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The conditions and procedure for the import and export, carrying for personal use and sending of goods that require a special authorisation of the State Agency of Medicines, the forms of special authorisations and the list of goods that require a special authorisation of the State Agency of Medicines

[RT I, 25.03.2014, 3 - entry into force 28.03.2014]

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Amended by the following acts

Passed	Published	Entry into force
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19.12.2008	RTL 2008, 102, 1457	01.01.2009
11.11.2011	RT I, 18.11.2011, 1	01.01.2012
06.05.2013	RT I, 10.05.2013, 1	13.05.2013
20.03.2014	RT I, 25.03.2014, 3	28.03.2014
04.04.2014	RT I, 09.04.2014, 2	01.07.2014
20.05.2016	RT I, 25.05.2016, 4	28.05.2016
22.02.2017	RT I, 07.03.2017, 20	10.03.2017, partially 03.05.2017

This Regulation is enacted in accordance with subsection 17 (1) and subsection 19 (5) of the Medicinal Products Act.

§ 1. Scope of application

(1) This Regulation establishes:
1) the list of goods that require a special authorisation of the State Agency of Medicines (hereinafter, ‘goods that require a special authorisation’);
2) the conditions and procedure for the import and export of goods for which a special authorisation of the State Agency of Medicines (hereinafter, ‘a special authorisation’) is required, including the conditions and procedure for applying for a special authorisation for import or export, for the issue of a special authorisation, for the notification of import or export, and the conditions under which a special authorisation or notification of the State Agency of Medicines is required for the import or export of cells, tissues and organs of human or animal origin used for medical or research purposes;
[RTL 2008, 102, 1457 – entry into force 01.01.2009]
3) the conditions for carriage, by travellers, of medicinal products to be used, for medical reasons, personally by the travellers or on animals accompanying the travellers, and the conditions for the sending of medicinal products;
[RT I, 25.03.2014, 3 – entry into force 28.03.2014]
4) the form of the application for the use of unauthorised medicinal products by a physician, a veterinarian or a professional association of physicians or veterinarians.
[RTL 2010, 10, 182 – entry into force 08.03.2010]

§ 2. List of goods that require a special authorisation

(1) The following goods require a special authorisation:

1) medicinal products, including medicinal products used in the clinical trial and unusable medicinal products;
2) active substances of a medicinal product;
3) tissues of human or animal origin, cells and organs or substances derived therefrom for medical or scientific use in the prevention, diagnosis, treatment of a disease or relief of a disease condition when used in a patient;
4) blood products, antisera, other blood fractions and immunological products for medical use, unless they are used in a patient;
5) narcotic drugs and psychotropic substances included in Lists I to IV and VI of narcotic drugs and psychotropic substances;
6) hormones, prostaglandins, thromboxanes and leukotrienes, natural or synthetic; derivatives and structural analogues thereof, including modified chain polypeptides, used primarily as hormones;
7) antibiotics;
8) vegetable alkaloids, natural or reproduced by synthesis, and their salts, ethers, esters and other derivatives;
9) glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

§ 3. Conditions for the import and export of goods that require a special authorisation

(1) Import or export permit is required:
1) upon importing medicinal products based on section 21 of Medicinal Products Act;
2) upon importing medicinal products used in clinical trials;
3) upon importing and exporting narcotic drugs and psychotropic substances;
4) upon importing and exporting other goods subject to a special authorisation.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(2) In cases not specified in subsection (1) of this section, the State Agency of Medicines must be notified of the import or export of goods subject to a special authorisation.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(3) The quantity and list of the imported and exported goods may not exceed the quantity stated in the special authorisation. The goods must be identifiable according to the shipment documents and the special authorisation.

(4) [Repealed – RT I, 10.05.2013 – entry into force 13.05.2013]
(4^1) If a person who holds the right to import a medicinal product wishes to import a medicinal product that the holder of the marketing authorisation of that product has not designated as a medical product imported by that person, the person notifies the marketing authorisation holder and the State Agency of Medicines of its intention to import the medicinal product. Where the marketing authorisation for the medicinal product has been issued by the European Commission, the person who holds the right to import medicinal products must notify the marketing authorisation holder and the European Medicines Agency of its intention to import the medicinal product.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(5) A medicinal product in whose respect a licence for parallel import has been issued may not be imported if, in its country of origin, the marketing authorisation of that medicinal product has been revoked or has expired.

(6) [Repealed – RT I, 07.03.2017, 20 – entry into force 10.03.2017]

§ 4. Applying for an authorisation for import or export

(1) The special authorisation of the State Agency of Medicines must be applied for in respect of each consignment of goods that require a special authorisation. Application shall be submitted by the consignee in Estonia (importer) upon importing goods subject to a special authorisation and the consignor in Estonia (exporter) upon exporting such goods, and it shall include the applicant’s name, address, email address and telephone number, the consignor’s name in the event of import and the consignee’s name in the event of export, address, date of application and details on the goods requiring a special authorisation.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(2) The following information must be presented with regard to the medicinal products:
1) the name of the medicinal product;
2) the pharmaceutical form;
3) the active substance(s) and their strength;
4) the quantity in a package;
5) the manufacturer and marketing authorisation holder for authorised medicinal products;
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]
6) the ATC code of the medicinal product;
7) the number of packages;
8) the packaging code, if available.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(3) If the imported goods subject to a special authorisation are not intended for use in Estonia, the corresponding declaration must be provided in the application.

[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(4) The application for authorisation for the import of an unauthorised medicinal product must state the number of the resolution adopted by the State Agency of Medicines for the use of the unauthorised medicinal product.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(5) The following information must be presented when applying for a special authorisation for the import of medicinal products intended for clinical trials:
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
1) the reference number assigned by the State Agency of Medicines in respect of the conduct of the clinical trial;
2) the name of the medicinal product;
3) the pharmaceutical form;
4) the active substance(s) and their strength;
5) the quantity in a package;
6) the number of packages.

(6) The following information must be presented with regard to other goods that require a special authorisation:
1) the name of the goods that require a special authorisation;
2) the quantity in a package;
3) the number of packages;
4) an explanation regarding the purpose of use of the goods that require a special authorisation;
5) a certificate of the cells, tissues and organs of human or animal origin, signed by the competent person of the handler of cells, tissues and organs.
[RTL 2008, 102, 1457 – entry into force 01.01.2009]

(7) [Repealed – RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(8) The application for a special authorisation for the import or export of narcotic drugs or psychotropic substances must contain the name and signature of the person responsible for the handling of these substances.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(9) The application for import or export shall be submitted to the State Agency of Medicines either electronically through the corresponding online environment of the State Agency of Medicines or signed on paper.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

§ 5. Notification of the import or export of goods that require a special authorisation

(1) In the case referred to in section 19(1)(2) of the Medicinal Products Act, the importer or exporter of medicinal products must submit the following information to the State Agency of Medicines:
1) the date of import or export;
2) the name, address and contact information of the consignor and consignee;
3) the name of the medicinal product;
4) the pharmaceutical form;
5) the active substance(s) and their strength;
6) the quantity in a package;
7) the manufacturer and marketing authorisation holder for authorised medicinal products;
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]
8) the ATC code of the medicinal product;
9) the number of packages;
10) packaging code, if available.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(1^1) When notifying the State Agency of Medicines of the import or export of cells, tissues and organs of human or animal origin, the handler of cells, tissues and organs must submit to the Agency the information required by subsections 4 (1) and (6).
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(1^2) When notifying the State Agency of Medicines of the import or export of medicinal products intended for clinical trials, the importer or exporter must submit to the Agency the information required by subsections 1 and 5 of section 4 and the date of import or export.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(2) Notification shall be submitted by the consignee in Estonia (importer) upon importing goods subject to a special authorisation and the consignor in Estonia (exporter) upon exporting such goods, and it shall include the notifier’s name, address, email address and telephone number, the consignor’s name in the event of import and

the consignee's name in the event of export, address, date of notification and details on the goods requiring a special authorisation.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(3) If the goods subject to a special authorisation are not used in Estonia, the notification must be confirmed accordingly.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]
(3^1) The notification of import or export shall be submitted to the State Agency of Medicines either electronically through the corresponding online environment of the State Agency of Medicines or signed on paper.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(4) The State Agency of Medicines informs the notifier of receiving the notification.

§ 6. Application for the use of unauthorised medicinal products

(1) In the case referred to in section 21(1) of the Medicinal Products Act, the application to be submitted to the State Agency of Medicines for the use of unauthorised medicinal products must contain the following information:
1) the active substance(s);
2) the pharmaceutical form and the strength of the active substance(s);
3) the route of administration of the medicinal product;
4) the quantity of the medicinal product for a maximum of 12 months;
5) the number of the prescription;
6) the code of the diagnosis and/or indication; where the medicinal product is to be used for veterinary purposes, the species and the indication;
7) the medical justification for the application;
8) the patient's surname if the medicinal product is applied for for a single patient, or the name of the health care or social welfare institution if the medicinal product is applied for with a view to be administered to the patients of the institution.

(2) In the cases referred to in sections 21(7) and 21(8) of the Medicinal Products Act, the application for the use of an unauthorised medicinal product must contain the information specified in points 1-4, 6 and 7 of subsection 1 of this section.

(3) In the case referred to in section 21(7)(1) of the Medicinal Products Act, the medical justification for the use of the medicinal product must specify all forms of treatment of the diagnosed condition as well as the efficiency and safety of the medicinal product concerning which the application is submitted in comparison to other therapies. The medical justification must contain references to research publications. Copies of the research publications are to be submitted at the request of the State Agency of Medicines.

(4) The application must state the name and contact information (position, address of the place of work, physician's code, number of the activity licence of the veterinarian, telephone, e-mail) of the physician or veterinarian. The application must be signed and dated. In the case referred to in section 21(7)(1) of the Medicinal Products Act, the application must be approved by a person authorised to represent the professional association.

(5) In order to use an unauthorised medicinal product with a specific patient under subsection 21 (1) of the Medicinal Products Act, the application shall be submitted through the Digital Prescription Centre. In order to use an unauthorised medicinal product in health care or social welfare institution under subsection 21 (1) of the Medicinal Products Act, the application shall be submitted in the form set out in Annex 7 to this Regulation. In order to use an unauthorised medicinal product for veterinary use under subsection 21 (1) of the Medicinal Products Act, the application shall be submitted in the form set out in Annex 8 to this Regulation. In cases specified in subsections 21 (7) and (8) of the Medicinal Products Act, the application shall be submitted in the form set out in Annex 12 or 13 to this Regulation.
[RT I, 07.03.2017, 20 – entry into force 03.05.2017]

§ 7. Formalisation of the authorisation for import and export

(1) The authorisation for import and export of goods that require a special authorisation is prepared on a document form of the State Agency of Medicines in the format set out in Annexes 1 and 2 to this Regulation.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(2) The authorisation for import of an investigational medicinal product is prepared on a document form of the State Agency of Medicines in the format set out in Annex 3 to this Regulation.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(3) The authorisation for the import of narcotic drugs and psychotropic substances and medicinal products containing such substances shall be printed on a pink document form of the State Agency of Medicines in the format set out in Annex 5 to this Regulation in two copies: the first copy is submitted by the importer to the customs administration for customs clearance during import; the second copy is issued by the State Agency of Medicines for submission to the competent authority in the source country.

[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(4) The authorisation for the export of narcotic drugs and psychotropic substances and medicinal products containing such substances shall be printed on a green document form of the State Agency of Medicines in the format set out in Annex 6 to this Regulation in three copies: the first copy is submitted by the exporter to the customs administration for customs clearance during export; the second copy is attached by the exporter to the shipment documents and the third is sent by the State Agency of Medicines for approval to the competent authority in the destination country.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(5) [Repealed – RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(6) [Repealed – RT I, 07.03.2017, 20 – entry into force 10.03.2017]

(7) The special authorisation for other goods is prepared by the State Agency of Medicines in a single copy, to be submitted by the importer or exporter for customs clearance during import or export.

(8) In case the import or export did not take place on the basis of an issued special authorisation, the importer or exporter must return the special authorisation on paper to the State Agency of Medicines immediately after its expiry and, in the event of a digitally issued special authorisation, immediately inform the State Agency of Medicines.
[RT I, 07.03.2017, 20 – entry into force 10.03.2017]

§ 8. Medicinal products for personal use

(1) [Repealed – RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(2) A maximum of ten different proprietary medicinal products, a maximum of five retail packages each, may be carried for personal use by a traveller, and a maximum of five different proprietary medicinal products, a maximum of three retail packages each, may be carried for animals accompanying the traveller without the authorisation of the State Agency of Medicines.
[RT I, 18.11.2011, 1 – entry into force 01.01.2012]

(3) The size of a retail package is up to 200 units of solid dosage forms, up to 500 g of powder for solution preparation, up to 50 g of homeopathic granules, up to 500 ml of solution for infusion and oral solutions, up to 30 ampoules or vials of injectable dosage forms, up to 200 ml or 200 g of topical medicinal products, up to 100 g of herbal substances, up to 200 doses of inhalation preparations, up to 10 units of medicated plasters.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(4) A maximum of one retail package containing up to 30 units or 25 ml of a narcotic drug or psychotropic substance may be carried for personal use without the authorisation of the State Agency of Medicines and the medicinal products must be accompanied by a physician's note or, in the case of medicinal products for animals, a veterinarian's note concerning the need for the medicinal product, or a copy of the prescription, except in the case described in subsection 41.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(4^1) A person who enters Estonia or who enters the territory of another Schengen member state from Estonia may carry narcotic drugs or psychotropic substances that are prescribed and dispensed in conformity to established requirements in the required quantity for the duration of the trip, but not more than required for 30 days of treatment, provided he or she carries a certificate issued in the country of residence in accordance with Article 75 of the Schengen Agreement (hereinafter, 'Schengen certificate') in respect of each narcotic drug or psychotropic substance carried.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(4^2) [Repealed – RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(5) If the quantity of the medicinal products carried exceeds the quantity stated in subsection 2, 3 or 4, the authorisation of the State Agency of Medicines must be applied for in respect of all medicinal products carried. With the authorisation of the State Agency of Medicines, narcotic drugs or psychotropic substances may be carried in the quantity required for a maximum of 30 days of treatment.
[RTL 2010, 10, 182 – entry into force 08.03.2010]

(6) Medicinal products may be sent to foreign countries or to Estonia only if the sender and the recipient are both natural persons. Without the authorisation of the State Agency of Medicines, one parcel may contain a maximum of five unopened retail packages of a size stated in subsection 3. The medicinal products must be in the manufacturer's packaging.
[RT I, 25.03.2014, 3 – entry into force 28.03.2014]

(7) If the quantity of medicinal products sent exceeds the quantity stated in subsection 3 or 6, the authorisation of the State Agency of Medicines must be applied for in respect of all medicinal products in the parcel.
[RT I, 25.03.2014, 3 – entry into force 28.03.2014]

(8) [Repealed – RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(9) In the cases referred to in subsections 5 and 7, in order to obtain the authorisation, an application must be submitted to the State Agency of Medicines with the following information:
1) the name, personal identification code or, in the absence of the latter, date of birth, and contact information of the applicant;
2) information on the source country and the destination country;
3) the list of medicinal products (the name of medicinal product, the strength of active substances and the pharmaceutical form, the size of the package and the total number of packages);
4) in the case of medicinal products subject to medical prescription, a physician's, note and, in the case of medicinal products designated to be used on animals, the veterinarian's note concerning the need for the medicinal product, except in the case of a medical prescription preserved in the Digital Prescription Centre.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(9^1) In order to apply for a Schengen certificate, the person with a permanent residence in Estonia must submit an application to the State Agency of Medicines in the form published on the website of the State Agency of Medicines with regard to each narcotic drug or psychotropic substance carried. Paper application forms must be available at the State Agency of Medicines, pharmacies and at the person who prescribed the medicinal product.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(9^2) On the basis of the data of the Digital Prescription Centre, the State Agency of Medicines scrutinises compliance with the established requirements of the prescription and dispensation of the narcotic drugs and psychotropic substances carried in accordance with a Schengen certificate and of the medicinal products subject to medical prescription carried in accordance with the authorisation specified in subsection 5 and verifies the need for their use during the trip.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(9^3) The State Agency of Medicines issues the Schengen certificate provided in Annex 11 to a person whose permanent residence is in Estonia within 5 working days from receiving the application conforming to the established requirements. The State Agency of Medicines may send the Schengen certificate by regular mail. A Schengen certificate is valid for up to 30 days.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(9^4) The State Agency of Medicines issues the authorisation referred to in subsections 5 and 7 within 5 working days from receiving the corresponding application. The State Agency of Medicines may send the authorisation referred to in subsections 5 and 7 by regular mail.
[RT I, 09.04.2014, 2 – entry into force 01.07.2014]

(10) [Repealed – RT I, 10.05.2013, 1 – entry into force 13.05.2013]

§ 9. Entry into force of this regulation

(1) This regulation enters into force on 1 March 2005

(2) Section 5(1)(10) of this regulation enters into force on 1 October 2005

Annex 1 Authorisation for the import of goods that require a special authorisation
[RT I, 07.03.2017, 20 - entry into force 10.03.2017]

Annex 2 Authorisation for the export of goods that require a special authorisation
[RT I, 07.03.2017, 20 - entry into force 10.03.2017]

Annex 3 Authorisation for the import of a medicinal product intended for clinical trials
[RT I, 07.03.2017, 20 - entry into force 10.03.2017]

Annex 4
[Repealed - RT I, 10.05.2013, 1 - entry into force 13.05.2013]

Annex 5 Import authorization
[RT I, 07.03.2017, 20 - entry into force 10.03.2017]

Annex 6 Export authorization
[RT I, 07.03.2017, 20 - entry into force 10.03.2017]

Annex 7 Application for the use of an unauthorised medicinal product
[RTL 2010, 10, 182 - entry into force 08.03.2010]

Annex 8 Application for the veterinary use of an unauthorised medicinal
[RTL 2010, 10, 182 - entry into force 08.03.2010]

Annex 9
[Repealed - RT I, 07.03.2017, 20 - entry into force 10.03.2017]

Annex 10
[Repealed -RT I, 09.04.2014, 2 - entry into force 01.07.2014]

Annex 11 A certificate issued in accordance with Article 75 of the Schengen Agreement with regard to narcotic drugs and psychotropic substances carried for the purpose of treatment
[RTL 2007, 96, 1616 - entry into force 21.12.2007]

Annex 12 Application of a professional association for the use of an unauthorised medicinal product
[RTL 2010, 10, 182 - entry into force 08.03.2010]

Annex 13 Application of a professional association for the veterinary use of an unauthorised medicinal product
[RTL 2010, 10, 182 - entry into force 08.03.2010]