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Selecting a name for a drug

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Abstract

The present article analyzes the features of naming in the pharmaceutical industry in the Russian Federation. The role of the status of international nonproprietary name in the creation of innovative medicinal products, as well as importance in the formation and development of identification means such as trademark and trade name on the pharmaceutical market are considered. Attention is drawn to the need of creation a national system of expert selection of generic names and legislative consolidation of the legal protection of international and national generic names, as well as the implementation of strict state control.

Key words: naming, trademark, generic, international nonproprietary name.

The development of the naming theory and its methodology in recent decades has contributed to the competition for markets in various sectors of the economy, including the pharmaceutical industry. In Russia in the 18th century pharmacy began to develop slowly within the framework of pharmacies and pharmacy gardens that were engaged in the procurement and processing of medicinal plant materials and the manufacture of prescription drugs. Only in 1898 it was allowed to produce complex pharmaceuticals in laboratories, at chemical plants and enterprises. Virtually until the revolution, pharmaceutical factories for the production of tinctures, syrups, extracts and ointments were also a part of chemical pharmaceutical industry. The latter was the reason for the change in the activity of pharmacies. They became agencies for sale of proprietary products. Their catalog expanded year after year. The situation changed in 1920, when the Scientific and Research Chemical and Pharmaceutical Institute was opened, which was engaged in the development and production of new drugs. Variety of the said drugs expanded drastically in the post-war period due to the creation of antibiotics, cardiovascular drugs, oncological meds etc... In 1954 academician M.D. Mashkovsky created and published the reference book “Medicines” in two volumes, describing the name of each drug, its structure, as well as physicochemical properties and application. The two-volume edition book had stood 17 editions and became indispensable not only for medical workers and pharmacists, but was also widely used by the public. In 1980, for the first time in the USSR, the Ministry of Medical Industry, together with the State Committee for Inventions, developed guidelines for trademarks for medicines.

The rules for developing names of new pharmaceutical forms have changed over the decades. So, until 1961, world standards for the names of new drugs were not developed. The name of a new drug corresponded to its chemical formula and was assigned to it by the International Union of Pure and Applied Chemistry. The situation changed in 1961, when medical organizations such as the American Pharmacopeial Convention, the American Medical Association and the American Pharmacists Association founded the The United States Adopted Names (USAN) Council. The said organization started approving the names of new drugs. In 1967, U.S. Food and Drug Administration joined USAN Council.

The main objective of the Council was the creation of easily remembered and easy-to-use names for drugs and their transfer to the World Health Organization (WHO), which, after approval, provided drugs to consumers around the world under international nonproprietary names. International nonproprietary name is one of the most important names for specialists in the field of medicine and pharmacy. It characterizes the active substance in the drug and

provides information about the drug. Currently, the WHO Drug Information journal and a reference book “International Nonproprietary Names for Pharmaceutical Substance. Cumulative List”, both having information on international generic names, are regularly published.

It should be noted that while in Japan, the USA, and Great Britain, along with international nonproprietary names, national nonproprietary names are also used. However, in Russia there is currently no such system, despite the fact that in the 20th century The pharmacological committee of the USSR Ministry of Health carried out this type of activity. At the same time, in the USSR the system of international nonproprietary names was not given any attention due to the lack of proper control over the compliance of intellectual property rights. As of 2008, only 1,305 items were presented in Russia, which accounted for 16% of the total (about 8,000) number of international nonproprietary names registered by WHO. Despite the fact that a large number of pharmaceutical companies were created and new drugs were developed, generics were produced. In subsequent years, an increase in the production of drugs and the development of naming in Russia took place more actively and in 2018 the number of generic names increased to 2,602 items. So, in Russian pharmacy there are medicines from more than 19 thousand trade names that cover both the original drugs and their generics.

As practice has shown, the number of registered generics related to one original drug varies from several to 100 or more items. For example, the drug “Diclofenac” (the trademark “Voltaren” is registered in Russia in more than 70 variants of the names of drugs).

Towards the end of the 20th century, against the backdrop of the transition to market relations and the introduction of the institution of patenting medicines, the range of medicines increased dramatically due to the emergence of homeopathic medicines, dietary supplements, vitamins, and many others. The pharmaceutical market of Russia, both for domestic and foreign manufacturers and suppliers, is becoming one of the most attractive having great growth potential. In connection with the increase in the release of new drugs, the choice of names for them has become urgent. For developers, this is a serious task, since the name of the newly created drug should reflect a large amount of information.

Choosing the right name for a drug is not only a matter of social significance, but also a safety issue. For example, in the United States, when studying the causes of errors in the use of drugs that led to death, they found that in 10% of cases the cause of death of patients was a confusion of the names of drugs.

A medicine, most commonly, enters into civil circulation under the trade name that identifies the drug, as well as the manufacturer, and protects the consumer from dangers (Article 4 of the Rules for the rational choice of the names of medicines for medical use, approved by order of the Ministry of Health of the Russian Federation No. 429n of 29 June 2016) (hereinafter referred to as the Rules). That is, the trade name of the medicine is included as an integral part along with the verbal name of the medicine (paragraph 3 of the Rules). The trade name is assigned by the developer, holder or owner of the registration certificate.

The choice of the name for the drug is of social importance and should carry information that guarantees the safety of the consumer. In the Russian Federation, the creation and use of the name is carried out in connection with the requirements of the Federal Law of April 12, 2010 No. 61-FZ “On the Circulation of Medicines”. Also, according to the Rules, the international non-proprietary name should not be used as a trade name, but can only be used as part of the company name of the organization that registers it. In addition, the trade name may be a trademark (designation of a drug for its individualization). It should be noted that a trademark may be corporate, for example, Akrikhin, Solofarm.

In turn, a trademark may evolve into a well-known trademark (Articles 1508–1509 of the Civil Code of the Russian Federation). This happens in the process when trademark acquires popularity in the market and the trust of the target audience. To create a positive

image of a drug in brand development, you need to constantly invest. A brand is an abstract concept, a market tool for influencing consumer consciousness.

Obviously, the brand drug has an expressive name and, when applied, an undoubted therapeutic effect (example, No-Spa). Moreover, each brand is a trademark, but not every trademark can become a brand.

A trade name as a means of individualizing a product can also be a trademark (logo, slogan, packaging, combined form, etc.) - designation as a way of distinguishing a medicine from one legal entity from a homogeneous medicine from other legal entities that are granted legal protection (exclusive right) and to which a certificate is issued. A legal owner of a trademark can be any legal entity and individual entrepreneur (Article 1477 of the Civil Code of the Russian Federation).

The criteria for evaluating a drug's trademark do not have features compared to other objects. A trademark is a legal term, not an economic one, which means it does not have the characteristics of, for example, a brand (exclusivity, association, emotion). A trademark has an exact date of registration for which a certain amount is paid. A brand is created and developed over a long time and requires large financial investments. That is, a trademark characterizes the legal component of the process of circulation of medicines, however, being an important component of the brand, determines its promotion in the market.

Any drug can be presented on the pharmaceutical market in the form of:

the original product with a trade name, where the technology, composition, and also the trademark are in the field of intellectual property protection;

brand drug, when a trademark becomes a brand of a reproduced drug (generic) with its own trade name;

generics sold under the international nonproprietary name.

It should be noted that when having a trademark for the drug after the expiration of the patent for it and entering the market of many generics, the manufacturer's sales volume practically does not drop. This happens if a trademarked designation has become a brand.

An example is the drug of the Novartis company (Diclofenac, the international non-proprietary name Diclofenac), which has a designation protected in the form of the Voltaren trademark. Patent protection of the drug has ended, but the population mainly buys the drug Voltaren, since it became the brand that is supported, despite the fact that there are more than 70 registered generics of diclofenac on the pharmaceutical market. High competition in the drug market and the intended use of drugs require professional approach to creating a name (naming of drugs).

Specialized firms (branding companies) participate in pharmaceutical naming. However, pharmaceutical companies can independently develop new names, using, most commonly, the brainstorming method: employees offer 50 "nice words", of which the manager chooses one. Meanwhile, such approaches do not guarantee the rationality of choice and can lead to conflicts.

The name of the drug should have a distinct spelling and sound, should not be in tune with the existing names. It is desirable that it reflects the generic relationship of drugs. Creating a new name is a complex and time-consuming process, because the name of the medicine contains a lot of information, among which may be information about its chemical formula, pharmacological properties, target organs, its functional and therapeutic properties, etc...

Thus, a drug has almost three names:

- full chemical (description of the structure of the molecule according to the international chemical nomenclature) - for example, the drug Diclofenac is 2-{2,6-diclophenyl} amino} benzene-acetic acid (in the form of sodium salt);
- international nonproprietary name (registered and issued by a special committee of the WHO and can be used by any manufacturer of drugs according to applicable patent rules (for example, Diclofenac);
- trade name (trademark), for example, Diclofenac, Voltaren, Diclofenac-Acre.

The rational choice of the name for the drug should also reflect and differentiate drugs that are different in their properties, active substances and composition:

- names should be short, easily pronounced and remembered not only by specialists, but also by consumers, for example, Bebinos, Bronchicum;
- it is possible to use a non-proprietary name as part of a name for medicines containing one pharmaceutical substance that has an international or national nonproprietary name;

It is recommended to include the name or abbreviation of the manufacturer in the name of drugs, which is relevant for drugs with the international nonproprietary name, for example, Bromhexine Berlin-Chemie, Bromhexine-Acre. I.A. Zanina and I.M. Razdorskaya consider that the closeness of the trade name to the international nonproprietary name and the image of the manufacturer (corporate brand) is of priority importance;

It is possible to include in the name of medicines Latin or Greek words and/or particles used in the scientific medical environment, for example, Monomitsin, Diazolin, Gendevit, Bitsillin.

To create a new name for a drug, certain word roots, such as Latin and Greek, found in many languages of the world, can be used. For example, the prefix “es–” indicates the specularity of the drug molecule, its S-configuration, and the prefix “zu–” characterizes the spatial structure of the molecule. Knowing the meaning of the constituent parts of a medicinal name, one can understand the mechanism of its action (for example, Oestrogel - 17beta-estradiol is chemically and biologically identical to endogenous human estradiol, and “gel” - means the form of release (actually, gel).

In addition, when choosing a name, the norms and features of the language are taken into account, involving specialists with higher philological education, as well as psychologists, analysts, lawyers. Specifics of the market are also taken into account as well as providing legal protection for the name of the drug.

Of great interest in choosing a name for pharmaceutical products is the method of semantic differential, which was developed by C. Osgood and his colleagues in 1952 and later applied in Russia by Dr. of Philology A.P. Zhuravlev. Phonosemantic analysis helps to assess the effect of sounds on a person’s emotions and select successful names using emotionally significant sound combinations.

Compliance with all the rules when creating new names of medicines allows us to guarantee not only safety for consumers, but also economic success for manufacturers. However, one has to consider the limitations when creating a new name. So, it is not recommended to:

- register the names of medicines that may mislead the consumer or its manufacturer if these names are contrary to the public interest or the principles of humanity;
- use for the designation of new drugs identical or similar phonetically or graphically to the names of already registered drugs having a different composition and effect;
- include in the names of the medicinal products words or parts of words characterising different drugs or chemical groups;
- use the dosage form of the drug in its name, with the exception of medicinal plant materials and medicines made from it and not having analogues;
- use the same names for medicines containing various combinations of pharmaceutical substances that differ in composition and ratio of their dosages;
- use the names for drugs that can mislead the consumer about the composition and its pharmacological properties;
- use such names for medicines that advertise it as the most effective, unique and without side effects;

- apply the names of diseases or their symptoms, colloquial vocabulary, geographical names, proper names, physiological or anatomical terminology, obscene expressions;
- introduce into the designation of medicinal products identical or having phonetic or graphic similarity of the names of objects of cultural heritage of the Russian Federation or of world significance, as well as objects of natural heritage.

It should be noted that there is a "List of trade names of domestic medicines registered before 1992" prepared by the Ministry of Health of Russia. The said trade names cannot be registered as trademarks. It is taken into account in the examination of trademarks.

Once a name is selected for a pharmaceutical product, it must be checked against the databases of registered and unpublished trademarks, as well as trademarks in the process of examination, as well as other search engines. In the search process, it is important to pay attention to the classes of ICGS for which protection of a trademark for the homogeneity of goods is obtained, which may form a false impression on the consumer of their belonging to one manufacturer.

In conclusion, it is worth noting that in Russia in recent years the number of registered new names of medicines has increased significantly compared to the number of newly created and registered drugs. This takes into account not only the existing regulatory and legal requirements, the results of monitoring the names being used or international experience, but also scientifically based methodological approaches that consider legal, medical and economic consequences. So, in the federal law of June 22, 1998 No. 86-FZ "On Medicines", not only the basic definitions of medicines are provided, but also the list including the said medicines (nomenclature of medicines), which is published annually by the authorized body in the State Register of Medicines and being an important characteristic of the pharmaceutical market.

However, for Russian innovative products entering the international market, it is important they obtain the status of an international nonproprietary name. For this, it seems necessary to recreate the national system of expert selection of generic names and legislatively consolidate the legal protection of international and national generic names.

In addition, when registering drugs and preparing them for release on the pharmaceutical market, strict control and thorough verification of existing trademarks and registered names should be carried out. This is necessary in order to avoid mixing them in the pharmaceutical market with other drugs.

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