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Republic of Latvia

Cabinet

Regulation No. 441

Adopted 17 June 2008

**Procedures for the Purchase, Receipt, Storage, Distribution, Dispensation,
Accounting and Destruction of Narcotic and Psychotropic Substances and
Medicinal Products in Manufacturing of Medicinal Products and
Veterinary Medicinal Products, at Drug and Veterinary Drug Wholesalers
and Pharmacies**

*Issued pursuant to
Section 37, Clauses 1, 2 and 3 of the
Law On Procedures for the Legal Trade of Narcotic
and Psychotropic Substances and Medicinal Products*

I. General Provisions

1. These Regulations prescribe the procedures, by which substances, medicinal products and veterinary medicinal products included in Schedule II and III of narcotic substances, psychotropic substances and precursors controlled in Latvia are received, purchased, distributed, dispensed, stored, accounted and destroyed (hereinafter – handling) in manufacturing of substances, medicinal products or veterinary medicinal products, at a drug or veterinary drug wholesaler and a pharmacy (except general-type or open-type pharmacies and closed-type pharmacies or a merchant of veterinary medical care).

2. Handling of substances, medicinal products and veterinary medicinal products included in Schedule II of narcotic substances, psychotropic substances and precursors controlled in Latvia (hereinafter – substances and medicinal products included in Schedule II) and substances, medicinal products and veterinary medicinal products included in Schedule III of narcotic substances, psychotropic substances and precursors controlled in Latvia (hereinafter – substances and medicinal products included in Schedule III) shall be allowed if:

2.1. a substance, drug or veterinary drug manufacturer (hereinafter – substance or drug manufacturer) has received a special permit (licence) for manufacturing or importation of substances, medicinal products or veterinary medicinal products and a condition of special activity – manufacturing of psychotropic medicinal products or veterinary medicinal products or manufacturing of narcotic and equivalent thereto psychotropic medicinal products or veterinary medicinal products – is indicated in the Annex thereto, as well as has appointed an official responsible for ensuring the procedures for manufacturing and handling of the substances, medicinal products and veterinary medicinal products included in Schedule II or III;

2.2. a drug or veterinary drug wholesaler (drug wholesaler) has received a special permit (licence) for opening (operation) of a drug or veterinary drug wholesaler and a condition of special activity – distribution of psychotropic medicinal products or veterinary medicinal products or distribution of narcotic and equivalent thereto psychotropic medicinal products or veterinary medicinal products – is indicated in the Annex thereto, as well as has appointed an official responsible for ensuring the procedures for handling of the substances or medicinal products included in Schedule II or III; or

2.3. a general-type pharmacy (drug retailer) or a closed-type pharmacy has received a special permit (licence) for the opening (operation) of pharmacy and a condition of special activity – distribution of psychotropic medicinal products or distribution of narcotic and equivalent thereto psychotropic medicinal products – is indicated in the Annex thereto, as well as has appointed an official responsible for ensuring the procedures for handling of the substances or medicinal products included in Schedule II or III.

3. The persons referred to in Paragraph 2 of these Regulations (hereinafter – licence holder) shall:

3.1. develop and approve an internal regulatory enactment or a document comparable thereto, in which the procedures for implementation of these Regulations are specified in detail according to the profile and structure of work;

3.2. appoint an official who is responsible for provision of the procedures for handling of the substances or medicinal products included in Schedule II or III or intermediate products, mixtures and unusable remained, which contain the substances included in Schedule II or III (hereinafter – products), (hereinafter – responsible official) and, where appropriate, also appoint a responsible official at the structural units; and

3.3. appoint an official or officials who are entitled to receive the substances or medicinal products included in Schedule II or III during absence of the responsible official.

II. Manufacturing, Purchase and Receipt of Substances and Medicinal Products Included in Schedule II or III

4. A substance or drug manufacturer shall ensure that manufacturing and control activities are clearly defined and conform to the instructions of the European Commission regarding good manufacturing practice of medicinal products, as well as ensure the fulfilment of the requirements specified in the regulatory enactments regarding manufacturing and control of medicinal products or veterinary medicinal products.

5. In addition to the requirements specified in the regulatory enactments regarding manufacturing and control of medicinal products or veterinary medicinal products a substance or drug manufacturer shall also include instructions regarding specific activities in relation to the manufacturing of the substances and medicinal products included in Schedule II and III, storage, inventory and destruction of medicinal products, substances and products in the documentation system.

6. A substance or drug manufacturer shall enter into contracts regarding the performance of manufacturing activities or control of substances and medicinal products included in Schedule II or III only with such persons who have received a corresponding special permit (licence) or a permit for activities involving substances included in Schedule II or III.

7. A substance or drug manufacturer and a drug wholesaler shall purchase, receive, distribute and dispense substances and medicinal products included in Schedule II and III pursuant to

these Regulations and regulatory enactments regarding the distribution of medicinal products or veterinary medicinal products in wholesale trade.

8. A pharmacy shall purchase, receive, distribute and dispense the substances and medicinal products included in Schedule II and III pursuant to these Regulations and regulatory enactments regarding the distribution of medicinal products or veterinary medicinal products in retail trade. If a condition of special activity – preparation of medicinal products – is not indicated in the Annex to a special permit (licence) for opening (operation) of a pharmacy, the pharmacy shall purchase only finished pharmaceutical forms.

9. Only the responsible official or officials indicated in Sub-paragraph 3.3 of these Regulations are entitled to receive the substances and medicinal products included in Schedule II and III.

10. The responsible official shall ensure:

10.1. drawing up of requests and bills of lading for the substances and medicinal products included in Schedule II and III (in printed, electronic or any other form) separately from the requests and bills of lading for other medicinal products;

10.2. inventory and storage of requests and bills of lading for the substances and medicinal products included in Schedule II and III separately from the requests and bills of lading for other medicinal products; and

10.3. that prescriptions, upon which medicinal products included in Schedule II and III are dispensed, are stored separately from the prescriptions of other medicinal products.

III. Inventory of Substances and Medicinal Products Included in Schedule II and III

11. The responsible official and the officials referred to in Sub-paragraph 3.2 of these Regulations in structural units shall register data regarding purchase, receipt, distribution, manufacturing, dispensation and destruction of the substances and medicinal products included in Schedule II in the strict accountability register of narcotic and equivalent thereto psychotropic substances and medicinal products within a time period of one working day. Also data regarding handling of such products obtained in the manufacturing process, which contain the substances included in Schedule II, shall be registered in the strict accountability register. The strict accountability register shall be approved with the signature and personal stamp (if any) of the responsible official and the seal of the licence holder. The last page of the register shall indicate the date when the first and the last entry was made. A substance or drug manufacturer and a drug wholesaler shall arrange a strict accountability register in accordance with Annex 1 to these Regulations, a pharmacy – in accordance with Annex 2 to these Regulations.

12. Substances, medicinal products and products included in Schedule III and containing the following substances included in Schedule III in pure form or mixture with indifferent substances shall also be registered in the strict accountability register:

12.1. ephedrine;

12.2. pseudoephedrine;

12.3. phenobarbital;

12.4. trihexiphenidyl; and

12.5. GHB (sodium oxybutirate and lithium oxybutirate).

13. The responsible official and the officials referred to in Sub-paragraph 3.2 of these Regulations in structural units shall register data regarding purchase, receipt, distribution, manufacturing, dispensation and destruction of the substances, medicinal products and products included in Schedule III in the strict accountability register or using electronic or another data processing system within a time period of one working day. Upon registration of data regarding a recipient or a supplier, date of transaction, name of the medicinal products or substances, name and quantity of received or dispensed, or supplied, or destroyed medicinal products, substances of products included in Schedule III, percentage composition of the substances included in Schedule III and the quantity of the substance included in Schedule III shall be indicated.

14. If an entry in the strict accountability register is incorrect, it shall be deleted so that the initial content of the entry would be visible. The correct entry shall be made next to it and the date of making the correction shall be indicated. The entry shall be confirmed by the performer of the entry and the responsible official with a signature and personal stamp (if any).

15. Once a month, the responsible official shall inspect the procedures for inventory of the substances and medicinal products included in Schedule II and III:

15.1. compare the remainder of the substances and medicinal products included in Schedule II and III, as well as products containing the substances included in Schedule II and III registered in the strict accountability register with the actual remainder. An entry in the strict accountability register shall be made regarding results of the inspection, indicating the date of inspection, and the entry shall be confirmed with a signature and personal stamp (if any); or

15.2. if accounting of the substances included in Schedule III, the medicinal products and products containing substances included in Schedule III is performed by electronic means or using another data processing system, a printout of data regarding the respective period of time shall be made and the remainder of the registered substances, medicinal products and products containing substances included in Schedule III shall be compared with the actual remainder of substances, medicinal products and products. The printout shall be dated and the responsible official shall confirm it with a signature and personal stamp (if any).

16. The strict accountability register (after making of the last entry) and the printouts referred to in Sub-paragraph 15.2 of these Regulations shall be kept for 10 years.

17. If a licence holder distributes or uses substances included in Schedule II and III for manufacturing or preparation of medicinal products or veterinary medicinal products, the admissible losses of substances may amount to 0.5% from the weight of the substances used. The weight loss norm shall be applied only in such case if an actual shortage of the substance is detected.

18. The responsible official shall draw up a statement regarding the detected actual loss of weight of the substances included in Schedule II and III. An entry in the strict accountability register shall be made regarding the actual loss of weight of the substances included in Schedule II and the substances referred to in Paragraph 12 of these Regulations. An entry in the strict accountability register shall be made regarding the actual loss of weight of the substances included in Schedule III by electronic means or using another data processing system. The entry shall be made pursuant to Paragraph 13 of these Regulations. The licence holder (individual merchant or a board member of a commercial company who is entitled to

represent the commercial company) and the responsible official shall sign the statement. Signatures shall be approved with a seal of the licence holder and a personal stamp (if any) of the responsible official.

19. The Health Inspectorate, in performing an inspection regarding conformity with the procedures for handling of the substances and medicinal products included in Schedule II and III, shall also inspect the printouts referred to in Sub-paragraph 15.2 of these Regulations and the strict accountability register. Date of inspection shall be indicated on the last page of the register. An official of the Health Inspectorate shall confirm the performed inspection with a signature and personal stamp.

IV. Storage of Substances and Medicinal Products Included in Schedule II and III

20. Substances, medicinal products and products included in Schedule II and III shall be stored in a separate room or in a room where a locked cabinet, a metal cabinet or a safe is placed. Entry of unauthorised persons is prohibited in the respective room. Medicinal products shall be stored in conformity with the storage conditions specified in the labelling or the instructions on the use of medicinal products, as well as the requirements specified in the regulatory enactments regarding the distribution of medicinal products and veterinary medicinal products.

21. A substance or drug manufacturer and a drug wholesaler shall store the substances, medicinal products and products included in Schedule II in a separate room, a metal cabinet, which is attached to a wall or to the floor, or in a safe. The separate room, the metal cabinet or the safe shall be equipped with an alarm system. The alarm system shall be connected to the centralised safety guard network.

22. In a pharmacy the substances or medicinal products included in Schedule II shall be stored in a separate room or a safe, or in a metal cabinet, which is attached to a wall or to the floor. The separate room, the safe or the metal cabinet shall be equipped with an alarm system. The safe or the metal cabinet shall be placed in a separate room or in a goods storage room, or in a room for the preparation of medicinal products, or in an office of the manager of the pharmacy (branch of a pharmacy). In a pharmacy (branch of a pharmacy), which does not have an office for the pharmacy manager (branch of a pharmacy) pursuant to the regulatory enactments regarding the opening and operation of pharmacies, the safe or the metal cabinet may be placed in the room, in which goods are received.

23. A substance or drug manufacturer, a drug wholesaler or a pharmacy shall store the substances, medicinal products and products included in Schedule III in locked cabinets, separately from other substances, medicinal products and products. Medicinal products shall be stored in conformity with the storage conditions specified in the labelling or the instructions on the use of medicinal products, as well as the requirements specified in the regulatory enactments regarding distribution of medicinal products and veterinary medicinal products.

24. A substance or drug manufacturer shall equip premises, in which the substances and medicinal products included in Schedule II and III are manufactured, with an alarm system that is connected to the centralised safety guard network.

25. A licence holder shall determine, in the document referred to in Sub-paragraph 3.1 of these Regulations:

25.1. the persons who have the right to enter the premises referred to in Paragraphs 20, 21, 22 and 24 of these Regulations;

25.2. the procedures for closing, applying a lead seal or sealing up a room or a metal cabinet, or a safe and for turning on an alarm system at the end of a working day; and

25.3. the procedures for storing keys.

V. Dispensation and Distribution of Substances and Medicinal Products Included in Schedule II and III

26. The responsible official shall ensure that:

26.1. in distributing the substances and medicinal products included in Schedule II and III, a bill of lading (in printed, electronic or any other form) is appended to each consignment. Information pursuant to the regulatory enactments regarding the distribution of medicinal products or veterinary medicinal products shall be indicated in the bill of lading;

26.2. substances and medicinal products included in Schedule II and III are accounted separately from the other substances and medicinal products in a bill of lading;

26.3. substances and medicinal products included in Schedule II and III are distributed only to such persons who have received the special permit (licence) referred to in Paragraph 2 of these Regulations, to medical treatment institutions, social care institutions, practising veterinarians and merchants of veterinary medical care who pursuant to the regulatory enactments regulating the field of pharmacy or veterinary pharmacy are entitled to purchase the medicinal products included in Schedule II and III.

27. A licence holder shall include a description of the precautionary measures in the document referred to in Sub-paragraph 3.1 of these Regulations in order to ensure that the substances, medicinal products or products included in Schedule II and III would not be stolen or looted during transportation or movement among structural units.

28. The responsible official or the officials referred to in Sub-paragraph 3.3 of these Regulations shall dispense the substances included in Schedule II and III necessary for manufacturing or preparation of substances or medicinal products in conformity with the procedures described in the document referred to in Sub-paragraph 3.1 of these Regulations.

29. Medicinal products included in Schedule II and III, which are necessary for medical treatment of a patient or an animal, shall be dispensed only on prescription, which is written out in accordance with the regulatory enactments regarding writing out a prescription or a veterinary prescription.

30. A pharmacy shall dispense the medicinal products included in Schedule II and III to a medical treatment institution, veterinary medical care institution, merchant of veterinary medical care, practising veterinarian and social care institution only upon a request. A bill of lading shall be drawn up in accordance with the requirements referred to in Paragraph 10 and Sub-paragraph 26.1 of these Regulations.

31. Substitution of prescribed medicinal products included in Schedule II and III shall be allowed only in such case if the following conditions are observed:

31.1. a physician has not indicated that the prescribed medicinal products may not be substituted;

31.2. the active substance of the dispensed medicinal product is identical to the active substance of the prescribed medicinal product;

31.3. the form of the dispensed medicinal product is identical to the form of the prescribed medicinal product;

31.4. single dose of the dispensed medicinal product is adequate, divisible or may be simply increased pursuant to the single dose of the prescribed medicinal product;

31.5. the total dose of the dispensed medicinal product does not exceed the total dose of the prescribed medicinal product; and

31.6. a patient is informed and agrees to receive a medicinal product with a different name (synonym).

32. In dispensing the medicinal products included in Schedule II and III on prescriptions, a pharmacist or an assistant pharmacist shall indicate the name, dosage, quantity, date of dispensation of the dispensed medicinal products and sign for dispensation of the medicinal products. The signature shall be approved with a personal stamp (if any).

33. It is prohibited to dispense medicinal products included in Register II and III on prescriptions, the layout of which does not conform to the regulatory enactments regarding writing out prescriptions. The referred to prescriptions shall be kept at a pharmacy. If there are suspicions that a prescription is forged, a pharmacist shall contact the medical practitioner who has written out the prescription prior to dispensation of the medicinal products.

34. At the end of a working day the prescriptions referred to in Paragraph 33 of these Regulations shall be registered in an accountability register of inadequately drawn-up prescriptions (Annex 3). The responsible official shall submit information regarding the medical practitioners who had written out the referred to prescriptions to the Health Inspectorate at the end of the quarter and indicate the given name, surname, speciality, medical treatment institution of the physician and mistakes made by him or her.

35. The inadequately drawn-up prescriptions shall be kept separately from other prescriptions.

36. The manager of a pharmacy or the responsible person has a duty to notify the Health Inspectorate regarding forged prescriptions, suspicious cases, as well as if there are doubts about unjustified writing-out of the medicinal products included in Schedule II and III on prescription or accordingly upon a request of a medical treatment institution, veterinary medical care institution, merchant of veterinary medical care, practising veterinarian or social care institution. The Health Inspectorate shall inform the Food and Veterinary Service without delay if such suspicious cases or doubts have occurred regarding writing-out of the medicinal products intended for treatment of animals included in Schedule II and III on prescription or upon a request of a veterinary medical care institution, merchant of veterinary medical care, practising veterinarian or a person who is engaged in veterinary medical practice.

37. If the composition of non-prescription medicinal products contains the substances included in Schedule II and III, it shall be allowed to dispense not more than one secondary packaging to a patient.

38. Medicinal products, which contain buphrenorphine, shall be dispensed if a patient submits a prescription and presents a personal identification document and the patient's programme card for buphrenorphine substitution therapy (Annex 4), in which a medical treatment practitioner has made an entry regarding the prescription of medicinal products. When

dispensing a medicinal product that contains buphrenorphine, a pharmacist or an assistant pharmacist shall indicate the quantity of the medicinal product dispensed, the date, the name of the pharmacy, the given name, surname and qualification of the dispenser of the medicinal product in the patient's programme card for buphrenorphine substitution therapy and confirm the entry with his or her signature and personal stamp (if any).

39. It is prohibited to dispense the following narcosis agents on the basis of a prescription in a pharmacy:

- 39.1. GHB (sodium oxybutyrate and lithium oxybutyrate);
- 39.2. fentanyl injection solution; and
- 39.3. diethyl ether.

VI. Destruction of Poor Quality Substances and Medicinal Products Included in Schedule and III

40. Poor quality substances and medicinal products included in Schedule II or III (hereinafter – poor quality medicinal products) shall be stored until the destruction thereof in a separate room, in a separated location or packaging, preventing the possibility of mixing them with medicinal products of good quality. Poor quality medicinal products shall be stored pursuant to the requirements referred to in Paragraphs 20, 21, 22 and 23 of these Regulations.

41. Poor quality products that are not returned to the supplier shall be destroyed in the presence of a commission established by a licence holder (consisting of at least three persons) pursuant to the requirements specified in the regulatory enactments regarding hazardous waste, or a contract regarding management of hazardous waste shall be entered into with a person who manages hazardous waste and has received an appropriate permit.

42. The commission referred to in Paragraph 41 of these Regulations shall draw up a deed of delivery and acceptance regarding the return of poor quality medicinal products to the supplier or transfer for management of hazardous waste. The given names, surnames and positions of members of the commission, the reason of destruction, the substance, the name, quantity, manufacturer of the medicinal product or product, the content and total quantity of the contained substance included in Schedule II and III shall be indicated in the deed. In addition, the pharmaceutical form, strength, the manufacturing batch number of the medicinal product, the manufacturer of the medicinal product shall be indicated. The deed shall be drawn up in two copies and all members of the commission shall sign it. One copy shall be sent within three days to the Health Inspectorate, the second copy shall be kept by a licence holder for 10 years.

43. An entry regarding the destruction or transfer of poor quality medicinal products for management of hazardous waste shall be made in the strict accountability register and the number of the destruction deed or a deed of delivery and acceptance shall be indicated.

VII. Shortage or Surplus of Substances and Medicinal Products Included in Schedule II and III

44. If a shortage or surplus of the substances, medicinal products or products included in Schedule II or III is detected, a criminal offence has taken place or if losses have occurred due to force majeure, a room or a safe, or a metal cabinet shall be sealed up and secured against the entry of unauthorised persons. A licence holder or the responsible official shall without

delay notify the State Police (except in cases when losses have occurred due to force majeure) and the Health Inspectorate thereof.

45. After determination of the facts referred to in Paragraph 44 of these Regulations the licence holder shall, without delay, establish a commission consisting of at least three persons. The following persons shall be included in the composition of the commission:

- 45.1. the licence holder or his or her authorised official; and
- 45.2. the responsible official.

46. The commission referred to in Paragraph 45 of these Regulations, in inviting a representative of the Health Inspectorate or a representative of the State Police (if a criminal offence has taken place), shall draw up a statement regarding a shortage or surplus of the substances, medicinal products or products included in Schedule II and III. The place and date of drawing up the deed, the given names, surnames and positions of the members of the commission, the name of the substances, medicinal products or products, the content and total quantity of substances included in Schedule II and III shall be indicated in the deed, pharmaceutical form, strength, in addition the manufacturing batch number of the medicinal product, the manufacturer of the medicinal product shall be indicated for medicinal products. The deed shall be signed by all members of the commission and the invited representatives of the Health Inspectorate or the State Police. The deed shall be kept for 10 years.

47. A shortage or surplus of the substances, medicinal products or products included in Schedule II and III shall also be registered in the strict accountability register and the number of the deed referred to in Paragraph 46 of these Regulations shall be indicated.

VIII. Duties and Control of a Licence Holder

48. A licence holder shall ensure:

48.1. the manufacturing and handling of the substances and medicinal products included in Schedule II and III pursuant to these Regulations, other regulatory enactments regarding handling of narcotic and psychotropic substances, as well as the regulatory enactments regulating the field of pharmacy or veterinary pharmacy;

48.2. documentation of all activities related to the manufacturing and handling of the substances and medicinal products included in Schedule II and III, providing an opportunity to trace each activity related to the handling of the referred to substances or medicinal products, or products;

48.3. the officials of the Health Inspectorate with free access to places, which are related to the manufacturing and handling of substances or medicinal products, or products included in Schedule II and III, and all documents related thereto;

48.4. that substances and medicinal products included in Schedule II and III do not enter illegal circulation; and

48.5. storage, for not less than 10 years, of data regarding manufacturing and handling of the substances, medicinal products and products included in Schedule II and III, as well as extracts made upon the request of the Health Inspectorate (in printed, electronic or any other form). Extracts shall be dated and confirmed by the signature and personal stamp (if any) of the responsible official.

49. A substance or drug manufacturer and a drug wholesaler shall submit the following information to the State Agency of Medicines regarding the handling of the substances and medicinal products included in Schedule II and III:

49.1. a quarterly report (shall be submitted within a time period of 15 days after the end of each quarter). Information shall be indicated in the quarterly report in accordance with Annex 5 to these Regulations;

49.2. a report on the preceding calendar year (hereinafter – accounting year) (shall be submitted until 15 February). Information pursuant to Annex 6 to these Regulations shall be indicated in the report and a summary regarding the amount of medicinal products manufactured, imported, exported in the accounting year in comparison with the respective amount of medicinal products in the preceding year, as well as an evaluation regarding the reasons for an increase or reduction shall be provided.

50. Upon a request of the Ministry of Health, the Health Inspectorate and the State Agency of Medicines, a substance or drug manufacturer and a drug wholesaler shall submit information regarding the distribution of particular substances and medicinal products included in Schedule II and III during a specific time period in accordance with Annex 6 of these Regulations.

51. At least once a month, a pharmacy shall, in accordance with an agreement for the processing of data on special prescriptions, provide information to the Health Compulsory Insurance State Agency regarding medicinal products, which have been written out on special prescription forms.

52. The State Agency of Medicines and the Health Compulsory Insurance State Agency shall provide information, which is at the disposal thereof, to the Ministry of Health and the Health Inspectorate pursuant to a request regarding the handling of substances and medicinal products included in Schedule II and III. The Food and Veterinary Service shall notify the Health Inspectorate regarding violations detected in the handling of substances and medicinal products included in Schedule II and III.

53. The Health Inspectorate shall inform the Food and Veterinary Service without delay if there are suspicious cases or doubts have occurred regarding unjustified writing-out of medicinal products intended for the treatment of animals included in Schedule II and III on prescription or upon a request form of a veterinary medical care institution, merchant of veterinary medical care, practising veterinarian or a person who is engaged in veterinary medical practice.

54. The Health Inspectorate shall inspect the handling of substances and medicinal products included in Schedule II and III:

54.1. in general-type pharmacies and closed-type pharmacies – not less than once every two years;

54.2. at drug wholesalers – not less than once a year.

55. The State Agency of Medicines shall inspect the manufacturing of substances and medicinal products included in Schedule II and III:

55.1. not less than once every two years if substances and medicinal products included in Schedule II are manufactured; or

55.2. not less than once every three years if substances and medicinal products included in Schedule III are manufactured.

Prime Minister

I. Godmanis

Minister for Health

I. Eglītis

**Strict Accountability Register of Narcotic and Equivalent Thereto Psychotropic Substances and Medicinal Products in Manufacturing of
Substances or Medicinal Products, or Veterinary Medicinal Products or in Drug or Veterinary Drug Wholesaler**

Name of the licence holder _____
(year, month)

Name of the substance, medicinal product or product _____

Pharmaceutical form, content of the substance included
in Schedule II or III _____

Remainder at the beginning of the month	Received				Dispensed to			Remainder	Signature of the responsible official
	date	location received from, document number	quantity	in total (received + remainder)	date	dispensed to	quantity		

Licence holder

(signature and full name)

Responsible official

(signature and full name)

Seal of the licence holder

Minister for Health

I. Eglītis

Strict Accountability Register of Narcotic and Equivalent Psychotropic Substances and Medicinal Products in a Pharmacy

Name of the licence holder and the pharmacy _____
Name of the substance or medicinal product _____
Pharmaceutical form and content of the substance _____
included in Schedule II and III

Month (from January to December)	Surplus of the substance or medicinal product on the first day of the month	Received			Dispensed to				Remainder on the last day of the month	Signature of the responsible official
		number, date of document	quantity	quantity in total per month (received + remainder)	method of dispensation	date (from 1 st to 31 st of the month)	quantity per month (for each type separately)	quantity per month in total		
					on prescriptions					
					upon a request of medical treatment institutions					

Pharmacy Manager

(signature and full name)

Responsible official

(signature and full name)

Seal of the licence holder

Minister for Health

I. Eglītis

Accountability Register of Inadequately Drawn-up Prescriptions

Name of the licence holder and of the pharmacy _____

No.	Date	Series, number of prescription	Given name, surname, speciality of the medical treatment practitioner	Name of the medical treatment institution	Address of the medical treatment institution	Mistakes made	Signature of the responsible official

Pharmacy Manager _____
(signature and full name)

Responsible official _____
(signature and full name)

Minister for Health I. Eglītis

Institution which issues the programme card of buphrenorphine substitution therapy _____
(name)

(address, registration number in the Enterprise Register, telephone number, e-mail address)

Buphrenorphine Substitution Therapy Programme Card No. ____

Date, month, year of issuance of the card _____

Card valid until _____

Patient _____
(given name, surname)

Personal identity number of the _____
patient

Residential address of the _____
patient

Attending physician _____
(given name, surname)

Name of the medical treatment institution _____

Address of the medical treatment institution _____

Initial daily dose of buprenorphine (in numbers and words) _____ mg

Date of prescribing the medicinal product	Name of the medicinal product	Daily dose, mg (in figures and words)	Prescribed quantity of medicinal product, mg (in figures and words)	Signature and personal stamp of the attending physician	Date of the dispensation of the medicinal product	Quantity of dispensed medicinal product, mg (in figures and words)	Name of pharmacy	Given name, surname, qualification of the dispenser of the medicinal product	Signature and personal stamp of the dispenser of the medicinal product

Given name, surname of the Chair of the _____
Doctor's Council

Signature and personal stamp of the Chair of the Doctors' _____
Council

Seal of the institution, which issues the programme card of buprenorphine substitution therapy

Minister for Health I. Eglītis

Report regarding the Receipt, Purchase, Dispensation, Destruction of Substances and Medicinal Products Included in Schedule II and III
____ quarter of year ____

Name of the licence holder _____

No.	Name, dosage and quantity of medicinal products and substances in a packaging (arranged according to the active substance)	Remainder at the beginning of the quarter (number of originals or weight in grams)	Received and purchased		Dispensed to		Remainder at the end of the quarter (number of originals or weight in grams)
			from	quantity (number of originals or weight in grams)	to	quantity (number of originals or weight in grams)	
			1. Manufactured 2. Imported (company, country) 3. From another drug or veterinary drug wholesaler (indicate, which) 4. From pharmacies, including also recalled medicinal products		1. Exported (company, country) 2. To another drug or veterinary drug wholesaler (indicate, which) 3. To general-type pharmacies (in total) 4. To closed-type pharmacies (in total) 5. To medical treatment institutions (in total) 6. Destroyed (in total)		

Responsible official

(given name, surname, personal stamp (if any), contact telephone)

Holder of the licence (individual merchant or a Board member of a commercial company who is entitled to represent the commercial company)

(given name, surname, signature)

Date_____

Seal of the licence holder

Note. The details “date, signature, personal stamp of the responsible official, signature and stamp of the licence holder (individual merchant or a Board member of a commercial company who is entitled to represent the commercial company)” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding drawing up of electronic documents.

Minister for Health

I. Eglītis

Report regarding the Receipt, Purchase and Export of Substances and Medicinal Products Included in Schedule II and III in year _____

Licence holder _____

No.	International designation of the substance	Remainder at the beginning of the year (g)	Received, purchased		Exported		Remainder at the end of the year (g)
			state	quantity (g)	state	quantity (g)	

Responsible official _____
(given name, surname, personal stamp, contact telephone)

Licence holder (individual merchant or a Board member of a commercial company who is entitled to represent the commercial company)

(given name, surname, signature)

Date _____
Seal of the licence holder

Note. The details “date, signature, personal stamp of the responsible official, signature and stamp of the licence holder (individual merchant or a Board member of a commercial company who is entitled to represent the commercial company)” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding drawing up of electronic documents.

Minister for Health I. Eglītis