Categories of drugs:

“medicines dispensed without a prescription” - medications that are dispensed to the patient without the patient presenting a prescription to the pharmacy employee;

“prescription drugs” - drugs that are dispensed to the patient only after the patient presents a prescription to the pharmacy employee, written in accordance with the rules established by the legislation of the Member States;

Categories of drugs:

“limited dispensing procedure” - dispensing of a medicinal product, carried out according to special requirements, only to healthcare institutions, without dispensing to patients through pharmacies;

“special prescription order of dispensing” is the dispensing of a medicinal product to a patient, carried out only after the patient presents to the pharmacy employee a prescription written out on a special form and executed in a special way in accordance with the rules established by the legislation of the Member States.

Rules for determining categories of drug supply:

When registering a medicinal product, when confirming registration (re-registration) and making changes to the registration dossier of the medicinal product (if such changes require an examination of the expected benefit compared to the possible risk), the authorized bodies must determine whether the medicinal product belongs to one of the following categories of release:

a **) prescription drugs;**

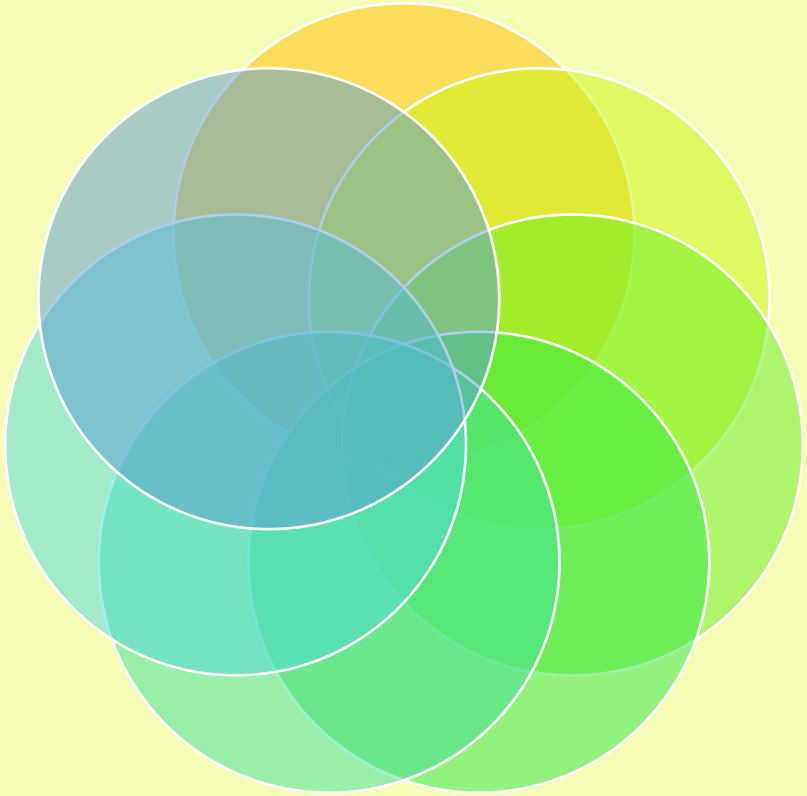
b) over-the-counter drugs.

Criteria for classifying a drug as over-the-counter or prescription

e) information about the drug available to the patient

d) the risk of incorrect use and the consequences of such use;

c) the patient's ability to perform a self-assessment of the condition;



1. Criteria for determining harm to human health caused by the use of a medicinal product

When determining harm to human health, the following criteria must be taken into account:

b) indirect harm of the drug;

a) direct harm (based on the safety profile) of the drug ;

The over-the-counter drug is characterized by:

a) low general toxicity and clinically insignificant reproductive toxicity, genotoxicity and carcinogenicity;

b) low risk of serious type A adverse reactions (reactions caused by an increase in the pharmacological effect of a drug used in therapeutic doses, which are usually dose-dependent) in the population as a whole;

c) very low risk of serious type B reactions (reactions the occurrence of which cannot be predicted on the basis of the pharmacological properties of the drug), **the absence of type C adverse reactions** (reactions that occur with prolonged use of the drug, including tolerance, development of dependence, cumulative effects, syndrome cancellation or rebound);

The over-the-counter drug is characterized by:

d) absence of type D adverse reactions (delayed adverse reactions, including carcinogenic, mutagenic, teratogenic effects);

e) low risk of serious adverse reactions (very rare in frequency: less than 0.01% or 1 adverse reaction per 10,000 medical prescriptions);

organ-damaging (cardiotoxic, hepatotoxic, nephrotoxic, hematotoxic , neurotoxic, pulmonary toxic) effects when used in accordance with UTI (LP) ;

g) the absence of drug interactions with drugs that cause serious adverse reactions and are used to treat common diseases;

The over-the-counter drug is characterized by (continued):

h) indications for use only in conditions the course, duration and control of symptoms of which, as well as the consequences of administration, the patient is able to independently assess;

i) comparable safety compared to alternative treatments.

In order to determine the absence of harm to human health caused by the use of a medicinal product , an over-the-counter drug is characterized by:

a) lack of ability to cumulate, wide therapeutic range (therapeutic breadth of the drug);

b) the presence of a short half-life (no more than 12 hours), the degree of binding to plasma proteins is less than 90% or the volume of distribution is more than 35 liters, the absence of clinically significant interactions with other drugs requiring a change in the dosage regimen of this drug or interacting with it medicines;

c) the absence of restrictions for use in children of any age, provided that the dosage form of this drug is available in dosages intended for use in children ; if a medicinal product has restrictions, its sale without a doctor's prescription is possible only if the age range is clearly indicated in the IMP (LP);

d) absence of medical contraindications during pregnancy and lactation.

Information about the medicinal product intended for the patient should be compiled taking into account the following features:

a) the method of use of an over-the-counter drug is usually different from that of prescription drugs, even if the indications or area of application are the same. At the same time, the risk that the patient will consider an over-the-counter drug safer than a prescription drug and refuse to take the latter should be minimized;

b) written information (given in the IMP (medicinal product) and labeling of the medicinal product) must:

- promote the effective and safe use of over-the-counter drugs;
- clearly explain how to correctly use an over-the-counter drug, while it must be correctly perceived by the patient and contribute to the appropriate use of the drug (which can be confirmed by the results of consumer testing of UTIs);

c) contraindications, drug interactions, precautions and warnings must be clearly stated in a language accessible to the patient and clearly presented in the IMP (LP) (in accordance with the requirements for instructions for medical use of drugs and the general characteristics of drugs for medical use, approved Commission);

d) in order to minimize risk and maximize benefit, UTI (UTI) and, if applicable, labeling should describe in detail and clearly the situations in which the use of an over-the-counter drug is unacceptable.

TRANSFER OF A PRESCRIPTION DRUG TO THE OTC CATEGORY

Despite the fact that the safety profile of a prescription drug is well studied, when transferring it to the category of an over-the-counter drug, it is necessary to reassess the benefit-risk ratio.

If a drug for a new indication or in a new dose has not been widely used and the specified reassessment of the benefit-risk ratio is difficult to perform, in some cases it is possible to extrapolate safety information from an existing prescription drug.

Such cases include:
- the drug has a small number of adverse reactions;
- lower doses of an over-the-counter drug compared to a prescription drug;
- patients who will use the over-the-counter drug are a subgroup of those patients who have already used this drug as a prescription drug.

A medicinal product containing a combination of 2 active substances, each of which was a separate over-the-counter drug, is not considered to be an original over-the-counter drug.

The determination of the categories of supply for such medicinal products must be carried out in accordance with international treaties and acts in the field of circulation of medicinal products, which constitute the law of the Union.

Other criteria for evaluating medicinal products when determining the category of release

- **Drugs for parenteral administration should be classified as prescription drugs** due to the additional risks and complexity of administration.
- According to the Rules , **medicinal products that fall under one of the prescription criteria may be prescribed without a prescription if the maximum single or daily dose, dosage, dosage form or certain types of packaging and (or) other circumstances of use allow the use of the medicinal product without medical supervision.**

In this case, the following factors should be especially analyzed:

a) packaging of the medicinal product:
the size of the secondary (consumer) packaging must be designed for the duration of use. **Limiting the dose of a medicinal product to small secondary (consumer) packaging is one of the measures in the fight against its misuse, especially overdose, as well as delays in patients seeking medical help;**
the medicinal product must be protected by primary (inner) packaging, which, as far as possible, should prevent it from falling into the hands of children;

b) regardless of the correctness or incorrectness of the use of the drug, a limitation of the maximum single or daily dose is required, which helps protect the patient from the potential dangers associated with overdose. In this case, it is necessary to confirm that the drug remains effective in low doses.

When justifying the preclinical and (or) clinical safety of an over-the-counter drug, the following requirements must be taken into account:

a) in order to confirm low overall toxicity and the absence of clinically significant reproductive toxicity, genotoxicity or carcinogenicity at appropriate exposure, appropriate references must be provided in reviews or summaries of preclinical and (or) clinical studies;

b) the experience of using the active substance in patients must be significant and described in the registration dossier of the medicinal product. **The active ingredients contained in medicinal products proposed to be transferred to the category of over-the-counter drugs must be widely used for 5 years as part of prescription drugs. Provided that the data is sufficient, this does not exclude the approval by the authorized body of the Member State of a decision to determine the category of non-prescription release** for medicinal products containing such active substances (active pharmaceutical ingredients), taking into account a shorter period of their use (for example, if the active substances (active pharmaceutical ingredients) substances) were used not only as part of a medicinal product (for example, in food products) or they are metabolites of another known active substance (active pharmaceutical substance)). Adverse reactions caused by the dosage form and (or) the route of administration and dosage of the medicinal product that meets the conditions and criteria for over-the-counter release specified in these Rules must be minor and resolve on their own, without requiring treatment, upon termination of taking the medicinal product;

c) it is necessary to analyze information on adverse reactions, including experience with the use of the medicinal product without medical supervision (for example, in other Member States or in other countries). When analyzing and interpreting data, factors such as the number of patients taking the drug, their demographic characteristics, indications for use and dosage must be taken into account;

d) the safety profile must be summarized in accordance with post-marketing surveillance reports, clinical studies and data published in the scientific medical literature concerning the safety of this medicinal product. It is necessary to analyze and explain:

- information about serious reactions of type A and B;
- how information about the use of a prescription drug can be extrapolated to individuals who will take this drug as an over-the-counter drug;

e) it is necessary to analyze potential drug interactions and their consequences, especially with commonly used drugs;

f) it is necessary to analyze cases of misuse, including cases of exceeding the recommended duration of treatment, accidental or intentional overdose and use of the drug in higher doses;

g) it is necessary to analyze the consequences of using the drug in cases of incorrect assessment by the patient of his own condition or symptoms;

h) it is necessary to analyze the consequences of incorrect or delayed diagnosis due to self-medication with a drug.

When justifying the clinical effectiveness of an over-the-counter drug, the following requirements must be taken into account:

a) if a change in the dispensing category of a medicinal product does not imply changes in the indications for use and dosage regimen, confirmation of the effectiveness of the medicinal product is not required;

b) if a change in the category of release is accompanied by a change in any data about the medicinal product (for example, indications for use, dosage regimen or dosage), the necessary documents must be submitted in accordance with the rules for registration and examination of medicinal products for medical use, approved by the Commission;

c) it is necessary to justify the selected duration of treatment for each of the proposed indications and provide justification, including justification for the proposed package size.

When changing the category of release, the following requirements for information about the medicinal product given in its IMP (LV) and labeling should be taken into account:

a) the submitted labeling and UTI of an over-the-counter drug are subject to examination to assess the completeness of the information and its ability to protect the patient from threats to his health associated with the use of this over-the-counter drug;

b) the IMP (LP) must contain complete information about the correct use of the drug and the circumstances under which it is necessary to seek medical help;

c) on the secondary (consumer) packaging of over-the-counter drugs, and in its absence, on the primary (internal) packaging, recommendations for the use of the over-the-counter drug must be provided;

d) if necessary, contraindications and precautions are indicated, including information about restrictions on the duration of use or the need to consult a doctor under certain circumstances;

e) information about the over-the-counter drug in its labeling and UTI (medicinal product) must be readable (in accordance with the requirements for instructions for medical use of drugs and the general characteristics of drugs for medical use, approved by the Commission).

Prescription of OTC drugs

OTC drugs are a means of symptomatic treatment, since they do not affect the cause and mechanism of development of the disease.

All of them are designed to be taken for a short period of time and are not intended for long-term treatment.

Over-the-counter drugs are used mainly for the treatment of non-severe, easily amenable to drug correction

conditions that do not require medical intervention

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Prescription of OTC drugs

The main purpose of their use:

· **quickly and effectively relieve symptoms of diseases that do not require medical advice** ;

· **in conditions of financial and personnel difficulties in the public health sector, enable the patient to independently relieve minor symptoms when feeling unwell** , which will lead to a reduction in the burden on medical services;

· increase the availability of medical care to the population living in remote regions where obtaining qualified medical advice is difficult.

Prescription of OTC drugs

There are more than 10 common conditions that can be treated with over-the-counter medications:

- headache, cold (cough, rhinitis, sore throat, fever),

- gastrointestinal disorders (heartburn, constipation or diarrhea),

- disorders of the central nervous system (increased anxiety, emotional lability,

- insomnia, increased fatigue), acne,

- muscle and joint pain,

- cuts and abrasions.

From an economic point of view, expanding the range of OTC drugs has definite benefits .

In the 1980s, large pharmaceutical companies showed little interest in producing and selling OTC drugs because the profitability of OTC drugs was lower than the profitability of brand-name prescription drugs.

However, in the 90s, the situation changed, and large pharmaceutical companies **began to pay increasing attention to the over-the-counter drug market.**

Reforms of health systems in the developed world have caused an increase in the consumption of over-the-counter drugs, which is associated with the encouragement of consumers by governments in these countries to take much greater responsibility for their health.

Increasing the possibility of transferring prescription drugs to the over-the-counter category.

· The assumption that governments will not heavily regulate the prices of over-the-counter drugs because their costs are generally not reimbursed by social security systems.

· Declining profitability of original drugs in the early 90s.

· Possibility of extending the life cycle of a medicinal product after the expiration of patent protection.

· Possibility of creating brands in the over-the-counter drug market.

A study of the age of brands and trademarks of over-the-counter drugs showed that 70% of brands are more than 10 years old, 35% of brands are more than 20 years old.

Successful OTC drug brands can be 50 years or more old.

An example is the drug “Aspirin” from the Bayer company, the age of the trademark is more than 100 years, the drug “Panadol” from the company “ GlaxoSmithKline ”, the age of the trademark is about 50 years.

When converting a prescription drug into an over-the-counter (OTC) category, the pharmaceutical company faces the question: how will this affect its "market fate"?

For a company that has been promoting prescription drugs, it may not be so **easy to shift its marketing strategy from promoting prescription drugs to physicians to promoting over-the-counter drugs directly to consumers.**

In addition, transferring to the over-the-counter category may even reduce sales volumes at first. This phenomenon is not due to a decrease in consumer demand for the drug, but most likely due to the fact that the drug was previously prescribed by doctors as an additional drug.

After the drug is transferred to the over-the-counter category, prescriptions are no longer written for it, as a result of which consumption is reduced. Sometimes the reduction in sales volume after transferring a drug to the over-the-counter category can range from 20 to 40%.

Definition of the concept of responsible self-medication:

The term “responsible self-medication” means the translation into Russian of the English “ self-care ”, which can be interpreted as “self-help” and “ self-care” .

The concept of responsible self-medication is to create conditions and prerequisites for the formation of a responsible attitude among the population towards their health, the health of children and loved ones through maintaining a healthy lifestyle, wider and more competent use of over-the-counter medicines for the purpose of prevention or self-treatment of minor ailments and chronic non-communicable diseases while continuing therapy prescribed by a doctor

A WHO working group in 2013 proposed the following definition of responsible self-care: "Responsible self-care is the ability of individuals, families and communities to maintain health, prevent disease, maintain health and cope with illness and disability with or without the support of a health professional."

Responsible self-medication does not mean the absence of any medical care, and does not imply that people are forced to take care of themselves. The overarching goal of responsible self-care is to free people from unnecessary dependence on overburdened doctors and health services, where possible, and to enable people with adequate knowledge and responsibility to take charge of their own health.

According to World Self-Medication The Industry defines responsible self-medication as a list of provisions that includes:

- Components of a healthy lifestyle, such as physical activity and a healthy diet, to maintain good health;

- Effective use of drug therapy and medical technologies;

- Self-diagnosis, including assessment of risk, symptoms based on available medical information and the ability to self-medicate, and, when possible, maintaining health through the responsible use of BLS;

- Self-medication through responsible use of BDS for treatment and self-monitoring by monitoring the severity of signs and symptoms that characterize changes in health status;

- Access to tools for responsible self-care, including EBP, improved health literacy, healthier diets and health outcomes, increased physical activity, and prevention and management of chronic diseases.

The strategic plan for the development of responsible self-medication around the world includes:

- Creating a universal definition and framework for responsible self-medication to drive research and transform the healthcare system;

- Helping the population in responsible self-medication by increasing medical literacy through the use of modern, including digital technologies;

- Integrating responsible self-medication into health policy through investment in prevention;

- Creating opportunities to gain knowledge and exercise the right to responsible self-medication;

- Encouraging healthcare professionals to support and ensure greater access and quality of responsible self-medication;

- Creation of databases and statistical information on the effectiveness of responsible self-medication;

- Create stronger public-private partnership enterprises and develop large-scale stakeholder collaboration to promote responsible self-medication practices.

Basic principles for practicing responsible self-medication

In an initiative supported by the European Union, the Standing Committee of European Physicians (CPME), in collaboration with the European Union of Medical Specialists (UEMS), the European Union of General Practitioners (UEMO) and the European Association for Responsible Self-Medication (AESGP), outlined

Basic principles for practicing responsible self-medication:

- **Responsible self-medication is the use of BLS by patients for symptomatic treatment and treatment of lungs and a number of stable chronic diseases.**
- **The patient bears full responsibility for self-medication, so it is important to carefully study the instructions for the purchased over-the-counter drug.**

Physicians and pharmacists play an important role in providing patients with information about responsible self-medication, providing assistance and advice on the rational use of medicinal products. Drug manufacturers are the providers of basic drug information, which is contained in the instructions for use .

The period for self-medication may vary depending on the circumstances, but usually should not exceed 3-7 days.

All medicinal products must be made to the same standards of safety, quality and effectiveness as prescription drugs.

Particular attention should be paid to women during pregnancy or breastfeeding, as well as when young children and infants are ill.

Nosologies and symptoms included in the concept of responsible self-medication

Based on international and domestic experience, as an example, some conditions are given in which responsible self-medication can be carried out, provided that the instructions for the use of drugs are correctly followed:

- Symptomatic treatment of colds (chills, headache and muscle pain, runny nose, sore throat, etc.).
- Treatment of allergic manifestations (allergic rhinitis, urticaria, etc.).
- Symptomatic treatment of dermatological diseases (eczema, dermatitis, etc.), treatment and treatment of small wounds and skin lesions (for example, cracked nipples during breastfeeding, trophic leg ulcers, bedsores).

Symptomatic treatment of mild functional disorders of the gastrointestinal tract (heartburn , flatulence , cramps and discomfort in the abdomen, a feeling of early satiety, etc.).

Symptomatic treatment of mild to moderate pain, incl. joint pain.

Treatment of febrile conditions associated with colds and flu.

Treatment and prevention of vitamin and mineral deficiency conditions, incl. prevention of neural tube defects in the fetus due to folate intake at the preconception stage .

Treatment of established chronic diseases prescribed by a doctor using both over-the-counter and prescription drugs (for example, in cardiology - taking antihypertensive, lipid-lowering, antianginal drugs , disaggregants , anticoagulants, diuretics, in pulmonology - taking anti-asthmatic drugs, in endocrinology - oral hypoglycemic drugs for diabetes mellitus).

The role of the pharmaceutical worker (pharmacist) as the primary link in the healthcare system

The professional standard “Pharmacist”, approved by Order of the Ministry of Labor dated March 6, 2016 No. 91n, **provides for the function of a pharmacist to inform the population about medicines and other pharmaceutical products. According to it, the pharmacist is obliged to provide advisory assistance to the population on the rules for taking and dosing of medications, and their storage at home; provide information and consulting assistance when choosing a BLS; provide advice on the use and compatibility of drugs, their interactions, including with food. In addition, the pharmacist must be able to recognize conditions and complaints that require consultation with a physician.**

The main functions of pharmaceutical workers are determined by order of the Ministry of Health of the Russian Federation dated August 31, 2016 No. 647n “On approval of the Rules for Good Pharmacy Practice of Medicines for Medical Use.” They include, in addition to the sale of pharmaceutical products of appropriate quality, the provision of reliable information about pharmaceutical products, pharmaceutical consulting, as well as “information about the rational use of medications for the purpose of responsible self-medication.”

Pharmaceutical guardianship involves the pharmacist accepting responsibility to a specific patient for the result of drug treatment.

Pharmaceutical care is a comprehensive program of interaction between the pharmacist and the patient during the entire period of drug therapy, starting from the moment the drug is dispensed until the end of its effect.

Today, the role of the pharmacist is being transformed, he should not worry about increasing the number of drugs (there are more than 350,000 of them on the global pharmaceutical market), he should not only dispense the drug, the main goal of his professional activity is increasing the effectiveness and safety of drug therapy for a particular patient .

In the Russian Federation, in connection with the introduction of the Federal State Educational Standard for Higher Education in the specialty 33.05.01 “Pharmacy”, the professional competencies of graduates include the ability to provide advisory assistance to medical workers and consumers of medicinal products in accordance with the instructions for use.

In addition, one of the basic skills demonstrated by a specialist during accreditation is professional pharmaceutical counseling of patients.

The market for over-the-counter drugs in Russia is constantly growing. This can be attributed to the following factors:

· popularity of self-medication among the population,

reluctance (or lack of time) to visit a doctor,

· massive advertising of over-the-counter products,

· increase in the number of pharmacies,

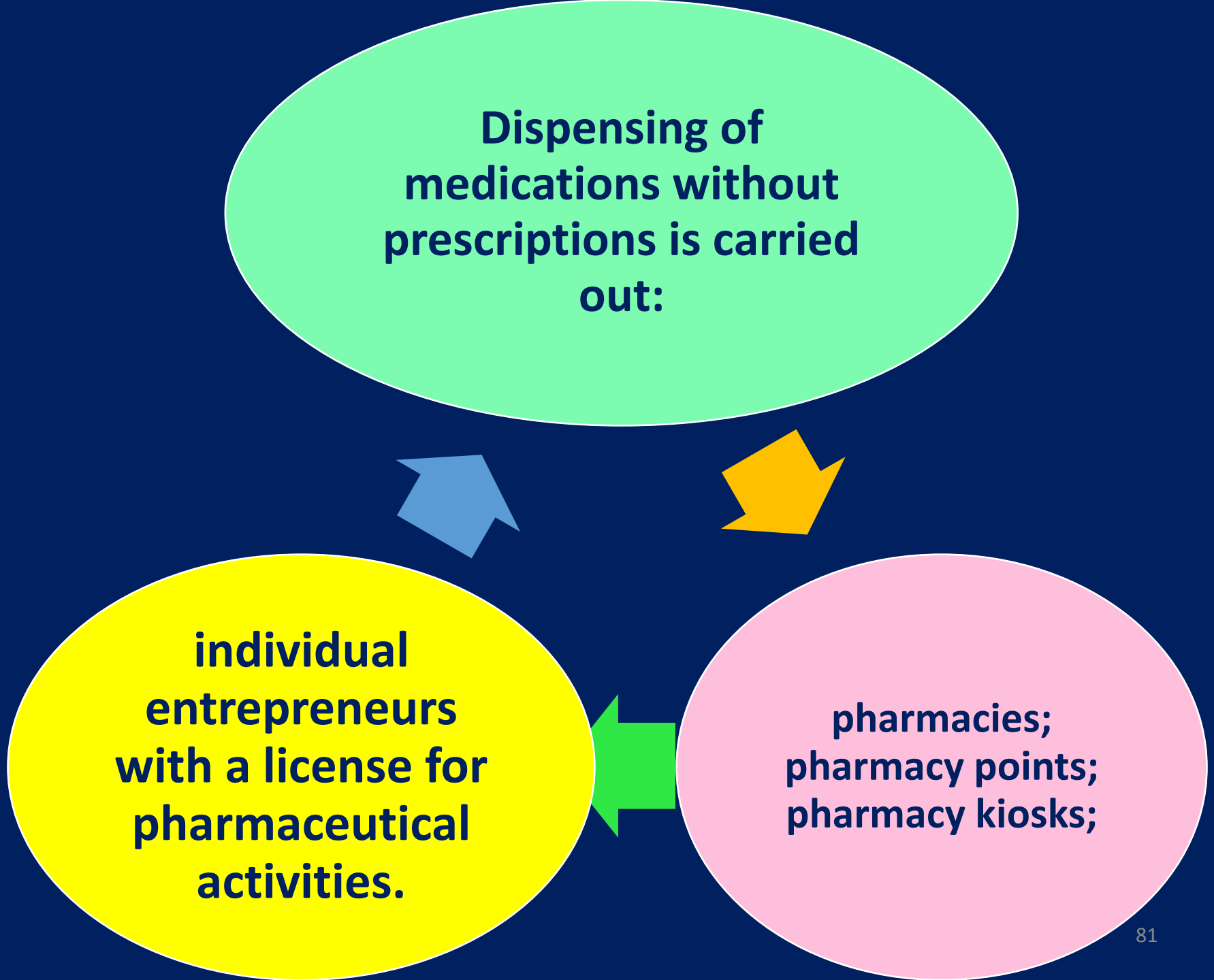
· improving the range and service in pharmacies and pharmacy chains.

In addition, in recent years, services such as ordering medications by phone, via the Internet, and delivering medications to your home and work have appeared.

These factors are driving the growth of the OTC drug market

Russian manufacturers of over-the-counter drugs are significantly inferior to their foreign competitors in terms of such an indicator as the share of the enterprise's products in the total volume of the Russian over-the-counter drug market.

In general, over-the-counter domestic drugs occupy only about 20% of the Russian market. At the same time, the majority of Russian over-the-counter drugs are inferior in quality to their foreign analogues, primarily in terms of the convenience of release form and packaging. Thus, over-the-counter drugs are mainly imported into Russia.


Dispensing of medications without prescriptions is carried out:
pharmacies; pharmacy points; pharmacy kiosks;
individual entrepreneurs with a license for pharmaceutical activities.

PROMOTION OF PRESCRIPTION AND OTC DRUGS IN THE PHARMACEUTICAL MARKET

According to the World Health Organization, **promotion from the point of view of the pharmaceutical industry is a complex of all information and promotional actions carried out by manufacturers and distributors, the effect of which is aimed at stimulating the prescription, supply, purchase and/or use of medicines.**

There is a huge variety of classifications and technologies for promoting goods on the market.

Taking into account the industry and social specifics, the convergence of biomedical, pharmaceutical, pharmacoeconomic and subject-legal characteristics of a pharmaceutical product, **two main macro-models for its promotion can be identified** .

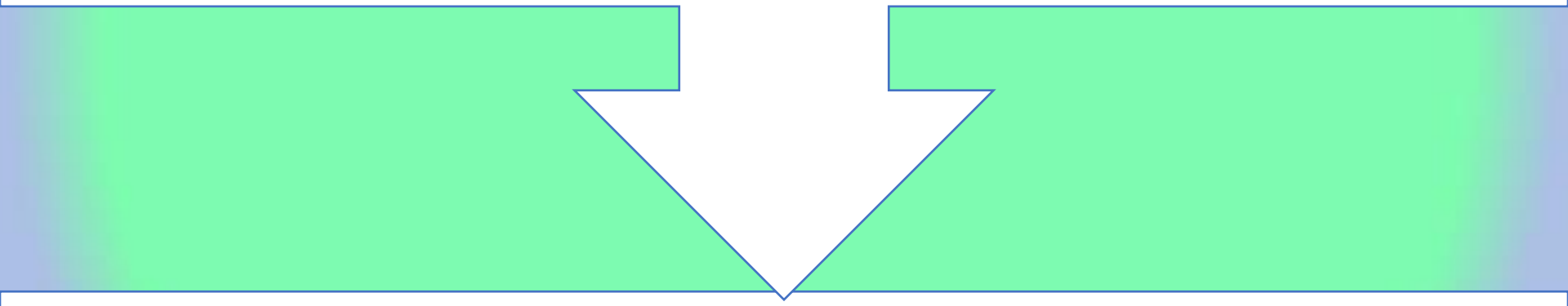
The essence **of the first model** is **to form a vector of promotional efforts in relation to innovative proprietary products, that is, patented medicines that have no analogues.**

The features of this model lie in its complexity **, the use of a complex of various tools** , which has an imperative **to influence the professional environment (doctors and opinion leaders) and / or end consumers (patients)** depending **on the relationship of the product to the Rx - (prescription drugs) or OTC group (over-the-counter medications).**

In this case, the promotion process begins at the stages preceding the launch (primary commercialization).

The promotion of such a product is carried out with the imperative of giving it the status of a new one and allowing it to solve previously insoluble health problems or carry out the necessary already known therapeutic measures with greater efficiency.

The implementation of this model **becomes more complicated once competitors obtain the rights to genericize** (copying the original pharmaceutical product). At this stage, the supporting marketing efforts of the originator company against the backdrop of growing competitive pressure from generic companies using aggressive strategies for increasing market share are becoming insufficient, forcing it to use defensive strategies. The level of effectiveness of this promotion model **is determined by the pharmacoeconomic characteristics of the drug, as well as the degree of risks of its use.**



The main **problem of this model is the steady annual increase in costs for the implementation of promotion strategies, which causes an increase in prices for pharmaceutical products and corresponding resistance from the financial authorities of states due to the increase in the budgets of national drug supply programs.**

The second model, as an antipode to the first, is based on genericization , which consists of registering a copy of the original pharmaceutical product and bringing it to the market.

In this case, promotion can be carried out under a different trade name or under an International Nonproprietary Name (INN).

Promotional efforts within the framework of this model are subordinated to the main task formulated by one of the marketing “gurus” J. Trout - “differentiate or die.”

At the same time, **one of the main problems is the choice of an effective method of communication with the target audience** (pharmacists and doctors in the case of Rx -products and end consumers - for OTC-products) **to create some image of a product that has advantageous distinctive properties in the possible complete absence of such.** First of all, this applies to medicines with a short period of time from the end of patent protection. As a rule, active and high-cost promotional actions are not taken for generics with INNs.

Many pharmaceutical companies have been using **the second model for decades, which, in the context of a general increase in demand for medicines, allowed them to receive a margin that was significantly lower compared to the original companies implementing the first model, but practically risk-free, since during the pre-generization period the pharmaceutical product underwent clinical testing and became sufficiently known in professional circles.**

Currently, there is **a reduction in the number of distributors and a transition to greater concentration of participants in the pharmaceutical market.** **The increase in the number of pharmacies and pharmacy chains occurs with a simultaneous increase in the level of concentration of retail market participants**

The number of pharmacies in a pharmacy chain and their regional presence indicate a **high level of competition among large and medium-sized chains of pharmacy organizations.**

In Russia, **the level of current competition** in the pharmaceutical market **is assessed for large chains as high.**

is expected **to increase over the coming years and the main drivers of competition will be aggressive pricing policies and high concentration of pharmacy chains** , expansion of local players and the development of new formats of pharmacies - discounters and supermarkets

Promotion of products in the pharmaceutical market is based on **three key strategies:**

- Retention of regular customers.

-Attracting new

- Replacement of drugs from competing companies with promoted products.

These strategies work equally well when promoting prescription drugs and those sold without a doctor's prescription.

Promoting prescription drugs using three key strategies is a little easier, experts say. To retain the existing audience and gain new clients, it is necessary to regularly work with medical personnel. The attending physician must be convinced that the demand for pharmacy products depends on his appointments.

Additionally, we work with pharmaceutical workers who should be interested in promoting over-the-counter drugs.

Promotion as an element of the marketing mix at the present stage of market development is in constant motion, like the entire marketing complex, and is undergoing significant changes due to the expansion of factors influencing marketing.

Over the past decades, to adapt the classic marketing mix to the service sector (which includes retail trade in medicines and pharmaceutical products), three “Rs for services” have been added:

Participants (Participants) who provide the service;

physical attributes (Physical evidence) – the environment of existence of a service organization, physical goods, symbols used in the process of communication and production;

process (Process) – procedures and mechanisms of activity and interaction during which the service is provided.

Later F. Kotler added two more “Rs” - political power **(Political power) and the formation of public opinion (Public opinion formation) – and suggested calling it megamarketing**

The current stage of development of pharmaceutical marketing is characterized by:

- transition of marketing from the "4P" concept to the "7P" concept - megamarketing – and a significant expansion of factors influencing all elements of the marketing mix, including promotion;

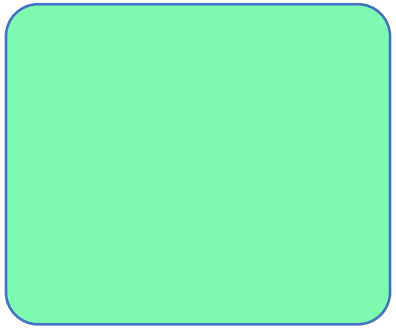
- **the increasing role of drug promotion in the marketing mix due to the peculiarities of the modern pharmaceutical market** (dominance of the share of sales of over-the-counter drugs, parapharmaceutical products in the structure of turnover of pharmacy organizations);

- development of information and digital technologies in the retail trade of medicines based on digital technologies ;

- the emergence of a new target audience when promoting drugs - regional and federal pharmacy chains .

Methods for promoting pharmaceutical products on the market have some features that are associated, first of all, with the specifics of the drug:

- unlike many other possible goods and services, drugs can seriously affect human health and life, which has caused ethical and legal restrictions on their promotion;



- the target audience for drug promotion is retail chains and consumers for over-the-counter drugs, as well as medical specialists for prescription drugs.

At the same time, promotion methods differ.

Features of drug promotion in Russia are determined by the characteristics of Russian consumers :

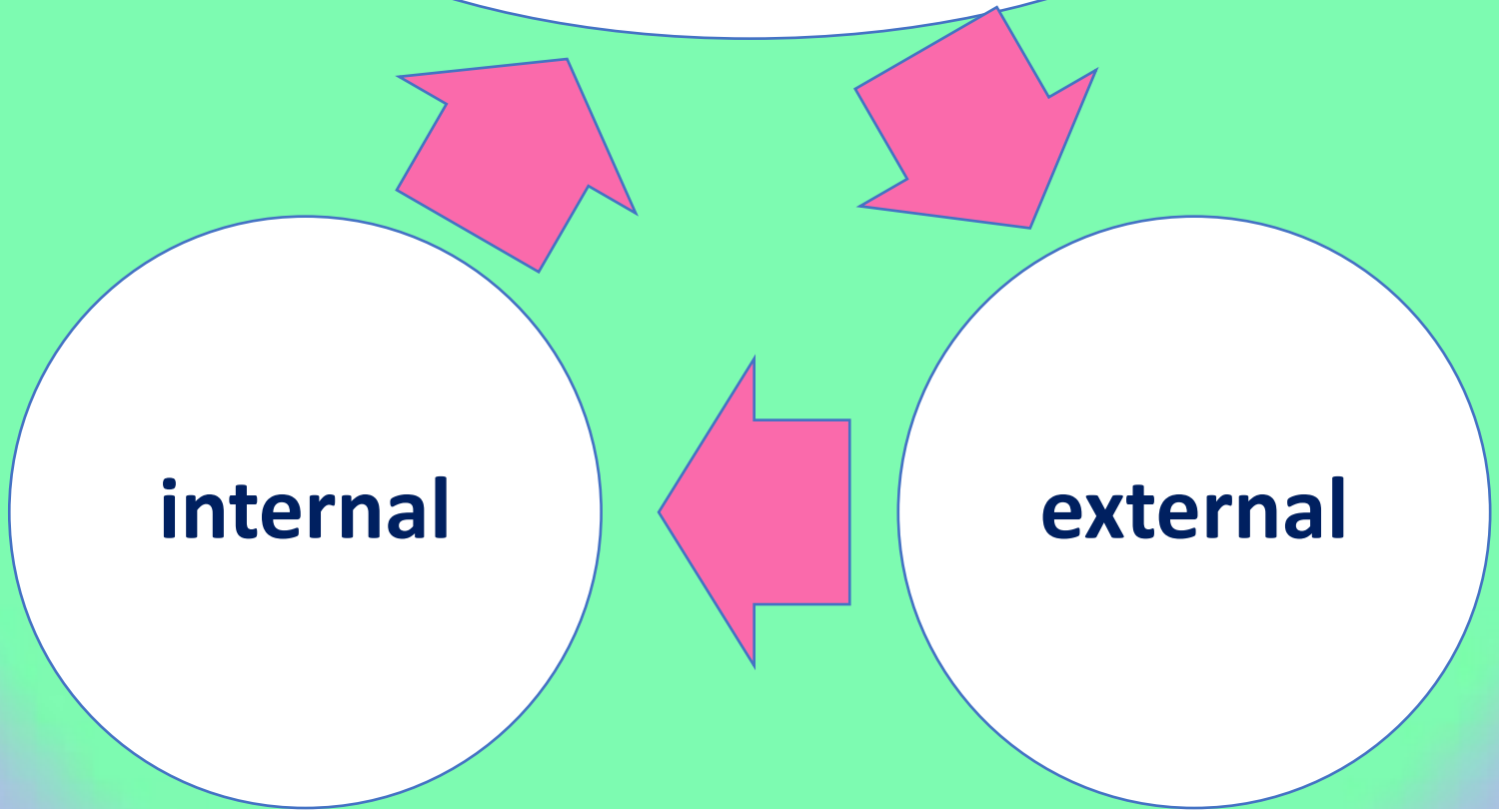
– **the effectiveness of a drug as the main reason for its choice in Russia** , and not the quality of life (USA and Europe);

– ease of use (form of release, number of doses per day, taste, etc.);

– **increased focus on the appearance of the drug** , and not on the convenience of the form of application;

– **theoretical unpreparedness of the Russian consumer due to the lack of educational campaigns** that increase knowledge about the causes and consequences of diseases, which is an obstacle to the promotion of drugs and requires long-term preparation of the population and formulation of the problem.

Two groups of factors influencing the effectiveness of drug promotion methods:



The first group – external factors – includes the following:

1. Characteristics of the target market and features of legal regulation of drug promotion on the Russian pharmaceutical market.

2 . Specifics of the regional pharmaceutical market and specifics of the target audience.

3. The consumer is at a certain stage of readiness to buy the product.

4. Ethics of relationships between subjects of the pharmaceutical market.

5. Government regulation of advertising, ethical codes and legal requirements.

6. Influence of reference groups - doctors, pharmacists, acquaintances.

7. Stage of life-cycle management (organization).

8. The health status of patients, their lifestyle, morbidity structure .

9. Quality of promotional and information materials and training of medical representatives.

10. Confirmation of the effectiveness of the drug by clinical studies, the level of awareness of doctors and patients about the possibility of solving a clinical problem by prescribing drug treatment, the image of the manufacturing company, the availability of free samples of the new drug.

11. Location of the pharmacy organization.

12. The influence of market conditions, the actions of competitors, changes in consumer behavior, etc.

13. Materials and methods of stimulating the retail network.

14. The effects of significant consumer concern about their health, sensitivity to information about the side effects or benefits of drugs.

16. Sociocultural factors. 15. Gender differences in consumers.

Internal factors influencing the choice of drug promotion methods:

Internal factors influencing the choice of drug promotion methods:

5. Assortment structure (presence in the assortment of over-the-counter and prescription drugs, established drugs, promoted drugs, original drugs, domestic and imported drugs).

6. The age of the company is over 40 years; origin of the company; nature of activity (production or sale of drugs).

7. The presence in the structure of specialized departments involved in promotion.

Legal relations in the field of promotion of medicines

In Russia, legal relations in the field of drug promotion are regulated by different government structures:

– The Government of the Russian Federation, federal executive authorities – Ministries.

According to Article 74 of the Federal Law “On the Fundamentals of Protecting the Health of Citizens in the Russian Federation” dated November 21, 2011 No. 323-FZ, **healthcare professionals cannot accept gifts or money from companies and their representatives, and companies should not give or pay them.**

They do not have the right to pay for entertainment, recreation, travel to a place of recreation, or to participate in entertainment events conducted at their expense, and doctors and pharmaceutical workers should not participate in them.

A physician must refrain from any form of advertising related to his professional activities.

The Federal Law “On the Circulation of Medicines” dated April 12, 2010 No. 61-FZ defines the requirements for organizing and **conducting events that medical representatives have the right to attend under certain conditions. The restrictions imposed on organizers include the prohibition of preventing competing companies from participating in their events or creating discriminatory conditions for some participants compared to others.**

Advertising is information disseminated in any way, in any form and using any means, addressed to an indefinite circle of people and aimed at attracting attention to the object of advertising, generating or maintaining interest in it and promoting it on the market.

Advertising functions:

- **economic** (at the enterprise level it is manifested by an increase in product sales and/or profits).

- **marketing** (impact on the target market through each element of marketing);

- communicative (is one of the forms of mass communications);

Advertising of medicines is regulated by the Federal Law “On Advertising” dated March 13, 2006 No. 38-FZ, according to which

Article 24. Advertising of medicines, medical products and medical services, methods of prevention, diagnosis, treatment and medical rehabilitation, methods of traditional medicine

1. Advertising of medicines should not:

1) contact minors;

2) contain references to specific cases of cure for diseases, improvement of human health as a result of the use of the object of advertising;

3) contain an expression of gratitude by individuals in connection with the use of the advertised item;

4) create an idea of the advantages of the advertised object by referring to the fact of conducting research required for state registration of the advertised object;

5) contain statements or assumptions about the presence of advertising consumers of certain diseases or health disorders;

6) help create an impression in a healthy person about the need to use the object of advertising;

7) create the impression that it is unnecessary to see a doctor;

8) guarantee the positive effect of the advertised object, its safety, effectiveness and absence of side effects;

9) present the object of advertising as a biologically active additive, food additive or other product that is not a medicinal product;

10) contain statements that the safety and (or) effectiveness of the advertised object are guaranteed by its natural origin.

etc.

One of the methods of the classic promotion process is **informing about a new drug.**

Information is provided **through various types of scientific research, educational conferences and seminars.** In this case, **various forms and methods of convincing the target audience are used** , for example, coverage of the results of clinical studies, practical experience in using these products, comparative analysis with competing products, PMS (post marketing studies), etc.

For many years, one of the key promotion tools for pharmaceutical companies was **working with doctors through medical representatives**

In Russia, employers traditionally prefer to hire **people with medical or pharmaceutical education and aged 25 to 35 years as medical representatives.**

Personal qualities: resilience, teamwork, result orientation, creative thinking, customer focus, communication skills.

Specific requirements of employers for future representatives : driver's license and driving experience, presence of a certain specialization (residency) and experience in promoting medicinal categories Rx (prescription drugs) and OTC (over-the-counter drugs)

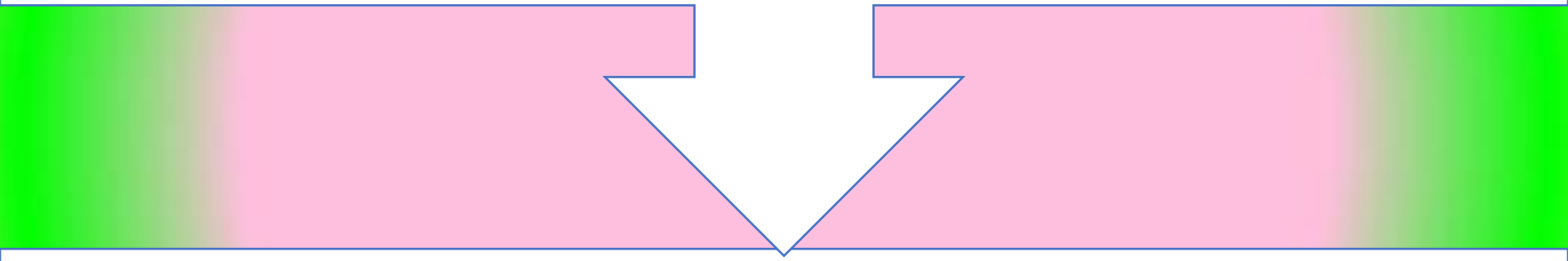
Medical representative

The position of a medical representative is not included in the list of medical and pharmaceutical positions.

Therefore, the activities of medical representatives in the Russian Federation when promoting medicines are not regulated.

At the same time, Article 74 of Federal Law No. 323-FZ “On the fundamentals of protecting the health of citizens in the Russian Federation” came into force (since January 1, 2012), as well as Chapter 14.1 “Restrictions imposed on organizations engaged in the circulation of medicines” , introduced by Federal Law No. 317 of November 25, 2013.

From now on, medical representatives when promoting drugs are prohibited from giving gifts to doctors, transferring money to the heads of medical organizations and other medical workers, paying for entertainment, leisure, recreation of doctors, providing samples of drugs for transfer to patients, as well as entering into agreements on the recommendation and prescription of any drugs.



Limiting the activities of medical representatives leads to a reorientation of promotional efforts in communications with doctors in the digital direction resources . Pharmaceutical companies, trying to compensate for the decrease in the volume of personal contacts of representatives with the target audience, are transferring communication on professional topics to the Internet.

It is customary to distinguish four areas as the main elements of “promotion”:

– **Various forms of advertising (advertising);**

– **Sales intensification, or sales promotion methods** (competitions, lotteries, discounts, etc.) **-** (sales promotion);

– Public **relations** _ relations);

– **Personal sales** (personal selling).

Some researchers also identify synthetic **elements of marketing communications, among which branding, packaging, and corporate identity should be mentioned.**

The consumer of pharmaceutical products is in dire need of information, therefore the pharmaceutical market is one of the most advertising and PR-intensive industries .

The pharmaceutical business actively uses **specialized forms of PR to promote drugs** :

a) sponsorship by the pharmaceutical industry of postgraduate medical and pharmaceutical education ;

b) financing of key “opinion leaders” (chief specialists) among doctors;

c) writing journal articles without indicating true authorship (shadow authorship, Ghost-writing);

d) financing the development of diagnostic and treatment standards;

e) campaigns aimed at the general public, including “disease-oriented” image advertising;

f) financing of groups (schools) of patients and medical societies;

g) research affecting the sales market.

Existing legislative differences in the procedure for dispensing drugs affect the structure of promotion methods.

The promotion of prescription drugs has its limitations due to the fact that it is addressed only to medical and pharmaceutical workers and is prohibited for the end consumer.

This circumstance requires manufacturers to use **special promotion methods** :

– distribution of information materials among doctors with the help of medical representatives;

– publication of clinical trial results in specialized press;

– organization of educational seminars and presentations of drugs at medical conferences;

– the work of leading medical specialists in specific areas.

For prescription drugs, the role of healthcare system personnel (doctors, pharmaceutical workers, other medical personnel) has sharply increased (Participants).

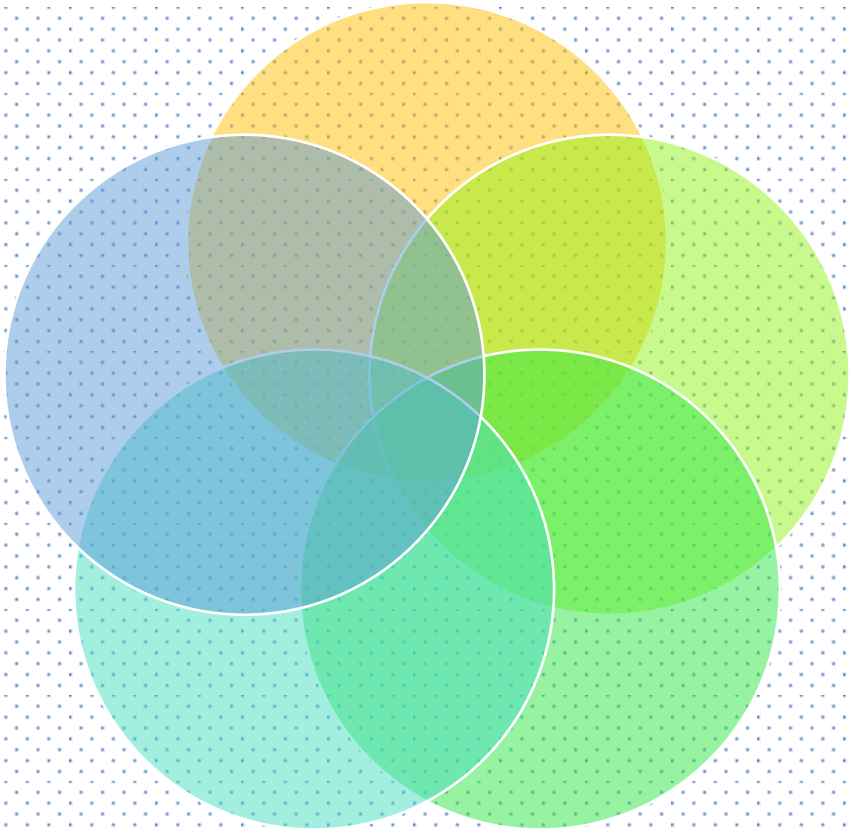
In some cases, close interaction with healthcare system personnel leads to a sharp increase in the efficiency of promotion of prescription drugs. This is reflected in the structure of the methods used to promote prescription drugs.

Today, not a single more or less large company can do **without serious investments in marketing communications.** To achieve market goals and spend budget effectively, marketing communications must first of all have a clearly formulated strategy and be integrated.

Determining a marketing budget is one of the most difficult and responsible tasks.

The most common methods for determining the promotion budget include the following methods:

goals and objectives method



assessment of opportunities

competitive matching method

fixation as a percentage of sales volumes

The shift in emphasis in promotion to the information interaction of all **promotion participants led to the emergence of the concept of "integrated marketing communications,"** which was based on an integrated approach to marketing communications.

There has been an increase in the activity **of personal e-mail invitations to visit the Internet resources** of a pharmaceutical company as an alternative to the more expensive direct communication **of medical representatives with the medical audience.**

Currently, there is **an intensive growth in the number of resources positioned by the organizers as exclusively professional Internet portals and social networks for practicing doctors** (In Russia - “Doctors of the Russian Federation”, “Doctor at Work”, “Eureka”; in the UK - Doctors.net. uk; Sermo.com - USA, etc.)

One of **the advantages of digital communication channels is the ability to establish feedback with consumers** , which, through monitoring and analysis of relevant information, helps improve the characteristics of products and services.

Also, **to solve the problem associated with legislative restrictions on the interaction of medical representatives** of companies and doctors, **its optimization is used using e- detailing on a tablet.**

The essence of the solution is as follows: **a medical representative working with e- detailing quickly finds and demonstrates to the doctor the necessary facts on the topic of the current visit, and can also transmit feedback from the doctor.** Since the content on the medical representative's tablet is synchronized with the main information storage (in the cloud), updates occur as often as necessary.

Automatic report generation and the ability to monitor the location of medical representatives using GPS allow you to determine the effectiveness of their work almost online and, accordingly, adjust plans.

In this case, the following options are possible: **virtual details , which are information programs on the Internet or on CD without accompaniment by a medical representative , as well as video details - virtual sales presentations with comments from a medical representative .**

A promising, but so far little used modification of this solution is teledetailing , which is the simultaneous viewing of information by a doctor and a medical representative during a telephone conversation.

Digital services as a bonus are a tool for increasing consumer loyalty to the company and its positioning among competitors. In this regard, some companies are creating mobile applications that range from applications that provide information about pharmaceutical products to applications that turn a smartphone into a mobile device for medical diagnostics.

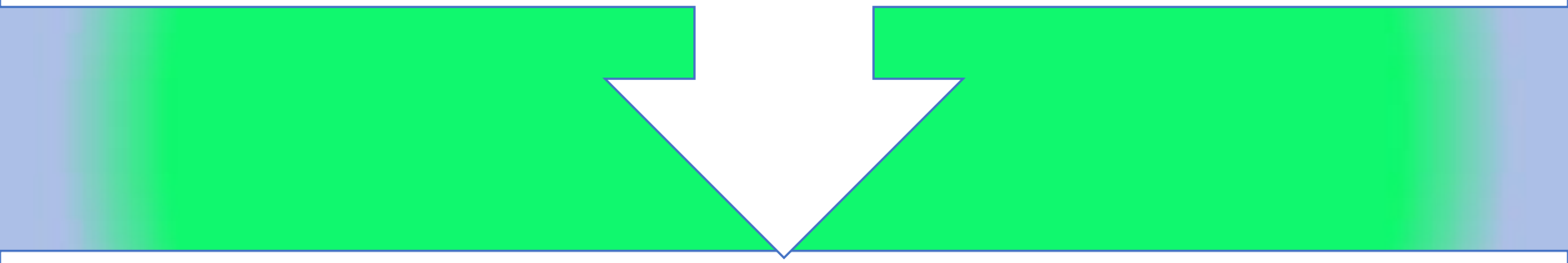
By adding special sensors to a smartphone, it transforms into a diagnostic device. The collected data is analyzed by a special application. Using a smartphone as a device that collects and processes clinical data makes this procedure more accessible and less complex.

Media campaigns used to promote prescription drugs are usually based on the involvement of famous doctors, pharmaceutical workers, medical and pharmaceutical officials, interviews with whom have a significant effect in attracting attention to the promoted drug.

Hotlines as a tool for promoting Rx -drugs provide the need for a specific consumer to consult a doctor without leaving home.

The creation of **non-profit organizations** (foundations, societies for the support and protection of patients, associations aimed at educational and propaganda work through **press conferences, seminars, meetings with opinion leaders** allows us to support existing and potential consumers and promote prescription drugs.

A modern trend in pharmaceutical marketing for over-the-counter drugs is the use of modern information technologies, in particular the Internet . Pharmaceutical companies began to actively use the Internet for promotion: contextual advertising, drug promotion on forums, media advertising.



At the moment, the Internet remains only an additional promotion tool, but after changes in the legislative framework, the Internet may become the necessary tool with which pharmaceutical companies will be able to interact with the target audience without breaking the law.

The development of marketing communications has led to the emergence of new promotion methods, which, along with classical methods, are used in the pharmaceutical market.

carrying out special promotions for pharmacies and distributors, etc.

Classic methods of drug promotion include:

personal sales through medical representatives – FFR (Field Force Resources),

advertising in the media and professional periodicals,

New methods include digital methods of drug promotion - **Digital marketing,** which includes:

Social media marketing (SMM) is the process of attracting attention to a drug through social platforms. This is a set of activities for using social media as promotion channels. Used for OTC drugs, dietary supplements and other pharmaceutical products with the exception of Rx drugs;

e- Meetings (E-meetings) – meetings, meetings, conferences in an electronic environment through web software;

e- mailing (Email marketing) is one of the most effective Internet marketing tools for business. It allows you to build **direct communication between a pharmaceutical organization and potential or existing drug consumers.** The result of such communication can be expressed both in increasing consumer loyalty to the pharmacy organization and in increasing new and repeat sales;

e- Detailing – denotes **a general strategy for the digital promotion of medicines** , such as information programs on the Internet or on digital media, virtual presentations via the Internet, telephone, personal contact.

Websites dedicated to specific nosologies are being created on the global network, on the pages of which there is advertising for pharmaceutical products of a particular company, as well as forums for doctors to discuss them.

Communication on professional topics on such sites is combined with various marketing techniques (competitions, lotteries, etc.).

Pharmaceutical companies use **remote communication through special closed portals, social networks and Skype, make personalized email campaigns, and actively use the format of video presentations.**

In 2018, many manufacturers **began to increase sales and promotion of drugs through online channels. This mainly applies to lines of dietary supplements, cosmetics and over-the-counter drugs.**

For example, the Evalar company doubled its costs for promoting drugs on the Internet in 2017.

Promotion at the present stage can act as a tool of economic pressure on industry and has a practical focus on the target audience. It was found that among the 10 best-selling drugs, 9 drugs had a specialized website, 9 drugs had Twitter / Friendster pages, 7 had Facebook pages, and 8 drugs were promoted on YouTube.

To effectively work with the target audience, many pharmaceutical companies use **a CRM strategy.**

CRM (English: Customer Relationship Management) is an interaction model that believes that the center of the entire business philosophy is the customer , and the main areas of activity are measures to support effective marketing, sales and customer service.

The mechanism for using social CRM seems to be the most effective. This is an application **software (SaaS) service designed for companies to use social networks and instant messaging** to interact with their customers as part of their CRM strategy.

The importance of both classical and digital technologies in drug promotion is confirmed by indicators of financial costs incurred in drug promotion.

The development of digital communications in the pharmaceutical market has led to a decrease and redistribution of financial flows between promotion methods.

Prescription drugs

It is forbidden	Can
Place advertisements in all media, except specialized ones	Place advertisements at medical and pharmaceutical exhibitions, seminars, conferences and other professional offline events
Provide doctors with product samples to give to patients	Place advertisements in specialized media
Place information about the drug on prescription forms in advance	Conduct educational and scientific events to inform medical professionals
	Educate health care workers about medications during personal visits using additional materials
	Post information about drugs on the websites of manufacturing companies

Over-the-counter drugs

It is forbidden	Can
Address minors in advertising	Place advertisements in the media
Describe specific cases of cure in advertising	Sponsor events
Contain statements about the presence of specific diseases in people	Carry out promotions
Give the impression that a visit to the doctor is not necessary	Educate health care workers about medications during personal visits using additional materials
Guarantee no side effects	Conduct educational and scientific events to inform medical professionals

Work of medical representatives with doctors and pharmaceutical workers

It is forbidden	Can
Give doctors gifts and money	Organize conferences, seminars, lectures and other informational and scientific events for doctors and pharmacists
Pay for entertainment, leisure, rest of doctors	Conduct training events
Provide product samples for distribution to patients	Communicate with doctors online and by phone
Enter into prescribing agreements with doctors	Send information to doctors by e-mail
	Conduct research, surveys and questionnaires

REMOTE SALES OF PRESCRIPTION DRUGS

An experiment in the remote sale of prescription drugs can take place in the Russian Federation from January 1, 2023.

Three Russian regions where electronic prescriptions were previously launched will take part in the pilot—for a period of a year in Moscow, Moscow and Belgorod regions.

Their choice was justified by the fact that electronic prescription platforms are already operating in these territories, which will ensure their identification during online ordering and delivery of drugs.

Online sales will not be possible for drugs containing narcotic, psychotropic and potent drugs or a volume fraction of ethyl alcohol exceeding 25%, radiopharmaceuticals and immunobiological drugs.

THANK YOU BEHIND ATTENTION !