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Registration of medicines in the Eurasian Economic Union

At the Pharmaceutical Forum of the EAEU and CIS countries held in Moscow in late February 2018, the Director of the Department of Technical Regulation and Accreditation of the Eurasian Economic Commission (EEC) said that the full-scale work on registration of medicines using the unified information system of the Eurasian Economic Union (EAEU) will start upon its launch scheduled on the first half of 2018. Currently, the integration segment of this system is ready, and the work to prepare national segments in each state of the EAEU is underway.

Representatives of the regulatory authority of Kazakhstan reported that the first applications for registration of medicines under the unified EAEU rules had already been submitted, and representatives of the Belarus regulator confirmed their readiness to accept such applications.

In 2018, EEC intends to adopt "third-level" acts regulating the common market of medicines in the EAEU: 67 documents concerning manufacturing, clinical research, regulation of herbal medicines, preparation of registration dossiers.

The rules for registration and expert appraisal of medicines for medical use within the EAEU were approved by the Decision of the EEC Council No. 78 dated 3 November 2016 (the 'Rules') and entered into force on 6 May 2017.

Medicines registered under the Rules can be circulated and offered for sale throughout the EAEU - in the territories of Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan without undergoing registration procedures in each of these member states.

The Rules provide for two procedures for registration of medicines:

- 1) the procedure for mutual recognition, under which the registration is first conducted in the reference state at the applicant's choice, then in the states of recognition at the applicant's request;
- 2) the decentralised procedure, under which the registration is conducted simultaneously in several member states in which an application has been filed, one of which is chosen as the reference state.

The registration certificate for a medicine initially registered in the reference state shall be issued for a period of 5 years, upon expiry of which and subject to confirmation of the medicine registration (re-registration), an unlimited registration certificate shall be issued.

When applying for registration or confirmation of registration (re-registration), or bringing the medicine in line with the EAEU requirements, the applicant must submit as part of the registration dossier a valid document confirming the compliance of the production site where they manufacture the finished dosage form and conduct release quality control of the medicine with the EAEU manufacturing practice.

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

For the purposes of registration in accordance with the Rules, preclinical trials of medicines safety assessments are conducted in accordance with the appropriate requirements of the EAEU laboratory practice, while clinical trials are conducted in accordance with the appropriate requirements of the EAEU clinical practice.

During expert appraisal of medicines, the results of pre-clinical and clinical trials conducted in the states that are not the EAEU member states shall be considered on the condition that they are planned, conducted and described in the clinical or preclinical research report, respectively, according to:

- the requirements of laboratory practice, equivalent to the EAEU requirements (or not lower) - for pre-clinical trials;
- the requirements of clinical practice, equivalent to the EAEU requirements (or not lower), as well as the principles of the Helsinki Declaration of the World Medical Association 'Ethical Principles of Medical Research involving Human Subjects'- for clinical research.

1. Registration and Expert Appraisal under the Mutual Recognition Procedure

An applicant shall submit the following documents and materials to the competent authority (expert organisation) of the reference state:

- application in hard copy and(or) in e-form;
- registration dossier in accordance with the Annexes 1 to 5 to the Rules in e-form (besides, module 1 of the registration dossier shall be submitted on paper);
- samples of the medicines;
- documents confirming the payment of the fee (duty) for the registration and expert appraisal of the medicine.

The registration and expert appraisal of the medicine in the reference state shall be carried out within and in term not exceeding 210 calendar days from the date of filing the required documents (this period does not include the time for submission of additional documents by the applicant at the request of the competent authority or expert organisation during the medicine's expert appraisal).

During the expert appraisal, the competent authority of the reference state may decide on the necessity of a pharmaceutical inspection for compliance with the EAEU good pharmaceutical practice. At that, an expert evaluation report shall be completed by the reference state only subject to receipt by the expert organisation of the inspection results.

The applicant shall, within 30 calendar days after the receipt of the information on the necessity for the inspection, arrange a visit to the production site and(or) to the research centre, and(or) an inspection of the pharmacovigilance system of the registration certificate holder, or inform the competent authority of the reference state on options for the dates of such inspection (but no later than 90 calendar days upon receipt of the information about the necessity for an inspection).

If based on the results of the medicine expert appraisal, the competent authority of the reference state takes a positive decision on the registration of the medicine, within 10 business days it shall:

- issue the medicine registration certificate to the applicant, an approved summary of the product characteristics (SPC), medication guide, quality regulation, package layouts, expert evaluation report, and an agreed risk management plan for the medicine use (if required);
- place information about the medicine and active pharmaceutical substances in its composition in the EAEU Unified Register of Registered Medicines (the 'Unified Register').

Upon registration of the medicine in the reference state, the applicant may initiate registration in other EAEU member states

(recognition states) at the applicant's choice by submitting applications to the respective competent authorities (expert organisations) of such member states, together with module 1 of the registration dossier in e-form and documents confirming the payment of the fee (duty) for registration and expert appraisal of the medicine.

At the same time, the applicant shall file a request to the competent authority (expert organisation) of the reference state to provide an access for the competent authorities (expert organisations) of the recognition states to the medicine registration dossier and the expert appraisal report through the Integrated Information System for Foreign and Mutual Trade of the Union (hereinafter - the 'Integrated System'). Such an access shall be provided within 5 business days after the receipt of the applicant's request.

Provided that there are no controversies between the competent authorities of the recognition state and those of the reference state and subject to availability of the opinion regarding the possibility to recognise the expert appraisal report issued in the reference state by the recognition state, the registration of a medicine in the recognition state shall be performed not later than 90 calendar days after getting access to the report.

Within 10 business days from the date of the positive decision to register the medicine, the competent authority of the recognition state shall:

- issue to the applicant the medicine registration certificate, approved SPC, medication guide, package layouts in the state language of the recognition state (if required);
- approve the quality regulation issued by the reference state;
- enter the information about the medicine and active pharmaceutical substances in its composition in the Unified Register.

Thus, according to the Rules, it is sufficient for an applicant to receive an expert appraisal report in one of the EAEU states so that upon its recognition in other member states the applicant can obtain registration certificates of the medicine without an additional laboratory appraisal.

2. Registration and Expert appraisal under the Decentralised Procedure

To register a medicine under the decentralised procedure, the applicant shall choose the reference state and the recognition state and submit the same documents to the competent authority (expert organisation) of the reference state, which are required for registration under the mutual recognition procedure.

Registration under the decentralised procedure includes the following steps that are conducted simultaneously:

- 1) registration of a medicine in the reference state;
- 2) recognition of the expert report and registration in the recognition states.

After submission of the documents to the competent authority (expert organisation) of the reference state, the applicant shall within 14 business days submit the application, module 1 of the registration dossier, documents confirming the payment of the fee (duty) for registration and expert appraisal to the competent authorities (expert organisations) of the recognition states.

The decentralised registration procedure and expert appraisal shall not exceed 210 calendar days from the date of the last applications for registration filed in the recognition state till the issue of registration certificates by the competent authorities of all the member states involved. This period does not include the time for submission by the applicant of the additional documents requested by the competent authority (expert organisation) in the course of expert appraisal of the medicine.

Expert appraisal of the medicine shall not be suspended in case of the pharmaceutical inspection for compliance with the EAEU pharmaceutical practice. In this case, the reference state shall complete the preparation of the expert appraisal report only upon receipt of the inspection results.

The applicant shall, within 30 calendar days after the receipt of the information on the necessity for an inspection, arrange a visit to the production site, the research centre, the pharmacovigilance system of the registration certificate holder, or notify the competent authority of the reference state on dates of the visit, but no later than 90 calendar days upon receipt of the information about the necessity for the inspection.

The competent authority (expert organisation) of the reference state shall, within 155 calendar days after submission of the application for registration, send a draft final expert appraisal report to the recognition states and to the applicant.

If the competent authorities (expert organisations) of the recognition states do not have any comments (or upon release thereof through negotiations) to the draft report, the competent authority (expert organisation) of the reference state and those of the recognition states shall complete the expert appraisal procedure of the medicine within 10 business days (175th calendar day after filing the application for registration).

Within 30 calendar days (205th calendar day from the date of filing the application for registration), the competent authorities of the reference state and recognition states shall:

- issue to the applicant the medicine registration certificate, approved SPC, medication guide, quality regulation, package layouts, and an agreed risk management plan for the medicine use (if required);
- enter the information about the medicine and active pharmaceutical substances in its composition in the Unified Register.

3. Confirmation of Registration (Re-Registration) of a Medicine

Not earlier than 210 calendar days prior to the expiry of the medicine registration certificate in the reference state, but not later than the expiry date, the certificate holder shall apply for confirmation of registration (re-registration) of the medicine.

Confirmation of registration (re-registration) shall be conducted within 120 calendar days from the date of filing an application.

To confirm the registration (re-registration) of a medicine, the applicant shall submit to the competent authority (expert organisation) of the reference state and each of the recognition states an application for confirmation of registration (re-registration) of the medicine, module 1 of the registration dossier in an e-form (in the reference state module 1 shall be also provided on paper), and documents confirming the payment of the fee (duty) for confirmation of registration (re-registration) and expert appraisal.

The competent authority (expert organisation) of the reference state shall conduct an expert appraisal of the medicine upon results of which, within a period not exceeding 90 calendar days from the date of filing the application, it shall prepare and approve the final expert appraisal report, and send it through the Integrated System to the competent authorities (expert organisations) of all recognition states involved.

Upon receipt of the final expert appraisal report of the reference state, the competent authority (expert organisation) of the recognition state shall, within 20 calendar days after the receipt, make, approve and send to the competent authority (expert organisation) of the reference state (through the Integrated System) the opinion on the possibility or impossibility of recognising the expert report issued by the reference state.

If, based on the results of the medicine expert appraisal in the reference state, it is established that the 'benefit-risk' ratio is

positive and the registration dossier as amended meets the requirements of the EAEU, the competent authorities of the reference state and those of the recognition states shall:

- issue to the applicant the termless registration certificate for the medicine, approved SPC, medication guide, quality regulation, package layouts (for recognition states – in the state language, if required by domestic law); and the competent authority of the reference state shall also issue the appraisal expert report and an agreed risk management plan for the medicine use (if required);
- enter the necessary information about the medicine and active pharmaceutical substances in its composition, as well as a summary of the agreed risk management plan for the medicine use (if required) in the Unified Register.

4. Bringing the Registration Dossier of a Medicine with the EAEU Requirements

Registration dossiers of medicines registered in the member states before the entry into force of the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union dated 23 December 2014 (hereinafter – the "Agreement") or under the national requirements before 31 December 2020, should be brought in compliance with the EAEU requirements until 31 December 2025.

If a medicine is registered in more than one member state of the EAEU before the entry into force of the Agreement or before 31 December 2020, the applicant shall choose one of them as a reference state, to the competent authority (expert organisation) of which the applicant shall submit:

- an application in the form attached to the Rules;
- modules 1 – 3 of the registration dossier of the medicine in e-form pursuant to Annexes 1 to 5 to the Rules;
- all available preclinical and clinical trials data prepared before the entry into force of the Agreement, as a part of modules 4 to 5 of the registration dossier as relevant reports (it is not required to bring the data in compliance with the EAEU requirements);
- documents confirming the payment of the fee (duty) for the bringing in compliance with the EAEU requirements.

The registration dossier of a medicine shall be brought in compliance with the EAEU acts within 100 calendar days after submission of the relevant application.

Based on the results of the registration dossier expert appraisal and subject to the positive decision on the compliance of the dossier with the Rules, the competent authorities of the member states, where the medicine is registered and the application for bringing the registration dossier of the medicine in compliance with the EAEU requirements is submitted to, shall:

- issue to the applicant the medicine registration certificate, approved SPC, medication guide, quality regulation, package layouts, and an agreed risk management plan for the medicine use (if required);
- enter the information on the medicine registration into the Unified Register.

In the event the medicine has been registered in 3 member states of the EAEU during 5 or more years, the competent authorities of such states shall issue the termless registration certificate based on the results of the procedure for bringing the dossiers in compliance with the EAEU requirements. If the medicine has been registered in 3 member states for less than 5 years, the competent authority of the reference state shall issue to the applicant the registration certificate for the term of 5 years, upon expiry of which the registration requires confirmation.

Medicines can be filed for the registration under the mutual recognition procedure in the member states where they have not been registered before the entry into force of the Agreement or before 31 December 2020, as soon as their registration dossiers are brought in compliance with the EAEU requirements.

5. Transitional Provisions

Until 31 December 2020, an applicant, at its choice, may file documents for the registration of a medicine either in accordance with the Rules or in accordance with the legislation of the member state of the EAEU, without regard to the Rules' requirements. However, the medicines registered under national law should be brought in compliance with the EAEU requirements until 31 December 2025.

Registration certificates 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.

Those medicines that are registered in the member states but not brought in compliance with the EAEU requirements, after 31 December 2025 can be sold only in the territory of the respective member state the competent authority of which issued the registration certificate, before the expiry of their validity.

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