

The Conditions and Procedure for the Issue of Prescriptions for Medicinal Products and for the Dispensing of Medicinal Products by Pharmacies and the Format of Prescriptions

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Amended by the following Regulations:

10.04.2006 No 37 entered into force 23.04.2006 - RTL 2006, 33, 598;

13.12.2007 No 82 entered into force 21.12.2007 - RTL 2007, 96, 1616;

09.07.2008 No 38 entered into force 26.07.2008, partially 01.01.2009 - RTL 2008, 61, 875;

18.09.2008 No 54 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099;

24.08.2009 No 76 entered into force 01.09.2009 - RTL 2009, 68, 1011;

08.12.2009 No 92 entered into force 01.01.2010 - RTL 2009, 93, 1351;

26.02.2010 No 12 entered into force 08.03.2010, partially 01.04.2010 - RTL 2010, 10, 180.

This Regulation is established on the basis of subsection 33 (7) of the Medicinal Products Act.

§ 1. General Provisions

(1) This Regulation establishes:

1) the conditions and procedure for the issue of prescriptions for medicinal products and for the dispensing of medicinal products on the basis of prescriptions or order forms, including for the preservation and registration of medical prescription forms, order forms and accompanying documents;

2) the format of prescriptions;

3) the conditions and procedure for the dispensing of medicinal products on the basis of the prescriptions of the Member States of the European Union, Member States of the European Economic Area and the Swiss Confederation (hereinafter EU prescription).

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(2) The provisions of this Regulation apply to the issue of prescriptions upon prescribing veterinary medicinal products by veterinarians in so far as it is not regulated by the regulation of the Minister of Agriculture established on the basis of subsection 15 (7) of the Medicinal Products Act, taking account of the specifications of prescribing veterinary medicinal products, and to the dispensing of medicinal products by pharmacies on the basis of veterinary prescriptions. The format of veterinary prescriptions is established by the abovementioned regulation of the Minister of Agriculture.

(3) Only one medicinal product may be entered in one prescription and only one medicinal product may be dispensed on the basis of one prescription, except in the case of EU prescriptions.

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

§ 2. Issue of prescriptions for medicinal products

(1) Prescriptions and order forms may be issued for medicinal products in respect of which a marketing authorisation is valid in Estonia, for preparation of medicinal products as magistral formulae in pharmacies and for unauthorised medicinal products in the case specified in subsection 21 (1) of the Medicinal Products Act. If a doctor qualified to prescribe medicinal products prescribes an unauthorised medicinal product, the doctor shall attach an application for obtaining a single authorisation for import and use of the medicinal product to the prescription.

(2) Medicinal products for medical purposes and for the purposes of treatment of other persons may be prescribed only by the doctors and dentists, who have the right to provide health services in the Republic of Estonia, for the out-patient treatment of the persons treated thereby.

(2¹) Prescriptions for medicinal products shall be issued in electronic form (hereinafter digital prescription) or on paper (hereinafter paper prescription).

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(3) Dentists have the right to prescribe only the following medicinal products and substances by indicating their official title on the prescription:

- 1) medicinal products for local treatment of teeth, gums and oral mucosae;
- 2) ATC code J01 – antibacterials for systemic use;
- 3) ATC code M01A – antiinflammatory and antirheumatic products, non-steroids;
- 4) ATC code R06 – antihistamines for systemic use;
- 5) ethyl alcohol;
- 6) other medicinal products the indication of which accepted upon granting a marketing authorisation valid in Estonia is dental or oral diseases.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(4) Medicinal products for dispensing at a discount rate may be prescribed to persons insured in the Estonian Health Insurance Fund by the persons specified in subsection 41 (2) of the Health Insurance Act. Medicinal products required for a person's stay in Estonia may be prescribed for dispensing at a discount rate to persons insured in a Member State of the European Union, a Member State of the European Economic Area or the Swiss Confederation (hereinafter person insured in EU), who certify their insurance cover on the basis of a valid European health insurance card or the provisional replacement certificate thereof or a valid standard format documentation (E112, E123) issued by a competent agency of the Member State of insurance.

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(5) Medicinal products shall be prescribed upon the existence of the corresponding indication and the treatment prescribed shall be recorded in a document certifying the

provision of the health care services with an indication of the number of the prescription. Entries shall be made pursuant to the procedure established on the basis of subsection 4² (2) of the Health Services Organisation Act.

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(6) A prescription shall be issued for a medicinal product in the amount required for undergoing one course of treatment in the case of an acute illness and two months' treatment in the case of a chronic or long-term illness. In the case of a chronic or long-term illness, a medicinal product may be prescribed in the amount required for less than two months' treatment only upon the commencement or changing of the treatment. If a limit has been established for the maximum amount of a medicinal product prescribed by one prescription in Annex 4 to this Regulation, this shall always be adhered to.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(6¹) The amount of a narcotic drug or psychotropic substance prescribed to a patient during one doctor's out-patient appointment shall not exceed the amount specified in Annex 4 to this Regulation. If several benzodiazepines are prescribed, the total amount shall not exceed the double amount specified in Annex 4.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(6²) A narcotic drug or psychotropic substance may be prescribed to a person for the period of a travel in the amount required for the treatment of the person, which exceeds the amount provided for in Annex 4 to this Regulation, but not for more than 30 days in the case specified in subsection 8 (4) of Regulation No. 31 of the Minister of Social Affairs of 18 February 2005 "The Conditions and Procedure for the Import and Export, Carrying for Personal Use and Sending by Post of Goods Requiring Special Authorisation of the State Agency of Medicines, the Forms of Special Authorisations and the List of Goods Requiring Special Authorisation of the State Agency of Medicines", by setting out in box 10 "for the period of the travel" and in adherence to the requirements provided for in § 9² in the case specified in subsection (4¹) and by making the corresponding entry in the patient's health history or health card.

(13.12.2007 entered into force 21.12.2007 - RTL 2007, 96, 1616)

(7) It is not permitted to issue prescriptions for injectable pharmaceutical forms containing ketamine, fentanyl, thiopental, sodium oxybutyrate, alfentanil, sufentanil and remifentanil and oral pharmaceutical forms of buprenorphine.

(09.07.2008 entered into force 01.01.2009 - RTL 2008, 61, 875)

(8) (Repealed - 09.07.2008 entered into force 01.01.2009 - RTL 2008, 61, 875)

(9) (Repealed - 09.07.2008 entered into force 01.01.2009 - RTL 2008, 61, 875)

(9¹) Only psychiatrists have the right to prescribe medicinal products containing methylphenidate.

(09.07.2008 entered into force 26.07.2008 - RTL 2008, 61, 875)

(10) A prescription for dispensing a medicinal product twice or three times (hereinafter repeat prescription) may be issued only if the person prescribing the medicinal product has used the corresponding medicinal product successfully in the treatment of the recipient of the medicinal product earlier and upon prescribing contraceptive preparations.

(11) A medicinal product shall be entered in a repeat prescription for dispensing at a discount rate in the amount required for two month's treatment.

(12) Upon issuing a repeat prescription the person prescribing the medicinal product shall determine the number of the prescriptions. Upon issuing a paper prescription the person prescribing the medicinal product shall fill in the copy of the repeat prescription and remove the sheet or sheets which have not been filled in.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(13) Repeat prescriptions shall not be issued for narcotic drugs, anxiolytics, soporifics, sedatives and also for antibacterial, immunological and radiopharmaceutical medicinal products and for medicinal products for which quantitative restrictions have been established in Annex 4 to this Regulation.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(14) Upon issuing a digital prescription the person who issues the prescription shall confirm that the prescription is justified and complies with the legislation after the Digital Prescription Centre has provided information concerning the correctness of the data submitted. In a paper prescription the person who issues the prescription shall confirm it by his or her signature and personal seal separately on each prescription sheet.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

§ 3. Types of, requirements for the format of and validity of prescriptions

(1) The types of prescriptions are single prescription, repeat prescription and prescription for narcotic drugs.

(2) The size of the original copy of a single prescription is 127×158 mm. It is printed in green on green paper, single sheet. In the upper left-hand corner under the name of the form there is a letter (the Latin alphabet is used, each prescription form series has its own letter starting from the last letter of the Latin alphabet – Z, Y, X, ...; the last letter used is D) and a 7-digit number in red. On the left-hand side there are binding holes with the hole distance of 80mm. On the margins of the form there is a security print.

(3) The size of the original copy of a repeat prescription is 127×158 mm, three sheets. It is printed in green on green self-copying paper. In the upper left-hand corner under the name of the form there is a letter (A on the first copy, B on the second copy and C on the third copy) and a 7-digit number in red (the same on all the copies). On the left-hand side there are binding holes with the hole distance of 80mm. On the margins of the form there is a security print. The prescription is glued on the upper edge.

(4) The size of the original copy of a prescription for narcotic drugs is 127×158 mm, three sheets. The pharmacy shall have the original prescription and one copy thereof and the health care provider shall have one copy. It is printed in green on red self-copying paper. In the upper left-hand corner there is a 7-digit number in black (the same on the original prescription and the copies thereof). On the left-hand side there are binding holes with the hole distance of

80mm. On the margins of the form there is a security print. The prescription is glued on the upper edge.

(5) A prescription of a non-narcotic medicinal product is valid for 60 days, a prescription of a narcotic product for 14 days and a repeat prescription is valid for 180 days after issuing unless a shorter term of validity is indicated in the prescription.

§ 4. Information entered in prescriptions upon prescribing medicinal products

(1) A prescription, except for a veterinary prescription, shall set out the following information:

1) the name, personal identification code and residential address of the patient, at least the state of residence and personal identification code according to the document certifying the insurance cover specified in subsection 2 (4) of this Regulation in case of a person insured in EU;

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2) the patient's age in years (in years and months in the case of children under 4 years of age);

3) the discount rate or absence of the discount;

4) in the case of a ready-prepared medicinal product, the pharmaceutical form, the name of the pharmaceutical preparation or active substance, the content of the active substance and the total amount of the medicinal product;

5) a notation concerning non-substitution of the medicinal product;

6) in the case of medicinal products prepared as magistral formulae, the complete composition, the content of the ingredients and the total amount of the medicinal product and reference to a pharmacy for the preparation and dispensing of the medicinal product;

7) instructions for use of the medicinal product (a single dose, route of administration, frequency of use and period of use);

8) the name, (in block letters, printed or as a seal) the number of the Health Board registration certificate, telephone number and signature (in a paper prescription) of the person who issued the prescription;

(8.12.2009 entered into force 01.01.2010 - RTL 2009, 93, 1351)

9) the date of issue and the term of validity of the prescription;

10) the place of employment (the name of the of the health care provider), the address of the place of business, the registry code (the commercial registry code the company or the code of the legal person entered in the non-profit associations and foundations register) or personal identification code (in the case of a sole proprietor not entered in the commercial register) of the person who issued the prescription;

(1¹) (Repealed - 26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(2) If a paper prescription for a medicinal product at a discount rate is issued to a person who certifies his or her insurance cover on the basis of a document specified in subsection 2 (4) of this Regulation, the health care provider shall attach a copy of the abovementioned document to the prescription.

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(2¹) If a digital prescription for a medicinal product at a discount rate is issued to a person who certifies his or her insurance cover on the basis of a document specified in subsection 2 (4) of this Regulation, the following information shall be set out in the Digital Prescription Centre in addition to the information provided in subsection (1):

- 1) the date of birth and sex;
- 2) the type of document provided for in subsection 2 (4);
- 3) the number of the document provided for in subsection 2 (4);
- 4) the state who issued the document provided for in subsection 2 (4);
- 5) the agency who issued the document provided for in subsection 2 (4);

6) the date of issue and the date of the beginning and end of the period of validity of the document provided for in subsection 2 (4).

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(2²) If a digital prescription is issued at a discount rate, the health care provider shall preserve a copy of the document provided for in subsection 2 (4) of the Regulation for at least three years.

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(3) In order to prescribe a medicinal product at a discount rate the following information shall be set out in the prescription in addition to the information provided for in subsection (1):

1) the 3-digit or 4-digit code of the diagnosis in accordance with the 10th version of the International Classification of Diseases (ICD-10) on the basis of which the prescription is issued;

2) the discount rate (100%, 90%, 75%, 50% or full price);

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3) the existence of the pension for incapacity for work arising from the State Pension Insurance Act;

4) a notation concerning the fact whether the patient is insured or not.

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(4) In order to enable the selection of the most suitable size of original packaging or number of packagings for the patient, the total amount of a medicinal product shall be indicated in the prescription as follows:

1) as an exact content of the active substance and the total number of the units to be dispensed (tablets, capsules, suppositories, etc.), or

2) as a single dose, the frequency of administration and the duration of the treatment (in days).

(5) A medicinal product shall be prescribed by using the name of the active substance in the medicinal product.

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(6) The person who prescribes a medicinal product may use the name of the pharmaceutical preparation if he or she considers it to be justified that the patient needs precisely this pharmaceutical preparation. In this case the person who prescribes the medicinal product shall define the medicinal product as non-substitutional in the Digital Prescription Centre. In a paper prescription the person who issues the prescription shall mark “not to be substituted” in box 7. The person who prescribes the medicinal product shall record the reasons for non-substitution of the pharmaceutical preparation in a document which proves the provision of the health care services.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(7) The person who prescribes a medicinal product shall notify the patient of the possibilities of and conditions for substituting the medicinal product and, in the case of a notation concerning non-substitution of the medicinal product, of the prohibition to substitute the medicinal product and the reason therefor.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(8) A request in a prescription to a pharmacy for the preparation and dispensing of a medicinal product shall be written in Latin. The active substances and excipients shall be written in Latin or Estonian. Abbreviations may be used in prescriptions only in case of Latin terms.

(9) Information concerning the patient and the instructions for use of a medicinal product shall be written in Estonian. If necessary, the instructions for use of a medicinal product may be written additionally in another language understood by the patient. The expressions used in

the instructions for use of medicinal products shall be understandable by the patient, in particular in the case of liquid dosage forms (the dosage shall be indicated in drops or spoonfuls) and superficial dosage forms (an explanation concerning both, a single dose and the size of the area to be covered by the medicinal product). Upon issuing a paper prescription for a narcotic drug the person prescribing the medicinal product shall write the instructions for use of the medicinal product in handwriting.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(10) All the numbers in a prescription shall be written in Arabic numerals.

(11) If the amount of a medicinal product in a prescription is indicated in other units than grams, the unit of measurement shall be indicated after the number.

(12) If the person who prescribes a medicinal product knowingly uses a type of dosage scheme or route of administration other than the one described in the summary of the product characteristics, "!!" shall be marked after the requested dose or route of administration in the prescription.

(13) All the copies of repeat prescriptions shall contain identical information and are valid for independent purchases.

§ 5. Issue of prescriptions

(1) A person who prescribes a medicinal product shall issue a prescription electronically unless the Digital Prescription Centre cannot be used for objective reasons.

(2) Paper prescriptions may be issued only on numbered prescription forms, the format of which is specified in Annexes 1 to 3 to the Regulation. A paper prescription shall be filled in in legible handwriting by using an indelible writing instrument or printed.

(3) The following requirements shall be taken into account upon filling in a paper prescription with the help of a computer and printer:

- 1) all the required information shall be entered in the boxes prescribed for that in the prescription;
- 2) no other information than the one specified in subsections 4 (1) and (3) shall be entered and no abbreviations shall be used in a prescription;
- 3) the names of the active substances or the names of the pharmaceutical preparations shall be used in the software and printed only in full;
- 4) the pharmaceutical form, the content of the active substance and the total amount of a medicinal product shall be used in the software and printed in the form identical to the information specified in the marketing authorisation granted with respect of the medicinal product;
- 5) as for the dosage of a medicinal product, a single dose shall be written in numbers (e.g. "30 mg") and the frequency of use in words (e.g. "twice in every twenty-four hours") and the total amount of the medicinal product shall be indicated in numbers in brackets (e.g. "(90 tablets)").

(4) The software used upon the issue of prescriptions:

- 1) shall ensure that upon the selection of the name of a medicinal product or for entry the name of the active substance is displayed first and thereafter the names of the pharmaceutical preparations are displayed in alphabetical order or in accordance with the discount rates applied;
- 2) shall not contain any references or links for preferring a certain pharmaceutical preparation;
- 3) shall ensure that advertising of a medicinal product or influencing persons prescribing medical products in any other way would be precluded during working with the software.

(5) A paper prescription shall be certified by the signature and the name, the seal indicating the code of the person who prescribes the medical product on all the copies of the prescription. Upon issuing a digital prescription, the prescription shall be confirmed by the person who prescribes the medicinal product after the Digital Prescription Centre has provided information concerning the correctness of the data submitted.

(6) Upon issuing a digital prescription, the person to whom the prescription is issued shall define the person purchasing the medicinal product as follows:

- 1) the person himself or herself;
- 2) a third person identified by name;
- 3) an unidentified purchaser.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

§ 6. Dispensing of medicinal products to persons by general pharmacies and veterinary pharmacies

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(1) Prescription medicinal products may be dispensed to persons by general pharmacies and veterinary pharmacies only on the basis of conforming medical or veterinary prescriptions.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(2) Narcotic drugs may be dispensed to persons by general pharmacies and veterinary pharmacies only on the basis of prescriptions of narcotic drugs or veterinary prescriptions of narcotic drugs taking into account the quantitative restrictions established for dispensing of medicinal products in Annex 4 to the Regulation and the restrictions for prescribing established in subsections 2 (6²), (7) and (9¹).

(9.07.2008 entered into force 26.07.2008 - RTL 2008, 61, 875)

(2¹) If narcotic drugs or other psychotropic substances are prescribed by an attending physician in compliance with the provisions of subsection 2 (6²), a pharmacy may dispense to the person the amount entered in the prescription, but not more than the amount required for 30 days. Upon dispensing of medicinal products the requirements specified in subsections 8 (9¹) and 9²) of Regulation No. 31 of the Minister of Social Affairs of 18 February 2005 “The

Conditions and Procedure for the Import and Export, Carrying for Personal Use and Sending by Post of Goods Requiring Special Authorisation of the State Agency of Medicines, the Forms of Special Authorisations and the List of Goods Requiring Special Authorisation of the State Agency of Medicines" shall be adhered to. A pharmacy shall preserve the application on the basis of which a medicinal product is dispensed or a copy thereof for five years.

(9.07.2008 entered into force 26.07.2008 - RTL 2008, 61, 875)

(3) It is prohibited to dispense separately the substances which belong to the composition of medicinal products prepared as magistral formulae. The following shall not be prescribed for the preparation of medicinal products as magistral formulae and shall not be included in the composition of medicinal products prepared as magistral formulae in pharmacies:

- 1) antibacterials for systemic use, antimycobacterials and anti-infectives used in urology;
- 2) anabolic substances and sex hormones;
- 3) glucocorticoids for systemic use.

(4) Ethyl alcohol may be dispensed as pure ethyl alcohol or in a mixture only on the basis of a prescription. If the concentration of ethyl alcohol is not indicated in the prescription, it shall be dispensed as a 70 per cent ethyl alcohol. If the alcohol is intended for a compress, the pharmacy shall also dilute it.

(5) If, upon prescribing a medicinal product, the name of the active substance of the medicinal product is used, the person dispensing the medicinal product shall notify the recipient of the medicinal product of the medicinal products containing the same active substance suitable for the recipient on the basis of the total amount of the medicinal product indicated in the prescription and the prices thereof.

(6) If a medicinal product which has a valid marketing authorisation in Estonia is prescribed but it is not available at a pharmacy at the moment, the pharmacy shall obtain the medicinal product within a reasonable period of time as of the submission of the prescription unless the State Agency of Medicines confirms that the medicinal product is not available in Estonia. In the latter case, the pharmacy shall notify the person who issued the prescription thereof and thereafter shall notify the person who submitted the prescription of the solution. In

consultation with and with the consent of the person who prescribed the medicinal product, the prescribed product may be substituted under the conditions specified in subsection (5) of this section.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(7) If the total amount of the prescribed ready-prepared medical product differs from the size of the original packaging, the original packaging with the closest size shall be dispensed. Dividing of a packaging is permitted only in the case of pharmaceutical forms upon the dividing of which the name of the medicinal product, the name of the authorisation holder, the content of the active substance, the batch number and the date of expiry are preserved on all the parts of the original packaging (blister, strip, tube, ampoule, vial).

(8) If a prescription is issued for a medicinal product which does not have a valid marketing authorisation in Estonia and the doctor's application to the State Agency of Medicines for importing of the unauthorised medicinal product as an exception is attached to the prescription, the pharmacy shall forward the application to the State Agency of Medicines. If the State Agency of Medicines makes a decision that importing of the unauthorised medicinal product is justified, the pharmacy shall make the corresponding inquiry to the persons who have the right to wholesale medicinal products in Estonia and shall obtain the medicinal product within a reasonable period of time as of the submission of the prescription unless the manufacturer of the medicinal product notifies that this pharmaceutical preparation cannot be supplied to Estonia. In the latter case, the pharmacy shall notify the person who prescribed the medicinal product thereof and notify the person who submitted the prescription of the solution. A pharmacy may dispense a medicinal product only after having verified that the same person is indicated in the doctor's application and the prescription.

(8¹) The medicinal products authorised to be imported and used on the basis of an application of a professional organisation may be dispensed only when the person dispensing the product has verified from the State Agency of Medicines that the code of the diagnosis indicated in the prescription complies with the one indicated in the application of the professional organisation.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(9) (Repealed - 10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(10) While dispensing a medicinal product the person dispensing the product shall enter the following information in the prescription, except a veterinary prescription:

- 1) the name, content of the active substance and amount in the packaging of the dispensed pharmaceutical preparation;
- 2) the price of the packaging of the medicinal product dispensed, the number of packagings dispensed and the total price of the medicinal product;
- 3) the share of the price paid by the recipient of the medicinal product;
- 4) the amount of discount in the case of dispensing a medicinal product at a discount rate;
- 5) the date of dispensing the medicinal product and the signature of the person dispensing the medicinal product (in a paper prescription).

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(11) Other information required in a prescription shall be entered in the prescription not later than within three working days after dispensing the medicinal product.

(12) The text concerning the use of the medicinal product shall be entered on the original packaging of the medicinal product or on a sheet attached to the packaging. Where a sticker is used, it shall not hide relevant information. Upon dispensing a medicinal product, the patient shall be notified orally of the correct and safe use of the medicinal product. Attention shall be directed to the correct storage of the medicinal product and other remarks on the packaging.

(13) If a prescription does not contain all the required information, corrections have been made in the prescription or incompatible substances have been prescribed, a pharmacy shall not dispense the medicinal products of on the basis of the prescription and the prescription shall be deposited in the pharmacy. Such prescriptions shall be stored in a pharmacy separately from other prescriptions.

(14) In the case of a prescription deposited on the basis of subsection (13), the person who prescribed the medicinal product shall be notified thereof immediately by telephone and the person who submitted the prescription shall be notified of the solution.

(15) In the case of doubt as to the correctness of a prescription, the person dispensing the medicinal product shall contact the person who prescribed the medicinal product, postpone dispensing of the medicinal product and preserve the prescription in the pharmacy until the circumstances have been ascertained. If doubt arises as to the authenticity of a prescription, the State Agency of Medicines shall be immediately informed thereof.

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(16) (Repealed - 09.07.2008 entered into force 26.07.2008 - RTL 2008, 61, 875)

(16¹) If a prescription for a medicinal product containing methylphenidate has been prescribed by a doctor not qualified to do so, a pharmacy shall not dispense the medicinal product on the basis of the prescription, the prescription shall be deposited in the pharmacy and the State Agency of Medicines shall be notified of such a prescription.

(9.07.2008 entered into force 26.07.2008 - RTL 2008, 61, 875)

(17) In all the cases when it is necessary to contact the person who prescribed a medicinal product and amendments are made with respect to the pharmaceutical preparation to be dispensed, the amount to be dispensed or other circumstances concerning the dispensing of the medicinal product, the person who dispenses the medicinal product shall forward the corresponding information to the Digital Prescription Centre. In the case of a paper prescription, the person who dispenses the medicinal product shall enter the corresponding information on the other side of the prescription and confirm it by his or her name and signature. The person dispensing a medicinal product shall not increase the amount of a narcotic drug or psychotropic substance to be dispensed.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(18) A person dispensing a medicinal product has the right to make corrections in a paper prescription if the information concerning the discount rate entered in the prescription by the person who issued the prescription has become incorrect due to amendment of legislation or is contrary to legislation in force. The person who makes the corrections shall be responsible for the correction of the prescription and for dispensing a medicinal product on the basis of it and shall confirm the corrections on the other side of the prescription by his or her name and

signature. Upon entering the information of a paper prescription in the Digital Prescription Centre, the corrections made shall also be indicated in the Digital Prescription Centre.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(19) The purchaser of a medicinal product shall receive a receipt concerning the price paid by him or her and the amount of the discount.

(20) The dispensing of prescription medicinal products shall be recorded in prescription accounts pursuant to the regulation of the Minister of Social Affairs established on the basis of clause 31 (6) 3) of the Medicinal Products Act.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

§ 6¹. Dispensing of medicinal products to persons by general pharmacies and veterinary pharmacies on basis of EU prescriptions

(1) Subsections 6 (1) – (2¹) and (8) of this Regulation do not apply to dispensing of medicinal products on the basis of EU prescriptions.

(2) A medicinal product shall not be dispensed from a pharmacy on the basis of an EU prescription if the person dispensing the medicinal product is not fully convinced in the legality and validity of the EU prescription. If doubt arises as to the authenticity of a prescription, the State Agency of Medicines shall be immediately informed thereof.

(3) Medicinal products may be dispensed to a person from a pharmacy on the basis of an EU prescription only if the prescription clearly sets out all the following information:

- 1) the name of the person to whom the medicinal product is prescribed;
- 2) the pharmaceutical form of the prescribed medicinal product, the name of the pharmaceutical preparation or active substance and the content of the active substance;
- 3) instructions for use of the medicinal product (a single dose, frequency of use);

- 4) the name and signature of the person who issued the EU prescription;
- 5) the date of issue of the EU prescription.

(4) If the age or date of birth or the personal identification code of the person to whom the medicinal product is prescribed is not indicated in the EU prescription, the person dispensing the medicinal product shall, in order to dispense the medical product safely, ask it from the person who submitted the prescription and enter the corresponding information on the other side of the prescription and confirm it by his or her name and signature.

(5) In all the cases when it is necessary to contact the person who prescribed a medicinal product and amendments are made with respect to the pharmaceutical preparation to be dispensed, the amount to be dispensed or other circumstances concerning the dispensing of the medicinal product, the person who dispenses the medicinal product shall enter the corresponding information on the other side of the prescription and confirm it by his or her name and signature.

(6) If the name of a pharmaceutical preparation is indicated in an EU prescription and it has not been specified whether the medicinal product may be substituted or not, or the pharmaceutical preparation indicated in the prescription does not have marketing authorisation in Estonia, the patient shall be informed thereof and with the consent of the patient the pharmaceutical preparation shall be substituted by a medicinal product containing the same active substance in the same amount and pharmaceutical form.

(7) If corrections have been made in an EU prescription, incompatible substances have been prescribed or a pharmaceutical form or dose has been prescribed which is unsuitable for the age of the person to whom the medicinal product has been prescribed, the medicinal product shall not be dispensed from the pharmacy.

(8) While dispensing a medicinal product the person dispensing the product shall enter the following information in the EU prescription:

- 1) the name, content of the active substance and amount in the packaging of the dispensed pharmaceutical preparation;

- 2) the price of the packaging of the medicinal product dispensed, the number of packagings dispensed and the total price of the medicinal product;
 - 3) the date of dispensing the medicinal product and the signature of the person dispensing the medicinal product;
 - 4) the name of the pharmacy and the address of the place of business.
- (9) An EU prescription shall be deposited in a pharmacy unless part of the amount of the prescribed medicinal product or of the medicinal products is not dispensed.
- (10) If an EU prescription is deposited in a pharmacy, the person dispensing the medicinal product shall give a copy of the EU prescription to the purchaser of the medicinal product. If an EU prescription is returned to the purchaser of the medicinal product, the person dispensing the medicinal product shall keep a copy of the EU prescription. A copy of an EU prescription shall contain the information specified in subsection (8) of this section.
- (11) The purchaser of a medicinal product shall receive a receipt concerning the price of the medicinal product paid by him or her.
- (12) The text concerning the use of the medicinal product shall be entered on the packaging of the medicinal product dispensed or on a sheet attached to the packaging.
- (13) The dispensing of prescription medicinal products shall be recorded in prescription accounts pursuant to the regulation of the Minister of Social Affairs established on the basis of clause 31 (6) 3) of the Medicinal Products Act.

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

§ 7. Dispensing of medicinal products to other persons by pharmacies

- (1) General pharmacies and veterinary pharmacies may dispense prescription medicinal products to health care providers, including to self-employed health care providers, and to other persons qualified to prescribe medicinal products, and to persons whose right to purchase prescription medicinal products arises from legislation.

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(2) Only medicinal products not subject to prescription may be dispensed to legal persons who are not health care providers.

(3) Prescription medicinal products shall be dispensed together with the accompanying documents prepared on the basis of an order form. A separate accompanying document shall be prepared on the basis of each order form. Medicinal products not subject to prescription shall be dispensed together with the accompanying documents.

(4) Hospital pharmacies may dispense medicinal products not subject to prescription and prescription medicinal products to health care providers together with the accompanying documents prepared on the basis of an order form.

(5) Pharmacies may dispense medicinal products not subject to prescription and prescription medicinal products to their branch pharmacies, other pharmacies, wholesalers and manufacturing enterprises together with the accompanying documents.

§ 8. Preparation of order forms and accompanying documents

(1) Order forms and accompanying documents shall be filled in in legible handwriting by using an indelible writing instrument or printed.

(2) An order form shall include the following information:

1) the name, address, telephone number of the legal person or sole proprietor who orders the medicinal product, in the case of a veterinarian the name, address, telephone number and the number of the activity licence, in the case of ordering from a hospital pharmacy the name of the hospital department;

2) the name and address of the pharmacy (except if a hospital orders from its own pharmacy);

3) the date of preparation of the order form;

4) the name of the active substance or pharmaceutical preparation, the pharmaceutical form, the content of the active substance, the total amount of the medicinal product with regard to each medicinal product;

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

5) the name, official title, signature and personal seal of the person qualified to prescribe medicinal products, upon ordering from a hospital pharmacy the name of the person who prepared the order form, in the case of a right to purchase prescription medicinal products arising from legislation the name, official title and signature of the person who is qualified order medicinal products.

(3) An order form for a narcotic drug, except an order for a narcotic drug prepared by a veterinarian, shall include, in addition to the information specified in subsection (2) of this section, the name and signature of the person responsible for handling narcotic drugs appointed by the health care provider.

(4) An accompanying document shall include the following information:

1) the name of the pharmacy;

2) the address and telephone number of the pharmacy, except upon dispensing from a pharmacy to its branch pharmacy or from a hospital pharmacy to a department of the same hospital;

3) the date of the order form, if a medicinal product is dispensed on the basis of an order form;

4) the name of the recipient;

5) the address of the recipient, except upon dispensing from a pharmacy to its branch pharmacy or from a hospital pharmacy to a department of the same hospital;

6) the date of the preparation of the accompanying document;

7) the name of the medicinal product, the pharmaceutical form, the content of the active substance(s), the quantity in the packaging, the total number of packagings with regard to each medicinal product;

8) if medicinal products are dispensed for resale, the batch number, whether the medicinal product belongs to medicinal products not subject to prescription or prescription medicinal products and in case of unauthorised medicinal products the corresponding notation;

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

9) the selling price;

10) the name of the person dispensing and of the recipient.

(5) Accompanying documents shall be prepared in at least two copies and confirmed by the signatures of the person dispensing and the recipient and the date of dispensing and receipt on both copies. One copy shall remain with the person dispensing, the other copy with the recipient. Upon dispensing from a hospital pharmacy to a department of the same hospital, the accompanying document may be prepared in a single copy which shall be stored in the hospital pharmacy.

(6) An order form may be used as an accompanying document if space has been left in the form for entry of the information listed in subsection (4).

§ 9. Preservation and registration of prescription forms, order forms and accompanying documents

(1) A regional unit of the Health Insurance Fund issues prescription forms to health care providers for a charge by verifying that the recipient of the prescription forms has a valid activity licence for the provision of health care services and by documenting the numbers of prescription forms and maintaining records of the prescription forms issued.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(2) Upon delivery of prescription forms to persons qualified to prescribe medicinal products, a health care provider shall record the name of the person and the numbers of the prescription forms issued thereto and notify the Health Insurance Fund thereof at the request of the latter.

(2¹) Upon termination of the validity or revocation of an activity licence for the provision of health care services or termination of the provision of health care services, the former health care provider shall return the unused prescription forms to the Health Insurance Fund.

(10.04.2006 entered into force 23.04.2006 - RTL 2006, 33, 598)

(3) The Health Insurance Fund and a health care provider shall preserve the accounts concerning the division of prescription forms for five years.

(4) Prescription forms shall not be stored with a signature and the personal seal of the issuer of the prescription. Unused prescription forms shall not be given to other persons. Falling of the prescription forms into the hands of another person shall be precluded upon storing prescription forms. The State Agency of Medicines shall be notified immediately of the theft or loss of prescription forms.

(5) The copy of a prescription on the basis of which a medicinal product is dispensed and which bears the signature of the person who dispensed the medicinal product from a pharmacy, except in the cases specified in subsection (7), the order forms and accompanying documents shall be preserved in the pharmacy in the order of the dates of dispensing for two years after dispensing the medicinal product. The original copy of a prescription for a narcotic drug which bears the signature of the person who dispensed the medicinal product from a pharmacy, the order forms and accompanying documents of a narcotic drug shall be preserved in the pharmacy in the order of the dates of dispensing for five years after dispensing the medicinal product.

(5¹) The EU prescriptions on the basis of which medicinal products are dispensed and the copies thereof shall be stored separately from other prescriptions.

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(6) The copies of the prescriptions of narcotic drugs shall be preserved at the place of employment (at the health care provider) of the doctor who prescribed the drug in the order of the dates of prescribing for five years after prescribing the narcotic drug.

(7) Paper prescriptions of medicinal products dispensed at a discount rate shall be preserved at a pharmacy in the order of the dates of dispensing until delivery to the Health Insurance Fund. The information forwarded to the Health Insurance Fund through the Digital Prescription Centre shall coincide with the information in the paper prescriptions.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(7¹) A pharmacy shall attach a copy of a document certifying the insurance cover specified in subsection 2 (4) of this Regulation, which has been attached by a health care provider, to the paper prescriptions for dispensing a medicinal product at a discount rate issued for a person insured in EU.

(26.02.2010 entered into force 08.03.2010 - RTL 2010, 10, 180)

(8) The Health Insurance Fund shall preserve the paper prescriptions delivered thereto for three years. At the written request of a pharmacy, the Health Insurance Fund shall issue a certified copy of a prescription of the pharmacy.

(18.09.2008 entered into force 26.09.2008 (implemented as of 01.09.2008) - RTL 2008, 78, 1099)

(9) The Health Insurance Fund shall respond within five working days to an inquiry of the State Agency of Medicines concerning the medicinal products dispensed from a pharmacy at a discount rate during the last six months. The response shall include all the information entered in the prescription forwarded from the pharmacy to the Health Insurance Fund, except the name and personal identification code of the patient.

(10) In order to obtain additional information for the inquiry of the State Agency of Medicines, the Estonian Health Insurance Fund and the regional health insurance funds shall respond within one month.

§ 10. Implementing provisions

- (1) This Regulation enters into force on 1 March 2005.
- (2) As of 1 May 2005 medicinal products may be prescribed only in prescription forms established on the basis of this procedure.
- (3) The prescription medicinal products prescribed before 1 May 2005 may be dispensed from pharmacies until the date of expiry indicated on the prescription.
- (4) The obligation of the provider of pharmacy services included in subsections 81 (5) and (11) of the Medicinal Products Act shall be deemed to be performed until the end of the contract entered into on the basis of subsection 46 (2) of the version of the Health Insurance Act which is in force until 1 September 2008, but not later than until 1 January 2010, if the provider of pharmacy services has delivered the paper prescription of a medicinal product dispensed at a discount and has forwarded in electronic form the information contained therein to the Estonian Health Insurance Fund.

(24.08.2009 entered into force 01.09.2009 - RTL 2009, 68, 1011)

- (5) If the Digital Prescription Centre cannot be used for objective reasons, the obligation of the provider of pharmacy services included in subsections 81 (5) and (11) of the Medicinal Products Act shall be deemed to be performed until 1 January 2010 if the provider of pharmacy services has preserved the paper prescription of a medicinal product not specified in subsection (4) in the pharmacy pursuant to the procedure provided for in this Regulation.

(24.08.2009 entered into force 01.09.2009 - RTL 2009, 68, 1011)