Question 1. Is it possible to submit application for renewal of medicines that registered in the Republic of Armenia before the entry into force of current rules?

Answer 1. The re-registration of medicines registered in the Republic of Armenia has not been implemented before the entry into force of this rules, therefore it is necessary first to submit an application for re-registration and after 5 years - an application for renewal.

Question 2. How to submit documents confirming the fact of payment of the state tax and assessment fee?

Answer 2. It is necessary to attach to the application documents confirming the fact of payment of the state tax and assessment fee of the medicinal product, and only the payment order of the state tax could be attached in original form, if the payment was made in the territory of the Republic of Armenia. The original payment order must be confirmed by the seal of the Bank executing the transaction and the signature of the responsible person.

In order to solve issues related to the assessment fee payment, as well as for the clarification of the application type (registration case), the applicant may apply to the Scientific Center for a proforma-invoice by e-mail (the procedure for applying, the Scientific Center's bank details are available on the Scientific Center's official website).

Question 3. Is it possible to submit variations at the same time with the application for re-registration?

Answer 3. Variations need to be submitted for assessment before the re-registration. If it is revealed during re-registration that it is a necessity to make changes, then upon receipt of the corresponding notification from the Scientific center the variation application should be submitted. The re-registration will be continued after variation assessment completion.

Question 4. What is the validity period of certificate for medicinal product registered/re-registered under the national procedures?

Answer 4. The applicant can apply for medicinal product registration/re-registration in accordance with the national procedure until December 31, 2020, and the registration certificates of medicinal products registered/re-registered via national procedure will be effective until December 31, 2025.

Question 5. How should assessment report of the reference competent authority and appended to it documents be submitted for the registration of medicinal product under the simplified procedure?

Answer 5. It is necessary to submit a paper version (Module 1), if needed, with a notarized translation and, in the case of the Member States of the Hague Convention, also approved by the Apostille. As regards medicines authorized under the centralized procedure by the European Medicines Agency, it is sufficient to submit a printed version of the report posted on the website of the European Medicines Agency, by attaching all required documents.

Question 6. What authority is considered as reference in the case of the simplified procedure?

Answer 6. As a reference competent authority are considered ICH member states medicines regulatory authority and, in the case of prequalification, the World Health Organization (WHO).

Question 7. How much is the state tax in case of registration of several presentation forms (quantitative changes of units included in the package)?

Answer 7. The Law "On State Tax" of the Republic of Armenia does not define the amount of the state tax for registration of each subsequent presentation form (quantitative

changes of units included in the package). In case of registration of different quantities of units included in one package of medicine, it is necessary to submit one application for registration, paying a state tax for a single medicinal product, and as much an assessment fee as presentation forms are listed in the application.