LessonNo. _ 14.

Topicofthelesson : Promotion of prescription drugs on the pharmaceutical market. Rolepatientonmarketprescriptiondrugs

Main issues to be discussed at the seminar:

1. The main marketing tools for promoting prescription drugs: public relations, personal contacts, advertising.
2. Clinical studies of drugs from a marketing point of view.
3. Opinion - leader. Definition of the concept. Mission and functions of opinion leader in the promotion of prescription drugs.
4. Tasks of medical representatives of drug manufacturing companies. Medical representatives as a marketing tool.
5. Patient participation in the choice of prescription drug.
6. Marketing tools for influencing patients when promoting Rx drugs.
7. Influence of regulatory authorities on the choice of prescription drugs

The Federal Law "On Advertising" does not allow the placement of information about prescription drugs on advertising platforms intended for ordinary consumers. As a result, direct advertising mentioning the brand on TV, radio and print media is prohibited. Pharmaceutical companies are forced to look for other options to promote their product. The work of medical representatives is traditional. They come to the doctor, tell him about the prescription drug, leave information materials with clinical data and handouts that the doctor can give to the consumer along with the prescription for the drug.

Traditional methods of promoting RX drugs also include placing publications in specialized media intended for doctors and medical specialists.

Pharmaceutical companies participate in thematic medical conferences, and also organize their own events: symposiums, launches , etc. The undoubted advantage of these projects is personal contact with a doctor who, with a high degree of probability, will begin to prescribe your drug or at least learn about it and think about it about his appointment. The disadvantage of such projects is the high cost of contact.

The task of pharmaceutical companies in promoting prescription drugs has been complicated by the COVID-19 situation. Many medical institutions have introduced a ban on medical representatives visiting doctors. For the same reason, in-person conferences and symposia have ceased to be organized.

In this situation, doctors began to actively use the Internet. According to various research companies, from 65% to 80% of doctors use the Internet to find the necessary information. Today, the Internet is becoming the most important tool for a successful marketing campaign. But even here you can't do without an Internet marketing specialist who can find the necessary loopholes, undergo moderation , overcome the limitations of sites and fill them with quality content.

Among the strategies for promoting prescription drugs in Internet marketing are the following:

- ✓ creation of websites about a drug, nosology or direction;
- ✓ promotion on specialized medical portals;
- ✓ promotion in medical communities of social networks; posting reviews about taking the drug on review sites ;
- ✓ organization of webinars , round tables, teleconferences;
- ✓ e- mail and SMS distribution.

Website about the drug. Your own website about a drug, disease or area of medicine, for example , cardiology, is an important component of promotion. On its portal, the manufacturer can clearly present the drug, talk about its mechanism of action, subtleties and dosage regimens, indications and contraindications. It is important to remember that the provision of specialized information for doctors should only be provided after the user confirms that he is a medical specialist.

On your website, you can create a section with popular scientific information and recommendations about regimen, diet and other important details for patients with diseases for which your drug is indicated.

Specialized medical portals . All medical portals can be divided into two groups: portals for doctors; portals dedicated to various diseases and methods of their treatment, portals about health and a healthy lifestyle.

Portals for medical specialists in modern realities are a very popular way of obtaining information. On some information portals, traffic reaches up to 2.5 million per month, which makes them very attractive for advertising prescription drugs in terms of reach and cost of contact. Portals about health and a healthy lifestyle are intended, as a rule, for a wide range of readers. They contain popular scientific information about various diseases, diets, regimens, and physical therapy. Placing publications mentioning a prescription brand is prohibited.

Portals dedicated to various diseases publish content about diseases, causes, course and methods of treatment. Among them there are both platforms where registered users - doctors - post their articles, and platforms for ordinary consumers, where content is published by site editors. The fundamental difference between these platforms is that on the former, the law allows you to post articles about prescription drugs, but on platforms for ordinary consumers you can only publish materials about over-the-counter drugs.

It is worth adding that promotion of prescription drugs on consumer portals is only possible in the form of PR publications. They reveal the topic of the disease, the characteristics of its course, and in the treatment section the INN is indicated, or the effect of the drug is described and a link is given to your website, where official information about its clinical effectiveness for doctors is posted. On the basis of many medical portals , it is possible to organize online events for registered users: teleconferences, webinars , round tables. For personal impact on the target audience, general and personalized e- mail mailings are carried out. It is also possible to place direct advertising in the form of banners, videos and promotional sites on portals for doctors.

A clinical trial (CT) is a study of the clinical, pharmacological, pharmacodynamic properties of an investigational drug in humans, including the processes of absorption, distribution , change and excretion, with the aim of obtaining, using scientific methods, assessments and evidence of the effectiveness and safety of drugs, data on expected side effects and effects of interaction with other drugs.

The purpose of clinical trials of medicines is to obtain, using scientific methods, assessments and evidence of the effectiveness and safety of medicines, data on the expected side effects from the use of medicines and the effects of interaction with other medicines.

In the process of clinical trials of new pharmacological agents, there are *4 interconnected phases:*

1. Determine the safety of drugs and establish the range of tolerated doses. The study is carried out on healthy male volunteers, in exceptional cases - on patients.

2. Determine the effectiveness and tolerability of drugs. The minimum effective dose is selected, the breadth of therapeutic action and the maintenance dose are determined. The study is carried out on patients of the nosology for which the drug under study is intended (50-300 persons).

3. Clarify the effectiveness and safety of the drug, its interaction with other drugs in comparison with standard methods of treatment. The study is carried out on a large number of patients (thousands of patients), with the involvement of special groups of patients.

4. Post-registration marketing studies study the toxic effects of the drug during long-term use and identify rare side effects. Different groups of patients can be included in the study - by age, according to new indications.

Types of clinical studies:

• open, when all trial participants know which drug the patient is receiving;

• simple "blind" - the patient does not know, but the researcher knows what treatment was prescribed;

• double-blind - neither the research staff nor the patient knows whether he is receiving the drug or a placebo;

• triple "blind" - neither the research staff, nor the examiner , nor the patient knows which drug he is being treated with.

One of the types of clinical trials is bioequivalence studies . This is the main type of control of generic medicines that do not differ in dosage form and content of active ingredients from the corresponding originals. Bioequivalence studies allow us to make reasonable

conclusions about the quality of compared drugs based on a smaller volume of primary information and in a shorter time. They are carried out mainly on healthy volunteers.

Clinical trials of all phases are carried out in Russia . Most of the international clinical trials and studies of foreign medicines belong to the 3rd phase, and in the case of clinical trials of domestic medicines, a significant part of them are phase 4 studies.

One of the trends in the development of the clinical trials sector in our country should be the rapid growth in the number of clinical trials on the bioequivalence of generic drugs . Obviously, this is fully consistent with the characteristics of the Russian pharmaceutical market: as is known, it is a market for generic drugs.

Clinical trials are conducted in accordance with Industry Standard OST 42-511-99 **"Rules for conducting high-quality clinical trials in the Russian Federation"** (approved by the Russian Ministry of Health on December 29, 1998) (Good Clinical Practice - GCP). The Rules for Conducting Quality Clinical Trials in the Russian Federation provide an ethical and scientific standard for the quality of planning and conducting human research, as well as documenting and presenting its results. Compliance with these rules serves as a guarantee of the reliability of the results of clinical trials, safety, protection of the rights and health of subjects in accordance with the fundamental principles of the Declaration of Helsinki. The requirements of these Rules must be observed when conducting clinical trials of medicinal products, the results of which are planned to be submitted to licensing authorities.

GCP establishes requirements for the design, conduct, documentation and control of clinical trials designed to ensure the protection of the rights, safety and health of persons participating in them, in which undesirable effects on human safety and health cannot be excluded, as well as to ensure reliability and accuracy information obtained during the research.

Opinion - leaders (from English , opinion leader - opinion leader) in pharmaceutical marketing are represented by the most authoritative specialists in the field of pharmacotherapy for a certain range of diseases. This term is most often understood in this interpretation. However, in functional terms, the psychophysiological essence of the opinion leader phenomenon is broader. It is defined more broadly in the marketing of consumer goods. Here, opinion leaders are the most influential part of buyers. These are not the wealthiest and "star" consumers, but those who follow innovations in your sector and do not miss a single new product. These people easily accept new things and understand the intricacies of your product. And, most importantly, they have the ability to shape public opinion, professionally from the pages of newspapers and magazines or through personal contacts on forums and social networks.

In medicine, the activity of opinion leaders plays a special role. To introduce it into practical medicine, it is completely insufficient to obtain and present evidence of the high activity of a new drug in the media. First of all, doctors need to believe them. The use of a new drug inevitably changes the method and effectiveness of treating this disease and forces the doctor to change his professional behavior. The treatment period may be shortened, there will be other contraindications and side effects, etc. The very principles of treating the disease may change, as happened with the introduction of chlorpromazine (domestic name - aminazine) into medical practice. When mastering new treatment methods, the doctor will inevitably have to change his own behavior.

But this is not enough: in practice, only the drug that is "inscribed" in the treatment strategy adopted at a given time in a given country can be used. The fact is that, despite great progress in the international unification of the treatment of major ailments, differences in the approaches of different scientific schools and the characteristics of national traditions continue to play a very important role in medicine.

One of the main means by which this complex problem is solved is the use of opinion leaders. In countries with a developed pharmaceutical industry, there is a real cult of opinion leaders.

The activities of opinion leaders play a vital role in the marketing activities of the company. First of all, these are precisely the people who ensure the demand for the drug. In addition, it is the determination of the opinion -leader of the drug niche in the overall therapeutic strategy that becomes the starting point for further marketing positioning of the drug.

It is necessary to clearly distinguish between the activities of opinion leaders as persons who determine the place of a drug in medical practice, and the marketing activities of companies to replicate recommendations (in any form, be it the organization of scientific symposia with the personal participation of opinion leaders or with reference to their opinion, sponsorship of relevant publications etc.). Opinion-leaders carry out a public mission independent of the interests of the manufacturer, which is to develop scientific medicine, optimize therapeutic methods through the introduction of innovative drugs into practice, as well as to identify new possibilities for the use (new indications) of known drugs.

Due to the enormous importance that opinion leaders have on the fate of prescription drugs, an extremely important marketing task is their identification. Typically, opinion leads are characterized by a combination of the following qualities:

- ✓ the status of a famous scientist (doctor of medicine, professor), heading a scientific school (medical field) or being a well -known representative;
- ✓ recognition of scientific authority and medical competence in their specialty by the entire medical community on a national, and better yet, international scale;
- ✓ authorship in numerous scientific publications, educational, methodological and scientific-practical literature;
- ✓ working at a hospital base (usually in a university clinic or research center);
- ✓ participation in or management of clinical trials;
- ✓ •membership in scientific and practical medical societies;
- ✓ high lecture activity.

In Russia, the role of opinion leaders is often played by scientific centers that have their own clinical bases, they are connected with local medical specialists, and often carry out advanced training for doctors, i.e., they have effective mechanisms for influencing the medical community as a whole. Naturally, the head of each center or its large division, being also a scientist with a widely known, sometimes worldwide, name and possessing enormous authority, almost automatically turns into an opinion leader. In our country, the development of drugs, their experimental research and clinical trials are carried out by such centers.

One of the differences between the Russian system of drug therapy and the introduction of new drugs is that mere recognition of the drug by the medical community is not enough. Various restrictive lists (such as the Vital and Essential Drugs list) play a great role in the

promotion of drugs on the market and their procurement. In addition, for guaranteed purchases, in particular in the regions, the drug must be included in the tender lists.

In addition to opinion leaders, there is another category of specialists whose participation is of great importance in the promotion of medicines - these are specialists (scientists or simple practitioners) who directly cooperate with manufacturing companies. These highly qualified doctors, of course, contribute to the promotion of drugs by participating in information events, publishing publications in the scientific press, talking about their own clinical observations and the experience of colleagues. Unlike opinion leaders, these specialists do not have the authority and independence of the former. However, they provide social resonance to the opinions of opinion leaders. The role of these specialists is especially important in situations where the benefits of a new drug are undisputed. That is, when in the professional medical environment, simultaneously with the opinion of the opinion leader supporting the drug, the opinion of another equally authoritative specialist is voiced, doubting the exceptional qualities of the new drug. This situation in psychology is called a conflict of interest. In conditions of conflict of interest, the opinion of one specialist, even a very authoritative one, may not play the proper role. A feature of the conflict of interests in social behavior is that in the competitive struggle of two tendencies, the opinion in whose favor is expressed by the largest number of participants in the dispute wins, therefore social support plays an extremely important role.

The most effective way to promote medicines is through the institute of medical representatives working in pharmaceutical companies. The pharmaceutical market has many directions, so there is a huge difference in the activities of representatives.

In the most general terms, the medical representative is faced with the task of not only talking about new and reminding about the company's well-known medicinal products, but also forming a positive attitude towards the company's products. Since the pharmaceutical market has many directions, there is a certain specialization of the activities of medical representatives working in different submarkets, creating significant differences in their activities.

The entire pharmaceutical market, as already mentioned, can be divided into three large segments: prescription (Rx market), over-the-counter (OTC market) and hospital or institutional market. The product range of pharmaceutical enterprises is often supplemented by parapharmaceuticals , cosmetics, dietary foods, etc. due to the high profitability of the latter. Medical representatives can specialize in one segment, two, or work together. There are different ways to divide these products between representatives: separately prescription and over-the-counter, all together, etc. This depends on the number of products, sales plans, profits expected from the sale of drugs, etc.

A peculiarity of the promotion of pharmaceutical products through representatives is that they do not contact the end consumer, but through his intermediaries: doctors and pharmacists, who themselves are not direct consumers of the promoted product, but are participants in the pharmaceutical market. These two categories of participants in the drug circulation process make up the clientele of medical representatives . Moreover, the latter are not connected with either doctors or pharmacists through industrial relations. Thus, the most important tool for influencing decision-making in favor of the company's drug by both categories of clients is the established interpersonal relationship between them and the representative. If in the consumer market the consumer will buy milk not where his friends work, but where, in his opinion, it is fresher, more natural, cheaper, etc., then in the pharmaceutical market, where the same product can Having 10-15 trade names, choosing according to the consumer qualities of the product can present serious difficulties. The doctor most often does not understand their differences, even if there are any. In this case, the offer coming from the medical representative will be an effective means of promotion, but the last statement will be true only if the representative managed to win over the doctor or attracted his attention to the company's products in another way. On average, one representative visit costs a pharmaceutical company from $20 to $75. This amount includes salaries, production of POSM materials, etc. This is the most expensive way to promote drugs, but it still remains one of the most effective.

The activities of a medical representative are focused on subjects who in marketing are usually called key clients. An entity can be classified as a key customer if it:

• brings stable and fairly high profits;
• cooperates with the company as a reliable partner;
• looks forward to long-term cooperation;
• helps increase sales growth;
• provides opportunities for new ways to earn money;
• influences the formation of the market in its industry
• is able to influence the consolidation of the company's image thanks to his circle.

Contact with key clients occurs through visits. What is the job of a medical representative?

The purpose of a medical representative's work can only be one - increasing the company's profits by increasing the number of prescriptions for its drugs written by doctors and purchasing them by pharmacies on the recommendations of pharmacists. This is achieved through oral presentations, brochures and flyers, holding pharmaceutical circles , round tables and symposiums for doctors. But the most important technique is to establish creative contact with the client, based on an understanding of his motivation. And this is exactly what the representative gets paid for.

The main form of work of a medical representative is visits. Regardless of whether a visit is made to a doctor or to a pharmacy, in any case it has certain common features.

The standard visit scheme is divided into seven stages:

1) preparation for the visit;
2) greeting, opening of the visit;
3) identification of needs;
4) presentation;
5) working with objections;
6) completion of the visit;
7) analysis of the visit.

The patient's role in the prescription drug market is not central. The patient's direct influence on the choice of drug is expressed in requests to the doctor to prescribe a particular drug. In practice, doctors follow the wishes of patients much more often than is recognized. International studies show that a doctor is more willing to satisfy a patient’s request to prescribe a particular drug in four situations: 1) if there is a wide choice of possible treatment options and the cooperation of the patient and the doctor is important in their implementation;

2) if taking into account subjective symptoms plays an important role when taking medications, for example , with depression;

3) if the drugs have side effects that the patient complains about;

4) in cases where the goal of treatment is to improve the quality of life, for example, with impotence.

Patient pressure on the doctor to prescribe a certain prescription is observed, as a rule, in situations where treatment is ineffective. Moreover, this ineffectiveness may not be a true lack of treatment results, but only a reflection in the patient’s mind of the real results of treatment and his ideas about what these results should be.

An important factor in patient behavior in the Rx market is self-medication using prescription drugs.

Traditionally, patients have been held to have no say in drug selection in the Rx marketplace . The role of patients in choosing prescription drugs underwent a major reassessment in the 1990s. At the same time, the implementation of the strategy ensuring the participation of patients in the choice of drugs was carried out using the so-called DTC marketing (an abbreviation of English words - direct-to - consumer marketing , i.e. marketing

directly aimed at the consumer). The ideology of this system, practiced mainly in America, is to provide the consumer with information about the properties of drugs as widely and openly as possible, since they are one of the most important products for him. However, the consumer does not have knowledge about these drugs and has only little control over their choice. He does not know why he was prescribed this drug and whether it is the most effective and safe for his disease. Having received the necessary information about drugs, the consumer can take a more meaningful approach to the doctor's recommendations, in particular, insisting on using the most modern or, conversely, not the most modern, but time-tested and inexpensive drugs. Modern American legislation (unlike Russian or European) allows advertising of prescription drugs in the media. The dispensing of prescription drugs in pharmacies is carried out strictly according to prescriptions, and, therefore, a consumer who has succumbed to the spell of advertising cannot, without the consent of the doctor, purchase an Rx drug he does not need.

The attitude towards DTC marketing in the world is ambiguous. Its positive aspects are considered to be that it contributes to the medical education of patients, improves the patient's understanding of the essence of therapy for his disease, and forms the patient's responsible attitude towards his own health. The negative consequences of DTC marketing, according to many, are that it:

- ✓ provokes unqualified pressure on doctors from patients;
- ✓ raises unreasonably high expectations of the effectiveness of drugs (everything looks better in advertising than in real life);
- ✓ creates in patients the illusion of understanding the essence of the disease and the principles of action of drugs, while in fact it introduces them only to a grossly simplified diagram of both;
- ✓ increases the cost of medicines due to huge expenditures on mass advertising.

As a result of the use of DTC marketing in a number of countries, it has shown the potential for market growth when impacting the patient.

6. Marketing tools to influence patients when promoting Rx drugs:

- ✓ 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;
- ✓ work of leading medical specialists in specific areas
- ✓ sponsorship of postgraduate medical and pharmaceutical education by the pharmaceutical industry;
- ✓ funding key "opinion leaders" (chief specialists) among doctors;
- ✓ writing journal articles without indicating true authorship (shadow authorship, Ghost-writing);
- ✓ funding the development of diagnostic and treatment standards;
- ✓ campaigns aimed at the general public, including "disease-specific" image advertising;
- ✓ funding patient groups (schools) and medical societies;
- ✓ research affecting the sales market

The country's centralized need for medicines is financed through government orders. The first source of financing for the prescription market is the state order, which is divided into the purchase of medicines for national and regional needs:

- 1) at the federal level it is called upon to provide the needs of the army with medicines; the need for medicines through the Ministry of Emergency Situations; requests from hospitals and clinics of central subordination; and must also maintain state reserves at the proper level;

- 2) at the regional level, the state order is mainly determined by the needs of medical institutions that receive budgetary funding. Local budgets also finance the payment of subsidized prescriptions for outpatient treatment.

The second source is funding from the Compulsory Health Insurance Fund (CHI). According to current legislation, contributions to the Federal Compulsory Medical Insurance Fund are made by employers and are set at 5.1% of the wage fund.

The Compulsory Medical Insurance Fund pays for medications used during treatment in hospitals, as well as in the provision of ambulance and emergency care. Local governments pay for medical services provided to the unemployed population.

The mechanism of influence of regulatory and funding bodies on the choice of prescription drug is approximately the same in all cases. The cardinal factor of this impact is, undoubtedly, payment for medicines. What drugs will be paid for from budgetary or insurance funds (i.e., given to the patient for free) is of great importance for the Rx market.

Thus, in a number of countries, a patient, with the consent of a doctor, has the right to replace drugs recommended by funding bodies with more expensive ones (for example, to purchase an original drug instead of a generic) with an additional payment of the difference in price out of his own pocket. The experience of these countries shows that patients agree to additional payments of even relatively small amounts only in the rarest cases. In other words, the possibility of receiving drugs "for free" is such a significant factor that a drug paid for by funding bodies has many times higher chances of being chosen than a drug that is not included in the payment scheme.

Payment is only the final act of influence of regulatory and funding bodies on the process of choosing a prescription drug. The key point is the procedure for including specific drugs in the appropriate forms. The choice factor is treatment standards (pharmacotherapy standards), established by the funding bodies themselves (taking into account the opinion of specialists, of course) or with their decisive participation. In this case, the doctor prescribing the drug must be guided by a more or less rigid system that prescribes the use of a strictly defined set of drugs in each specific situation.

A company can achieve inclusion of its drug in the standard of care mainly through three channels:

- working with opinion leaders,
- interaction with economic departments of funding bodies;
- •creating public opinion (i.e. using PR methods).

The procedure for creating a future standard inevitably involves the development of its draft by a narrow group of authoritative specialists. This objectively makes the central figures in the standardization of opinion leaders in the relevant fields of medical science. In such conditions, the opinion of an authoritative scientist can often influence the inclusion (or non-inclusion) of a drug in formularies, VED lists, lists of drugs dispensed with preferential prescriptions, etc. In addition, in our country there are so-called official, or formal, opinion - leaders, i.e. persons who, due to their official position, have great scientific and administrative authority in regulatory circles. Accordingly, working with them becomes an important marketing task for pharmaceutical companies.

In such conditions, of course, it is possible to "push" your drugs through official opinion leaders, regardless of the real merits of these drugs. However, in areas such as medical standards, where the end result is visible to everyone and open to criticism by large groups of doctors, unfair success can only be temporary. It is much more important for the manufacturer to provide the opinion leader with undeniable evidence-based information about the benefits of his drug in order to make him a convinced supporter of this drug.

In addition to opinion leaders, persons responsible for the financial side of the matter always participate in the development of standards. It is also necessary to work with them, since they are more likely than doctors to listen to economic arguments.

Finally, public relations should not be neglected. The history of pharmaceutical marketing is full of stories of "underestimated diseases." Success for a drug that solved a corresponding problem came only when it began to cause public concern.

A system of standards cannot exist without monitoring the effectiveness of therapy. In this aspect, insurance medicine should play a special role. The fact is that an insurance company or state insurance fund receives its income in the form of a relatively stable stream of mandatory payments. The expenditure side of their activities depends on the level of morbidity. A funding body can increase its profit (the difference between income and expenses) only by reducing the incidence of diseases. And it depends on the quality of medical care.

The funding body, unlike the average patient, has much more effective means. He has at his disposal a staff of qualified experts capable of assessing the correctness of the doctor's actions. In fact, insurance medicine is a way to restore the unity of consumer functions in the Rx market. Indeed, the insurance company is interested in:

- in minimizing the cost of treatment, including medication;
- high quality of treatment, since an undertreated patient will require new expenses;
- qualified control of the correctness of therapy (correct choice of medication).

Thus, the insurance company, in principle, has both the motives and the opportunities to achieve effective pharmacotherapy, i.e., achieving the greatest result at the least cost. When describing a harmoniously functioning insurance medicine system, it is necessary to make a reservation that this is the case only if it is well-functioning. The actual insurance medicine system in Russia does not yet fully meet this requirement. In particular, the quality control system for medical care provided to the population is not working well.

At the same time, the restoration of the unity of consumer functions in the Rx market by means of insurance medicine should not be perceived as an abstract, unattainable ideal. In many countries around the world (particularly the United States), insurance companies have become major players in the prescription drug submarket. Having concentrated in their hands most of the funds used to pay for medical services and medicines, they were able to speak from a position of strength with both health care facilities and drug suppliers. Strict requirements for the quality of medical care and prices for drugs put forward by insurance companies have become everyday practice. And the task of ensuring that the characteristics of the drugs offered and their prices comply with these requirements has become the most important marketing task of manufacturing companies. In a somewhat different form (large role of the state and, therefore, non-profits), similar processes are taking place in the EU. In particular, in Germany, the most important entity in the Rx market has become "health insurance funds".