ANNEX

to Decision No.
of the Eurasian Economic Commission's Council
dated , 20

AMENDMENTS
to the Decision of the Council of the Eurasian Economic Commission
November, 3, 2016 No. 78

1. Paragraph 2 subparagraph c shall be amended as follows:

«c) the validity period of marketing authorizations for pharmaceuticals declared for registration (conduct of expert works with the aim of registration) in accordance with the Member States' legislation before December 31, 2020, may be extended in accordance with the Member States' legislation but no longer than until December 31, 2025. In addition, marketing authorization applications for such pharmaceuticals formed in accordance with the Member States' legislation shall be amended according to the Member States' legislation on or before December 31, 2025;».

2. In the Rules for Registration and Expert Examination of Medicines for Human Use approved by the above Decision:

a) paragraph 13 shall be supplemented by the following indents:

«In case of application withdrawal, the fees (duties) or any other compulsory payments paid by the applicant as contemplated hereby shall not be refunded to the applicant if the declaration of withdrawal is filed after the

commencement of expert examination (issuance of the assignment to conduct an expert examination/conclusion of an agreement for expert examination).

The Union Member States' legislation may contemplate the possibility of refunding the fees (duties) or any other compulsory payments paid hereunder to the applicant in case of application withdrawal.»;

b) paragraph 23 shall be supplemented by the following indents:

«The applicant shall be entitled to withdraw its application at any time before the end of the pharmaceutical registration procedure by notifying in writing the authorized authority of the Member State reviewing the application.

In case of application withdrawal, the authorized authority of the Member State reviewing the application shall terminate its review on the merits and return to the applicant the original documents and/or information submitted together with the application.»;

c) the words «the determination of affiliated persons in Recognition States,» shall be deleted from paragraph 26;

d) paragraph 59 shall be supplemented by the following indent:

«Based on the expert examination of marketing authorization application for a generic or a hybrid, the expert organization of the Reference State shall draw up expert reports using the forms provided in Annexes Nos. 8, 10, 12, and 22 hereto.»;

e) paragraph 94 shall be supplemented after Indent 1 by the following indent:

«Based on the expert examination of marketing authorization application for a generic or a hybrid, the expert organization of the Reference State shall draw up expert reports using the forms provided in Annexes Nos. 8 and 22 hereto and the preliminary evaluation report using the form provided in Annex No. 11 hereto.»;

f) paragraph 103 shall be supplemented after Indent 1 by the following indent:

«Based on the expert examination of marketing authorization application for a generic or a hybrid, the expert organization of the Reference State shall draw up expert reports using the forms provided in Annexes Nos. 8, 10, 12, and 22 hereto.»;

g) paragraph 123 shall be supplemented by the following indents:

«The applicant shall be entitled to withdraw its application at any time before the end of pharmaceutical registration confirmation (re-registration) procedure by notifying in writing the authorized authority of the Member State reviewing the application.

In case of application withdrawal, the authorized authority of the Member State reviewing the application shall terminate its review on the merits and return to the applicant the original documents and/or information submitted together with the application.»;

h) paragraph 152 shall be supplemented by the following indents:

«The applicant shall be entitled to withdraw its application at any time before the end of the procedure of amending marketing authorization application for the registered pharmaceutical by notifying in writing the authorized authority of the Member State reviewing its application.

In case of application withdrawal, the authorized authority of the Member State reviewing the application shall terminate its review on the merits and return to the applicant the original documents and/or information submitted together with the application.»;

i) paragraph 175 shall be supplemented after Indent 1 by the following indents:

«The applicant shall be entitled to withdraw its application at any time before the end of the procedure of aligning marketing authorization

application with the Union's requirements by notifying in writing the authorized authority of the Member State reviewing the application.

In case of application withdrawal, the authorized authority of the Member State reviewing the application shall terminate its review on the merits and return to the applicant the original documents and/or information submitted together with the application.»;

j) paragraphs 184-185 shall read as follows:

«184. Registration, registration confirmation (re-registration), and amendment of marketing authorization applications for pharmaceuticals declared for registration, registration confirmation (re-registration), and amendment of marketing authorization applications for pharmaceuticals in the Member States before December 31, 2020 shall be performed in accordance with the Member States' legislation.

Upon the applicant's request, the pharmaceutical filed for registration (conduct of expert works with the aim of registration) before December 31, 2020 may be registered in accordance with the Member State's legislation with no regard for the requirements hereof. Marketing authorization applications for pharmaceuticals registered in accordance with this paragraph shall be aligned with the Union's requirements before December 31, 2025.»;

«185. Registration confirmation (re-registration) and amendment of marketing authorization applications for pharmaceuticals registered in the Member States in accordance with the Member States' legislation that did not pass the procedure of alignment with the Union's requirements shall be performed in accordance with the Member States' legislation before December 31, 2025.»