DECISION OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA ON ESTABLISHING THE PROCEDURE FOR IMPORTING INTO AND EXPORTING FROM THE TERRITORY OF THE REPUBLIC OF ARMENIA MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS, THE PROCEDURE FOR CONDUCTING EXPERT EXAMINATION FOR THE PURPOSE OF IMPORTING AND EXPORTING MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS AND THE LIST OF REQUIRED DOCUMENTS, AS WELL AS ON REPEALING THE DECISION OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA No 581 OF 20 SEPTEMBER 2000

Գլխավոր տեղեկություն

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GOVERNMENT OF THE REPUBLIC OF ARMENIA

DECISION

No 202-N of 28 February 2019

ON ESTABLISHING THE PROCEDURE FOR IMPORTING INTO AND EXPORTING FROM THE TERRITORY OF THE REPUBLIC OF ARMENIA MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS, THE PROCEDURE FOR CONDUCTING EXPERT EXAMINATION FOR THE PURPOSE OF IMPORTING AND EXPORTING MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS AND THE LIST OF REQUIRED DOCUMENTS, AS WELL AS ON REPEALING THE DECISION OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA No 581 OF 20 SEPTEMBER 2000

Pursuant to parts 1, 4 of Article 21, point 1 of part 7, point 5 of part 8 and part 10 of Article 21 of the Law of the Republic of Armenia “On medicines”, the Government of the Republic of Armenia ***hereby decides:***

1. To establish:

(1) the procedure for importing into and exporting from the territory of the Republic of Armenia medicines, medical substances, herbal raw materials and researched pharmaceutical products, pursuant to Annex No 1;

(2) the procedure for conducting expert examination for the purpose of importing or exporting medicines, medical substances, herbal raw materials and researched pharmaceutical products and the list of required documents, pursuant to Annex No 2.

2. To repeal the Decision of the Government of the Republic of Armenia of 20 September 2000 “On approving the procedure for importing into and exporting from the territory of the Republic of Armenia medicines and medical substances” No 581.

3. This Decision shall enter into force on the tenth day following the date of its official promulgation. Until the procedure for issuing a licence for wholesale of medicines, defined by part 2 of Article 24 of the Law of the Republic of Armenia “On medicines”, enters into force, the availability of a licence shall not be mandatory for import of medicines, medical substances, herbal raw materials and researched pharmaceutical products.

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

14 March 2019
Yerevan

Annex No 1
to Decision of the Government
of the Republic of Armenia
No 202-N of 28 February 2019

PROCEDURE

FOR IMPORTING INTO AND EXPORTING FROM THE TERRITORY OF THE REPUBLIC OF ARMENIA MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS

1. GENERAL PROVISIONS

1. This Procedure shall regulate the relations pertaining to the import (hereinafter referred to as “the import”), parallel import of medicines, medical substances, herbal raw materials and researched pharmaceutical products (hereinafter referred to as “the pharmaceutical products”), by means of crossing the state border of the Republic of Armenia, from a country not holding membership in the Eurasian Economic Union (hereinafter referred to as “the EAEU”) (hereinafter referred to as “the third country”), as well as from a Member State of EAEU, as well as those pertaining to the export of pharmaceutical products from the territory of the Republic of Armenia to a third country and EAEU Member States.

2. In accordance with the Law of the Republic of Armenia “On medicines”, the requirements of this Procedure shall extend to:

(1) import of pharmaceutical products from EAEU Member State and export to EAEU Member State;

(2) pharmaceutical products imported from third countries under the customs procedures “Release for domestic consumption”, “Re-import”, “Processing for domestic consumption” or “Abandoning in favour of the state”, or those exported to third countries under the customs procedure “Export”;

(3) medicines of the treatment plan of a natural person departing to a foreign State and arriving from a foreign State or those for personal use, as well as medicines for personal use imported by a carrier or by international postal deliveries in the name of a natural person.

(Point 2 amended by No 1197-N of 12 September 2019, supplemented by No 1302-N of 6 August 2020)

3. This Procedure shall not extend to veterinary medicinal products, including vaccines, serums and diagnostic products.

4. Pharmaceutical products shall be imported into the territory of the Republic of Armenia on the basis of the import (conformity) certificate issued by the Ministry of Health of the Republic of Armenia (hereinafter referred to as "the Authorised Body"). The export of pharmaceutical products from the territory of the Republic of Armenia, if the exporter so wishes, may be carried out on the basis of the export certificate issued by the Authorised Body.

5. The import (conformity) and export certificate of pharmaceutical products, pursuant to the Law of the Republic of Armenia "On medicines" and this Procedure, shall be issued by the Authorised Body based on the expert opinion of the expert organisation (hereinafter referred to as "the Organisation") prescribed by the Decision of the Government of the Republic of Armenia.

6. The expert examination conducted in order to issue a certificate of import (conformity) of pharmaceutical products into the territory of the Republic of Armenia shall include the following:

(1) conformity inspection of data of samples of imported pharmaceutical products (coloured diagram of the labels of the primary and secondary packages of medicines and the leaflet) and of accompanying documents thereof (documentary study);

(2) identification of imported medicines with samples of appropriate medicines registered in the Republic of Armenia;

(3) laboratory expert examination for medical substances and herbal raw materials imported by a non-pharmaceutical manufacturer, as well as for medicines imported within the scope of charitable and humanitarian programmes;

(4) conformity inspection of data of the final product registration documents for medical substances and herbal raw materials imported for the purposes of production of medicine registered in the Republic of Armenia;

(5) inspection of the temperature regime ("cold chain") for the transportation and storage of the medicine or medical substances;

(6) inspection of the lack of grounds for refusal specified in sub-point 17 of point 8 of Article 21 of the Law "On medicines";

(7) conformity inspection of the packaging, labelling, and marking of medical substances, herbal raw materials, and researched pharmaceutical products with the requirements set by legislation.

(Point 6 supplemented by No 1197-N of 12 September 2019, amended, supplemented by No 1926-N of 5 December 2024)

7. The importer shall, following the receipt of the import (conformity) certificate but prior to sales, certify through the responsible person thereof the compliance of the medicine with the requirements established in the Republic of Armenia (series release) pursuant to the procedure described in points 37-45 of this Procedures, except for the medicines imported within the scope of charitable and humanitarian programmes.

(Point 7 supplemented by No 1197-N of 12 September 2019)

8. Import (conformity) or export certificates shall be issued for actually importing or exporting each product group of pharmaceutical products across the customs border once.

9. Import or export certificates shall be issued for a period of one year and shall expire after the customs clearance of the product group.

10. Pharmaceutical products shall be imported into and exported from the territory of the Republic of Armenia with certificates in accordance with the commodity nomenclature of foreign economic activity of the Eurasian Economic Union (hereinafter referred to as "CN of FEA"), according to the following codes — 2904-2909, 2912-2942000000, 3001-3004, 3006 30 0000, 3006 60 000, 3006 930000, 2936, 3913, and medicines included in the following positions — as of codes 2106909300, 2106909303, 2106909808, as well as according to the names of products

(Point 10 edited by No 1197-N of 12 September 2019, No 776-N of 2 June 2022)

11. In case of import, for non-pharmaceutical purposes, of declared substances or plants or parts of plants of the CN of FEA shall not be subject to certification by the authorised body. In this case, the importer shall declare to the customs bodies that the product is being imported for non-pharmaceutical purposes.

(Point 11 edited by No 1197-N of 12 September 2019, No 1926-N of 5 December 2024)

12. Medicines registered in the Republic of Armenia may be imported into the territory of the Republic of Armenia, except for the cases prescribed by law.

13. No Import (conformity) or export certificate shall be required in the cases provided for by part 7 of Article 21 of the Law of the Republic of Armenia "On medicines".

14. For the purpose of the treatment plan of a natural person departing to a foreign State and arriving from a foreign State or of personal use, as prescribed by point 1 of part 7 of Article 21 of the Law of the Republic of Armenia "On medicines", the import or export — without a certificate — of medicines registered or not registered in the Republic of Armenia shall be permitted in the

amount of “up to 10 units, three consumer packages each”, where the documents on the prescription of the medicine (prescription or extract from the disease history or other document signed by the physician) do not justify a larger amount necessary for the treatment plan.

14.1. Import of medicines for personal use imported by a carrier or by international postal deliveries in the name of a natural person without a certificate shall be permitted once during the given calendar year in the amount of “up to 5 units, three consumer packages each”. In order to import the medicines, the data on the natural person and on medicines shall be record-registered by the customs body in the unified automated information system of the customs body, by carrying out control over the periodicity of import. Until the introduction of the possibility of record-registration of the data on the natural person and on medicines in the unified automated information system of the customs body, the record-registration of these data shall be carried out by the employees of the customs body who are vested with appropriate powers, in a new, separated system of record-registration. In case of exceeding the quantities prescribed by this point, it shall be necessary to obtain a prior authorisation from the Authorised Body and an import certificate in the case of import by the supplier in accordance with points 49-51 of this Procedure.

(Point 14.1 supplemented by No 1302-N of 6 August 2020, edited by No 1926-N of 5 December 2024)

14.2. Within the meaning of points 14 and 14.1 of this Procedure, the individual packaging of a medicine, by which it is presented for retail sales, shall be considered as a consumer package.

(Point 14.2 supplemented by No 1302-N of 6 August 2020)

15. At the time of import into the territory of the Republic of Armenia, the remaining part of shelf-life of the pharmaceutical product must be at least six months. The import of pharmaceutical products with a shorter shelf-life, including medicines imported within the scope of charitable and humanitarian programmes, shall be permitted for the needs of the State, based on the decision of the Authorised Body.

(Point 15 edited by No 1197-N of 12 September 2019)

16. State duty shall be levied for issuing import or export certificate of pharmaceutical products in the amount specified by point 52 of part 1 of Article 20 of the Law of the Republic of Armenia “On state duty”.

17. In the Republic of Armenia, the Authorised Body shall issue import or export certificate of pharmaceutical products containing narcotic drugs and psychotropic (psychoactive) substances in accordance with the Law of the Republic of Armenia “On medicines”, Law of the Republic of Armenia “On narcotic drugs and psychotropic (psychoactive) substances” and other regulatory legal acts.

2. PROCEDURE FOR IMPORTING PHARMACEUTICAL PRODUCT INTO THE TERRITORY OF REPUBLIC OF ARMENIA

18. Entities defined by part 2 of Article 21 of the Law of the Republic of Armenia “On medicines” or persons authorised thereby (hereinafter referred to as “the applicant”) shall have the right to submit an application for the purpose of obtaining an import (conformity) certificate of pharmaceutical products.

19. The applicant shall, for the purpose of importing pharmaceutical product into the territory of the Republic of Armenia, submit an electronic application (hereinafter referred to as “the application”) to the Authorised Body through the "Permitting documents (sw.gov.am)” system available on the electronic platform of the “National Single Window for Foreign Trade of the Republic Of Armenia” (trade.gov.am) (hereinafter referred to as the System), by attaching coloured scanned copies of the required documents (in the form of files in “PDF” format).

(Point 19 edited by No 977-N of 10 June 2021, No 1926-N of 5 December 2024)

(Point 19 with regard to the amendment of sub-point 1 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permit ting documents (sw.gov.am)" system)

20. Registration of electronic applications submitted by the applicant shall be ensured during working days and hours. The electronic applications submitted on non-working days and hours shall be considered as submitted on the following working day.

21. The fact as to the application being registered in the Authorised Body shall be confirmed by a return e-mail notification within the same day, which contains the registration number of the application in the System, being forwarded to the

e-mail address from which the application was sent.

(Point 21 supplemented by No 977-N of 10 June 2021, amended by *No 1926-N of 5 December 2024*)

(Point 21 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the " Permitting documents (sw.gov.am)" system)

22. After registration of the application, the submitted documents shall, within maximum one working day, be examined by the Organisation, and the applicant shall be notified about sampling, by the phone number or e-mail address specified by the applicant, with an indication on the date, time and place of sampling.

23. In case of inaccuracies, omissions in the application or attached documents, as well as incomplete and/or illegible documents, the applicant shall be notified thereon through the System from the moment of detecting them, and the applicant shall submit the necessary and corrected documents through the same system.

(Point 23 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 23 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permit ting documents (sw.gov.am)" system)

24. If the applicant fails to eliminate the shortcomings within ten working days after receiving the notification, the issuance of the import certificate shall be rejected by the Authorised Body.

(Point 24 amended by No 1926-N of 5 December 2024)

25. The period starting from the moment of entry in the Authorised Body of the application on obtaining an import certificate or conformity certificate, and of the required documents, up to the issuance of the certificate of import (conformity) or its substantiated rejection, may last not more than six working days. In case of problems related to the quality and safety of the pharmaceutical product, the process may be extended for another ten working days for the purpose of making clarifications with the manufacturer. The Organisation shall place the information on the decision on extending the deadline of applications and substantiations of adopting the decision, in Section “Notes” of the System.

(Point 25 supplemented by No 977-N of 10 June 2021, amended by No 438-N of 28 March 2024, No 1926-N of 5 December 2024)

(Point 25 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permit ting documents (sw.gov.am)" system)

26. The time limit for elimination of shortcomings provided for by point 23 of this Procedure shall not be calculated within the time period prescribed by point 25 of this Procedure.

27. In case of import from a third country, the sampling of pharmaceutical products shall be carried out in the customs control zone, and in case of import from an EAEU Member State — in the warehouse of the applicant, as prescribed by Annex No 2 to the Decision of the Government of the Republic of Armenia No 202-N of 28 February 2019.

28. The Organisation shall conduct expert examination of imported pharmaceutical products, and the results of the expert examination in the form of an expert opinion shall be submitted, through the System, to the Authorised Body within maximum five working days. In case of a need for additional expert examination prescribed by point 25 of this Procedure, this time limit may be extended for another ten working days.

(Point 28 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 28 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permit ting documents (sw.gov.am)" system)

29. The Authorised Body shall, within one working day following the receipt of the expert opinion, grant or reject the application. The electronic certificate (Form No 3) of import (conformity) of pharmaceutical products or the electronic order on rejecting the import shall be provided to the applicant through the System after the entry, through the System, of the payment receipt for the state duty paid by the applicant.

(Point 29 supplemented by No 977-N of 10 June 2021, amended by No 438-N of 28 March 2024, No 1926-N of 5 December 2024)

(Point 29 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

30. Upon written application of the applicant, the latter or the person authorised thereby shall be given an opportunity to get familiarised with the materials of the proceedings within three working days from the date of submission of the application.

31. ***(Point repealed by No 776-N of 2 June 2022)***

32. The Authorised Body shall provide the hard copy of the import (conformity) certificate of pharmaceutical product based on the application of the applicant or the person authorised thereby.

33. The issuance of the certificate of import of pharmaceutical products into the territory of the Republic of Armenia shall be rejected on the grounds provided for by part 8 of Article 21 of the Law of the Republic of Armenia “On medicines”.

(Point 33 amended by No 1926-N of 5 December 2024)

34. The order of the head of the Authorised Body, related to rejection of the issuance of import certificate on the grounds provided for by point 33 of this Procedure, must clearly state the legal grounds for rejection.

35. When importing the medicine directly from the holder of the registration certificate, in case of compliance of all indicators with the sample for registration, merely the inconsistency of the design of the outer package shall not serve as a ground for rejecting the import of the medicine. In this case the import of the medicine shall be permitted, though at the same time the Organisation

shall immediately make an inquiry to the holder of the registration certificate regarding the inconsistency of the package of the medicine. In case of receiving from the holder of the registration certificate substantiated data on terminating the circulation of the medicine, the circulation of the medicine shall be terminated as prescribed by the legislation of the Republic of Armenia, and its recall shall be arranged.

36. In case of rejecting the issuance of import certificate, the pharmaceutical product may not be sold in the Republic of Armenia and/or shall be subject to destruction or export. Following the receipt of the order on rejecting the issuance of the certificate, the applicant shall inform the Authorised Body, in writing, of the destruction or export within 90 working days, by attaching relevant documents certifying the destruction or export.

37. Following the receipt of the import (conformity) certificate, the importer shall carry out the series release of pharmaceutical products prior to sales, in accordance with the requirements set by the legislation of the Republic of Armenia.

38. For the purpose of carrying out series release, the importer must possess a licence for the wholesale of medicines with an indication on the series release.

39. In the course of series release by the importer, the responsible person shall carry out an assessment of the conformity of the medicine and its supply process with the requirements established by the legislation of the Republic of Armenia. Based on the results of assessment and import (conformity) certification, the responsible person of the importer shall take a decision on conducting laboratory control.

40. The laboratory control of quality may be performed at least by the economic operator holding a licence for production of medicines, containing an indication on quality control, where the holder of the registration certificate must provide thereto the quality indicator (specification) approved in the course of registration of the medicine in the Republic of Armenia. The quantities of samples required for quality control of the medicine, shall be defined in the respective table of this Procedure.

41. In the cases where the holder of the registration certificate fails to provide the quality indicator (specification), the importer may outsource the quality control of series to the Organisation.

42. In case of import directly from the holder of the registration certificate or a person duly authorised thereby, the importer needs not, at the time of series release of the medicine and upon the decision of the responsible person, to carry out laboratory control, based on the Pharmaceutical Inspection Co-operation Scheme (PIC/S) or the results of laboratory control by manufacturers holding the certificate of proper production activity issued by the competent authorities of EAEU Member States.

43. The Authorised Body shall ensure the publicity of the list of manufacturers mentioned in point 42 of this Procedure (www.moh.am).

44. The importer shall inform the Authorised Body, in writing, of the data on pharmaceutical products rejected as a result of series release process, within maximum three working days.

45. The pharmaceutical product rejected as a result of series release process may not be sold in the Republic of Armenia and shall be subject to destruction or export.

46. The importer shall provide access to complete information (including the name of the product, dosage, pharmaceutical form, serial number, import (conformity) certificate number) on each package of the product sold, through label stamps defined by the Tax Code of the Republic of Armenia.

(Point 46 supplemented by No 1197-N of 12 September 2019)

47. The absence of the leaflet in Armenian of the imported medicine shall not serve as a ground for rejecting the import of the medicine. In this case, the medicine shall be provided with a leaflet (in case of absence thereof — with a leaflet of relevant registered medicine) in Armenian after the import, as prescribed by the Authorised Body, pursuant to part 3 of Article 20 of the Law of the Republic of Armenia “On medicines”.

(Point 47 supplemented by No 1197-N of 12 September 2019)

48. In the case where the indications for the application of the imported medicine or the release status of the imported medicine (with prescription or without prescription) do not correspond to the sample for registration, the importer shall, prior to the sales of the medicine, submit a letter of commitment to indicate these on the packaging of the medicine in compliance with the sample for registration by means of coating, or to carry out re-labelling through a licensed pharmaceutical manufacturer. Where the language of the packaging or labelling of the imported medicine differs from the language of the packaging or labelling of the medicine registered in the Republic of Armenia, the importer is required, prior to the sales, to submit a letter of commitment to carry out the re-labelling of the medicine through a licensed pharmaceutical manufacturer. The re-labelled medicine shall be provided with the package leaflet, registered in the Republic of Armenia.

Where the indications on special terms of storing the medicine, special warnings, permissible period of the use thereof after opening the primary package are missing in the records of packaging of the imported product or fail to comply with the sample for registration, the importer shall mark “see package leaflet” on the pill box by means of coating and shall provide the medicine with a leaflet of the medicine registered in the Republic of Armenia.

(Point 48 supplemented by No 1197-N of 12 September 2019, edited, supplemented

by No 1926-N of 5 December 2024)

49. For the purpose of obtaining non-registered or registered medicine for individual patients, which are missing in the pharmaceutical market of the Republic of Armenia (hereinafter referred to as “the non-registered medicine”), legal persons providing medical aid and service, pharmacy activities, individual entrepreneurs, as well as natural persons (hereinafter referred to as “the applicant”) shall apply to the Authorised Body, by substantiating the necessity for applying the non-registered medicine. The application shall contain the commercial and/or international common names of the medicine, pharmaceutical form, dosage, form of release, data of the personal identification document of the patient, diagnosis, the quantity required for treatment, name (title) and address of the applicant. A carbon copy of the personal identification document of the patient and the medicine prescription document shall be attached to the application.

50. The Authorised Body shall, within one working day, forward the application on obtaining the non-registered medicine for individual patients to the Organisation, which shall, within maximum two working days, check the absence of registered equivalent of non-registered medicine (not registered or registered but not imported) and shall report thereon, in writing, to the Authorised Body.

In the absence of a registered equivalent medicine, the Authorised Body shall provide the applicant with a prior authorisation for importing the medicine, and in case of availability thereof — shall deliver a rejection. In case of availability of a prior authorisation, the medicine may be ordered from suppliers, by attaching a carbon copy of the prior authorisation from the Authorised Body, or may be acquired by international postal deliveries.

51. In case of import of non-registered medicine by the supplier, the import certificate shall be provided in accordance with this Procedure, by attaching a carbon copy of the prior authorisation from the Authorised Body. The cargo sent from another country through international postal deliveries to a natural person or to their authorised representative, as prescribed by the legislation of the Republic of Armenia, is released based on the prior authorisation by carrying out the registration of the data related to the natural person and the medicine as prescribed by the procedure established in point 14.1 of this procedure.

(Point 51 supplemented by No 977-N of 10 June 2021, edited by No 1926-N of 5 December 2024)

(Point 51 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

52. ***(Point repealed by No 1926-N of 5 December 2024)***

3. PROCEDURE FOR AND PECULARITIES OF ISSUING AUTHORISATION FOR PARALLEL IMPORT OF MEDICINES

53. Parallel import shall be deemed as bringing the registered medicine into the territory of the Republic of Armenia by crossing the state border, not directly from the holder of the registration certificate in the Republic of Armenia or from a person duly authorised thereby.

54. In case of parallel import, the importer shall, pursuant to part 14 of Article 21 of the Law of the Republic of Armenia “On medicines”, bear responsibility for the safety, effectiveness and quality of the imported medicine.

55. The medicine imported in parallel shall be imported into the territory of the Republic of Armenia based on the import (conformity) certificate issued by the Authorised Body.

56. The importer shall receive free of charge information from the Organisation, related to the packages of registered medicines, leaflets and documents required for import.

57. The parallel import operator may apply to the Authorised Body, in writing, before ordering the medicine and carrying out its transportation, in order to find out the existence of the grounds for parallel import permit of the medicine, the traceability of the supply, and to obtain a parallel import permit. The availability of a parallel import permit shall not be required to obtain an import (conformity) certificate.

58. Application for parallel import permit pursuant to Form No 2 shall be submitted to the Authorised Body by e-mail at info@moh.am. The following shall be attached to the application:

(1) sample of the medicine subject to import or photos of all sides of primary and secondary packages thereof — separately for each series, and the leaflet;

(2) Armenian translations, made in a prescribed manner, of primary and external packaging and of the leaflet, where the language of the records on the packaging of the medicine to be imported does not correspond to any of the languages accepted for the packaging of medicines under the legislation of the Republic of Armenia;

(3) a document certifying the fact of payment of the expert examination fee.

59. On the same day, following the receipt of the application and the necessary materials from the Authorised Body, the Organisation shall carry out a preliminary expert examination within five working days and shall notify the applicant, in writing, of the results.

60. In case of inaccuracies, omissions in the application on receiving parallel import permit or in documents attached thereto, as well as in case the documents are incomplete and/or illegible, the Organisation shall, from the moment of detection thereof, offer the applicant to eliminate the

shortcomings within ten working days, by informing thereof at respective e-mail address.

61. After having eliminated the shortcomings, the Organisation shall continue the expert examination and in case of receiving no necessary data from available official sources, it shall make an inquiry also to the competent authority of the supplying country wherefrom the medicine is being imported.

62. Following the receipt of the application, the Organisation shall, within maximum 30 working days, assess the conformity of the medicine to be imported and the medicine registered in the Republic of Armenia and shall submit the expert opinion to the Authorised Body on the working day following the completion of the expert examination.

63. The order on authorising or rejecting the parallel import by the Authorised Body shall be adopted within two working days following the receipt of the expert opinion, where in case of rejection the legal grounds for rejection shall be clearly indicated.

64. Issuance of a parallel import permit of medicines shall be rejected on the grounds provided for by part 11 of Article 21 of the Law of the Republic of Armenia “On medicines”.

65. The Authorised Body shall declare as invalid the parallel import permit, where:

(1) the registration of the given medicine was declared as invalid in the Republic of Armenia or in the country producing the medicine or in the supplying country, given the safety, effectiveness and quality of the medicine;

(2) after issuance of the permit it appeared that the production of medicine imported in parallel does not comply with the rules of proper production activity;

(3) after issuance of the permit it appeared that the importer submitted false information on the medicine imported in parallel.

66. The parallel import operator shall, for the purpose of obtaining import (conformity) certificate, submit an application to the Authorised Body under the procedure prescribed by Section 2 of this Procedure.

67. The issuance of the import certificate shall be rejected in case of existence of at least one of the grounds provided for by point 33 of this Procedure.

(Point 67 amended by No 1926-N of 5 December 2024)

68. Where inconsistencies exist between the indications or contraindications for the application of the medicine imported in parallel and those of the registered medicine, in case they are not indicated on the package and are specified only in the leaflet, the importer shall provide the medicine with the leaflet of the medicine registered in the Republic of Armenia, pursuant to the point 71 of this Procedure.

(Point 68 edited by No 1926-N of 5 December 2024)

69. Where a difference exists in the name or location of the holder of the registration certificate of the medicine imported in parallel with those of the registered medicine, the importer shall, prior to the sales of the medicine, cover the record related to the name or location of the holder of the registration certificate by means of coating on the pill box, by indicating its name and location.

70. If the language of packaging and labelling of the medicine imported in parallel differs from the language of packaging or labelling of the medicine registered in the Republic of Armenia, the importer shall, prior to the sales, ensure re-packaging of the medicine in compliance with the sample for registration by submitting bill of commitment on the re-labelling of the medicine through a pharmaceutical manufacturer holding a licence.

(Point 70 edited by No 1926-N of 5 December 2024)

71. The parallel imported medicine must be provided by the importer with the package leaflet of the medicine registered in the Republic of Armenia, adding its name, address, and contact details for consumer communication in the notes. The import certificate is issued to the importer only if there is a bill of commitment to fulfil the requirement prescribed by this point.

(Point 71 edited by No 1926-N of 5 December 2024)

4. PECULARITIES OF IMPORTING PHARMACEUTICAL PRODUCTS INTO THE TERRITORY OF THE REPUBLIC OF ARMENIA FROM A MEMBER STATE OF THE EURASIAN ECONOMIC UNION

72. The provisions of the Treaty On Eurasian Economic Union, the requirements of the Law of the Republic of Armenia “On medicines”, those of this Procedure and other regulatory legal acts shall apply to the relations pertaining to the import of pharmaceutical products from EAEU Member States.

73. When importing pharmaceutical products from EAEU Member States into the territory of the Republic of Armenia, following the transportation of the product accross the state border of the Republic of Armenia, the importer shall, within three working days, apply to the Authorised Body for the purpose of receiving import (conformity) certificate, by submitting an application pursuant to Form No 1 and by attaching the documents of the list approved by this Procedure.

74. The importer shall transport the pharmaceutical product, imported into the territory of the Republic of Armenia from the Member State of EAEU, to its warehouse and shall not sell, distribute, release or use it until receiving an import (conformity) certificate and carrying out series release.

75. Where the issuance of import (conformity) certificate is rejected, the pharmaceutical product may not undergo series release, sold in the Republic of Armenia and shall be subject to

destruction or export. Following the receipt of the order on rejecting the issuance of the import (conformity) certificate, the importer shall, within 90 working days, inform, in writing, the Authorised Body of the destruction or export of pharmaceutical products.

5. PROCEDURE FOR EXPORTING PHARMACEUTICAL PRODUCTS FROM THE TERRITORY OF THE REPUBLIC OF ARMENIA

76. In case of exporting pharmaceutical products from the territory of the Republic of Armenia, the existence of a certificate issued by the Authorised Body shall not be mandatory. It shall be issued if the applicant so wishes, pursuant to the Law of the Republic of Armenia “On medicines” and this Procedure.

77. The period starting from the entry of the application and the required documents up to the issuance of the export certificate may last maximum three working days.

78. The applicant shall, for the purpose of exporting pharmaceutical products from the territory of the Republic of Armenia, submit an application to the Authorised Body through the application System, by attaching coloured scanned copies of the required documents (files in PDF format).

(Point 78 edited by No 1926-N of 5 December 2024)

79. Registration of electronic applications submitted by applicants shall be ensured during working days and hours. The electronic applications submitted on non-working days and hours shall be considered as submitted on the following working day.

80. The fact as to the application being registered in the Authorised Body shall be confirmed by a return e-mail notification within the same day, which contains the registration number of the application in the System, being forwarded to the e-mail address from which the application was sent.

(Point 80 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 80 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

81. From the moment the application is registered, the applicant shall be informed of the absence of documents and/or detection of shortcomings therein, if any, through the System. In case the documents submitted in an electronic form are not legible, the applicant may be required to submit legible copies of the documents to the Authorised Body.

(Point 81 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 81 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

82. After being notified as prescribed by point 81 of this Procedure, the applicant shall, within ten working days, in addition to the submitted application, submit through the System a scanned copy (copies) of the required or corrected document(s) to the Authorised Body.

(Point 82 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 82 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

83. The time period for elimination of shortcomings prescribed by point 81 of this Procedure shall not be calculated within the time period prescribed by point 77 of this Procedure.

84. In case of failing to eliminate the shortcomings within ten working days after being notified, the Authorised Body shall reject the application.

85. In case of absence of the ground provided for by point 81 of this Procedure, the Organisation shall, within maximum two working days, submit the results of expert examination in the form of expert opinion to the Authorised Body through “the System.

(Point 85 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 85 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

86. (Point repealed by No 1926-N of 5 December 2024)

87. The Authorised Body shall, within one working day, grant or reject the application following the receipt of the expert opinion. The electronic order on rejecting the electronic certificate of export of pharmaceutical products or application shall be provided to the applicant through the System after the entry, through the System, of the payment receipt for the state duty paid by the applicant.

(Point 87 supplemented by No 977-N of 10 June 2021, amended by No-1926-N of 5 December 2024)

(Point 87 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting

documents (sw.gov.am)" system)

88. The Authorised Body shall provide the hard copy of the certificate of export of pharmaceutical products and of the order on rejecting the application, based on the application of the applicant or the person authorised thereby.

(Point 88 amended by No 1926-N of 5 December 2024)

89. The issuance of the export certificate shall be rejected in case of existence of one of the grounds provided for by part 8 of Article 21 of the Law of the Republic of Armenia “On medicines”.

(Point 89 amended by No 1926-N of 5 December 2024)

90. The order of the head of the Authorised Body on rejecting the export on the grounds provided for by point 89 of this Procedure, must clearly state the legal grounds for rejection.

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

Form No 1

Minister of Health
of the Republic of Armenia

_____
(name, surname)

_____
(name, surname of an individual entrepreneur; name of the legal person)

_____
(place of residence (location) of an individual entrepreneur (legal person))

APPLICATION No _____

city of Yerevan _____ ___20

Please provide _____ certificate
(import (conformity) or export)

_____
(supplying (exporting) country and organisation)

_____

The required documents shall be attached to the application, pursuant to the decision of the Government of the Republic of Armenia:

1. Documents (bill/invoice) attesting the acquisition of medicines, medical substances, herbal raw materials and researched pharmaceutical products

_____
(name, reference number and date of the document)

2. Documents for transportation of medicines, medical substances, herbal raw materials and researched pharmaceutical products, according to the type of vehicle

_____
(name, reference number and date of the document)

The application shall be filled in by an individual entrepreneur or the director of a legal person, by using the login and password of “National Single Window for Foreign Trade of the Republic Of Armenia” electronic system.

Form No 2

Minister of Health
of the Republic of Armenia

_____
(name, surname)

_____
(name, surname of an individual entrepreneur) (name of the legal person)

_____
(place of residence (location), e-mail address and telephone number)

APPLICATIO No N _____

city of Yerevan _____ ___20

Please grant parallel import permit _____

_____
(supplying country and organisation)

_____
(name of medicine, pharmaceutical form, dosage, composition, release form)

_____

Name(s) of manufacturer(s) responsible for product re-packaging, location of manufacturing area

Data on the manufacturing process being implemented

☐ Re-packaging
☐ Re-labelling
☐ Replacement of package leaflet
☐ Other (provide details)

Form No 3

MINSITRY OF HEALTH OF THE REPUBLIC OF ARMENIA

(Government Building No 3, Yerevan 0010, Republic of Armenia)

Tel.: (+ 374 60) 80 80 03

E-mail:info@moh.am

CERTIFICATE OF IMPORT (CONFORMITY) OR EXPORT OF MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS

1. Name and address of the importer	TIN		3. Reference number of the certificate	4. (Date of issue)		5. Valid through	
			6. Type of application (purpose of import)	7. Reference number of application		8. Date of application	
			9. Gross weight (kg)	10. Net weight (kg)		11. Reference number of the document	
2. Name and address of the exporter (supplier)							
			12. Trading country	14. Permitted quantity		15. Rejected quantity	
			13. Exporting country	16. Shipping method		17. Transit country	
18. Supporting documents							
NN i/s	Name		Code	Reference number		Date	
1.							
2.							
3.							
4.							
19. Authorised pharmaceutical products							
NN i/s	Name	CN FEA Code	Quantity	Unit	Responsible country	Series	Time limit
20. Special notes			Secretary General of the Ministry of Health of the Republic of Armenia				

TABLE

on quantities of quality control samples of medicines, medical substances and herbal raw materials

Pharmaceutical form	Quantity of laboratory control samples
1. Tablets	60 pcs
2. Capsules	60 pcs
3. Dragees	60 pcs
4. Tiles (for instance, briquettes or cubes)	40 pcs
5. Chewing gums	40 pcs
6. Suppositories	40 pcs
7. Pharmaceutical powders, including granules for making solutions	40 g
8. Respiratory medicated powder	20 g
9. Dusting powder	20 g
10. Suspensions	100 ml
11. Emulsions	100 ml
12. Syrups	100 ml
13. Medicinal liquid, mixture (drug mixture)	100 ml
14. Tinctures, extracts	60 ml
15. Drops (for instance eye, ear, nose) — single-component,	40 ml
16. multi-component	60 ml
17. Oils (for instance, castor, rose hip, sea buckthorn, etc.)	100 ml (g)
18. Solutions regardless of the type of solvent	50 ml
19. Aerosol up to 50 ml	3 packages
20. Above 50	2 packages
21. Spray	50 ml
22. Solutions for injection	30 ml
23. Intravenous solutions	200 ml
24 Intravenous concentrates	50 ml
25. Sterile (lyophilised) powders	minimum 10 g (8-10 vials)
26. Creams, ointments, jellies	60 g
27. Liniments	150 g
28. Pastes	60 g
29. Sterile or small scale creams, oils, ointments, jellies (for example: eye, ear, nose, lip)	30 g
30. Pencils	30 g
31. Medicated pads, sponges, wipes, films, inserts and plasters	10 pcs
32. Conditioners	5 packages
33. Liquid soaps	150 ml
34. Lotion	150 ml
35. Varnishes	5 ml
36. Glues	2 packages
37. Medical substances	30 g
38. Herbal raw materials in a consumer package	30 g

(Form amended by No 1197-N of 12 September 2019)

(Annex amended, supplemented and edited by No 1197-N of 12 September 2019, supplemented by No 1302-N of 6 August 2020, edited and amended by No 776-N of 2 June 2022, No 776-N of 2 July 2022, edited, supplemented by No 977-N of 10 June 2021, amended by No 438-N of 28 March 2024, amended, supplemented, edited by No 1926-N of 5 December 2024)

Annex No 2
to Decision of the Government
of the Republic of Armenia
No 202-N of 28 February 2019

PROCEDURE FOR CONDUCTING EXPERT EXAMINATION FOR THE PURPOSE OF IMPORTING OR EXPORTING MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS AND THE LIST OF REQUIRED DOCUMENTS

1. This Procedure shall regulate the legal relations pertaining to the conduct of expert examination for the purpose of issuing a certificate of import (conformity) (including parallel import (conformity) of medicine) into and export from the territory of the Republic of Armenia of medicines, medical substances, herbal raw materials and researched pharmaceutical products (hereinafter referred to as “the pharmaceutical products”).

2. The expert examination for the purpose of issuing a certificate of import (conformity) into and export from the territory of the Republic of Armenia of pharmaceutical products shall be carried out by the Organisation specified in point 5 of Annex No 1 to the Decision of the Government of the Republic of Armenia No 202-N of 28 February 2019.

3. The expert examination of pharmaceutical products shall consist of the stage of documentary expert examination, and in respect of medicines — also that of identification with the sample for registration.

4. The expert examination of pharmaceutical products, serving as a preliminary expert examination, shall be launched in the customs control zone in case of import thereof into the territory of the Republic of Armenia from a country not holding membership (hereinafter referred to as “the third country”) in the Eurasian Economic Union (hereinafter referred to as “the EAEU”), and in the warehouse where the pharmaceutical product is kept (hereinafter referred to as “the warehouse of the applicant”) — in case of import from the Member States of EAEU.

5. During the preliminary expert examination, an external inspection of cargo shall be carried out, as well as the completeness of packaging of pharmaceutical products and the storage conditions thereof shall be checked.

6. The expert of the Organisation shall carry out sampling in the customs control zone with participation of the employee of the customs body and the person authorised by the applicant, and in the warehouse of the applicant — with participation of the person authorised by the applicant, moreover, in case of carrying out sampling in the warehouse of the applicant, the applicant shall ensure free access of the expert to the warehouse.

7. Sampling in the customs control zone and in the warehouse of the applicant shall be carried out, according to the order of receipt of applications.

8. One sample each shall be selected from all series of all units of imported pharmaceutical products (hereinafter referred to as “the samples”) in order to verify the conformity of the product accompanying documents and samples and to certify as to the samples and the samples for registration of corresponding medicines being identical.

9. The sampling process shall be formalised by the act of sampling in the form approved by this Procedure, according to Form No 1, which in case of sampling in the customs control zone shall be signed by an expert of the Organisation, an employee of the customs body and an authorised person of the importer, and in case of sampling in the warehouse of the applicant — by an expert of the Organisation and an authorised person of the importer. The act of sampling shall not serve as a ground for customs formalities.

10. The following shall not be subject to sampling:

(1) samples and laboratory standards of medical substances envisaged for state registration of medicines in the Republic of Armenia;

(2) goods exported from the territory of the Republic of Armenia;

(3) medical substances and excipients imported for manufacturing purposes;

(4) samples envisaged for pre-clinical and clinical testing;

(5) samples of medicines imported without the right to realisation, envisaged for exhibitions, conferences or other similar measures;

(6) medicines imported for separate patients.

11. The selected samples shall be separated from the imported product group and transferred to the Organisation in packages that ensure the integrity thereof, i.e. in bags that ensure the integrity and thermal regime of samples.

12. Documentary expert examination shall be conducted in the Organisation through examining the integrity of documents, conformity of accompanying documents and samples.

13. The identification of samples of imported medicines shall be carried out through comparison with the samples of corresponding medicines having undergone state registration.

14. In case of export of pharmaceutical products, only documentary expert examination shall be conducted.

15. After completion of the expert examination, the samples shall be returned to the applicant along with the act of return of samples of the form approved by this Procedure, pursuant to Form No 2, by making an appropriate indication on the reverse side of the act of sampling.

16. After completing the expert examination within time limits prescribed by this Decision, the Organisation shall, through "Permitting documents (sw.gov.am)" electronic system, submit the results of expert examination in the form of an expert opinion to the Authorised Body, according to Form No 3.

(Point 16 supplemented by No 977-N of 10 June 2021, amended by No 1926-N of 5 December 2024)

(Point 16 with regard to the amendment of sub-point 2 of point 11 of Decision No 977-N of 10 June 2021 shall enter into force from the date of launch of the "Permitting documents (sw.gov.am)" system)

17. A state duty shall be charged for the examinations related to the import or export of pharmaceutical products in the manner and amount prescribed by Law “On state duty”. Where the amount of the state duty paid for the examination does not match the established rates, the organisation notifies the applicant about the underpaid state duty before the completion of the examination. The underpaid state duty shall be subject to payment within 5 days from the receipt of the notification. "

(Point 17 edited by No-1926-N of 5 December 2024)

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

Form No 1

OF EXAMINATION AND SAMPLING OF MEDICINES, MEDICAL SUBSTANCES, HERBAL RAW MATERIALS AND RESEARCHED PHARMACEUTICAL PRODUCTS

ACT No _____ _____201

Expert of the organisation (name) _____
(name, surname)

Applicant or a person authorised thereby as prescribed by law _____
_____
(name, surname of an individual entrepreneur or name of the organisation)

_____
(name, surname of the person authorised by the applicant)

Employee of the customs service _____
(name, surname)

Place of taking samples _____
The product was received according to _____
(accompanying documents)

Special thermal conditions maintained during sampling (for pharmaceutical products requiring refrigeration regime).	yes	no

Name of medicines, medical substances, herbal raw materials and researched pharmaceutical products	Measurement unit	Series	Manufacturer		Shelf-life	Packaging and labelling condition	Quantity of selected samples
			Organisation	Country			

Expert of the organisation (name) _____ _____
(signature) (name, surname)

Person authorised by the applicant _____ _____
(signature) (name, surname)

Employee of the customs service _____ _____
(signature) (name, surname)

Form No 2

(reverse side)

ACT OF RETURN OF SAMPLES
_____ _____ 20

I: _____
(name, surname of the deliverer)

Receiver :
To _____
(name, surname of the person authorised by the applicant)

I have returned the samples of all medicines, medical substances, herbal raw materials of No --- sampling act, in specified quantities, except for:

SAMPLES OF MEDICINES, MEDICAL SUBSTANCES, HARBAL RAW MATERIALS	Quantity

Deliverer _____ _____
(signature) (name, surname)

Acceptor _____ _____
(signature) (name, surname)

(Form amended by No 1197-N of 12 September 2019)

Form No 3

EXPERT OPINION No ____

Pursuant to import application No ____ of __00.00.0000 __ of the Ministry of Health of the Republic of Armenia, the organisation (name) has carried out sampling of medicines, medical substances, herbal raw materials and researched pharmaceutical products (CN of FEA Code __0000_) imported into the territory of the Republic of Armenia by the applicant (name) according to No _____ invoice as of _00.00.0000___, identification of samples and examination of documents.

During the expert examination it was found that:

1. The imported medicine is registered/is not registered in the Republic of Armenia.
2. The imported medicine conforms to the sample for registration/does not conform to the sample for registration.
3. Absence of required documents (if any) approved by the procedure for issuing the import (conformity) and export certificate.
4. Additional notes (if any).

Director _____ _____
(signature) (name, surname)

Expert: _____
(name, surname, phone number)

LIST

OF DOCUMENTS REQUIRED FOR ISSUING CERTIFICATE FOR IMPORT (COMFORMITY) INTO OR EXPORT FROM THE TERRITORY OF THE REPUBLIC OF ARMENIA OF MEDICINES, RESEARCHED PHARMACEUTICAL PRODUCTS, MEDICAL SUBSTANCES AND HERBAL RAW MATERIALS

1. For the purpose of carrying out commercial import into or export from the territory of the Republic of Armenia of medicines, researched pharmaceutical products, medical substances and herbal raw materials, the entities prescribed by point 18 of Annex No 1 to the Decision of the Government of the Republic of Armenia No 202-N of 28 February 2019 shall submit (in an electronic form) to the Authorised Body the following:

(1) application pursuant to Form No 1;

(2) ***(Sub-point repealed by No 1197-N of 12 September 2019)***

(3) licence (of the applicant) for the wholesale of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products;

(4) licence for the production of medical substances and herbal raw materials — in case of importing medicines, researched pharmaceutical products, medical substances and herbal raw materials for production purposes;

(5) invoice — signed and/or sealed (in case of existence of a seal) by the supplier;

(6) documents for the transportation of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products according to the type of vehicle:

a. air bill of lading (sealed with the stamp of the customs warehouse and relevant notes of the customs officer),

b. transit declaration (if any) or transport (transportation), commercial or other documents,

c. international waybill (CMR),

d. postal bill of lading;

(7) the quality certificate of each series of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products issued by the manufacturing organisation and/or right-holder, with mandatory indication of the series, manufacturing date and shelf-life of the imported batch, and in case of vaccines — also the release certificate issued by the competent authority and the summary protocol issued by the manufacturing organisation, except in emergency situations, when the vaccine release certificate and summary report are submitted, if available. In case of acquiring medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products from intermediary organisations, the quality certificate issued by the manufacturing organisation must be signed and/or sealed with the seal of the intermediary organisation (if any);

(8) a document certifying the production chain of the organisations participating in the production of given series of imported medicines and/or medical substance, in case of absence of the data required to verify conformity with the registered medicine;

(9) data on the thermal indicator of transportation process for medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products requiring special thermal storage conditions (in case of import);

(10) packing list with mandatory indication of series and quantity;

(11) the parallel import permit issued by the Authorised Body (if any);

(12) the photo of the package label of the imported medical substances, herbal raw materials, and researched pharmaceutical products;

(13) the document certifying the payment of the state duty *set for* examination;

(14) certified Armenian translations of the primary, outer packaging, and package leaflet, should the language of the packaging entries of the imported medicine not correspond to any of the languages accepted for pharmaceutical packaging under the legislation of the Republic of Armenia.

(Point 1 amended, edited and supplemented by No 1197-N of 12 September 2019, amended, supplemented by No 1926-N of 5 December 2024)

2. For the purpose of importing into the territory of the Republic of Armenia the samples envisaged for state registration of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products, for conferences, exhibitions and other similar events, the following shall be submitted (in an electronic form) to the Authorised Body:

(1) application pursuant to Form No 1;

(2) invoice — signed and/or sealed (in case of existence of a seal) by the supplier;

(3) the quality certificate of each series of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products issued by the manufacturing organisation, with mandatory indication of the series, manufacturing date and shelf-life of the imported batch, and in case of vaccines — also the release certificate issued by the competent authority and the summary protocol issued by the manufacturing organisation, except in emergency situations, when the vaccine release certificate and summary report are submitted, if available;

(4) documents for the transportation of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products according to the type of vehicle:

a. air bill of lading (sealed with the stamp of the customs warehouse and relevant notes of the customs officer),

b. transit declaration (if any) or transport (transportation), commercial or other documents,

c. international waybill (CMR),

d. postal bill of lading;

(5) data on the thermal indicator of transportation process for medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products requiring special thermal storage conditions (in case of import);

(6) packing list, with mandatory indication of series and quantity.

(7) the document certifying the payment of the state duty set for examination.

(Point 2 supplemented by No 1197-N of 12 September 2019, supplemented, amended by No 1926-N of 5 December 2024)

3. For the purpose of carrying out import into and export from the territory of the Republic of Armenia of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products, within the scope of charitable and humanitarian programmes, the following shall be submitted (in an electronic form) to the Authorised Body:

(1) application pursuant to Form No 1;

(2) the decision of the Commission for Co-ordination of Charitable Programs of the Government of the Republic of Armenia on qualifying the programme of the given organisation as charitable;

(3) invoice or other document accompanying cargo sealed (in case of existence of a seal) and/or signed by the supplier, with mandatory indication of the series, quantity and shelf-life of the imported batch (in the absence of indications on the quantity, to be submitted after sampling);

(4) documents for the transportation of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products according to the type of vehicle:

a. air bill of lading (sealed with the stamp of the customs warehouse and relevant notes of the customs officer),

b. transit declaration (if any) or transport (transportation), commercial or other documents,

c. international waybill (CMR),

d. postal bill of lading;

(5) the quality certificate of the given batch of pharmaceutical product (if any), with mandatory indication of the series, manufacturing date and shelf-life of the imported batch, a document confirming registration in a country that is a member of an international professional organisation or prequalification by the World Health Organisation, as established by a decision of the Government of the Republic of Armenia, and in case of vaccines — also the release certificate issued by the competent authority and the summary protocol issued by the manufacturing organisation, except in emergency situations, when the vaccine release certificate and summary report are submitted, if available;

(6) data on the thermal indicator of transportation process for medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products requiring special thermal storage conditions (if any) (in case of import);

(7) packing list.

(8) ***(Sub-point repealed by No 1197-N of 12 September 2019)***

(Point 3 amended and supplemented by No 1197-N of 12 September 2019, edited by No 1926-N of 5 December 2024)

4. For the purpose of carrying out import into and export from the territory of the Republic of Armenia of samples envisaged for clinical research of medicines, medical substances and herbal raw materials, as well as researched pharmaceutical products, the following shall be submitted (in an electronic form) to the Authorised Body:

(1) application pursuant to Form No 1;

(2) invoice signed and/or sealed by supplier, with mandatory indication of the series, quantity and shelf-life of the imported batch;

(3) the quality certificate of medicines, researched pharmaceutical products, medical substances and herbal raw materials, issued by the manufacturing organisation, with mandatory indication of the series, manufacturing date and shelf-life of the imported batch, and in case of vaccines — also the release certificate issued by the competent authority and the summary protocol issued by the manufacturing organisation, except in emergency situations, when the vaccine release certificate and summary report are submitted, if available;

(4) the documents of goods transportation in accordance with the type of the vehicle:

a. air bill of lading (sealed with the stamp of the customs warehouse and relevant notes of the customs officer),

b. transit declaration (if any) or transport (transportation), commercial or other documents,

c. international waybill (CMR),

d. postal bill of lading;

(5) clinical trial permit issued by the Authorised Body as prescribed by the legislation of the Republic of Armenia;

(6) data on the thermal indicator of transportation process for pharmaceutical products requiring special thermal storage conditions (in case of import);

(7) packing list, with mandatory indication of series and quantity.

(8) the photo of the package label of the imported medical substances, herbal raw materials, and researched pharmaceutical products;

(9) the document certifying the payment of the state duty set *for* examination.

(Point 4 supplemented by No 1197-N of 12 September 2019, supplemented, amended by No 1926-N of 5 December 2024)

(Annex amended, edited and supplemented by No 1197-N of 12 September 2019, supplemented by No 977-N of 10 June 2021, amended, edited, supplemented by No 1926-N of 5 December 2024)

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Փոփոխման պատմություն

Փոփոխող ակտ	Համապատասխան ինկորպորացիան

Փոփոխված ակտ

Փոփոխող ակտ	Համապատասխան ինկորպորացիան