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CREATION OF DRUGS AND THEIR NAMES

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Today, the pharmaceutical market of Uzbekistan presents the products of manufacturers from 90 countries of the world, many domestic manufacturers, in turn, are planning or have already established the export of their products. In this regard, the pre-registration examination of drug names should be based on the methodological and organizational principles adopted in international practice, and, above all, the regulatory agencies of countries with a high level of development of pharmaceutical legislation.

In this regard, of particular interest is the experience of a single expert and control body, the European Agency for the Control of Medicines (European Agency for the Evaluation of Medicinal products - European Medicines Agency) (hereinafter EMEA). One of the main tasks of EMEA is to create harmonized evidence-based and mutually recognized requirements for drug registration in all EU countries.

As part of solving these problems, EMEA developed and since 1998 has been successfully operating a single regulatory document for all 25 countries of the European Union - "Guideline on the acceptability of invented names for human medicinal products processed through the centralized procedure", which is translated into Russian may be titled as "Guidelines for the Acceptability of New Names for Medicinal Products Intended for Human Use for Use in the Centralized Registration Procedure" (hereinafter referred to as the "Guidelines"). In 2005, the 4th edition of this document was adopted, representing the result of the evolutionary development of the views of the European Community on the criteria for the acceptability of newly formed names for medicinal products and the organization of the procedure for their pre-registration examination and post-registration control.

This article presents the main provisions of this document, which is, unfortunately, little known to domestic specialists. The preamble of the guide contains the following provisions. The Community marketing authorization is valid throughout the EU and the newly formed drug name forms an integral part of the authorization. As the EC Commission stated in its Communication on Community marketing

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authorization procedures for medicinal products (OJ C 229/4 of 07.1998), “usually only one trade name should be approved for marketing authorization”. Although not mandatory under Community law, in practice, pharmaceutical companies applying for marketing authorization under the Centralized Procedure tend to use newly formed names for their medicinal products.

If companies do not wish to use such newly formed names, it is envisaged that an application for marketing authorization may be submitted using the newly formed name or the common or scientific name together with the trademark or manufacturer's name. By law, in accordance with Article 21 of Directive 2001/83/EC, as amended, the common name should be understood as "The International Nonproprietary Name (INN) recommended by the World Health Organization, or, if it does not exist, the common common name". As part of its role in assessing the safety of medicinal products in the authorization process, EMEA is also required to consider whether a proposed new name for a medicinal product could create public health problems and, more importantly, potential safety risks.

Obviously, even in cases where a newly formed name has already been registered for a medicinal product in an EU Member State, security considerations should determine the possibility of further use of this newly formed name in the EU. In particular, EMEA seeks to ensure that a medicinal product does not carry a name that could potentially be confused with the name of another medicinal product, as such confusion could cause safety concerns for the use of both of these medicinal products. It should be emphasized that it is not the task of EMEA to decide whether the choice of a name similar to the name of another company's drug is an infringement of intellectual property and, therefore, is not taken into account by EMEA when assessing the acceptability of a proposed name.

Moreover, consideration of trademarks (Trademarks) is not a function of EMEA, since there are other competent authorities dealing with this issue both at the national and European levels. Section 2, devoted to the criteria for evaluating the acceptability of proposed newly formed drug trade names, occupies the main place in the Guidelines. In the first place among all the criteria are safety issues when using newly formed trade names. The guidelines expressly state that the highest criterion for evaluating the

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acceptability of a proposed newly formed name is the criterion of "potential security risk".

When proposing newly formed names using the Centralized Procedure, applicants must be guided by the following criteria:

1. The newly formed name of the medicinal product must not contain misleading therapeutic or pharmaceutical information.

2. The newly formed name of the medicinal product should not be misleading regarding the composition of the drug.

3. The newly formed name of the medicinal product should not cause confusion when printed, written by hand or in oral speech with the name of another existing drug.

Objection to newly formed names based on the risk of confusion is the most common ground for EMEA's refusal to recommend a proposed name. Further, the issues of using INN when choosing a newly formed trade name for drugs are considered. When selecting a newly formed trade name, the applicant must comply with the resolution of the World Health Organization Assembly (WHA46.19), which states: were used in the newly formed trade names". This recommendation is implemented in the current Directive 2001/83/EC, as amended, which specifically states: "…a trade name should not be identified with a common name…". By the time of submitting an application to EMEA for examination of a newly formed trade name, the applicant must check it for the possibility of similarity with existing INN.

Considering that the list of recommended INNs is constantly updated, the applicant is recommended to use the operational information contained on the WHO website, where, in particular, the list of WHO recommended INNs and the list of "common stems" INN are published: "The use of common stems in the selection of International Non-proprietary Names (INN) for pharmaceutical substances (2004)". Compliance with these WHO recommendations is carefully monitored by EMEA during the review of newly formed drug names.

This section of the Guidelines concludes with a list of criteria used by EMEA to determine the acceptability of newly formed drug trade names. To date, the following criteria have been developed and used:

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1. The trade name should, if possible, consist of one word. It is best to avoid using extra letters or numbers. The use of short prefixes/abbreviations that are not long used in the EU and carry an important meaning is not allowed. It is unacceptable to use advertising prefixes/abbreviations/manufacturer codes. However, if other prefixes/abbreviations are required, justification should be provided to the EMEA.

2. The trade name must not contain any promotional designations related to the use of medicines.

3. The trade name must not have an offensive meaning or negative connotation when written in one of the languages of the EU member states.

4. The use of capital letters in a trade name must be consistent with the filed/trademarked name.

5. Trade names of fixed combinations of medicinal products must be completely different from the trade name of each of the active substances in this combination, since information about errors in the administration of drugs of this type has been previously received.

6. If the product contains a prodrug, use a trade name that is different from the trade name of the product containing the substance in its active form.

7. When changing the status of a drug registered through a centralized procedure from "prescription" to "over-the-counter", the organization - the holder of a permit for the marketing of a pharmaceutical product may choose a new trade name or leave the previous one.

8. To designate medicinal products intended for the treatment of very rare diseases (Orphan medicinal products), the sponsor may submit for examination a name different from the name previously registered for this drug for other indications.

In this case, when applying for registration, the sponsor must declare a separate registration (under a different trade name) that will be valid only for these indications. Section 3 of the manual describes the EMEA procedure for identifying inconsistencies in newly formed drug trade names. In 1999, after the entry into force of the first edition of the Guidelines, the Committee for Human Medicinal Products (Committee for

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Human Medicinal Products) approved the organization in its composition of an ad hoc expert group, which is called the “Trade Names Study Group” (“in vented Name Review Group (NRG) (hereinafter referred to as the "Names Group"). The "Names Group" is chaired by a representative of EMEA and is composed of representatives of the national health authorities of the EU Member States from South, Central, Northern and Eastern Europe, with scientific qualifications, expertise and administrative powers In addition, the Names Group includes representatives from the European Commission and the EMEA Secretariat.

If necessary, other consultants are involved in the work. This Group is responsible for evaluating new trade names proposed by applicants from a safety/public health perspective, amending the Guidelines, and making recommendations to the Committee for Medicinal Products for Human Use. The Names Group meets monthly, in parallel with the meetings of the Committee for Medicinal Products for Human Use. Decisions of the Names Group are approved by the plenary meeting of the Committee for Medicinal Products for Human Use. The powers of EMEA established by the EU legislation in conducting a centralized registration procedure make it possible to identify possible inconsistencies in newly formed trade names proposed by the applicant.

EMEA operates in accordance with a procedure for the early identification of possible objections by regulatory authorities of EU Member States to a proposed new trade name for medicinal products, due to a potential safety risk, as well as in accordance with other criteria. The practical experience of EMEA shows that pre-screening of newly formed trade names and early intervention allows further processing of applications for registration of medicinal products without delays associated with difficulties in choosing trade names. The procedure for evaluating proposed new names can be divided into several stages, namely: filing an application, consultations, discussion / acceptance or rejection of the name, as well as actions related to newly formed trade names after registration of medicinal products.

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