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Conditions and procedure for the issue of prescriptions for medicinal products and for the dispensation of medicinal products by pharmacies and the format of the prescription[1]

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30.06.2014	RT I, 04.07.2014, 14	01.08.2014
10.07.2014	RT I, 12.07.2014, 167	15.07.2014

This regulation is enacted in accordance with section 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 dispensation of medicinal products in accordance with prescriptions or order forms, including requirements for the preservation and registration of medical prescription forms, order forms and cover documents;
2) the format of prescriptions;
3) the conditions and procedure for the dispensation of medicinal products in accordance with prescriptions issued in the member states of the European Union, member states of the European Economic Area and the Swiss Confederation (hereinafter, 'EU prescription');
[RTL 2010, 10, 180 – entry into force 08.03.2010]
4) the conditions and procedure for distance sales of medicinal products.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(2) The provisions of this regulation apply to the formalisation of prescriptions in relation to the prescribing of veterinary medicinal products by veterinarians in so far as this is not governed by the regulation of the Minister of Agriculture enacted in accordance with section 15(7) of the Medicinal Products Act, taking into account the

special rules governing the prescribing of veterinary medicinal products, and to the dispensation of medicinal products by pharmacies under veterinary prescriptions. The format of veterinary prescriptions is established by the above-mentioned regulation of the Minister of Agriculture.

(3) No more than one medicinal product may be prescribed in any prescription and no more than one medicinal product may be dispensed under any prescription, except in the case of EU prescriptions.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

§ 2. Issue of prescriptions for medicinal products

(1) Prescriptions and order forms may be issued in respect of medicinal products that have a valid marketing authorisation in Estonia, for the preparation of medicinal products as magistral formulae in pharmacies and, in the cases described in subsections 1 and 7 of section 21 of the Medicinal Products Act, for unauthorised medicinal products. If a person qualified to prescribe medicinal products prescribes an unauthorised medicinal product under section 21(1) of the Medicinal Products Act, he/she must submit an application for the use of the unauthorised medicinal product to the State Agency of Medicines.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(2) Medicinal products may be prescribed for medical purposes and for the purposes of treatment of other persons only by the physicians, dentists and midwives who are authorised to provide health services in the Republic of Estonia in relation to the out-patient treatment of the persons treated by them.
[RTL 2010, 15, 289 – entry into force 01.04.2010]

(2^1) Prescriptions for medicinal products are issued in electronic form (hereinafter, 'digital prescription') or on paper (hereinafter, 'paper prescription').
[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

(3) Dentists, stating their position title on the prescription, are authorised to prescribe only the following medicinal products and substances:
1) medicinal products for local treatment of teeth, gums and oral mucosae;
2) ATC code J01 – antibacterials for systemic use;
3) ATC code M01A – non-steroidal anti-inflammatory and anti-rheumatic products;
4) ATC code R06 – antihistamines for systemic use;
5) ethyl alcohol;
6) other medicinal products whose indications as stated in the marketing authorisation that is valid in Estonia include dental or oral diseases.
[RTL 2006, 33, 598 – entry into force 23.04.2006]

(3^1) Midwives, stating their position title on the prescription, are authorised to prescribe only the following medicinal products and substances:
1) ATC code A02B – medicinal products blocking the secretion of gastric acid, except for initial prescriptions;
2) ATC code A03A – antispasmodic and carminative preparations;
3) ATC code B03A – antianemic preparations;
4) ATC code C05A – topical use agents for the treatment of haemorrhoids, except for medicinal products containing glucocorticoids;
5) ATC code G01A – anti-infectives for topical use;
6) ATC code G02B – contraceptives for topical use;
7) ATC code G03A – hormonal contraceptives;
8) ATC code G03DA02 – medroxyprogesterone in cases in which the prevention of pregnancy is indicated, except for initial prescriptions;
9) ATC code H01BB – oxytocin and analogues for oral administration after the delivery of the infant;
10) ATC code J01XE – antibacterials.
[RT I, 04.07.2014, 14 – entry into force 01.08.2014]

(4) Medicinal products for dispensation at the discount rate may be prescribed to persons insured by the Estonian Health Insurance Fund by the persons listed in section 41(2) of the Health Insurance Act. Medicinal products required for a person's stay in Estonia may be prescribed for dispensation at the discount rate to persons who are 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')and who provide proof of their insurance cover by presenting a valid European health insurance card or the provisional replacement certificate of such a card or a valid certificate in standard format (E112, E123, S2, DA1) issued by a competent agency of the Member State providing the insurance.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(5) Medicinal products are prescribed where the corresponding indication exists and the treatment prescribed must be recorded in a document certifying the provision of the health care services with an indication of the number of the prescription. Entries are made following the procedure established in accordance with section 4^2(2) of the Health Services Organisation Act.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(6) The prescription for a medicinal product is issued in the amount required to undergo one course of treatment in the case of an acute illness and two to three months' treatment in the case of a chronic or long-term illness. In the case of a chronic or long-term illness, medicinal products may only be prescribed in an amount required for less than two months' treatment when commencing or changing the treatment.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(6^1) The amount of a medicinal product prescribed to a patient under the prescription for a narcotic medicinal product may not exceed the quantity required for one month. If a limitation has been established in Annex 4 to the present regulation in regard to the maximum quantity of the medical product permitted to be prescribed by means of a single prescription, the limitation always prevails. If several prescriptions are issued for benzodiazepines or benzodiazepine-like substances, the total quantity may not exceed twice the quantity provided in Annex 4.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(6^2) A narcotic drug or psychotropic substance may be prescribed to a person for the duration of the person's travel in an amount exceeding the amount specified in Annex 4 to this regulation in the case referred to in section 8(4) of Regulation no. 31 of the Minister of Social Affairs of 18 February 2005 entitled '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', but not for more than 30 days, by marking in box 7 on the prescription 'for the duration of the travel', and in the case referred to in section 8(41) of the same regulation following the requirements provided in section 92 by making a corresponding entry to the patient's file or medical history.
[RTL 2007, 96, 1616 – entry into force 21.12.2007]

(7) It is not permitted to issue prescriptions for injectable pharmaceutical forms containing ketamine, fentanyl, thiopental, sodium oxybate, alfentanil, sufentanil and remifentanil and oral pharmaceutical forms of buprenorphine.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(8) [Repealed – RTL 2008, 61, 875 – entry into force 01.01.2009]

(9) [Repealed – RTL 2008, 61, 875 – entry into force 01.01.2009]

(9^1) Only psychiatrists are authorised to prescribe medicinal products containing methylphenidate.
[RTL 2008, 61, 875 – entry into force 01.01.2009]

(9^2) Medicinal products containing substances listed in Schedules I and II of narcotic drugs and psychotropic substances as appearing in the regulation of the Minister of Social Affairs are to be prescribed using the prescription form for narcotic drugs.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(10) A prescription for the dispensation of a medicinal product on two or three occasions (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, and when prescribing treatment by a contraceptive medicinal product.

(11) The amount of the medicinal product entered on a repeat prescription for dispensation at a discount rate must be such as to cover two to three month's treatment.
[RT I, 23.12.2010, 6 – entry into force 01.01.2011]

(12) When issuing a repeat prescription, the person prescribing the medicinal product determines the number of repeat dispensations of the medicinal product under the prescription. When issuing a paper prescription, the person prescribing the medicinal product fills out the copy of the repeat prescription and removes the sheet or sheets that have not been filled out.
[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

(13) Repeat prescriptions may 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.
[RTL 2006, 33, 598 – entry into force 23.04.2006]

(14) When issuing a digital prescription, the person who issues the prescription declares 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 makes the corresponding declaration by affixing his or her signature and personal seal separately to each prescription sheet.

[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

§ 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 by 158 mm. It is printed in green on green paper, single sheet. In the upper left-hand corner under the title of the form, there is a letter (the Latin alphabet is used, each series of prescription forms 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 binder holes separated by a distance of 80 mm. The margins of the form contain a security print.

(3) The size of the original copy of a repeat prescription is 127 by 158 mm, three sheets. It is printed in green on green self-copying paper. In the upper left-hand corner under the title of the form, there is a letter (E on the first copy, F on the second copy and G on the third copy) and a 7-digit number in red (the same on all the copies). On the left-hand side, there are binder holes separated by a distance of 80 mm. The margins of the form contain a security print. The prescription sheets are glued together at the upper edge.
[RTL 2010, 26, 457 – entry into force 31.05.2010]

(4) The size of the original copy of a prescription for narcotic drugs is 127 by 158 mm, three sheets. The pharmacy receives the original prescription and one copy thereof and the health care provider receives 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 binder holes separated by a distance of 80 mm. The margins of the form contain a security print. The prescription sheets are glued together at the upper edge.

(5) Unless a shorter term of validity is indicated on the prescription, the prescription of a non-narcotic medicinal product is valid for 60 days, the prescription of a narcotic medicinal product for 30 days and a repeat prescription for 180 days after issue.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

§ 4. Information to be entered on the prescription when prescribing a medicinal product

(1) The prescription, except for a veterinary prescription, must set out the following information:
1) the name, personal identification code and residential address of the patient, in the case of a person insured in the EU, at least the country of residence and personal identification code according to the document constituting proof of the insurance cover as described in section 2(4) of this regulation;
[RTL 2010, 10, 180 – entry into force 08.03.2010]
2) the patient's age in years (in years and months in the case of children under 4 years of age);
2^1) a three-or four-digit code of the diagnosis on which the prescription is based according to version 10 of the International Classification of Illnesses (RHK-10);
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]
3) discount rate (100%, 90%, 75%, 50%) or the absence of discount (full price);
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]
3^1) whether or not the patient receives an incapacity for work pension under the State Pension Insurance Act
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]
3^2) a note regarding whether the patient is insured;
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]
4) in the case of a ready-made medicinal product, the pharmaceutical form, the name of the proprietary medicinal product or active substance, the concentration of the active substance and the total amount of the medicinal product;
5) where the name of a proprietary medicinal product is stated, a justification concerning the prohibition of substitution of the medicinal product;
[RT I, 21.02.2014, 1 – entry into force 01.03.2014]
6) in the case of medicinal products prepared as magistral formulae, the complete composition, the strength of the ingredients and the total amount of the medicinal product, as well as request to the pharmacy for the preparation and dispensation of the medicinal product;
7) instructions for the use of the medicinal product (the amount of a single dose, route of administration, frequency of use and period of use);
8) the name of the person who issued the prescription (in capital letters, in printed form or as a stamp), the number of his or her Health Board registration certificate, his or her specialisation (in the case of a digital prescription), telephone number, e-mail address (in the case of a paper prescription) and signature (in the case of a paper prescription) of the person who issued the prescription;
[RT I, 21.02.2014, 1 – entry into force 01.03.2014]
9) the date of issue and the term of validity of the prescription;
10) the place of employment (the name of the health care provider), the address of the place of business, the registry code (the commercial registry code of the company or the code of the legal person entered in the non-profit associations and foundations register) or the personal identification code (in the case of a sole proprietor not registered in the commercial register) of the person who issued the prescription.

(1^1) [Repealed – RTL 2010, 10, 180 – entry into force 08.03.2010]

(2) If a paper prescription for a medicinal product to be dispensed at the discount rate is issued to a person who proves his or her insurance cover by means of a document described in section 2(4) of this regulation, the health care provider attaches a copy of such document to the prescription.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(2^1) If a digital prescription for a medicinal product to be dispensed at the discount rate is issued to a person who proves his or her insurance cover by means of a document described in section 2(4) of this regulation, in addition to the information specified in subsection 1, the following information must be added in the Digital Prescription Centre
1) the date of birth and sex;
2) the type of the document described in section 2(4);
3) the number of the document described in section 2(4);
4) the state who issued the document described in section 2(4);
5) the agency who issued the document described in section 2(4);
6) the date of issue and the date of the beginning and end of the period of validity of the document described in section 2(4).
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(2^2) If a digital prescription is issued for dispensation at the discount rate, the health care provider must preserve a copy of the document described in section 2(4) of this regulation for at least three years.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(3) [Repealed – RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(4) In order to the enable the selection of the most suitable size of the original package or number of packages for the patient, the total amount of the medicinal product must be indicated in the prescription as follows:
1) as an exact strength of the active substance and the total number of 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 is prescribed by using the name of the active substance in the medicinal product.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(6) The person who prescribes the medicinal product may use the name of a proprietary medicinal product if he or she deems the substitution of the medicinal product with another proprietary medicinal product containing the same amount of the same active substance and having the same or equivalent pharmaceutical form to be medically unsuitable for the patient, including where a biological medicinal product is prescribed. In this case, the person who prescribes the medicinal product adds a justification concerning the prohibition on the substitution of the medicinal product on the prescription and enters the justification also in the document certifying the provision of the health care services.
[RT I, 21.02.2014, 1 – entry into force 01.03.2014]

(7) The person who prescribes a medicinal product must notify the patient of the possibilities of and conditions for substituting the medicinal product and, in the case of a note concerning non-substitution of the medicinal product, of the prohibition to substitute the medicinal product and the justification for this.
[RTL 2008, 78, 1099 – entry into force 01.03.2014 – implemented as of 1.09.2008]

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

(9) Information concerning the patient and instructions for the use of the medicinal product must be written in Estonian. If necessary, the instructions for the use of a medicinal product may be written additionally in another language understood by the patient. The expressions used in the instructions for the use of medicinal products must be such as can be understood by the patient, in particular in the case of liquid dosage forms (the dosage is indicated as a number of 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). When issuing a paper prescription for a narcotic drug, the person prescribing the medicinal product must write the instructions for the use of the medicinal product in his or her own hand.
[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

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

(11) If the amount of a medicinal product in a prescription is indicated in units other than grams, the unit of measurement must 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, "!!" must be written after the requested dose or route of administration in the prescription.

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

§ 5. Formalisation of prescriptions

(1) The person who prescribes a medicinal product must issue the prescription electronically except where the Digital Prescription Centre cannot be used for objective reasons or where the person to whom the prescription is issued requires the prescription in order to receive a cross-border health care service within the meaning of the Health Services Organisation Act in another member state of the European Union.
[RT I, 21.02.2014, 1 – entry into force 01.03.2014]

(2) Paper prescriptions may be issued only on numbered prescription forms, the format of which is described in Annexes 1 to 3 to this regulation. Paper prescriptions must be filled out in legible handwriting by using a permanent writing instrument or printed.

(3) The following requirements must be taken into account when filling out a paper prescription using a computer and a printer:
1) all the required information must be entered in the relevant boxes in the prescription;
2) no other information than the information required under section 4(1) may be entered and no abbreviations may be used in the prescription;
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]
3) the names of the active substances or the names of the proprietary medicinal products may only be entered into the software and printed in their full form;
4) the pharmaceutical form and the strength of the active substance must be entered into the software and printed out;
[RTL 2010, 10, 180 – entry into force 01.04.2010]
5) as for the dosage of the medicinal product, the single dose must be written in numbers (e.g., '30 mg') and the frequency of use in words (e.g., 'twice every twenty-four hours') and the total amount of the medicinal product must be indicated in numbers in brackets (e.g., '(90 tablets)').

(4) The software used for the issue of prescriptions:
1) must ensure that when selecting or entering the name of a medicinal product, the name of the active substance is displayed first, followed by the names of the proprietary medicinal products which are displayed in alphabetical order or in accordance with the discount rates applied;
2) may not contain any references or links implying a preference for a particular proprietary medicinal product;
3) must ensure that, while working with the software, no advertisements of medicinal products are made or other ways of exerting influence on the person prescribing medical products are used.

(5) A paper prescription is validated, on all the copies of the prescription, by the signature of the person who prescribes the medical product and the seal stamp stating the name and code number of that person. When issuing a digital prescription, the prescription is validated by the person who prescribes the medicinal product after the Digital Prescription Centre has provided the information that the data submitted is correct.

(6) When a digital prescription is issued, the person to whom the prescription is issued appoints the party to purchase the medicinal product as follows:
1) the person himself or herself;
2) a third party identified by name;
3) an unidentified party.
[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

§ 6. Dispensation to individuals of medicinal products from general pharmacies and veterinary pharmacies

[RTL 2006, 33, 598 – entry into force 23.04.2006]

(1) Medicinal products subject to medicinal prescription may be dispensed to individuals from a general pharmacy or veterinary pharmacy only under medicinal or veterinary prescriptions that are filled out in accordance with established requirements.
[RTL 2006, 33, 598 – entry into force 23.04.2006]

(2) Narcotic drugs may be dispensed to persons from 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 the dispensation of medicinal products in Annex 4 to this regulation and the restrictions for prescribing established in subsections 6^1, 62, 7 and $9^1$of section 2.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(2[1]) If narcotic drugs or other psychotropic substances are prescribed by an attending physician in compliance with the provisions of section 2(6[2]), a pharmacy may dispense to the individual the amount entered in the prescription, but not more than the amount required for 30 days. When dispensing the medicinal products, the requirements specified in subsections 9[1]and 9[2]of section 8 of Regulation No 31 of the Minister of Social Affairs of 18 February 2005 entitled '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' must be adhered to. The pharmacy preserves the application on the basis of which the medicinal product is dispensed or a copy thereof for five years.
[RTL 2008, 61, 875 – entry into force 01.01.2009]

(3) It is prohibited to dispense separately the substances which belong to the composition of medicinal products prepared as magistral formulae. The following may not be prescribed for the preparation of medicinal products as magistral formulae and may 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 under a prescription. If the concentration of ethyl alcohol is not stated on the prescription, ethyl alcohol must be dispensed as a 70 per cent solution. If the alcohol is intended for a compress, the pharmacy must also dilute it.

(5) If, when prescribing a medicinal product, the name of the active substance of the medicinal product is used, the person dispensing the medicinal product must suggest to the patient, from among the medicinal products suitable for the patient, the proprietary medicinal product in the case of which the amount that the patient must pay for the product is the lowest. If the individual presenting the prescription refuses to purchase the most favourable proprietary medicinal product or if the most favourable proprietary medicinal product is not available from the wholesalers in Estonia, the person dispensing the medicinal product enters the corresponding reasons on the prescription.
[RTL 2010, 10, 180 – entry into force 01.04.2010]

(6) Where a proprietary medicinal product has been prescribed that is not available at the pharmacy at the moment, the pharmacy must acquire the medicinal product within a reasonable period of time as of the presentation of the prescription, unless confirmation is provided by the State Agency of Medicines that the medicinal product is not available in Estonia. In the latter case, the pharmacy must notify the person who issued the prescription thereof and communicate the solution to the person who submitted the prescription. In consultation with and with the consent of the person who prescribed the medicinal product, the prescribed product may be substituted having regard to the requirements set out in subsection 5 of this section.
[RTL 2010, 10, 180 – entry into force 01.04.2010]

(7) If the total prescribed amount of the ready-prepared medical product differs from the amount in the original package, the original package with the closest amount must be dispensed in accordance with subsection 5 of this section. It is only permitted to divide an original package if, upon the division, the name of the medicinal product, the name of the authorisation holder, the strength of the active substance, the batch number and the date of expiry are preserved on all parts of the package (blister, strip, tube, ampoule, vial).
[RTL 2010, 10, 180 – entry into force 01.04.2010]

(8) If the prescription is issued for a medicinal product which does not have a valid marketing authorisation in Estonia and with respect to which the State Agency of Medicines has made a decision regarding the justifiability of use of the product, the pharmacy must make a corresponding inquiry to the persons who are authorised to wholesale medicinal products in Estonia and acquire the medicinal product within a reasonable period of time as of the presentation of the prescription, unless the wholesaler of the medicinal product notifies the pharmacy that the suitable medicinal product cannot be imported to Estonia. In the latter case, the pharmacy notifies the person who prescribed the medicinal product thereof and communicates the solution to the person who submitted the prescription.
[RTL 2010, 10, 180 – entry into force 01.04.2010]

(8[1]) The medicinal products authorised to be imported and used on the basis of an application of a professional association may be dispensed only after the person dispensing the product has checked with the State Agency of Medicines that the code of the diagnosis indicated on the prescription matches the code states in the application of the professional association.
[RTL 2006, 33, 598 – entry into force 23.04.2006]

(9) [Repealed – RTL 2006, 33, 598 – entry into force 23.04.2006]

(9[1]) The software used for the dispensation of medicinal products may not contain any references or links implying preference for any particular proprietary medicinal product, except for the purpose of fulfilling the obligation set out in subsection 5 of this section to suggest the proprietary medicinal product in the case of which the patient's share of the cost-sharing is minimum. The software used for the dispensation of the medicinal product must preclude the possibility of advertising the medicinal product or otherwise influencing the person dispensing the medicinal product during the time of working with the software.
[RTL 2010, 10, 180 – entry into force 01.04.2010]

(10) The person dispensing a medicinal product enters on the prescription the information regarding the dispensation of the medicinal product in accordance with the regulation of the Government of the Republic enacted under section 81(2) of the Medicinal Products Act.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(11) The information referred to in subsection 10 of this section must be entered on the prescription when the medicinal product is being dispensed or, if the Digital Prescription Centre cannot be accessed at the time when the medicinal product is being dispensed, immediately after the dispensation of the medicinal product.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(12) The text concerning the use of the medicinal product is entered on the original package of the medicinal product or on a sheet attached to the package. Where a sticker is used, it may not cover important information. When dispensing a medicinal product, the patient must be notified orally of the correct and safe use of the medicinal product. Attention must be directed to the correct storage of the medicinal product and to other notes on the package.

(13) If the prescription does not contain all the required information, corrections have been made in the prescription or incompatible substances have been prescribed, the pharmacy may not dispense the medicinal products under the prescription and must the prescription into its keeping. Such prescriptions must be kept in the pharmacy separately from other prescriptions.

(14) In the case of a prescription kept in accordance with subsection 13, the person who prescribed the medicinal product must be notified thereof immediately by telephone and the individual who presented the prescription must be notified of the solution.

(15) In the case of doubts as to the correctness of a prescription, the person dispensing the medicinal product must contact the person who prescribed the medicinal product, postpone the dispensation of the medicinal product and keep the prescription in the pharmacy until the circumstances have been clarified. If doubts arise as to the authenticity of a prescription, the State Agency of Medicines must be immediately informed.
[RTL 2010, 10, 180 – entry into force 01.04.2010]

(16) [Repealed – RTL 2008, 61, 875 – entry into force 26.07.2008]

(16[1]) If the prescription for a medicinal product containing methylphenidate has been issued by a physician not authorised to do so, or if a medicinal product has been prescribed whose dispensation under a prescription is not permitted, the pharmacy may not dispense the medicinal product under the prescription. The State Agency of Medicines must be notified of such a prescription and, in the case of a paper prescription, the pharmacy must take the prescription into its keeping.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(17) In all cases when it has been necessary to contact the person who prescribed the medicinal product and when, based on the information provided by that person, corrections were made with respect to the proprietary medicinal product to be dispensed, the amount to be dispensed or other circumstances concerning the dispensation of the medicinal product, the person who dispenses the medicinal product must forward the corresponding information to the Digital Prescription Centre. In the case of a paper prescription, the person who dispenses the medicinal product enters the corresponding information on the reverse of the prescription and certifies it by affixing his or her name and signature. The person dispensing a medicinal product may not increase the amount of a narcotic drug or psychotropic substance to be dispensed.
[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

(18) The person dispensing the medicinal product is authorised 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 the legislation in force. The person who makes the corrections is responsible for correcting the prescription and for the dispensation of the medicinal product under the prescription and certifies the corrections on the reverse of the prescription by affixing his or her name and signature. When entering the information of a paper prescription into the Digital Prescription Centre, the corrections made must also be shown in the Digital Prescription Centre.
[RTL 2008, 78, 1099 – entry into force 26.09.2008 – implemented as of 1.09.2008]

(19) The purchaser of a medicinal product is given a receipt concerning the price paid by him or her and the discount rate.

(20) The dispensation of medicinal products subject to medical prescription must be entered into prescription records in accordance with the regulation of the Minister of Social Affairs enacted on the basis of section 31(6) (3) of the Medicinal Products Act.

§ 6[1]. Dispensation of medicinal products to persons from general pharmacies and veterinary pharmacies on the basis of EU prescriptions

(1) Subsections 1 –2[1] and 8 of section 6 of this regulation do not apply to the dispensation of medicinal products on the basis of EU prescriptions.

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

(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 proprietary medicinal product or active substance and the concentration of the active substance;
3) instructions for the 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 stated in the EU prescription, the person dispensing the medicinal product must, in order to dispense the medical product safely, request the person who presented the prescription to provide the corresponding information, enter it on the reverse of the prescription and certify it by affixing his or her name and signature.

(5) In all cases when it has been necessary to contact the person who prescribed the medicinal product and when, based on the information provided by that person, corrections were made with respect to the proprietary medicinal product to be dispensed, the amount to be dispensed or other circumstances concerning the dispensation of the medicinal product, the person who dispenses the medicinal product must enter the corresponding information on the reverse of the prescription and certify it by affixing his or her name and signature.

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

(7) If corrections have been made on 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 may not be dispensed from the pharmacy.

(8) When dispensing a medicinal product, the person dispensing the product must enter the following information in the EU prescription:
1) the name, strength of the active substance and amount in the package of the dispensed proprietary medicinal product;
2) the price of the package of the medicinal product dispensed, the number of packages 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) The pharmacy takes the EU prescription into its keeping unless a part of the amount of the prescribed medicinal product remains or one or several of the medicinal products prescribed remain to be dispensed.

(10) Where an EU prescription is taken into the pharmacy’s keeping, the person dispensing the medicinal product gives 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 keeps a copy of the EU prescription. The copy of an EU prescription must contain the information listed in subsection 8 of this section.

(11) The purchaser of a medicinal product is given a receipt concerning the price of the medicinal product paid by him or her.

(12) The text concerning the use of the medicinal product is entered on the package of the medicinal product dispensed or on a sheet attached to the package.

(13) The dispensation of medicinal products subject to medical prescription is entered into prescription records in accordance with the regulation of the Minister of Social Affairs enacted on the basis of section 31(6)(3) of the Medicinal Products Act.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

§ 6^2. Dispensation of medicinal products to individuals by distance sale

(1) In the case of distance sale of medicinal products, the medicinal products must be released in a transportation package, completed according to the order, which ensures the delivery of the medicinal products to the recipient such that their properties remain unchanged.

(2) Before the transportation package is released, its contents must be verified and the results of the verification must be documented.

(3) A shipment document is attached to the transportation package that sets out the name of the person ordering the medicinal product, the number of the order, the name and contact information of the pharmacy dispensing the medicinal product, the business name of the holder of the activity licence for the provision of pharmacy services, the name of the person who verified the contents of the package and, in the case of a medicinal product subject to medical prescription, the number of the prescription.

(4) The transportation package must include the information that the dispensed medicinal products will not be bought back and may be returned to the pharamacy only to be destroyed. The transportation package must also include a warning that the medicinal product must not be used if the delivered package does not match the order, is opened or damaged or if there is doubt that the product may be defective, and that in such a case the pharmacy that dispensed the medicinal product must be promptly contacted. The transportation package must include a note advising the recipient to read the package leaflet before using the medicinal product.

(5) The transportation package may not bear any reference to a particular medicinal product.

(6) Information concerning the storage conditions, place of delivery, the latest delivery time and the number of the order is to be entered on the transportation package in such terms as can be understood by the person delivering the medicinal products. Until delivery of the package to the recipient is complete, the pharmacy that issued the medicinal products remains responsible for the products.

(7) Delivery of the package is made to the recipient or the representative appointed by the recipient against his or her signed receipt or other mark allowing personal identification.

(8) The cover document of the transportation package must show the name and contact information of the pharmacy that dispensed the medicinal product, the business name of the holder of the activity licence for the provision of pharmacy services, the name and contact information of the provider of the transport service of the goods, the date of receipt of the package and the number of the order. The same or a related cover document must show the date of the delivery of the package and the name and signature of the recipient or the recipient's representative, taking into account the special rule set out in subsection 7 of this section. The person delivering the package sends the documents to the pharmacy within five working days as of completing the delivery of the package.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(9) The requirements set out in this section are also applied to the provision of the service of delivery of medicinal products referred to in section 31(5^7) of the Medicinal Products Act.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

§ 7. Dispensation of medicinal products from pharmacies to other persons

(1) General pharmacies and veterinary pharmacies may dispense medicinal products subject to medical prescription to health care providers, including to self-employed health care providers, and to other persons authorised to prescribe medicinal products, and to persons who are authorised by legislation to purchase medicinal products under medical prescriptions.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(1^1) General pharmacies may dispense to midwives only the following medicinal products and substances:
1) medicinal products that midwives are authorised to prescribe under subsection 3^1 of section 2 of this regulation;
2) ATC code A03BA01 – atropine;
3) ATC code B05X – I.V. solution additives;
4) ATC code C01CA24 – epinephrine or adrenaline;

5) ATC code N01B – local anaesthetics;
6) ATC code G02A – uterotonics;
7) ATC code H01BB – oxytocin and analogues.
8) ATC code B02BA01 – phytomenadione (vitamin K)
[RT I, 04.07.2014, 14 – entry into force 01.08.2014]

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

(3) Medicinal products subject to medical prescription are dispensed together with the cover document prepared on the basis of the order form. A separate cover document is prepared regarding each order form. Medicinal products not subject to medical prescription are dispensed together with a cover document.

(4) When a hospital pharmacy dispenses to health care providers medicinal products that are or are not subject to medical prescription it attaches to the products a cover document drawn up in accordance with the order form.

(5) When a pharmacy dispenses medicinal products that are or are not subject to medical prescription to its branch pharmacies, other pharmacies, wholesalers or manufacturing companies, it attaches to the products a cover document.

§ 8. Preparation of order forms and cover documents

(1) Order forms and cover documents are filled out in legible handwriting by using a permanent writing instrument or are printed out.

(2) The order form must include the following information:
1) the name, address, telephone number of the legal person or self-employed person 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) with regard to each medicinal product, the name of the active substance or proprietary medicinal product, the pharmaceutical form, the concentration of the active substance, the total amount of the medicinal product;
[RTL 2010, 10, 180 – entry into force 08.03.2010]
5) the name, position title, signature and personal seal of the person authorised to prescribe medicinal products or, when ordering from the hospital's own pharmacy, the name of the person who drew up the order form or, in the case of authority to purchase prescription medicinal products arising from legislation, the name, position title and signature of the person who is authorised order medicinal products.

(3) The order form for a narcotic drug must include, in addition to the information listed in subsection 2 of this section, the name and signature of the person appointed by the health care provider, veterinarian or company operating the veterinary practice as responsible for handling narcotic drugs.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(4) A cover document must include the following information:
1) the name of the pharmacy;
2) the address and telephone number of the pharmacy, except when the pharmacy is dispensing to its branch pharmacy or when the hospital pharmacy is dispensing to a department of the same hospital;
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]
3) the date of the order form, if a medicinal product is dispensed under an order form;
4) the name of the recipient;
5) the address of the recipient, except when the pharmacy is dispensing to its branch pharmacy or when the hospital pharmacy is dispensing to a department of the same hospital;
6) the date on which the cover document was drawn up;
7) with regard to each medicinal product, the name of the medicinal product, the pharmaceutical form, the concentration of the active substance(s), the quantity in the package, the total number of packages;
8) if medicinal products are dispensed for resale, the batch number, a note concerning whether dispensation of the medical product is or is not subject to medicinal prescription and in the case of unauthorised medicinal products, the corresponding note;
[RTL 2006, 33, 598 – entry into force 23.04.2006]
9) the selling price;
10) the name of the person dispensing the product and the name of the recipient.

(5) Cover documents must be prepared in at least two copies and authenticated on both copies by the signatures of the person dispensing the products and of the recipient and by the date of dispensation and receipt. One copy is kept by the person dispensing the products, the other copy by the recipient. When the hospital pharmacy dispenses medical products to a department of the same hospital, the cover document may be prepared in a single copy to be stored in the hospital pharmacy.

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

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

(1) Regional units of the Health Insurance Fund issue prescription forms to health care providers for a charge and verify that the recipient of the prescription forms has a valid activity licence for the provision of health care services, and document the numbers of prescription forms and keep records of the prescription forms issued.
[RTL 2006, 33, 598 – entry into force 23.04.2006]

(2) When delivering prescription forms to persons authorised to prescribe medicinal products, the health care provider must record the name of the person and the numbers of the prescription forms delivered to such persons and must notify this to the Health Insurance Fund on receiving the corresponding inquiry from the Fund.

(2^1) When the validity activity licence for the provision of health care services expires or the licence is revoked, or when the provision of health care services is discontinued, the former health care provider must return the unused prescription forms to the Health Insurance Fund.
[RTL 2006, 33, 598 – entry into force 23.04.2006]

(3) The Health Insurance Fund and the health care provider must preserve the records concerning the distribution of prescription forms for five years.

(4) Prescription forms must not be stored such that they are signed and stamped with the personal seal of the issuer of the prescription. Unused prescription forms must not be handed over to third parties. When storing prescription forms, measures must be taken that preclude their falling into the hands of third parties. The State Agency of Medicines must be notified immediately of the theft or loss of prescription forms.

(5) The copy of the prescription under which the medicinal product is dispensed and which bears the signature of the person who dispensed the medicinal product from the pharmacy, the order forms and cover documents must be preserved at the pharmacy in the order of dispensing dates for three years after the dispensation of the medicinal products.
[RT I, 22.03.2014, 1 – entry into force 25.03.2014]

(5^1) The EU prescriptions under which medicinal products are dispensed and any copies thereof must be stored separately from other prescriptions.
[RTL 2010, 10, 180 – entry into force 08.03.2010]

(6) When prescribing a narcotic drug, the copies of the paper prescription of the narcotic drug that remain with the person prescribing such a medicinal product must be preserved at the place of employment of the physician (on the premises of the health care provider) who prescribed the drug in the order of the prescription dates for five years after prescribing that drug.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(7) [Repealed – RT I, 22.03.2014, 1 – entry into force 25.03.2014]

(7^1) [Repealed – RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(8) At the written demand of the Health Insurance Fund, the pharmacy issues to the Fund a certified copy of the prescription that is the subject of the demand.
[RT I, 22.03.2014, 1 – entry into force 25.03.2014]

(9) The Health Insurance Fund responds within five working days to any inquiry of the State Agency of Medicines concerning the medicinal products dispensed from a pharmacy. The response must include all information entered in the prescription forwarded from the pharmacy to the Health Insurance Fund, except for the name and personal identification code of the patient.
[RT I, 22.03.2014, 1 – entry into force 25.03.2014]

(10) The Estonian Health Insurance Fund and the regional health insurance funds respond within one month to any inquiry submitted by the State Agency of Medicines concerning additional information.

§ 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 on prescription forms established in accordance with this regulation.

(3) The medicinal products subject to medical prescription that are prescribed before 1 May 2005 may be dispensed from pharmacies until the date of expiry shown on the prescription.

(4) The obligations of the provider of pharmacy services set out in subsections 81(5) and 81(11) of the Medicinal Products Act are deemed to have been performed until the end of the contract entered into under section 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 the medicinal product dispensed at a discount and has forwarded the information contained therein in electronic form to the Estonian Health Insurance Fund.
[RTL 2009, 68, 1011 – entry into force 01.09.2009]

(5) If the Digital Prescription Centre cannot be used for objective reasons, the obligations of the provider of pharmacy services set out in sections 81(5) and 81(11) of the Medicinal Products Act are deemed to have been performed until 1 January 2010 if the provider of pharmacy services has preserved the paper prescription of the medicinal product not covered by subsection 4 in the pharmacy following the procedure provided in this regulation.
[RTL 2009, 68, 1011 – entry into force 01.09.2009]

(6) Physicians and dentists are authorised to use prescription forms that were issued and printed before 1 April 2010.
[RTL 2010, 15, 289 – entry into force 01.04.2010]

(7) Physicians, dentists and midwives are authorised to use repeat prescription forms issued and printed before 1 July 2010.
[RTL 2010, 26, 457 – entry into force 31.05.2010]

(8) Prescription forms printed before 1 October 2011 may be issued and used until 30 September 2013.
[RT I, 03.05.2012, 2 – entry into force 01.10.2012]

(9) Prescription forms printed before 1 March 2014 may be issued and used until 31 October 2015.
[RT I, 21.02.2014, 1 – entry into force 01.03.2014]

[1]Commision Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (OJ L 356, 22.12.2012, pp. 68–70).

Annex 1 Single prescription
[RT I, 21.02.2014, 1 - entry into force 01.03.2014]

Annex 2 Repeat prescription
[RT I, 21.02.2014, 1 - entry into force 01.03.2014]

Annex 3 Prescription for a narcotic drug
[RT I, 21.02.2014, 1 - entry into force 01.03.2014]

Annex 4 Narcotic drugs and psychotropic substances whose prescription and dispensation from a pharmacy on the basis of a prescription is subject to quantitative restrictions
[RT I, 03.05.2012, 2 - entry into force 01.10.2012]