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THE DECREE OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA ON ADOPPTING THE RULES FOR STATE REGISTRATION, RE-REGISTRATION, EXTENSION OF THE TERM OF THE CERTIFICATE OF MEDICINAL PRODUCT, AS WELL AS FOR REFUSAL OF REGISTRATION, RE-REGISTRATION AND OF EXTENSION OF THE TERM OF THE CERTIFICATE, FOR SUSPENSION OF REGISTRATION, WITHDRAWAL THEREOF, THE RULES FOR CARRYING OUT ASSESSMENTS FOR THESE PURPOSES, AS WELL AS THE RULE FOR SUBMISSION AND ASSESSMENT OF POST-REGISTRATION CHANGES, THE LIST OF REQUIRED DOCUMENTS, THE LIST OF CHANGES OF REGISTERED MEDICINAL PRODUCT WHICH DO NOT REQUIRE NEW REGISTRATION, THE RULE FOR INSPECTION AND FOR RECOGNITION OF INSPECTION REPORTS OF COMPETENT AUTHORITIES OF OTHER COUNTRIES, IN THE REPUBLIC OF ARMENIA, AND ON REPEALING THE DECREE OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA NO 347 OF 25 APRIL 2001

D E C R E E

OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA

No 162-N of 28 February 2019

ON ADOPTING THE RULES FOR STATE REGISTRATION, RE-REGISTRATION, EXTENSION OF THE TERM OF THE CERTIFICATE OF MEDICINAL PRODUCT, AS WELL AS FOR REFUSAL OF REGISTRATION, RE-REGISTRATION AND OF EXTENSION OF THE TERM OF THE CERTIFICATE, FOR SUSPENSION OF REGISTRATION, WITHDRAWAL THEREOF, THE RULES FOR CARRYING OUT ASSESSMENTS FOR THESE PURPOSES, AS WELL AS THE RULE FOR THE SUBMISSION AND ASSESSMENT OF POST-REGISTRATION CHANGES, THE LIST OF REQUIRED DOCUMENTS, THE LIST OF CHANGES OF REGISTERED MEDICINAL PRODUCT WHICH DO NOT REQUIRE NEW REGISTRATION, THE RULE FOR INSPECTION AND FOR RECOGNITION OF INSPECTION REPORTS OF COMPETENT AUTHORITIES OF OTHER COUNTRIES, IN THE REPUBLIC OF ARMENIA, AND ON REPEALING THE DECREE OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA NO 347 OF 25 APRIL 2001

Taking as a basis parts 2, 10, 17, 19, 20 and 22 of Article 16 of the Law of the Republic of Armenia "On medicinal products", The Government of the Republic of Armenia hereby ***decides:***

1. To approve:

(1) The Rule for state registration, re-registration, extension of the term of the certificate of medicinal product, as well as for refusal of registration, re-registration and of extension of the term of the certificate, for suspension and withdrawal of registration, in the Republic of Armenia, in accordance with Annex No 1;

(2) The Rule for assessment carried out for the purpose of state registration, re-registration, extension of the term of the certificate of medicinal product, as well as that for submission and assessment of post-registration changes, in accordance with Annex No 2;

(3) The List of documents necessary for assessment carried out for the purpose of state registration, re-registration, extension of the term of the certificate of medicinal product, as well as those necessary for submission and assessment of post-registration changes, in accordance with Annex No 3;

(4) The List of changes of registered medicinal product which do not require new registration, in accordance with Annex No 4;

(5) The Rule for inspection and for recognition of inspection reports of competent authorities of other countries, in accordance with Annex No 5;

2. To repeal the Decree of the Government of the Republic of Armenia "On adopting the rule for state registration of medicinal products and the amounts of fees for assessment of state registration of medicinal products, in the Republic of Armenia" No 347 of 25 April 2001.

3. This Decree shall enter into force on the tenth day following the day of its official publication.

Prime Minister of the Republic of Armenia **N. Pashinyan**

7 March 2019

Yerevan

Annex No 1

to the Decree of the Government of the

Republic of Armenia No 162-N of 28 February 2019

R U L E

FOR STATE REGISTRATION, RE-REGISTRATION, EXTENSION OF THE TERM OF THE CERTIFICATE OF MEDICINAL PRODUCT, AS WELL AS FOR REFUSAL OF REGISTRATION, RE-REGISTRATION AND OF EXTENSION OF THE TERM OF THE CERTIFICATE, FOR SUSPENSION AND WITHDRAWAL OF REGISTRATION, IN THE REPUBLIC OF ARMENIA

1. GENERAL PROVISIONS

1. This Decree regulates the relations pertaining to state registration, re-registration, extension of the term of the certificate of medicinal product, as well as to refusal of registration, re-registration and of extension of the term of the certificate of medicinal product, those pertaining to suspension and withdrawal of registration, in the Republic of Armenia. In the cases where the applicant has applied for registration of the medicinal product also in another Member State(s) of the Eurasian Economic Union (hereinafter referred to as "the EEU"), the EEU rules of registration and assessment of medicinal products shall apply.

2. In the Republic of Armenia it is permitted to manufacture, import, distribute, dispense, realization of and use the medicinal products which are registered in the Republic of Armenia, except for the cases prescribed by part 23 of Article 16 and part 6 of Article 21 of the Law of the Republic of Armenia "On medicinal products".

3. Pursuant to part 2 of Article 16 of the Law of the Republic of Armenia "On medicinal products", the requirements of this Rule shall not extend to legal relations pertaining to state registration, as well as refusal, suspension and withdrawal of registration of veterinary vaccines, serum and diagnostic materials.

4. Prior to the entry into force of this Rule the medicinal products registered in the Republic of Armenia may be re-registered after having been registered in accordance with this Rule or after bringing the dossier in compliance, if the applicant so wishes, with the EEU rules of registration and assessment.

5. The registration, re-registration, extension of the term of the certificate of medicinal product, as well as refusal, suspension and withdrawal of registration shall be carried out by the Ministry of Health of the Republic of Armenia (hereinafter referred to as "the authorised body") based on the

assessment report delivered as a result of the assessment carried out in accordance with the Annex No 2 of this Decree.

6. Pursuant to part 21 of Article 16 of the Law of the Republic of Armenia "On medicinal products" a state duty shall be levied for registration, re-registration, reformulation and extension of the term of the certificate of medicinal product, under the procedure and in the amount prescribed by the Law of the Republic of Armenia "On state duty".

7. Assessments aimed at registration, re-registration, extension of the term of the certificate of medicinal products, withdrawal of registration, re-registration and of extension of the term of the certificate, suspension of registration of medicinal product, as well as for post-registration changes, shall be carried out by the expertise organization prescribed upon the decree of the Government of the Republic of Armenia (hereinafter referred to as "the organisation").

8. The decisions on refusal of registration, re-registration and of extension of the term of the certificate of medicinal product, on withdrawal and suspension of registration of medicinal product may be appealed against under the rule adopted by the Law of the Republic of Armenia "On fundamentals of administrative action and administrative proceedings" or through judicial procedure.

2. STATE REGISTRATION OF MEDICINAL PRODUCTS

9. Pursuant to part 4 of Article 16 of the Law of the Republic of Armenia "On medicinal products", the registration of medicinal product shall be based on the scientifically-justified criteria of product safety, efficacy and quality, which are adopted as prescribed by legislation of the Republic of Armenia, as well as on the requirements of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals (hereinafter referred to as "the ICH").

10. Pursuant to part 3 of Article 16 of the Law of the Republic of Armenia "On medicinal products", in the Republic of Armenia the medicinal products shall be registered under the simplified procedure and general procedure in case of existence of a positive assessment report.

11. The simplified procedure for registration of medicinal product shall be applied to medicinal products registered in ICH Member State or to pre-qualified medicinal products of World Health Organisation (hereinafter referred to as "the WHO")(hereinafter referred to as "the reference competent authority") within the time periods prescribed by point 20 of this Rule.

12. In all other cases the general procedure for registration of medicinal product shall be applied within the time periods prescribed by point 19 of this Rule.

13. The person referred to in part 9 of Article 16 of the Law of the Republic of Armenia "On medicinal products" may, for the purpose of registration, act as an applicant and (or) submit the registration documents.

14. For the purpose of registration, re-registration and making post-registration changes the applicant shall submit to the organisation an application and the necessary documents — according to the list approved by Annex No 3 of this Decree, the samples, standards and specific reagents (hereinafter

referred to as “the materials”) of laboratory assessment. The documents shall be submitted in person, and (or) through electronic mail, and (or) electronic system, and (or) mail delivery. The data on the application and on list of documents shall be available at www.moh.am, with distinction between the lists of registration documents of medicinal products for human use and those of registration documents of veterinary medicinal products.

15. For the purpose of extension of the term of the certificate, the holder of registration certificate shall, in the manners referred to in point 14, submit a request by indicating the name, strength, pharmaceutical form, the reference number of the previous certificate of medicinal product and the necessary documents — according to the Annex No 3 of this Decree.

16. The registration of an application and request within organisation shall be ensured on working days and hours. The documents submitted on non-working days and hours shall be deemed as submitted on the next working day.

17. The fact as to the application or request being registered within organisation shall be approved during the same day by forwarding a return mail to the electronic address of the applicant. Following the registration of the applications and requests, the organisation shall inform the authorised body thereof.

18. The organisation shall ensure the confidentiality of data existing in the documents submitted for registration, which shall be deemed as information protected by law of the Republic of Armenia and shall not be subject to publication.

19. The general maximum time period for registration of medicinal product shall constitute 150 calendar days, which shall include the time period of assessment for the purpose of registration the maximum duration whereof shall constitute 140 calendar days.

20. The maximum time period of registration under simplified procedure shall constitute 31 calendar days, which shall include the time period of assessment for the purpose of registration, the maximum duration whereof shall constitute 21 calendar days.

21. At the time of assessment, in case of making amendments, by the applicant, to relevant documents, the time period of assessment shall be extended by 10 calendar days, whereon the applicant shall be notified within a period of 2 working days following the receipt of the documents through mail delivery or electronic mail.

22. The period for submission of materials, data and documents required from the applicant at the time of assessment shall not be calculated in the general time period of carrying out assessment.

23. The applicant shall have the right to waive the registration in any stage of assessment. In this case the fee for assessment shall not be subject to return irrespective of the stage of assessment.

24. Pursuant to part 5 of Article 16 of the Law of the Republic of Armenia “On medicinal products” each name, composition, strength, pharmaceutical form, presentation (form of presentation as of certain quantity of units included in the package), new indication, manufacturer (including each performer of production process), holder of registration certificate of medicinal product, shall be subject to registration.

25. The primary and (or) external package, labeling (including in the form of coloured mock-ups of packages), instruction for medical application (summary of product characteristics), instruction for use (patient information leaflet) and quality indicators (specifications) of medicinal product shall be approved at the time of registration.
26. The quality of product, active substances and excipients, container, and closure material subject to registration in the Republic of Armenia in accordance with part 7 of Article 16 of the Law of the Republic of Armenia "On medicinal products", must correspond to the requirements of pharmacopeias included in the list approved by the Government of the Republic of Armenia in accordance with point 33 of part 1 of Article 3 of the Law of the Republic of Armenia "On medicinal products". Studies on quality, safety, and efficacy of medicinal products registered in the Republic of Armenia must be carried out in accordance with the guidelines of ICH and WHO, unless otherwise provided for by international treaties and other international instruments.
27. At the time of registration, the classification of medicinal product under the groups of medicinal products dispensed with or without prescription and (or) groups of controlled medicinal products shall be determined in accordance with part 24 of Article 16 of the Law of the Republic of Armenia "On medicinal products".
28. Registration of medicinal products containing different active substances under the name that is the same or similar to a confusing extent, shall be prohibited on the ground of part 8 of Article 16 of the Law of the Republic of Armenia "On medicinal products". The authorised body shall set the requirements to the respective names.
29. The organisation shall, in accordance with the Rule prescribed by Annex No 2 of this Decree, submit the assessment report to the authorised body on the working day following the completion of the assessment.
30. The order on registration of medicinal product shall be adopted by the authorised body within a period 3 working days following the receipt of positive assessment report.
31. The registration of medicinal product shall be valid for 5 years, which shall be calculated from the date of entry into force of the order of the authorised body relating to registration of medicinal product. The authorised body shall, within a period of 5 working days, issue to the applicant a registration certificate of a form approved by the authorised body. The holder of registration certificate shall be provided also with primary and (or) external package, label, instruction for medical application (summary of product characteristics) in Armenian, instruction for use (patient information leaflet) of medicinal product, which serve as a ground for identification of and (or) official information on medicinal products in all stages of circulation of medicinal products in the Republic of Armenia. The registration certificate and the documents attached thereto shall be issued to the applicant in person and (or) through electronic mail, and (or) mail delivery.
32. The data on registered medicinal product, as well as the primary and (or) external package, label, instruction for medical application (summary of product characteristics) and instruction for use (patient information leaflet) of medicinal product in Armenian shall be included in the register as prescribed by the authorised body. The organisation shall ensure the publicity of register, that of

primary and (or) external package, label, instruction for medical application (summary of product characteristics) and instruction for use (patient information leaflet) of medicinal product in Armenian as well as shall ensure to post them on the official Internet website. The same information must be available at www.moh.am.

33. The order on registration of medicinal product shall be published as prescribed by law.

34. Pursuant to part 22 of Article 16 of the Law of the Republic of Armenia "On medicinal products" the holder of registration certificate of medicinal product shall bear liability, as prescribed by law, for safety, efficacy and quality of registered product and shall be obliged to immediately communicate, in writing, to the authorised body each new data and (or) change relating thereto, which have been detected and (or) made during post-registration, including the data of the competent authority of any country relating to the prohibition or restriction of product application. These changes shall be submitted and subject to assessment according to Annex No 2. The changes shall be deemed as accepted from the date of entry into force of the order of authorised body relating thereto, on the basis of which these changes shall be included also in the register.

3. RE-REGISTRATION AND EXTENSION OF THE TERM OF REGISTRATION CERTIFICATE OF MEDICINAL PRODUCT

35. Pursuant to part 19 of Article 16 of the Law of the Republic of Armenia "On medicinal products", following the expiry of the term of registration of medicinal product, a re-registration for a period of 5 years may be carried out.

36. Re-registration may be carried out on the basis of written application of the holder of registration certificate, which shall be submitted to the organisation in person and (or) through electronic mail, and (or) electronic system, and (or) mail delivery.

37. In the course of carrying out re-registration of medicinal product the product safety, efficacy and quality shall be re-evaluated taking as a basis the results of post-registration inspections of safety.

38. The maximum time period of re-registration of medicinal product shall constitute 31 calendar days, which shall include the time period of assessment for the purpose of registration, the maximum duration whereof shall constitute 21 calendar days.

39. The organisation shall, in accordance with the Rule prescribed by Annex No 2 of this Decree, submit the assessment report to the authorised body on the working following the completion of assessment.

40. The order on re-registration of medicinal product shall be adopted by the authorised body within a period of 3 working days following the receipt of positive assessment report, and an amendment shall be made in the registerby adding the data on re-registration.

41. The order on re-registration of medicinal product shall be published as prescribed by law.

42. Within a period of 5 working days following the entry into force of the order of the authorised body relating to re-registration of medicinal product, the applicant shall be issued a re-registration

certificate valid for 5 five years which shall be calculated from the day following the completion of previous registration.

43. Following the expiry of the term of re-registration, the authorised body may extend the term of registration certificate, once in every 5 years, on the basis of the results of post-registration inspections of safety.

44. Following the expiry of the term of re-registration, the term of registration certificate shall be extended in case of existence of a request of the holder of registration certificate, which shall be submitted to the organisation in person and (or) through electronic mail, and (or) electronic system, and (or) mail delivery.

45. The maximum time period of the process of extension of the term of registration certificate of medicinal product shall constitute 10 calendar days, including the time period of assessment.

46. The organisation shall, in accordance with the Rule prescribed by Annex No 2 of this Decree, submit the assessment report to the authorised body on the working day following the completion of assessment.

47. The order on extension of the term of registration certificate of medicinal product shall be adopted by the authorised body within a period of 3 working days following the receipt of positive assessment report, and an amendment shall be made in the registerby adding the data on extension of the term of the certificate.

48. The order on extension of the term of registration certificate of medicinal product shall be published as prescribed by law.

49. Within a period of 5 working days following the entry into force of the order of the Minister relating to extension of the term of registration certificate of medicinal product, the applicant shall be issued a new certificate valid for 5 five years which shall be calculated from the day following the completion of previous registration.

50. The new registration certificate shall be issued to the applicant through electronic mail and (or) mail delivery.

4. REFUSAL OF REGISTRATION, RE-REGISTRATION AND OF EXTENSION OF THE TERM OF THE CERTIFICATE OF MEDICINAL PRODUCTS, WITHDRAWAL OF REGISTRATION, SUSPENSION OF REGISTRATION OF MEDICINAL PRODUCT

51. The registration, re-registration, extension of the term of the certificate of medicinal product shall be refused in the cases prescribed by part 27 of Article 16 of the Law of the Republic of Armenia “On medicinal products”.

52. The order on refusal of registration, re-registration and of extension of the term of the certificate of medicinal product shall be adopted within a period of 5 working days following the receipt of assessment report.

53. The order of the Minister relating to refusal shall, within a period of 2 working days following its adoption, be forwarded to the applicant through electronic mail and (or) mail delivery.

54. The application submitted by the same applicant and in respect of the same medicinal product with refused registration, re-registration or refused extension of the term of the certificate, shall not be proceeded as prescribed by this Rule if the ground for refusal has not been eliminated.
55. The registration, re-registration, extension of the term of the certificate of medicinal product shall be withdrawn in the cases prescribed by part 29 of Article 16 of the Law of the Republic of Armenia "On medicinal products".
56. The order on withdrawal of registration, re-registration or of extension of the term of the certificate of medicinal product shall be adopted within a period of maximum 3 working days following the receipt of assessment report.
57. The order on withdrawal of registration, re-registration or of extension of the term of the certificate of medicinal product shall, within a period of one working day following its entry into force, be forwarded to the applicant, the Healthcare and Labour Inspectorate of the Republic of Armenia (hereinafter referred to as "the Inspectorate") and to entities engaged in circulation of medicinal products, through electronic mail or mail delivery.
58. Following the entry into force of the order on withdrawal of registration, re-registration or of extension of the term of the certificate, the medicinal product shall be removed from register, and a recall of medicinal product shall be made as prescribed by the decree of the Government of the Republic of Armenia.
59. In case of withdrawal of registration of medicinal product pursuant to part 30 of Article 16 of the Law of the Republic of Armenia "On medicinal products", the manufacturing, import, distribution, dispensing, realization and use of medicinal product shall be prohibited.
60. The registration of medicinal product shall be suspended in the cases prescribed by part 31 of Article 16 of the Law of the Republic of Armenia "On medicinal products".
61. In the cases prescribed by point 1 of part 31 of Article 16 of the Law of the Republic of Armenia "On medicinal products" the registration of medicinal product shall be suspended for a period indicated by the holder of registration certificate, whereas in the cases prescribed by points 2-4 — until the elimination of violations or inconsistencies.
62. The order on suspension of registration of medicinal product shall be adopted within a period of one working day following the receipt of assessment report by indicating the period of suspension.
63. The order on suspension of registration of medicinal product shall, within a period one working day following its adoption, forwarded to the applicant, the Inspectorate and to entities engaged in circulation of medicinal products, through electronic mail and (or) mail delivery, as well as relevant note shall be made in the register of medicinal products.
64. Based on the request of the holder of registration certificate, the suspended registration of medicinal product shall be restored on the day following the expiry of the suspension period. In other cases the suspension of registration of medicinal product shall be restored in case of existence of positive assessment report.

65. In case of suspending the registration of medicinal product pursuant to part 32 of Article 16 of the Law of the Republic of Armenia “On medicinal products”, the manufacturing, import, distribution, dispensing, realization and use of medicinal product shall be temporarily prohibited.
66. Where the registration has been suspended in the cases prescribed by part 31 of Article 16 of the Law of the Republic of Armenia “On medicinal products” due to quality, safety and efficacy, which has directly affected the manufactured and imported series, a recall of medicinal product shall be made after termination of circulation, as prescribed by the decree of the Government of the Republic of Armenia.

Prime Minister of
the Republic of Armenia **N. Pashinyan**

Annex No 2
to the Decree of the Government of
the Republic of Armenia No 162-N of
28 February 2019

R U L E

FOR ASSESSMENT CARRIED OUT FOR THE PURPOSE OF STATE REGISTRATION, RE-REGISTRATION, EXTENSION OF THE TERM OF THE CERTIFICATE OF MEDICINAL PRODUCT, AS WELL AS THAT FOR SUBMISSION AND ASSESSMENT OF POST-REGISTRATION CHANGES

1. GENERAL PROVISIONS

1. This Rule shall regulate the legal relations pertaining to assessment carried out for the purpose of state registration, re-registration, extension of the term of the certificate of medicinal products, those pertaining to assessment carried out for the purpose of withdrawal of registration, re-registration and of extension of the term of the certificate, suspension of registration of medicinal product, as well as legal relations pertaining to assessment carried out for post-registration changes.
2. Pursuant to part 14 of Article 16 of the Law of the Republic of Armenia “On medicinal products”, the expert carrying out assessment for the purpose of registration shall be obliged to sign a declaration, of a form specified by the authorised body, in respect of conflict of interests and ensuring confidentiality.
3. The documents necessary for assessment may be submitted through electronic or other tangible medium. The Module 1, except for the main file on risk management plan and safety monitoring (pharmacovigilance), shall be submitted in hard copy.
4. The documents for assessment and the coloured figures of packages of medicinal products (including the post-registration changes) may be submitted in Armenian and (or) Russian, and (or) English.
5. The samples, standards, specific reagents (hereinafter referred to as “the materials”) of laboratory assessments shall be submitted only for medicinal products being registered for the first time in Armenia and in the cases where changes relating to quality have been made in specifications, except for the simplified procedure. The materials shall be submitted in the amounts which are sufficient for making three analyses according to specification. The remaining part of term of the submitted materials must constitute at least six months, except for the cases where the term thereof is less than six months.
6. Materials shall not be required in the case where the accessibility thereof is related to certain difficulties, in particular given the medicinal products containing narcotic drugs and psychotropic

(psychoactive) substances, or in the case where it is impossible to ensure the specific conditions of transfer or maintenance thereof. In above mentioned cases the laboratory analysis shall be carried out during first import for which additional sample shall be submitted.

7. In case of existence of items of medical significance in the packet of the medicinal product, the registration documents must include data and respective opinion delivered by the competent authority relating to its safety, quality and efficacy, as well as relating to its effect on clinical characteristics of medicinal product, or must include a registration certificate.

8. The applicant shall bear liability for accuracy of submitted documents, as well as for authenticity, updated nature of information and for bringing it in compliance with the requirements of legislation. In case of any derogation it is necessary to submit relevant justification for making evaluation during assessment.

9. The assessment shall start after forwarding, by the organisation, the notification on receipt of the application, in case of existence of the documents attesting the fact of payment of state duty and of the fee for assessment in any manner not prohibited by the legislation of the Republic of Armenia.

10. In case of submitting application for simultaneous registration of each next dosage form, dosage, production area and pharmaceutical form of the same medicinal product, the applicant shall be provided a discount in the amount of 5 per cent of the fee approved, by the Government of the Republic of Armenia, for assessment for the purpose of registration thereof.

11. In case of submitting the application for re-registration or the request for extension of the term of the certificate six months prior to the expiry of the term of registration of medicinal product, the applicant shall be provided a discount in the amount of 5 per cent of the fee approved, by the Government of the Republic of Armenia, for assessment for the purpose of re-registration and extension of the term of the certificate.

12. The assessment of registration, re-registration, extension of the term of the certificate, and of post-registration changes in respect of vital medicinal products with low demand, may be carried within the framework of state-funded scheme granted by the authorised body. In this case only the state duty shall be paid by the applicant.

13. In the first stage of assessment, a preliminary examination of documents and materials submitted by the applicant shall be carried out, which shall include the verification of integrity, completeness and accuracy of elaboration of the package of documents (dossier), on the results (including the incomplete or missing documents and materials) whereof the applicant shall be notified in writing.

14. In case of failure to submit the necessary materials and documents within 60 calendar days following the notification of the results of the first stage of assessment, the application shall be rejected on the ground of incompleteness of the submitted documents and (or) materials. The mentioned period shall not be calculated in the general time period of carrying out assessment.

15. At the time of assessment the applicant may not, by its initiative, make amendments to the submitted documents.

16. In the second stage of assessment, for the purpose of assessing the efficacy, safety and quality of medicinal products, the applicant shall, in case of existence of a written request justified by the

organisation, submit — at the time of assessment — additional materials and data, make amendments and supplements to the records of primary and (or) external package of the medicinal product, the summary of product characteristics (instruction for medical application), instruction for use (patient information leaflet) and (or) specifications of the medicinal product. The inquires following the first request shall be permitted only in the case where clarifications are required with regard to materials forwarded in response of the previous one.

17. The maximum time period for submission of responses shall constitute 120 calendar days. Following the expiry of 120 calendar days after having been duly informed of the necessity of submitting additional or missing materials required at the time of assessment, failure to submit them shall result in termination of assessment, and an assessment report shall be drawn up on refusal of registration.

18. In case of general procedure, assessment reports on quality, pre-clinical studies, clinical trials and accompanying information, as well as the conclusion of laboratory inspection and the inspection report (if available) shall serve as a ground for delivering an assessment report.

19. In case of simplified procedure, the comparative assessment report, signed by relevant expert, on the data relating to the composition, specifications, production areas of, research data and accompanying information on the medicinal product approved by the reference competent authority and that registered in the Republic of Armenia, shall serve as a basis for delivering an assessment report.

20. Where at the time of assessment it appears that the fee for assessment does not correspond to the case of registration, the fee shall be recalculated as of the results of assessment, whereon the applicant shall be notified in writing until the completion of assessment.

21. Irrespective of the results of assessment, the documents, materials submitted and the fee provided for assessment for the purpose of registration, shall not be subject to return by ensuring the permanent maintenance and record-registration of documents within the organisation.

22. Prior to submission of the application, the organisation may, if the applicant so wishes, give paid consultation for the purpose of clarifying the selection of registration processes, the volume of documents and submission of data from the point of ensuring the integrity of dossiers in accordance with different types of applications for registration.

2. ASSESSMENT FOR THE PURPOSE OF REGISTRATION

23. The materials, submitted at the time of assessment for the purpose of registration, shall be subjected to assessment by evaluating the quality, safety, efficacy, risk-benefit ratio, and the authenticity of information.

24. The maximum duration of assessment under general procedure shall constitute 140 calendar days.

25. At the time of assessment under general procedure, the compliance of data on quality, safety, efficacy with the requirements of guidelines of ICH and (or) WHO, shall be verified.

26. The quality, active ingredients and excipients, container, and closure material of medicinal products must comply with the requirements of European Pharmacopeia. In case of absence of relevant Articles in European Pharmacopeia, the quality thereof must comply with the requirements of Pharmacopeia of EU Member State, or Pharmacopeia of the Eurasian Economic Union or EEU Member State, or British Pharmacopeia, or US Pharmacopeia, or International Pharmacopeia, or Japan Pharmacopeia, whereas the quality of homeopathic medicinal products — with the requirements of German Homeopathic Pharmacopeia.

27. Reports on pre-clinical studies and (or) clinical trials shall be required for registration of new combinations of medicinal products or medicinal products reproduced in a new dosage, or a new dosage form, or a new indication, different from the original, as well as for registration of bioanalogues.

28. The pre-clinical studies of medicinal product being registered, must be carried out in accordance with the rules of good laboratory practice approved by the authorised body, whereas the clinical trials — in accordance with the rules of good clinical practice approved by the authorised body. The production of medicinal products, medicinal substances and studied pharmaceutical products (in all production areas engaged in production process) must comply with the rules of good manufacturing practice approved by the authorised body, whereas the herbal raw material — with the rules of appropriate processing and collection of medicinal herbs approved by the authorised body.

29. At the time of registration of reproduced medicinal product, the applicant shall not be required to submit data of pre-clinical studies and (or) clinical trials, if the applicant submits documents proving that the medicinal product has been reproduced from the original medicinal product which was registered in the Republic of Armenia or ICH Member State for not less than 8 years. In this case the application for registration of reproduced medicinal product shall be accepted and the assessment shall be carried out, nevertheless the medicinal product may be put into circulation 10 years after the registration of the original medicinal product. In case of registration, by the holder of registration certificate, one or several new indications within a period of 10 years, the time period shall be extended by additional 1 year.

30. The studies of biological medicinal products must comply with the requirements of documents adopted by ICH and (or) those of guidelines of WHO.

31. The bioequivalence studies of reproduced medicinal products must be carried out in accordance with the requirements of guidelines of WHO and (or) the requirements of ICH Member State. The applicant shall not submit data of bioequivalence studies of reproduced medicinal product, where the documents submitted thereby attest that this medicinal product was applied in the Republic of Armenia or ICH Member State for more than 10 years. In these cases the applicant shall submit only relevant data of scientific literature.

32. In case the quality indicators (specifications) comply with the pharmacopeias existing in the Republic of Armenia the laboratory assessment of the quality of submitted samples shall commence for the purpose of verifying the compliance of quality with specifications and the reproducibility of the described methods. A protocol shall be drawn up on the laboratory assessment.

33. Depending on the application, assessment reports shall be drawn up on the results of pre-clinical studies, clinical trials and on evaluation of quality.
34. At the time of assessment, for the purpose of evaluating the compliance of submitted documents, product or production process, a pre-registration inspection may be carried out in accordance with Annex 5 of this Decree. The inspections shall be carried out within the period prescribed for assessment.
35. In case of simplified procedure, the maximum duration of assessment shall constitute 21 calendar days.
36. In case of simplified procedure, the report of the assessment conducted by the reference competent authority with regard to medicinal products registered in ICH Member State or pre-qualified medicinal products of WHO shall be evaluated, by comparing with the submitted documents and data.
37. In case of simplified procedure, the applicant shall be notified of incompliance of the data on quality and quantity composition, production area, stability and specifications, as well as of incompliance of accompanying information, and after making the necessary payments upon the consent thereof the registration shall be made under the general procedure prescribed by this Decree.
38. At the time of assessment for the purpose registration under general procedure and simplified procedure, the compliance of primary and (or) external packages, summary of product characteristics (instruction for medical application), instruction for use (patient information leaflet) of medicinal product with the requirements prescribed by the legislation of the Republic of Armenia shall be verified, by simultaneously elaborating the Armenian version of the patient information leaflet.
39. Where at the time of assessment it appears that the name of the medicinal product is the same as or similar, to a confusing extent, to the name of medicinal product having been already registered and containing other medicinal substances, the applicant shall be offered to change the name, whereas in case of failure to change it an opinion on refusal of registration shall be drawn up.
40. At the time of assessment, the classification of medicinal product under the groups of medicinal products sold with or without prescription shall be also determined, in accordance with the legislation of the Republic of Armenia taking as a basis part 24 of Article 16 of the Law of the Republic of Armenia “On medicinal products”.
41. The results of assessment shall be summarised within the organisation, and an assessment report shall be delivered — in accordance with the annexed form, by attaching thereto the primary and (or) external figures of medicinal product, summary of product characteristics (instruction for medical application), instruction for use (patient information leaflet) in Armenian, the quality specifications and the agreed risk management plan (if available) of the medicinal product.
42. The owner of registration certificate shall, prior to the import of medicinal product and (or) at the time of first import, submit to the organisation samples per each primary and (or) external package, out of finished printed samples.
43. The organisation shall, on the working day following the completion of assessment, notify the applicant in writing of the results of assessment.

3. ASSESSMENT FOR THE PURPOSE OF RE-REGISTRATION

44. At the time of assessment for the purpose of re-registration, the quality, safety, efficacy and risk-benefit ratio of medicinal product shall be re-evaluated, taking as a basis the results of post-registration inspections.
45. The duration of assessment shall constitute 21 calendar days.
46. Re-registration shall be refused in case of existence of the grounds prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicinal products".
47. The assessment report shall be submitted to the authorised body, in accordance with the Rule prescribed by Annex No 1 approved by this Decree.

4. ASSESSMENT FOR THE PURPOSE OF EXTENSION OF THE TERM OF THE CERTIFICATE

48. At the time of assessment for the purpose of extension of the term of the certificate, the data on safety of medicinal product shall be evaluated, which have been obtained during post-registration.
49. The maximum duration of assessment shall constitute 5 working days.
50. The assessment report shall be submitted to the authorised body, in accordance with the Rule prescribed by Annex No 1 approved by this Decree.
51. The extension of the term of the certificate shall be refused in case of existence of the grounds prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicinal products".

5. THE SUBMISSION AND ASSESSMENT OF POST-REGISTRATION CHANGES

52. All changes made after registration shall be subject to assessment.
53. The assessment shall be carried out within a period of 30-90 calendar days depending on the type of amendment — as of impact on quality, safety and efficacy (first — the impact is minimum and (or) is missing, second — the impact is essential).
54. The changes relating to the quality, safety and efficacy of medicinal product registered under simplified procedure, must be approved by the reference competent authority.
55. The results of assessment shall be summarised upon assessment report.
56. The assessment report shall be submitted to the authorised body on the working day following the completion of assessment.
57. The post-registration changes shall be refused in case of existence of the grounds prescribed by part 27 of Article 16 of the Law of the Republic of Armenia "On medicinal products".
58. The order on accepting or refusing the post-registration changes of medicinal product shall be adopted by the authorised body within a period of 3 working days following the receipt of the assessment report.

59. The order of the Minister shall, within a period of 2 working days following its adoption, be forwarded to the applicant by electronic mail and (or) mail delivery.
60. In case of accepting the changes, an amendment shall be made in the registerby indicating the type of the change and the date of acceptance thereof.
61. The organisation shall notify the applicant, in writing, of the results of assessment, on the working day following the completion of assessment, by informing about the changes requiring new registration (if available).
62. The changes listed in Annex No 4 of this Decree shall, according to the order of the Minister, be attached to the package of documents, by making a reformulation of the certificate under the procedure approved by the authorised body.
63. The reformulated certificate shall be issued to the applicant within a period of 5 working days following the entry into force of the order of the authorised body relating to acceptance of changes.
64. As regards the illustrations (coloured design) of the bar-code and the instruction for use, as well as in case of the changes not relating to quality, efficacy and safety, the previous approved packages of medicinal product shall remain in effect within a period of additional 180 calendar days following the acceptance of new changes.
65. Within a period of maximum one month after drawing up the assessment report of post-registration changes, a supplement shall be made also to the assessment report of registration of medicinal product and to the assessment report thereof, taking into account the new information.

Prime Minister of
the Republic of Armenia **N. Pashinyan**

Form

ASSESSMENT REPORT **ON EVALUATION OF SAFETY, EFFICACY AND QUALITY**

Name of the product ————————————-

Strength ————————————-

Pharmaceutical form ————————————-

Composition, by indicating the international nonproprietary name, the quantity(ies) of active substance(s)————————————

Packaging, presentation ————————————

Type of the product (for human use, veterinary, homeopathic, immunological, herbal, radioactive etc.)----------

Dispensing (with prescription, without prescription, controlled) ————

Manufacturers engaged in the production process, including the manufacturer of pharmaceutical form, bulk manufacturer, packer of finished product, quality controller, series release entity (name, address, country) ————————————----------
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Holder of registration certificate (name, address, country) ————

Anatomical Therapeutic Chemical (ATC) code ————————

Indications for use ————————————

Expiry date ————————————-

Maintenance conditions ————————————

Case of registration ————————————-

Registration procedure (simplified, general, re-registration etc.) ----------
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Data of registration (refusal) in other countries ————————————

Results of assessment of quality ————————————-

Results of assessment of efficacy and safety —

Conclusion---------

Day, month, year ————————-

Signature ————————-

Annex No 3
to the Decree of the Government
of the Republic of Armenia No 162-N
of 28 February 2019

L I S T
OF THE DOCUMENTS NECESSARY FOR ASSESSMENT CARRIED OUT FOR THE PURPOSE OF STATE REGISTRATION, RE-REGISTRATION, EXTENSION OF THE TERM OF THE CERTIFICATE OF MEDICINAL PRODUCT, AS WELL AS THOSE NECESSARY FOR SUBMISSION AND ASSESSMENT OF POST-REGISTRATION CHANGES

1. DOCUMENTS REQUIRED FOR REGISTRATION OF MEDICINAL PRODUCT

1. Application containing information on the case of registration and on medicinal product,
2. Package of documents (dossier) according to ICH common technical document,
3. The report of assessment carried out by the competent authority of another country or during WHO pre-qualification and the original copies of the approved specifications and instructions for application which form an integral part thereof, as well as their translated versions, in case of not being drawn up in Russian or English (mandatory — in case of simplified procedure),
4. The original copies of the documents attesting the fact of payment of state duty and of the fee for assessment.

2. DOCUMENTS REQUIRED FOR RE-REGISTRATION OF MEDICINAL PRODUCT

1. Application containing information on re-registration and on medicinal product,
2. Module 1 of the dossier — according to ICH common technical document,
3. The monitoring reports on adverse effects, drawn up in the format approved by the authorised body,
4. The original copies of the documents attesting the fact of payment of state duty and of the fee for assessment.

3. DOCUMENTS REQUIRED FOR EXTENSION OF THE TERM OF THE CERTIFICATE

1. Request,
2. The original copies of the documents attesting the fact of payment of state duty and of the fee for assessment.

4. DOCUMENTS REQUIRED AT THE TIME OF SUBMISSION OF POST-REGISTRATION CHANGES

1. Application containing the description of the type of the change(s),
2. Documents regarding the change(s), including relevant justifications and (or) clarifications,
3. The original copy of the document attesting the payment of the fee for assessment.

Prime Minister of the
Republic of Armenia **N. Pashinyan**

Annex No 4
to the Decree of the Government
of the Republic of Armenia No 162-N
of 28 February 2019

L I S T

OF THE CHANGES OF REGISTERED MEDICINAL PODUCT WHICH DO NOT REQUIRE NEW REGISTRATION

1. Taking as a basis the requirement of part 20 of Article 16 of the Law of the Republic of Armenia "On medicinal products", this Annex shall define the list of the changes on registered medicinal products where new registration is not required, and a reformulation of the registration certificate of medicinal product shall be made.
2. The changes of registered medicinal product which do not require new registration, shall be as follows:
   1) change in the name or registered office of the holder of registration certificate, where the legal person has not changed,
   2) change only in the name of the medicinal product, without any other changes,
   3) change in the common name, without any changes in the medicinal substance,
   4) change in the name of manufacturer, without change of the manufacturer and the registered office thereof,
   5) change in the pharmaceutical form which is related to the changes in quantity of units included in the package.

Prime Minister of
the Republic of Armenia **N. Pashinyan**

Annex No 5
to the Decree of the Government
of the Republic of Armenia No 162-N
of 28 February 2019

R U L E

FOR INSPECTION AND FOR RECOGNITION OF INSPECTION REPORTS OF COMPETENT AUTHORITIES OF OTHER COUNTRIES

1. This Rule shall regulate the relations pertaining to the conduct of inspections at the time of state registration of medicinal products in the Republic of Armenia and recognition of the reports of inspections conducted by the competent authorities of other countries.
2. The inspections or the recognition of inspection reports of competent authorities of other countries shall be carried out by the assessment organisation defined upon the decree of the Government of the Republic of Armenia (hereinafter referred to as "the organisation").
3. All experts of the organisation carrying out inspection shall be obliged to sign a declaration, of a form specified by the authorised body, in respect of conflict of interests and ensuring confidentiality.
4. The costs related to inspections shall be compensated by the applicant, based on the contract concluded between parties as prescribed by law.
5. Inspections shall be carried out directly within production areas, as well as in the places of carrying out pre-clinical studies, clinical trials and bioequivalence studies (including those carrying out relevant activities on a contractual basis).
6. Inspections shall be carried out within time periods prescribed for assessment of registration of medicinal products under the Law of the Republic of Armenia "On medicinal products", based on the assessment reports on the results of documentation assessment.
7. Taking as a basis the results of evaluation of risks, in the cases not posing high risks the inspections may be carried out after the registration within a period of maximum 180 calendar days.
8. For the purpose of continuously evaluating the risk-benefit ratio, data on the registration of respective medicinal product or those related thereto may be required at the time of inspection.
9. The evaluation of Good Manufacturing Practice (GMP) compliance in a production area, shall be carried out under the procedure approved by the Government of the Republic of Armenia in accordance with the Law of the Republic of Armenia "On medicinal products".
10. In the places of carrying out pre-clinical studies, clinical trials and bioequivalence studies, the inspections shall be conducted within 30 calendar days after notifying the applicant. The maximum time period of inspections shall constitute 5 working days. A protocol shall be drawn up on the basis of inspection results, which shall be signed by the expert(s) carrying out inspection and by relevant representative of the applicant.

11. In case of positive results of inspections in respect of Pharmaceutical Inspection Co-operation Scheme compliance and GMP compliance, carried out within the last three years by the competent authorities of the countries holding membership in Eurasian Economic Union, the relevant reports shall be recognised and no inspection shall be carried out.

12. In case of positive results of inspections carried out during WHO pre-qualification, as well as carried out by the competent authorities of the countries holding membership both in the ICH and Eurasian Economic Union, in the places of pre-clinical studies, pre-clinical trials and bioequivalence studies, the relevant reports shall be recognised and no inspection shall be carried out.

Prime Minister
of the Republic of Armenia **N. Pashinyan**