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Guidelines for the selection of trade names of medicines and for manufacturing of finished dosage forms in the Eurasian Economic Union

The Board of the Eurasian Economic Commission (EEC) approved on 29 January 2019 the Recommendations on the Guidelines for the Selection of Trade Names of Medicinal Products and the Guidelines for Manufacturing of Finished Dosage Forms of Medicinal Products in order to eliminate differences in the requirements for the manufacturing of finished dosage forms of medicines in Eurasian Member States Economic Union (EAEU).

The EAEU Member States are recommended to apply these Guidelines after 6 months from the date of their publication on the official EAEU website.

1. Guidelines for the Selection of Trade Names of Medicinal Products

The Guidelines establish rules for the selection and assessment of trade names of medicinal products for medical use that are registered in accordance with the Rules for registration and examination of medicinal products for medical use, approved by the EEC Decision No. 78 of 3 November 2016 (the "Registration Rules").

The trade name of the medicinal product constitutes an element of the registration dossier and may be:

- a newly invented word (phrase);

- international non-proprietary, common or scientific name, accompanied by a trademark or the name of the holder of the registration certificate.

If the trade name of a medicine is a new invented word (phrase), it should not be confusingly similar (graphically or phonetically similar) or reproduce another international non-proprietary common name.

In all EAEU member states where registration application is filed, it is recommended to register the medicine with one trade name.

Different trade names of the same medicinal product in different Member States may be used in cases where the use of the proposed trade name may be contrary to law and morality or otherwise does not take into account national cultural and / or linguistic characteristics, as well as in some other cases stipulated by the Registration Rules.

The applicant (the holder of the registration certificate) when using the trademark in the trade name of the medicinal product shall ensure compliance with the intellectual property laws of the Member States.

The Guidelines provide for criteria (listed below) which the applicant (holder of the registration certificate) it is recommended to comply with before including the proposed trade name of the medicinal product in the application for registration or the application for making changes in registration dossier.

1) Safety and public health

When choosing a trade name for a medicine, it is necessary to avoid confusing it in print or in writing, or when pronouncing it

with the trade name of another medicine.

The trade name of the medicinal product must not have deceptive connotations based on therapeutic and / or pharmaceutical information.

It is not allowed to use the trade name of the medicinal product, which:

- may be misleading with regard to its composition;

- is advertising in terms of therapeutic and / or pharmaceutical characteristics and / or composition of the medicine.

The applicant (the holder of the registration certificate) should provide in the registration dossier of the medicinal product a letter of guarantee that the proposed trade name for the medicinal product - a new invented word does not fully reproduce the name of the dietary supplement.

2) The use of international non-proprietary names (INN)

The applicant (the holder of the registration certificate) is advised to check the proposed trade name of the medicinal product before submitting documents for the evaluation of trade name:

- the potential similarity of the proposed trade name of the medicine with the INN of the active substance that is part of the medicine or with other INN;

- on the inclusion of the INN base in the proposed trade name of the medicinal product.

If the applicant (holder of the registration certificate) proposes to use the INN, the common name or scientific name as the trade name together with the trademark or name of the applicant (holder of the registration certificate), the Guidelines provide for the rules that are recommended to be taken into account.

3) Medicine-specific factors in the proposed trade names

The trade name for radiopharmaceutical medicines should not include target organs, nor should numbers be used.

It is recommended to provide a separate (other) trade name, which will be assigned to a medicinal product with an exclusively orphan indication (orphan indications) for use.

Special attention should be paid to the proposed trade name of a hybrid medicine to ensure that it can be distinguished by the consumer from the reference medicine or generic medicines that are present in the market, with respect to the content of the active substance and / or the indication for use of this hybrid medicine.

The trade name of the combination medicine must be sufficiently different from the names of the individual active ingredients and (or) other combination medicines containing the same active ingredient (active ingredients).

Evaluation of the trade name of a medicinal product is carried out by authorised bodies (expert organisations) of the EAEU Member States as part of the procedure for registering a medicinal product and is an integral part of the safety review of medicinal products.

Documents on the approval of the trade name of the medicinal product are submitted as part of the registration dossier for registration or when changes are made to the registration dossier of the registered medicinal product.

The applicant (the holder of the registration certificate) is obliged to clearly indicate whether the proposed trade name of the medicinal product will be used in several registration dossiers (for example, in the registration dossiers of the line of dosage forms).

The authorised body (expert organisation) of the reference state, after receiving of the conclusions from the recognition states, approves the proposed trade name of the medicinal product within one registration dossier.

If, during the assessment, the proposed options for trade names are not approved, the expert opinion shall include the decision on approval of the trade name of the medicinal product corresponding to its INN, common or scientific name.

The applicant (the holder of the registration certificate) in the course of approval of the trade name is entitled, in particular:

- to send a request for approval of a new trade name of the medicinal product;

- to justify keeping of the trade name of the medicinal product, taking into account all objections raised;

- to apply to the authorised body (expert organisation) of the reference Member State with the request to send documents to the Expert Committee on Medicines of the EEC for consideration within the framework of resolving the differences of the authorised bodies in cases of impossibility to approve the proposed trade name of the medicinal product.

A trade name may be changed at the post-registration stage as part of the procedure for amending the registration dossier at the request of the registration certificate holder, as well as in the following cases:

- prior to the adoption of decisions by the authorised body of the reference state, the trade name, which is a new invented word, was not approved and the INN, the common name or the scientific name was approved in instead;

- it is established that the trade name violates the rights to intellectual property of third parties in the Member States.

The Guidelines do not apply to the choice of trade names of medicines submitted to the procedure of bringing the registration dossier in accordance with the requirements of the EAEU, registered in the Member States by 31 December 2020.

2. Guidelines for Manufacturing of Finished Dosage Forms of Medicines

The Guidelines were adopted to clarify the type and level of detail of the information containing a description of the manufacturing process of finished dosage forms of medicines, which should be included in module 3 of the registration dossier attached to the registration application.

The provisions of the Guidelines apply to changes made to the registration dossier of registered medicinal products in the event that such changes in the manufacturing process of medicinal products affect the content of the registration dossier.

The Guidelines detail the requirements for the description of the method of manufacturing (process) in module 3 of the registration dossier, supplementing Appendix No. 1 to the Registration Rules.

For each stage of the manufacturing process (including packaging), it is necessary to include in the registration dossier information on all participating manufacturing sites (including those belonging to one manufacturer) and testing laboratories, including control and analytical laboratories (quality control laboratories).

The use of several batch sizes of a medicinal product must be sufficiently justified from the point of view of absence of undesirable influence on the critical indicators of the quality of the finished medicinal product in accordance with the Guidelines

for the Validation of the manufacturing process of medicinal products for medical use (Recommendation of the EEC Board of 26 September 2017 No. 19).

Module 3 of the registration dossier should contain:

- names, content of all ingredients used during manufacturing, as well as quality standards applied to them;

- a complete description of the manufacturing process of the medicinal product and the scheme attached to it, which will show each stage of the process with appropriate internal manufacturing control (if necessary), and also indicate (indicated) each stage at which materials are introduced into manufacturing.

The Appendix to the Guidelines contains an example of a detailed description of the conditional manufacturing process, depending on the chosen approach to the development of a medicinal product.

The manufacturing stages and critical points at which the following events are held must be defined:

- manufacturing control;

- intermediate tests;

- control of finished products.

Information that allows to establish the extent to which the quality assurance of the finished medicinal product is introduced into the manufacturing process should be provided in section 3.2.P.2 of module 3 of the registration dossier.

The Guidelines establish the principle of a uniform medicine manufacturing process regardless of the number of manufacturing sites involved in the manufacturing of this medicine.

If technological modifications are proposed to the manufacturing process, they must be fully substantiated and accompanied by data confirming that all proposed modifications will on an ongoing basis produce an intermediate product and a medicine that meets the criteria for acceptability of in-process control indicators and medicine specifications.

With the help of separate schemes, it is also necessary to confirm the justified technological modifications of the various stages of the manufacturing process of one or more manufacturers and the corresponding manufacturing control.

The use of alternative manufacturing processes based on different principles, regardless of whether they are accompanied by changes in internal control measures and (or) the quality of the medicine, as opposed to technological modifications, is unacceptable.

All critical stages and intermediate products considered as such during the manufacturing of the finished product, including all types of internal control, used analytical methods and acceptance criteria, must be specified in section 3.2.P.3.4 of module 3 of the registration dossier.

Section 3.2.P.8 of the registration dossier of the medicine in relevant cases should indicate, adequately substantiate and confirm with the data the maximum storage time (interruption) between operations for the bulk preparation or, alternatively, the maximum manufacturing time of the batch from the start of manufacturing of the medicine to the end of packaging into the final primary container for release on the market.

The procedure for transporting semi-finished and unpackaged products between manufacturing sites should be described and

justified, taking into account the principles of the Rules of Distribution Practices within the EAEU approved by the EEC Council Decision No. 80 of 3 November 2016 and the provisions of Appendix No. 15 to the Rules of Good Manufacturing Practice.

The suitability of the proposed packaging (capping) system for unpacked products must also be justified.

Section 3.2.P.3.5 of module 3 of the registration dossier should provide a description, results of validation and / or evaluation studies and relevant documentation in accordance with the Guidelines for Validation of the manufacturing process of medicines for medical use (Recommendation of the ECE Board of 26 September 2017 Number 19).

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