

Conditions and Procedure for Handling of Narcotic Drugs and Psychotropic Substances for Medical and Research Purposes, and Conditions and Procedure for Maintaining Records and Reporting in that Area and Schedules of Narcotic Drugs and Psychotropic Substances

Regulation No. 73 of the Minister of Social Affairs of 18 May 2005
(RTL 2005, 57, 807),
entered into force 5 July 2005,

This Regulation is established on the basis of subsections 3¹ (1) and 4 (15) of the Act on Narcotic Drugs, Psychotropic Substances and Precursors thereof.

Chapter 1 General Provisions

§ 1. Scope of application

This regulation regulates the handling of narcotic drugs and psychotropic substances for medical and research purposes and the maintenance of records and reporting related to handling and establishes the Schedules I-IV of narcotic drugs and psychotropic substances (Annex 1).

[[RTL 2007, 88, 1477](#) – entered into force 26.11.2007]

§ 2. Application of regulation

The requirements established by this Regulation are subject to application in the use of narcotic drugs or psychotropic substances within the framework of economic or professional activities of a natural person or a legal person, including on ships and aircraft (hereinafter enterprise).

§ 3. Narcotic drugs and psychotropic substances

(1) Narcotic drugs and psychotropic substances are substances listed in the Schedule established in Annex 1 to this Regulation and isomers, esters, ethers and salts of these substances, and medicinal products containing such substances.

[[RT I, 09.02.2011, 3](#) – entered into force 12.02.2011]

(2) The proprietary medicinal products which are used only for medical or scientific purposes and which contain the following substances listed in Schedule I, II, III and IV under the conditions set out in this subsection shall not be considered narcotic drugs and psychotropic substances:

1) proprietary medicinal products of opium and morphine containing less than 0.2 weight percentage of morphine (expressed as morphine base) and one or several non-narcotic active substances.

2) proprietary medicinal products containing one or several non-narcotic active substances in addition to amobarbital, butalbital, glutethimide, cathine, meprobamate, pentazocine, pentobarbital, phenobarbital, butobarbital or cyclobarbital;

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3) oral pharmaceutical preparations containing only dextropropoxyphene of narcotic drugs on the condition that one dose of the medicinal product does not contain more than 135 milligrams of such drug or that the content of this drug in the medicinal product does not exceed 2.5 per cent of the total weight of the pharmaceutical form;

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4) proprietary medicinal products containing one or several non-narcotic active substances in addition to acetyldihydrocodeine, dihydrocodeine, ethylmorphine, pholcodine, codeine, nicodicodine, nicocodine or norcodeine;

5) proprietary medicinal products containing acetyldihydrocodeine, dihydrocodeine, ethylmorphine, pholcodine, codeine, nicodicodine, nicocodine or norcodeine on the condition that the content of such substances per single dose of the medicinal product does not exceed 100 milligrams; or that their content does not exceed 2.5 per cent of the total weight of the pharmaceutical form;

- 6) proprietary medicinal products containing difenoxin not more than 0.5 milligrams per one dose of the medicinal product and atropine sulphate in a quantity which exceeds 5 per cent of the dose of difenoxin;
- 7) proprietary medicinal products containing diphenoxylate not more than 2.5 milligrams per one dose of the medicinal product (expressed as pure substance), and atropin sulphate in a quantity which exceeds one per cent of the dose of diphenoxylate;
- 8) proprietary medicinal products containing propiram not more than 100 milligrams per one dose of the medicinal product and containing at least the same quantity of methylcellulose.
- (3) Narcotic drugs and psychotropic substances subject to special recording (hereinafter substances subject to special recording) are the substances listed in Schedules I and II and medicinal products containing these substances and codeine and ethylmorphine as pure substances.
- (4) Narcotic drugs and psychotropic substances subject to recording (hereinafter substances subject to recording) are the substances listed in Schedules III and IV and medicinal products containing these substances except codeine and ethylmorphine as pure substances.

§ 4. Rules for handling of narcotic drugs and psychotropic substances and for maintaining records and reporting and person responsible for handling of narcotic drugs and psychotropic substances

- (1) In every enterprise which handles narcotic drugs and psychotropic substances, the director of the enterprise or a person designated by him or her shall appoint in writing a natural person who is responsible for the handling of narcotic drugs and psychotropic substances, maintaining records and reporting and the person substituting for him or her in his or her absence.
- (2) The director of the enterprise or a person designated by him or her shall appoint in writing a person (persons) who have access to narcotic drugs and psychotropic substances and who have the right to receive and dispense such drugs and substances.
- (3) Rules confirmed by the signature of the director of the enterprise or the responsible person specified in subsection (1) and by the date of preparation shall be established for handling, maintaining of records and reporting of narcotic drugs and psychotropic substances. The rules shall be up-to-date and upon amendment of the rules, the earlier versions thereof shall be preserved for a period of at least five years.
- (4) The rules for handling of narcotic drugs and psychotropic substances and for maintaining records and reporting in that area shall set out a detailed description of the performance of all acts, the maintaining of records and reporting and the documentation of acts and the preservation of documentation related to narcotic drugs and psychotropic substances.
- (5) The employees related to handling narcotic drugs and psychotropic substances shall be familiarised with the rules specified in subsection (3). The employees shall confirm that they have been familiarised with the rules by their signature and the date.

Chapter 2

Handling of Narcotic Drugs and Psychotropic Substances

§ 5. Importation and exportation

- (1) Narcotic drugs and psychotropic substances shall be imported and exported under the conditions and pursuant to the procedure provided for in the Medicinal Products Act (RT I 2005, 2, 4; 13, 63; 24, 180) and in legislation established on the basis thereof.
- (2) An application reasoned by a doctor and the approval of a member of the corresponding specialist commission of the Ministry of Social Affairs is required for the use for medical purposes of substances specified in Schedule I and medicinal products containing such substances.

§ 6. General requirements for storage

- (1) Narcotic drugs and psychotropic substances shall be stored such that to preclude their falling into the hands of unauthorised persons.
- (2) The storage room of narcotic drugs and psychotropic substances may be open only if the person specified in clause (4) 1) or 2) is staying there.
- (3) The cupboard or safe in which narcotic drugs and psychotropic substances are stored may be open only when substances belonging to the Schedules established by this Regulation are being placed into or taken from the cupboard or safe.
- (4) The room where narcotic drugs or psychotropic substances are stored shall be equipped with a security alarm system. This requirement does not apply on ships and aircraft.
- (5) Narcotic drugs and psychotropic substances which have been assembled for dispensing to a client shall be stored in the place of storage until dispensation from the enterprise.
- (6) A hospital pharmacy is required to check at least once every half-year the storage of narcotic and psychotropic medicinal products and maintaining of records by the health care provider who formed the hospital pharmacy. The results shall be documented and confirmed by the date of performing the check and the signature of the employer who performed the check and of the person specified in subsection 4 (1).

§ 7. Storage of substances subject to special recording

- (1) In a manufacturing enterprise or a wholesale enterprise of medicinal products, the storage room of substances subject to special recording shall meet the following requirements:
 - 1) the room shall be without windows and separated from the surrounding rooms by partitions extending up to the ceiling;
 - 2) the room shall have a metal door;
 - 3) the room shall be lockable and non-passable;
 - 4) the room shall be equipped with a separate alarm system connected to the security centre.
- (2) In a manufacturing enterprise or a wholesale enterprise of medicinal products, the substances subject to special recording shall be stored in a safe or metal cupboard in a room which meets the requirements specified in subsection (1). It is permitted to store only narcotic drugs and psychotropic substances and documentation related thereto in the storage room of substances subject to special recording.
- (3) In enterprises other than those specified in subsection (1), the substances subject to special recording shall be stored in a safe or in a safe or iron cupboard in a room which meets the requirements provided for in subsection (1). In a pharmacy, the safe for storing substances subject to special recording shall not be placed in sales area. On ships and aircraft, the substances subject to special recording shall be stored in a lockable cupboard in the absence of a safe.

§ 8. Storage of substances subject to recording

- (1) Substances subject to recording shall be stored in a lockable room or cupboard. In a pharmacy, the cupboard for storing the substances subject to recording shall not be placed in sales area.
- (2) Substances subject to recording may be stored together with substances subject to special recording in a separate cupboard or an open shelf in a room which meets the requirements specified in subsection 7 (1).
- (3) The substances subject to recording may be stored in an unlocked cupboard in the sales area of a general pharmacy or veterinary pharmacy in the quantity necessary for the sale during one day. At the end of the working day, the substances subject to recording shall be taken to the place of storage specified in subsection (1) or (2).

§ 9. Reception and dispensation

- (1) The check to be carried out on the reception of narcotic drugs and psychotropic substances shall be performed immediately on the arrival of such substances.

- (2) In a manufacturing enterprise or a wholesale enterprise of medicinal products a list of persons shall be prepared who, on the import of substances subject to special recording, may belong to the commission formed for the reception of such substances.
- (3) In a manufacturing enterprise or a wholesale enterprise of medicinal products, on the import of substances subject to special recording, such substances shall be received in the presence of the committee of at least three members appointed from among the persons specified in subsection (2). Substances subject to special recording shall be received not later than on the next working day after the arrival.
- (4) The person specified in subsection 4 (1) shall be the chairman of the committee specified in subsection (3).
- (5) An instrument of receipt shall be prepared concerning the receipt of substances subject to special recording in a manufacturing enterprise or a wholesale enterprise of medicinal products in two original copies which shall be signed by all the members of the committee. Discrepancies in comparison with the accompanying document shall be documented.
- (6) The following shall be documented in the instrument of receipt specified in subsection (5):
 - 1) the date of receipt of the narcotic drug or psychotropic substance in the enterprise;
 - 2) the date of performance of the check to be carried out on the reception of narcotic drug or psychotropic substance;
 - 3) the number of the special permit of the Agency of Medicines;
 - 4) quantity set out on the accompanying document;
 - 5) actually received quantity, by batch numbers;
 - 6) the number of defective medicinal products and the nature of the defect, if these exist;
 - 7) the number of packages allowed for dispense.
- (7) The instrument of receipt specified in subsection (5) shall be sent to the Agency of Medicines within five working days as of the performance of check to be carried out on the reception of substances subject to special recording. The second original copy of the instrument of receipt shall be preserved together with documents concerning substances subject to special recording.
- (8) A wholesale enterprise or manufacturing enterprise of medicinal products may dispense narcotic drugs and psychotropic substances only to a pharmacy, wholesale enterprise and manufacturing enterprise who has the corresponding right of handling, and to other enterprises who have the authorisation of the Agency of Medicines or the right arising from legislation for procurement of these medicinal products.
- (9) The consignment of substances subject to special recording shall be assembled, packaged and closed in the storage room of such substances in the wholesale enterprise or manufacturing enterprise of medicinal products. The accompanying documents of substances subject to special recording shall be included in the transport package. The transport package shall be sealed or closed such as to make opening of the package detectable before arrival at its destination.
- (10) The transport package of substances subject to special recording shall be delivered to the recipient of these substances against a signature and the quantities of medicinal products shall be checked immediately on the delivery and receipt of substances subject to special recording in the presence of the deliverer and recipient.
- (11) Narcotic drugs and psychotropic substances shall be dispensed from a pharmacy under the conditions established for the dispensation of medicinal products from a pharmacy in the Medicinal Products Act and on the basis thereof with specifications arising from the Act on Narcotic Drugs, Psychotropic Substances and Precursors thereof and from this Regulation.
- (12) Substances subject to special recording shall be dispensed from a pharmacy to enterprises on the basis of a separately prepared order form.
- (13) On dispensation of substances subject to special recording from a pharmacy, a manufacturing enterprise or wholesale enterprise, a separate delivery note shall be prepared.
- (14) On dispensation of substances subject to special recording from a pharmacy, the deliverer and recipient shall set out on both original copies of the delivery note the name of the medicinal

product dispensed and received, the pharmaceutical form, the content and quantity of active substance in a package and the number of originals dispensed and shall confirm by their signature, including the date of dispensation and receipt of medicinal product. The quantities of medicinal products dispensed and received shall be set out in words.

- (15) The substances subject to special recording shall be dispensed from a pharmacy to the person authorised by the enterprise. The authorisation shall set out the name and position of the authorised person and his or her specimen signature and the authorisation shall be issued for a specified term.
- (16) Upon dispensation of substance subject to special recording, the deliverer of the medicinal product shall write in hand-writing on the recipe which remains in the pharmacy the name of the medicinal product, the pharmaceutical form, the content of active substance, the size of the original and the quantity dispensed and shall confirm this by his or her signature.
- (17) Injectable pharmaceutical forms containing ketamine, fentanyl, thiopental, sodium oxybutyrate, alfentanil, sufentanil and remifentanil and oral pharmaceutical preparations of buprenorphine may be dispensed from general pharmacy or veterinary pharmacy only on the basis of order form. It is prohibited to dispense the specified medicinal products on prescription.
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§ 10. Gathering for destruction and destruction of narcotic drugs and psychotropic substances

- (1) The health care provider and the pharmacy with the right to handle narcotic medicinal products is required to collect the remaining substances subject to special recording for destruction upon the death of the patient. Medicinal products shall be referred for destruction pursuant to the procedure established by the Medicinal Products Act and on the basis thereof.
- (2) A hospital and a social welfare institution shall gather the used sales packages of injectable medicinal products containing substances listed in Schedules I and II and destroy these in the presence of the committee. The procedure for destruction and the membership of the committee shall be approved by the director of the enterprise or a person designated by him or her.
- (3) A report shall be prepared concerning the destruction of sales packages of injectable medicinal products specified in subsection (2) which shall set out the following information:
 - 1) the type and quantity of packages;
 - 2) the manner, date and place of destruction;
 - 3) signatures of the members of the committee.

Chapter 3

Maintaining of Records of Narcotic Drugs and Psychotropic Substances

§ 11. General procedure for maintaining records of substances subject to special recording and substances subject to recording

- (1) Separate records of substances subject to special recording and substances subject to recording shall be maintained in every enterprise and a structural unit thereof.
- (2) Records of substances subject to special recording and substances subject to recording shall be maintained in a document with sheets which are bound with string and numbered (hereinafter special ledger); duplicate recording may be maintained electronically.
- (3) Records of substances subject to recording may be maintained both electronically and on paper. If maintaining records on paper is replaced by maintaining records electronically, parallel records shall be maintained at least half a year.
- (4) The recording documentation shall be available for supervision authority in the enterprise at any time.
- (5) Rules concerning the use of the computer program or electronic database used in maintaining records (entry of data, making corrections therein, the frequency and manner of making copies, changing of codes, etc.) shall be established in an enterprise.

- (6) Deviations in the functioning of the computer program or electronic database shall be documented. Entries made in the electronic database, amendments and corrections of entries, the person who made the entries, amendments and corrections and the time of making the entries, amendments and corrections shall be identifiable.
- (7) The entries of records maintained on paper shall be in legible and indelible written form. Corrections shall be indicated by the signature of the person who made the corrections and the date and the original entry shall be visible. It is prohibited to use eraser, correction pen, correcting fluid, etc., in making a correction.
- (8) Separate records shall be maintained concerning different narcotic drugs and psychotropic substances and concerning medicinal products with different names, content of active substance, pharmaceutical form and size of package. Records shall be maintained by original packages of the manufacturer.
- (9) The information concerning receipt and dispensation of substances subject to special recording shall be entered in the special ledger within one working day as of the arrival or dispensation of the medicinal product. The receptions of substances subject to recording shall be entered in the recording documentation within one working day as of the arrival of the medicinal product.
- (10) Calculated residues by the end of the month shall be set out as at the last day of the month. Actual residues shall be checked not later than on the first working day after the end of the month. The calculated and actual residues shall be available for verification at all times on the basis of documents concerning receipt and dispensation. The calculated residue shall always correspond to the actual residue.
- (11) The special ledger and the documents which were the basis for maintaining records of substances subject to special recording shall be preserved for at least five years as of the date on which the last entry is made. The recording documentation of substances subject to recording and the documents which were the basis for maintaining records shall be preserved for at least two years as of the date on which the last entry is made.
- (12) Records shall be maintained in a manufacturing enterprise or wholesale enterprise of medicinal products pursuant to the procedure established for the specified enterprise by the Medicinal Products Act and on the basis thereof with specifications arising from this Regulation.

§ 12. Maintaining of records of substances subject to special recording in manufacturing enterprise or wholesale enterprise of medicinal products and in pharmacy

- (1) The special ledger shall be provided with the signature of the representative of the Agency of Medicines and the seal of the Agency of Medicines.
- (2) Concerning every substance subject to special recording, the following shall be entered in the special ledger:
 - 1) every receipt (date, reference to document of receipt, quantity);
 - 2) dispensation by days (indicating separately the quantities which have been given for control analysis, withdrawn from the market or returned);
 - 3) total quantity received within a month;
 - 4) total quantity dispensed within a month;
 - 5) total quantity withdrawn from the market and returned within a month;
 - 6) total quantity given for control analysis within a month;
 - 7) the residue as at the last day of the month according to the entries of the special ledger;
 - 8) the actual inventory as at the last day of the month.
- (3) With respect to the information specified in clauses (2) 2) and 4), the quantity dispensed on the basis of prescription and the quantity dispensed on the basis of order form shall be indicated separately in a general pharmacy or veterinary pharmacy. In a hospital pharmacy, the quantity dispensed to a health care provider maintaining a hospital pharmacy and the quantities dispensed to other enterprises shall be indicated separately.

- (4) At the end of each month, the residue shall be calculated on the basis of documents of receipt and dispense and on the basis thereof the actual inventory shall be checked. The person who performs the checks shall confirm the checked quantities by his or her signature and shall include the date of performing the check.
- (5) Discrepancies between calculated and actual inventory shall be documented. The discrepancies shall be communicated to the Agency of Medicines within three working days by telephone and in writing and a new inventory shall be conducted in the presence of a representative of the Agency of Medicines.
- (6) The documents which were the basis for receipt and dispensation of substances subject to special recording or copies thereof (delivery notes, instruments of receipt, recipes, order forms, reports prepared concerning medicinal products withdrawn from the market, reports concerning taking samples for control analysis, etc.) shall be maintained chronologically and separately from other documents.

§ 13. Maintaining of records of substances subject to special recording in other enterprises

- (1) In enterprises not specified in § 12, the special ledger shall be confirmed with the signature of the director of the enterprise or a person appointed by him or her and the date. Duplicate recording may be on electronic data media.
- (2) Concerning every substance subject to special recording, the following shall be entered in the special ledger:
 - 1) every receipt (date, reference to document of receipt, quantity);
 - 2) use by days (indicating separately the quantities which have been withdrawn from the market and returned);
 - 3) total quantity received within a month;
 - 4) total quantity used within a month;
 - 5) the residue as at the last day of the month according to the entries of the special ledger;
 - 6) the actual inventory as at the last day of the month.
- (3) Every instance of the use of a substance subject to special recording shall be documented.
- (4) The actual residue of substances subject to special recording in the enterprise shall be checked at the end of every month. The person who performs the checks shall confirm the checked quantities by his or her signature and shall include the date of performing the check.
- (5) Discrepancies between calculated and actual residue shall be documented.

§ 14. Maintaining of records of substances subject to recording in manufacturing enterprise or wholesale enterprise of medicinal products and in pharmacy

- (1) The records shall set out the following information:
 - 1) every receipt (date, reference to document of receipt, quantity);
 - 2) total quantity received within a month;
 - 3) total quantity dispensed within a month;
 - 4) total quantity withdrawn from the market and returned within a month;
 - 5) total quantity given for control analysis within a month.
- (2) At the end of each month, the residue shall be calculated on the basis of documents of receipt and dispense. The receipt and dispensation within a month and the residue as at the last day of the month shall be documented on paper. The actual inventory shall be checked on the basis of calculated residue. The person who performs the checks shall confirm the checked quantities by his or her signature and shall include the date of performing the check. Discrepancies shall be documented.
- (3) The documents which were the basis for receipt and dispensation of substances subject to recording or copies thereof shall be maintained chronologically or a reference to the relevant document shall be indicated in the records.

§ 15. Maintaining of records of substances subject to recording upon provision of health care service and by holder of activity licence of veterinarian

- (1) The records shall contain the following information concerning each substance subject to recording:
 - 1) every receipt (date, reference to document of receipt, quantity);
 - 2) total quantity received within a month;
 - 3) total quantity used within a month;
 - 4) total quantities which have been withdrawn from the market or returned;
 - 5) the total quantity of the medicinal product given for control analysis;
 - 6) the residue as at the last day of the month according to the recording documents;
 - 7) the actual residue as at the last day of the month.
- (2) The receipt and dispensation within a month and the residue as at the last day of the month shall be documented on paper. The actual residue shall be checked on the basis of calculated residue. The person who performs the checks shall confirm the checked quantities by his or her signature and shall include the date of performing the check. Discrepancies shall be documented.

§ 16. Maintaining of records of substances subject to recording in other enterprises

- (1) In enterprises not specified in §§ 14 and 15, records shall be maintained on paper. Duplicate recording may be maintained electronically.
- (2) The records shall contain the following information concerning each substance subject to recording:
 - 1) every receipt (date, reference to document of receipt, quantity);
 - 2) total quantity used within a month;
 - 3) total quantities withdrawn from the market, returned, delivered, indicating the date and the reason;
 - 4) the residue as at the last day of the month according to the recording documents;
 - 5) the actual residue as at the last day of the month.
- (3) The person who performs the checks shall confirm the checked quantities by his or her signature and shall include the date of performing the check.
- (4) Every instance of the use of a substance subject to recording shall be documented.

Chapter 4

Reporting of Substances subject to Special Recording and Substances subject to Recording

§ 17. General provisions

- (1) Reports submitted on a quarterly basis shall be submitted to the Agency of Medicines by the twentieth date of the first month of each quarter.
- (2) Copies of the reports submitted to the Agency of Medicines shall be accessible in the enterprise.

§ 18. Reporting in manufacturing enterprise or wholesale enterprise of medicinal products

- (1) A manufacturing enterprise or wholesale enterprise of medicinal products shall submit reports concerning the following activities on a quarterly basis:
 - 1) receipt and dispensation of substances subject to special recording;
 - 2) the importation and exportation of substances subject to special recording and substances subject to recording.
- (2) The following information shall be set out in the report specified in clause (1) 1):
 - 1) the name of the holder of the activity licence for manufacture of medicinal products or wholesale trade in medicinal products and the address of the enterprise;
 - 2) the name of the responsible person;
 - 3) the name of the substance subject to recording, the pharmaceutical form, the content of active substance and the quantity in package;
 - 4) inventory as at the last date of the quarter;

- 5) total quantity received within a quarter by suppliers, indicating the numbers of the batches received and dates of receipt;
 - 6) total quantity dispensed within a quarter by recipients, indicating the numbers of the batches dispensed and the dates of dispense with regard to each recipient;
 - 7) total quantity dispensed within a quarter;
 - 8) total quantity withdrawn from the market and returned within a quarter;
 - 9) total quantity given for control analysis within a quarter;
 - 10) the calculated residue by the last date of the quarter;
 - 11) the actual inventory by the last date of the quarter;
 - 12) the date of preparation of the report and the name and signature of the person who prepares the report.
- (3) The following information shall be set out in the report specified in clause (1) 2):
- 1) the name of the holder of the activity licence for manufacture of medicinal products or wholesale trade in medicinal products and the address of the enterprise;
 - 2) the name of the responsible person;
 - 3) the name of the substance subject to special recording or the substance subject to recording, the pharmaceutical form, the content of active substance and the quantity in package;
 - 4) total number of packages;
 - 5) the name of foreign importer or exporter;
 - 6) the number of the special permit of the Agency of Medicines;
 - 7) the date of importation or exportation;
 - 8) the date of preparation of the report and the name and signature of the person who prepares the report.
- (4) A manufacturing enterprise of medicinal products shall submit a forecast for the next year for quantities of substances subject to special recording and substances subject to recording to be used in manufacturing to the Agency of Medicines by 1 May each year.

§ 19. Reporting in pharmacy

- (1) A pharmacy shall submit a report concerning substances subject to special recording on a quarterly basis setting out the following information:
- 1) the name of the holder of an activity licence for provision of pharmacy services, the name and address of the pharmacy;
 - 2) the name of the responsible person;
 - 3) the name of the substance subject to recording, the pharmaceutical form, the content of active substance and the quantity in package;
 - 4) inventory as at the last date of the quarter;
 - 5) total quantity received within a quarter by suppliers, indicating the numbers of the batches received;
 - 6) total quantity dispensed within a quarter;
 - 7) total quantity withdrawn from the market and returned within a quarter;
 - 8) total quantity given for control analysis within a quarter;
 - 9) residue by the last date of the quarter;
 - 10) the date of preparation of the report and the name and signature of the person who prepares the report.
- (2) With respect to the information specified in clause (1) 6), the quantity dispensed on the basis of prescription, the quantity dispensed on the basis of order form and the total quantity shall be indicated separately in a general pharmacy or veterinary pharmacy. In a hospital pharmacy, the quantity dispensed to a health care provider maintaining a hospital pharmacy and the quantities dispensed to other institutions shall be indicated separately.

§ 20. Reporting in other enterprises

- (1) The enterprises not specified in §§ 18 and 19 shall prepare a report concerning the previous calendar year by 1 February each year which shall be submitted to the Agency of Medicines at the request thereof.
- (2) The following information shall be set out in the report specified in subsection (1):
 - 1) the name of the substance subject to special recording and the substance subject to recording, the pharmaceutical form, the content of active substance and the quantity in package;
 - 2) the residue as at 1 January of the previous calendar year;
 - 3) total quantity received within a year by suppliers,
 - 4) the quantity used within a year, by purposes of use;
 - 5) the total quantity written off, destroyed, returned and delivered within a year;
 - 6) residue by the end of reporting year;
 - 7) the date of preparation of the report and the name and signature of the person who prepares the report.