COMMON MARKET OF MEDICINES OF THE EURASIAN ECONOMIC UNION:
LABELLING REQUIREMENTS AND RULES FOR REGISTRATION
AND EXAMINATION OF MEDICINES
On 3 November 2016, the Council of the Eurasian Economic Commission (EAEC) adopted a set of regulations aimed at the implementation of the Agreement for Common Principles and Rules of Medicines Circulation within the Eurasian Economic Union, dated 23 December 2014 (hereinafter - the 'Agreement'), including:

- Decision No. 76 'On Approval of Labelling Requirements to Medicines for Medical Use and Veterinary Medicines' (hereinafter - the 'Labelling Requirements');
- Decision No. 78 'On the Registration and Examination Rules for Medicines for Medical Use' (hereinafter - the 'Registration Rules').

Both instruments come into force upon expiry of 10 calendar days after the entry into force of the Protocol dated 2 December 2015 on accession of the Republic of Armenia to the Agreement, but not earlier than on 1 December 2016 (except for the provisions of the Labelling Requirements regarding labelling of veterinary medicines).

**Labelling Requirements to Medicines for Medical Use and Veterinary Medicines**

Pursuant to the Requirements, labels of medicines (veterinary medicines) applied to the packaging shall be in Russian and, when required by the legislation of the EAEU member-states, in the official language (languages) of the respective member-state.

Labelling of medicines (veterinary medicines):

- shall not contradict to or distort the information contained in the registration dossier or be of advertising nature;
- shall be easy-to-read, legible, understandable and true and shall not mislead consumers (purchasers) of the respective medicine and veterinary medicine.

According to the general requirements to labelling on the primary (internal) packaging and secondary (consumer) packaging of medicines (veterinary medicines) middle packaging that does not allow reading of information on the primary packaging shall at least repeat the information provided on the primary packaging.

The requirements to the text of labelling are established, in particular:

- dosage and(or) activity, and(or) concentration of the active pharmaceutical substance (substances) shall be given with the obligatory units of measure indication;
- the list of case in which excipients (components), in particular, for medicines (veterinary medicines) for oral administration, shall be obligatory indicated in the secondary packaging, if they are included in the list of excipients under the Annex to the Requirements;
- composition of homeopathic medicines (veterinary medicines) shall be indicated in accordance with the terminology used in the homeopathy;
- references to quality control standards for active pharmaceutical substances and(or) excipients shall not be indicated.

There are also requirements to the methods of labelling, including:

- the method of labelling shall ensure its safety for the entire shelf life of a particular medicine (veterinary medicine), subject to the specified conditions of storage;
- important information for the correct and safe use of a medicine (veterinary medicine) shall be indicated with the most large font size possible on the most optimal packaging surfaces;
labelling shall be uniform for medicines (veterinary medicines) put into circulation in the territories of member-states; if the information (release conditions, etc.) differs, it shall be indicated on an additional label (sticker) in a specified area of a secondary packaging;

- if a primary and/or secondary packaging contain texts in several languages, such texts shall be clearly distinguished.

Provisions of the Labelling Requirements regarding labelling of veterinary medicines shall enter into force on the date of entry into force of the rules regulating circulation of veterinary medicines approved by the EAEC Council.

Registration and Examination Rules for Medicines for Medical Use

Decision No. 78 of the EAEU Council and the Registration Rules establish the following transitional provisions:

1) registration, confirmation of registration (re-registration), changes in the registration dossier and other procedures relating to the registration of medicines provided for by the legislation of the EAEU member-states and not completed by the competent authorities of the member-states by 1 January 2016 shall be completed in accordance with the laws of the member-states;

2) until 31 December 2020 by the choice of an applicant medicines can be registered either pursuant to the Registration Rules or in accordance with the legislation of a particular member-state. In this case, medicines registered in accordance with the legislation of a member-state shall be admitted for circulation in the territory of that member-state only;

3) the validity of registration certificates for medicines issued by the competent authorities of the member-states before 1 January 2016 can be extended in accordance with the laws of the member-states, but not more than until 31 December 2025;

4) medicines registered in accordance with the laws of the member-states shall be brought into line with the requirements of international treaties and instruments constituting the EAEU law, including the Registration Rules, by 31 December 2025;

5) registration certificate for medicines issued in accordance with the laws of the member-states shall be valid until the expiry of their validity but not later than 31 December 2025;

6) confirmation of registration (re-registration) and changes in the registration dossier of medicines registered in the member-states before the entry into force of the Agreement that were not brought in line with the EAEU requirements shall be performed in accordance with the legislation of the member-states by 31 December 2025.

An applicant (legal entity entitled to apply for registration, confirmation of registration (re-registration), changes in the registration dossier of medicines and other procedures relating to the registration, and responsible for the accuracy of information contained in the documents and registration dossier provided thereby) can at its own discretion choose the registration procedure:

- successively in several member-states in accordance with the procedure of mutual recognition; or

- simultaneously in several member-states, where the application for registration of a medicine was filed, selecting a reference state in accordance with the decentralised procedure.

The mutual recognition procedure is implemented:

a) by the reference state in accordance with the Rules for the purpose of medicines circulation on the market of this state only (national registration procedure);
b) in the states of recognition - at the applicant's request after the registration of the medicine in the reference state under the mutual recognition procedure.

Registration of medicines with different qualitative structure of the active substances under the same trade name shall be prohibited.

Requirements to the documents and data of registration dossier in the form of a common technical document submitted for the registration of a medicine are established by the Annexes to the Registration Rules.

When applying for registration, confirmation of registration (re-registration), or bringing a medicine into line with the EAEU requirements, the applicant shall submit as a part of the registration dossier a valid document proving compliance of the production site (sites), where the finished dosage form and quality control of the medicine is performed, with the EAEU good manufacturing practice.

Until 31 December 2018, the applicant may submit a document proving compliance with good manufacturing practice issued to the manufacturer of the medicine by a competent authority of the EAEU member-states as a document confirming compliance with the EAEU good manufacturing practice.

Preclinical and clinical trials performed in the states being not member-states of the EAEU can be considered during the examination of medicines under the following conditions:

- preclinical trials of medicines safety have been structured, performed and described in the respective pre-clinical trials report in accordance with the requirements of the good laboratory practice equivalent (or not lower) to the EAEU requirements.
- clinical trials of medicines have been structured, performed and described in the respective clinical trials report in accordance with the requirements of the good clinical practice equivalent (or not lower) to the EAEU requirements, as well as to the World Medical Association Declaration of Helsinki 'Ethical Principles of Medical Trials Involving Human as an Object of Study'.

In the course of an expert appraisal of a medicine, the competent authority of the reference state may in certain cases appoint an unscheduled inspection for compliance with the rules of the EAEU good laboratory practice.

Expert appraisal of a medicine shall not be suspended for the duration of unscheduled pharmaceutical inspections for compliance with the requirements of production, laboratory, clinical and pharmacovigilance practices of EAEU, but the final expert report can be issued by the competent authority of the reference state only based on the results of such unscheduled pharmaceutical inspections (if any).

**Registration and Examination of Medicines under the Mutual Recognition Procedure**

If a medicine is registered under the mutual recognition procedure, the period for registration and expert appraisal in the reference state shall not exceed 210 calendar days after filing the application for registration.

Upon registration of a medicine in the reference state, the applicant may initiate registration of the medicine under the mutual recognition procedure in other EAEU member-states selected by the applicant as recognition states.

Subject to no controversies between the competent authorities of the recognition state and those of the reference state and given the availability of the opinion regarding the possibility to recognise the expert report, the registration of a medicine in the recognition state shall be performed not later than 90 calendar days after getting access to the expert report.
The registration certificate for a medicine shall be issued by the competent authority of the recognition state with a validity term as established by the reference state.

**Registration and Examination under the Decentralised Procedure in the Reference State and Recognition States**

Registration under the decentralised procedure includes the following simultaneous steps:

a) registration of a medicine in the reference state;

b) recognition of the expert report and registration in the recognition states.

Duration of the decentralised registration and examination procedure shall not exceed 210 calendar days from the date of the last applications for registration filed in the recognition state before the issue of registration certificates by the competent authorities of all member-states involved.

The registration certificate for a medicine shall be issued by the competent authority of the recognition state with a validity term as established by the competent authority of the reference state.

The grounds for refusal to register a medicine, in accordance with both the mutual recognition procedure and decentralised procedure, include the following:

a) unfavourable ratio of the expected benefit to the possible risks associated with the use of the medicine;

b) effectiveness of the medicine is not confirmed by the information submitted by the applicant;

c) quality of the medicine is not proved;

d) proposed methods and quality control procedures are not enforceable;

e) the applicant submitted false information;

f) results of the inspection appointed in the course of registration of the medicine do not confirm compliance with the EAEU good pharmaceutical practice.

In the decentralised procedure, the competent authority of the recognition state shall not accept the expert report issued by the expert organisation of the reference state and refuse to register a medicine under the decentralised procedure if upon examination of the registration dossier of the medicine and settlement of disputes within the Expert Committee the competent authority decides that information provided in the expert report cannot be considered as sufficient to prove the quality and(or) efficiency, and(or) favourable 'benefit - risk' ratio of the medicine.

The competent authority (expert organisation) of the reference state in registration and implementation of the registration-related procedures may establish one or more of the following additional requirements, in particular:

- inclusion into the risk management system of certain measures to ensure the safe use of the medicine;
- conduct of post-registration studies for safety and/or efficiency of the medicine;
- establishment of additional requirements to the registration of the medicine and submission of suspected adverse reactions reports.
Validity of a Registration Certificate and Confirmation of Registration

A registration certificate for a medicine is issued as per a common form contained in the Annex to the Registration Rules by the competent authority that registered the medicine.

Validity of the registration certificate for a medicine registered for the first time in the reference state (a member-state of the EAEU, where the expert report on the safety, efficiency and quality of the medicine is issued on the basis of a medicine expert appraisal) shall be 5 years. Upon expiry of this period, the termless registration certificate for the medicine shall be issued subject to confirmation of the registration (re-registration).

To confirm the registration (for re-registration) of a medicine, the applicant shall file an application in all the member-states, where the medicine was registered, no earlier than 210 days before expiry of the registration certificate for the medicine in the reference state, but not later than the expiry date of the registration certificate.

Confirmation of registration (re-registration) is effected on the basis of the revaluation of the 'benefit - risk' by the competent authority (expert organisation) of the reference member-state, with preparation of the expert report on the medicine evaluation.

In the course of the confirmation of registration (re-registration) of a medicine, the competent authority (expert organisation) of the EAEU member-state analyses compliance by the registration certificate holder of the conditions relating to the medicine registration, if applicable.

The following obligations are established for registration certificates holders:

- to make changes in the registration dossier of the registered medicine, which may be required to ensure compliance of production and quality control of the medicine with the modern level of generally accepted scientific methods;
- to ensure compliance of information on the medicine with the current science-based medical standards, including expert opinions and recommendations of competent authorities in the area of medicines circulation in other countries;
- to submit promptly exhaustive information requested by the competent authority of any member-state where the medicine is registered;
- to notify the competent authority of a member-state on the planned termination of production or sale of the medicine in the EAEU market not later than 60 calendar days prior to such termination.

In case of a change of the registration certificate holder in the reference state or recognition state, a new holder of the registration certificate shall provide a documentary support for such a change (transfer) and confirmation of the possibility to cooperate with the certificate holders in the other member-states so to ensure the new holder is capable to perform properly all the obligations.

Bringing the Registration Dossier of Earlier Registered Medicines in Compliance with the EAEU Requirements

The registration dossier of medicines registered in the EAEU member-states before the entry into force of the Agreement or before 31 December 2020 (according to national requirements) shall be brought in compliance with the EAEU requirements on or before 31 December 2025.

To that effect, the applicant shall submit the following documents to the competent authority (expert organisation) of the reference of the state, where the medicine is registered:
an application in the established form;

documents confirming payment of the fee (duty);

modules 1 - 3 of the registration dossier of the medicine in e-copies in accordance with the Annexes to the Registration Rules, and

module 1 of the registration dossier in a hard copy, if the medicine is intended for circulation in the territory of the member-state, where it is registered.

If a medicine is registered in more than one member-state before the entry into force of the Agreement or before 31 December 2020, the applicant shall choose one of the states as the reference state, with the competent authority (expert organisation) of which an application, documents and registration dossier shall be submitted.

A medicine can be filed for the registration under the mutual recognition procedure in the member-states, where it has not been registered before the entry into force of the Agreement or before 31 December 2020, as soon as its registration dossier is brought in compliance with the EAEU requirements.

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Best Regards,

GRATA International Law Firm (Moscow)

Corporate and Commercial Law Department

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What we do:

– advising on the statutory requirements and restriction regarding the import and distribution in Russia and other EAEU member-states of medicines and medical products;
– advising and legal support in participating in public procurement;
– advising on legal compliance of advertising and marketing materials and activities, marking, packing, and labels;
– representing interests in the course of public discussions of the drafts of regulatory legal acts including acts of Eurasian Economic Commission.

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