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Republic of Latvia

Cabinet

Regulation No. 293

Adopted 21 April 2008

Procedures by which a Permit for the Utilisation of Plants, Substances and Medicinal Products Included in Schedules I, II or III of Narcotic Substances, Psychotropic Substances and Precursors Controlled in Latvia for Medical and Veterinary Medical Scientific Research, Specification of Physical and Chemical Properties or for Educational Purposes is Issued, Suspended and Revoked

*Issued pursuant to
Section 7 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 a permit for the utilisation of plants, substances and medicinal products included in Schedules I, II or III of narcotic substances, psychotropic substances and precursors controlled in Latvia (hereinafter – Schedules I, II or III) for medical and veterinary medical scientific research, for the specification of physical and chemical properties or for educational purposes, for the handling of substances and medicinal products included in Schedules I, II or III or the cultivation of plants included in Schedules I, II or III (hereinafter – permit) (Annex 1) is issued, suspended and cancelled, as well as the requirements, the conformity with which is ensured by a recipient of the permit in receiving, purchasing, utilising, storing, accounting and destroying plants, substances and medicinal products included in Schedules I, II or III in cases when persons need the plants, substances and medicinal products included in Schedules I, II or III for medical and veterinary medical scientific research, specification of physical and chemical properties, as well as for educational purposes.

2. A person who wants to receive a permit (hereinafter – applicant) shall:

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

2.2. appoint a person who is responsible for provision of the procedures for receiving, purchasing, utilising, storing, accounting and destroying (hereinafter – handling) plants, substances and medicinal products included in Schedules I, II or III to be utilised, as well as the intermediate products, mixtures and unusable remainder, which contain substances

included in Schedules I, II or III (hereinafter – products), (hereinafter – responsible official) and, where necessary, also responsible officials in structural units; and

2.3. appoint at least one official who is entitled to receive plants, substances and medicinal products included in Schedules I, II or III during the absence of the responsible official.

3. An applicant shall ensure that he or she has at his or her disposal:

3.1. premises, equipment and facilities in order to ensure the handling of plants, substances, medicinal products and products included in Schedules I, II or III pursuant to the requirements specified in these Regulations and regulatory enactments regarding the handling of plants, substances and medicinal products so that the plants, substances and medicinal products included in Schedules I, II or III would not enter illegal circulation; and

3.2. the responsible official referred to in Sub-paragraph 2.2 of these Regulations.

II. Procedures for Issuing of a Permit

4. In order to receive a permit, an applicant shall submit an application for receipt of a permit (hereinafter – application) to the State Agency of Medicines (hereinafter – Agency) (Annex 2).

5. The following documents or copies of documents (the original shall be presented) shall be appended to an application:

5.1. the documents referred to in Paragraph 2 of these Regulations;

5.2. documents regarding the place where activities involving plants, substances, medicinal products and products included in Schedules I, II or III are intended:

5.2.1. a building inventory plan of the premises where activities involving plants, substances, medicinal products or products included in Schedules I, II or III are intended;

5.2.2. a document confirming the right of the applicant to use the land or premises where activities involving plants, substances, medicinal products and products included in Schedules I, II or III are intended;

5.3. a written certification of the applicant that the applicant (if the applicant is an individual merchant) and the responsible official do not suffer from mental illness, addiction to alcohol, narcotic, psychotropic or toxic substances.

6. The Agency shall register an application and shall send the application and the documents appended thereto to the Health Inspectorate within a time period of five working days after evaluation of the information provided in the application and the documents appended thereto.

7. The Agency shall ascertain in the Penalties Register that the applicant and other persons referred to in Section 11, Clause 2 of the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products have not been penalised for a criminal offence, as well as have not been administratively penalised for violations, which are related to the handling of narcotic and psychotropic substances and precursors.

8. The Health Inspectorate shall perform an inspection of the application and the documents appended thereto within 10 working days after receipt thereof in order to ascertain that an applicant is able to meet the requirements specified in these Regulations and other regulatory enactments regarding the handling of narcotic and psychotropic substances pursuant to the

profile and structure of the work, as well as the conformity of the information provided in the application and the documents appended thereto to the actual conditions.

9. Officials of the Health Inspectorate shall draw up an inspection statement regarding the inspection referred to in Paragraph 8 of these Regulations in three copies. One copy shall be issued to the applicant, the second copy shall remain with the Ministry of Health, the third copy shall be sent to the Agency within a time period of three days. The inspection statement shall be signed by the official of the Health Inspectorate who performed the inspection and by the person referred to in Sub-paragraph 10.9 of these Regulations who participated in the inspection and who has the right to make notes regarding the procedure of the performed inspection in the inspection statement.

10. The following shall be indicated in an inspection statement:

10.1. name of the applicant (for an individual merchant – also the given name, surname and personal identity number), registration number in the commercial register (for State administrative institution – taxpayer registration code), legal address and address of the place where handling of plants, substances, medicinal products and products included in Schedules I, II or III will be performed;

10.2. activities performed and facts detected during the inspection;

10.3. the comparison of the submitted information and the documents with the determined facts and conclusions;

10.4. the conformity with the requirements specified in these Regulations and other regulatory enactments regarding the handling of narcotic and psychotropic substances. If non-conformity with the requirements specified in these Regulations and other regulatory enactments regarding the handling of narcotic and psychotropic substances is detected, the respective Section, Paragraph, Clause or Sub-clause of the regulatory enactment shall be indicated;

10.5. the date when the previous inspection was performed (if performed);

10.6. information regarding the elimination of deficiencies detected during the previous inspection (if any);

10.7. information regarding detected violations and deficiencies to be eliminated (if any) and the deadline for elimination thereof;

10.8. a proposal regarding issuance or suspension, or revocation of a permit;

10.9. the given name, surname and position of the applicant or the responsible official (or another official who is authorised to participate in inspection); and

10.10. the given name, surname and position of the officials of the Health Inspectorate who performed the inspection.

11. The Agency shall evaluate the information included in the documents referred to in Paragraphs 4 and 5 of these Regulations, as well as the information referred to in Paragraph 7 of these Regulations and the inspection statement of the Health Inspectorate and take a decision regarding issuance of a permit or a refusal to issue a permit, as well as regarding suspension of a permit in accordance with Sub-paragraph 10.8 of these Regulations.

12. If the submitted information is insufficient or if there are doubts about the accuracy thereof, the Agency is entitled to:

12.1. demand the necessary additional information from the applicant;

12.2. request the Health Inspectorate to perform an additional inspection;

12.3. invite experts in the field of pharmacy, veterinary pharmacy, chemistry, biochemistry or of scientific institutions with adequate qualifications in order to evaluate the

submitted information and the necessity and validity of utilisation of the plants, substances, medicinal products and products included in Schedules I, II or III; and

12.4. request information from experts in the field of pharmacy, veterinary pharmacy, chemistry or biochemistry or from non-governmental organisations.

13. The Agency shall issue a permit for an unspecified period of time. The Agency shall issue the permit or the re-registered permit (a permit with the amendments referred to in Paragraphs 14 and 17 of these Regulations) after an applicant has presented a document regarding payment made in accordance with the public services pay rates of the Agency. If the plants, substances, medicinal products and products included in Schedules I, II or III are necessary for the provision of the functions of a State administrative institution, payment for the issuance and re-registration of the permit shall not be collected.

14. If a person who has received a permit (hereinafter – permit holder) needs to make amendments to the quantity or nomenclature of the plants, substances, medicinal products and products included in Schedules I, II or III indicated in the permit and to include therein plants, substances or medicinal products from the same Schedule or Schedule in which less dangerous plants, substances or medicinal products are referred to than the ones specified in the permit, the permit holder shall submit the application referred to in Paragraph 4 of these Regulations. The documents referred to in Paragraph 5 of these Regulations shall be appended to the application if changes have been made therein. The Agency shall take a decision regarding re-registration of the permit or a refusal to register the permit after evaluation of the submitted information.

15. If a permit holder needs to make amendments to the nomenclature of the plants, substances, medicinal products and products included in Schedules I, II or III indicated in the permit and to include therein plants, substances or medicinal products from a Schedule in which more dangerous plants, substances or medicinal products are referred to than the ones specified in the permit, the permit holder shall submit the application referred to in Paragraph 4 of these Regulations. The documents referred to in Paragraph 5 of these Regulations shall be appended to the application if changes have been made therein. The Agency shall evaluate the submitted documents and take a decision regarding issuance of a permit or a refusal to issue a permit in accordance with the procedures specified in this Chapter.

16. If changes have been made to the documents referred to in Paragraph 5 of these Regulations, the permit holder shall submit information regarding changes in the referred to documents to the Agency within a time period of five working days.

17. If the changes referred to in Paragraph 16 of these Regulations in the submitted documents are related to the information indicated in the permit, the Agency shall issue the re-registered permit.

III. Refusal to Issue a Permit, Suspension and Revocation of Operation of a Permit

18. The Agency shall take a decision regarding refusal to issue a permit if:

18.1. on the basis of the documents referred to in Paragraphs 4 and 5 of these Regulations and the inspection report of the Health Inspectorate, it detects that an applicant is not able to ensure the handling of plants, substances, medicinal products and products included in Schedules I, II or III pursuant to the requirements specified in these Regulations;

18.2. the information included in the documents referred to in Paragraphs 4 and 5 of these Regulations does not conform to the actual conditions;

18.3. an opinion from the experts referred to in Sub-paragraph 12.3 of these Regulations has been received that the utilisation of plants, substances, medicinal products and products included in Schedules I, II or III is not necessary and justified;

18.4. an applicant or any of the persons referred to in Section 11, Clause 2 of the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products has been penalised for a criminal offence or has been administratively penalised for violations, which are related to the handling of narcotic and psychotropic substances and precursors; or

18.5. an applicant or the responsible official is included in the National Register of narcological patients and users of addictive substances.

19. The Agency shall take a decision regarding suspension of operation of a permit if:

19.1. a permit holder permit does not ensure the handling of plants, substances, medicinal products and products included in Schedules I, II or III pursuant to the requirements specified in these Regulations and in other regulatory enactments regarding the handling of narcotic and psychotropic substances;

19.2. a permit holder has not appointed the responsible official; or

19.3. a permit holder has not informed regarding changes in the submitted documents.

20. The Agency shall take a decision regarding revocation of a permit if:

20.1. the information or data referred to in an application or the submitted documents does not conform to the actual conditions;

20.2. during an unscheduled (unplanned) inspection the Health Inspectorate has detected that a permit holder has committed significant violations of the requirements specified in these Regulations or other regulatory enactments regarding narcotic and psychotropic substances in relation to the handling of plants, substances, medicinal products and products included in Schedules I, II or III;

20.3. the deficiencies indicated in the inspection report of the Health Inspectorate have not been eliminated in the specified period of time;

20.4. a permit holder or any of the persons referred to in Section 11, Clause 2 of the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products has been penalised for a criminal offence or has been administratively penalised for violations, which are related to the handling of narcotic and psychotropic substances and precursors;

20.5. a permit holder or the responsible official is included in the National Register of narcological patients and users of addictive substances; or

20.6. it has been detected that a permit holder has purchased and utilises plants, substances, medicinal products or products included in Schedules I, II or III, which are not referred to in the permit.

IV. Purchase and Receipt of Plants, Substances, Medicinal Products and Products Included in Schedules I, II or III

21. A permit holder is entitled to purchase plants, substances, medicinal products and products included in Schedules I, II or III only from such person who has received an appropriate special permit (licence) for pharmaceutical or veterinary pharmaceutical activity or a permit for the utilisation of plants, substances, medicinal products and products included

in Schedules I, II or III for medical and veterinary medical scientific research, specification of physical and chemical properties or for educational purposes.

22. The responsible official shall ensure the drawing up and storage of requests, bills of lading-invoices and deeds of delivery and acceptance of the plants, substances, medicinal products and products included in Schedules I, II or III separately from the requests, bills of lading-invoices and deeds of delivery and acceptance of other plants, substances, medicinal products and products.

23. Only the responsible official or the officials referred to in Sub-paragraph 2.3 of these Regulations are entitled to receive plants, substances, medicinal products and products included in Schedules I, II or III.

24. Requests, bills of lading-invoices and deeds of delivery and acceptance of plants, substances, medicinal products and products included in Schedules I, II or III shall be stored for 10 years.

V. Utilisation, Accounting and Storage of Plants, Substances, Medicinal Products and Products Included in Schedules I, II or III

25. Plants, substances, medicinal products and products included in Schedules I, II or III shall be utilised only for the purpose specified in an application.

26. The responsible official, within a time period of one working day, shall register data regarding the purchase, receipt, utilisation, dispensation of plants, substances, medicinal products and products included in Schedules I, II or III to another person or structural unit in a strict accountability register of the plants, substances and medicinal products included in Schedules I, II or III (hereinafter – strict accountability register) (Annex 3), the pages of which shall be numbered and bound together. Handling of products shall also be recorded in the strict accountability register. The strict accountability register shall be approved with a signature and a personal stamp (if any) of the responsible official and the seal of the permit holder. The date of the first and the last entry shall be indicated on the last page of the strict accountability register.

27. Entries in the strict accountability register shall be made pursuant to the procedures specified in the document referred to in Sub-paragraph 2.1 of these Regulations. If an entry is inaccurate, it shall be deleted so that the initial content of the entry is visible, the correct entry shall be made next to it, the date of making the correction shall be indicated and the entry shall be confirmed with a signature and the personal stamp (if any) of the responsible official.

28. The responsible official shall once a month compare the remainder of the plants, substances, medicinal products and products registered in the register with the actual remainder of plants, substances, medicinal products and products and shall make an entry regarding the results of the inspection in the strict accountability register, indicate the date of the inspection and confirm the entry with a signature and a personal stamp (if any).

29. The strict accountability register, after making of the last entry, as well as documentation related to the handling of plants, substances, medicinal products and products included in Schedules I, II or III, shall be stored for at least 10 years.

30. The admissible amount of losses of plants, substances, medicinal products and products included in Schedules I, II or III shall be up to 0.5% from the amount of utilised plants, substances, medicinal products and products. Loss norms shall be applied only in such case if an actual shortage of plants, substances, medicinal products or products is detected.

31. The responsible official shall draw up a statement regarding the actual loss of plants, substances, medicinal products and products included in Schedules I, II or III detected and shall make an entry in the strict accountability register pursuant to Paragraph 26 of these Regulations. The responsible official and the permit holder shall sign the statement and confirm it with a personal stamp (if any).

32. The Health Inspectorate, in performing an inspection of the conformity with the procedures for the handling of plants, substances, medicinal products and products included in Schedules I, II or III, shall indicate the date of inspection on the last page of the strict accountability register. An official of the Health Inspectorate shall confirm the entry with a signature and a personal stamp.

33. The room where plants, substances, medicinal products and products included in Schedules I, II or III are stored shall be secured against the entry of unauthorised persons and looting. The storage conditions specified in the labelling of substances or the instructions on the use of medicinal products shall be ensured during storage.

34. Plants, substances, medicinal products and products included in Schedules I and II shall be stored in a metal cabinet attached to a wall or to the floor, or in a safe, or in a separate room. The safe or metal cabinet shall be equipped with a sound or light alarm system and placed in a room, which is secured against the entry of unauthorised persons. If plants, substances, medicinal products and products included in Schedules I and II are stored in a separate room, the room shall be equipped with an alarm system, which is connected to the centralised safety guard network.

35. A permit holder shall determine in the document referred to in Sub-paragraph 2.1 of these Regulations:

35.1. persons who have the right to enter the premises referred to in Paragraph 33 or 34 of these Regulations;

35.2. 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

35.3. the procedures for storing keys.

36. Substances, medicinal products and products included in Schedule III shall be stored in locked cabinets, separately from other substances, medicinal products and products.

37. In moving plants, substances, medicinal products and products included in Schedules I, II or III among structural units of a permit holder, the permit holder shall ensure appropriate safety measures in order to prevent stealing or looting of the plants, substances, medicinal products and products. The permit holder shall determine the necessary safety measures for moving plants, substances, medicinal products and products included in Schedules I, II or III among structural units of the permit holder in the document referred to in Sub-paragraph 2.1 of these Regulations.

VI. Destruction of Poor Quality Plants, Substances, Medicinal Products and Products Included in Schedules I, II or III

38. Plants, substances, medicinal products and products included in Schedules I, II or III, the quality of which does not conform to the performance of the intended activities (hereinafter – poor quality products), shall be stored in a separate room, separated area or packaging until destruction or return thereof to the supplier, preventing a possibility to mix them with plants, substances, medicinal products and products included in Schedules I, II or III of good quality. Poor quality products shall be stored in accordance with the requirements specified in Paragraphs 33, 34 and 36 of these Regulations.

39. Poor quality products that are not returned to the supplier shall be destroyed by a commission, which is established by a permit holder and consists of at least three persons, pursuant to the requirements specified in the regulatory enactments regarding hazardous waste, or a contract shall be entered into with a person who manages hazardous waste and has received an appropriate permit. The commission shall draw up a deed of delivery and acceptance regarding the return of poor quality products to the supplier or transfer for management of hazardous waste.

40. The commission referred to in Paragraph 39 of these Regulations shall draw up a statement regarding the destruction of poor quality products or a deed of delivery and acceptance, in which the reason of destruction, the name, serial number, quantity of medicinal product, the quantity or the substance included in registers or the quantity of the product, the percentage content and the total amount of the substance in the product included in registers, the given name, surname and position of members of the commission shall be indicated. The statement shall be drawn up in two copies and all members of the commission shall sign it. One copy shall be sent to the Health Inspectorate within a time period of three working days. The statement shall be stored for at least five years.

41. An entry regarding destruction of poor quality products shall be made in the strict accountability register and the number of the writing-off deed or the deed of delivery and acceptance shall be indicated.

VII. Shortage of Plants, Substances, Medicinal Products and Products Included in Schedules I, II or III

42. If a shortage or surplus of plants, substances, medicinal products or products included in Schedules I, II or III is detected, a criminal offence has taken place or if losses have occurred due to force majeure, a room, metal cabinet or safe shall be sealed up and secured against the entry of unauthorised persons. The permit holder or the responsible official shall notify the State Police (exception – losses, which have occurred due to force majeure) and the Health Inspectorate about it without delay.

43. After determination of the facts referred to in Paragraph 42 of these Regulations the permit holder shall establish a commission consisting of at least three persons without delay. The following persons shall be included in the composition of the committee:

the permit holder or his or her authorised official; and

43.2. the responsible official.

44. The commission referred to in Paragraph 43 of these Regulations, in inviting a representative of the Health Inspectorate and a representative of the State Police (if a criminal offence has taken place), shall draw up a statement regarding a shortage or surplus of plants, substances, medicinal products or products included in Schedules I, II or III. The place and date of drawing up the statement, the given name, surname and position of members of the commission, the names of the plants, substances, medicinal products and products, the percentage content and the total amount of substances included in Schedules I, II or III (the pharmaceutical form, strength, serial number of manufacturing of medicinal products, medicinal product manufacturer shall be indicated in addition for medicinal products, the percentage content and the total amount of substances in the product included in Schedules I, II or III shall be indicated for products) shall be indicated in the statement. The statement shall be signed by all members of the commission, as well as by the invited representative of the Health Inspectorate and the representative of the State Police (if a criminal offence has taken place). The statement shall be stored for five years.

45. A shortage or surplus, theft or looting, as well as loss of plants, substances, medicinal products and products included in Schedules I, II or III due to force majeure shall also be registered in the strict accountability register and the number of the statement referred to in Paragraph 44 of these Regulations shall be indicated.

VIII. Duties and Control of a Permit Holder

46. A permit holder shall:

46.1. ensure the handling of plants, substances, medicinal products and products included in Schedules I, II or III pursuant to the requirements specified in these Regulations and regulatory enactments regarding handling of narcotic and psychotropic substances;

46.2. provide officials of the Health Inspectorate with an opportunity to control the procedures for handling plants, substances, medicinal products and products included in Schedules I, II or III and the documentation related thereto;

46.3. document all activities related to the handling of plants, substances, medicinal products and products included in Schedules I, II or III, providing an opportunity to control each referred to activity;

46.4. submit to the Agency a quarterly report (within a time period of 15 working days after the end of each quarter) on the purchase, utilisation, destruction and losses of plants, substances, medicinal products and products included in Schedules I, II or III; and

46.5. perform all the necessary measures so that plants, substances, medicinal products and products included in Schedules I, II or III would not enter illegal circulation.

47. The Health Inspectorate shall control the conformity of a permit holder to the procedures for handling of plants, substances, medicinal products and products included in Schedules I, II or III:

47.1. not less than once a year – if the permit holder operates with plants, substances, medicinal products and products included in Schedules I and II; or

47.2. not less than once in two years – if the permit holder operates with substances, medicinal products and products included in Schedule III.

IX. Closing Provision

48. Permits, which have been issued by the Ministry of Health until the date of coming into force of these Regulations, shall be valid until the expiry date thereof. In order to receive a new permit, a permit holder shall submit an application to the Agency not later than 30 days before the expiry date of the permit in accordance with Paragraph 4 of these Regulations and append the documents referred to in Paragraph 5 of these Regulations.

Prime Minister I. Godmanis

Minister for Health I. Eglītis

STATE AGENCY OF MEDICINES

(address, taxpayer registration code, telephone and fax number)

**Permit
for the Utilisation of Plants, Substances and Medicinal Products Included in Schedules I,
II or III of Narcotic Substances, Psychotropic Substances and Precursors Controlled in
Latvia for Medical and Veterinary Medical Scientific Research, Specification of Physical
and Chemical Properties or for Educational Purposes**

_____ In Riga No. _____
(date)*

1. Issued to _____
(name of the person (for an individual merchant – also the given name, surname,
personal identity number of the merchant))

(registration number of the person in the Commercial Register (for a State
administrative institution – taxpayer registration code))

(legal address of the person (for an individual merchant – also the address of the
declared place of residence))

1.1. telephone number _____
1.2. fax number _____
1.3. e-mail address _____

2. Information regarding the place where activities involving plants, substances and medicinal
products included in Schedules I, II or III are intended:

2.1. address _____
2.2. telephone number _____
2.3. fax number _____
2.4. e-mail address _____

3. Name and quantity of plants, substances, medicinal products and products included in
Schedules I, II or III

No.	Name of the plants and substances	Medicinal products containing the substances included in Schedules I, II or III (name)	Quantity intended to be utilised within a year

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4. Permitted activities involving plants, substances and medicinal products included in Schedules I, II or III

Director

(signature and full name)*

Place for a seal*

Minister for Health

I. Eglītis

* The document details “signature”, “date” and “place for a seal” shall not be completed if the electronic document has been drawn up in conformity with the regulatory enactments regarding drawing up of electronic documents.

**Application for Receipt of a Permit
for the Utilisation of Plants, Substances and Medicinal Products Included in Schedules I,
II or III of Narcotic Substances, Psychotropic Substances and Precursors Controlled in
Latvia for Medical and Veterinary Medical Scientific Research, Specification of Physical
and Chemical Properties or for Educational Purposes**

1. Information regarding the Applicant:

1.1. name (for an individual merchant – also the given name, surname, personal identity number of the merchant)

1.2. registration number in the Commercial Register (for a State administrative institution – the value added taxpayer registration code)

1.3. legal address of the person (for an individual merchant – also the address of the declared place of residence)

2. Information regarding the place where activities involving plants, substances and medicinal products included in Schedule I, II or III are intended:

2.1. address _____

2.2. telephone number _____

2.3. fax number _____

2.4. e-mail address (if any) _____

3. Responsible official:

3.1. given name, surname _____

3.2. position _____

3.3. education _____

3.4. telephone number _____

3.5. fax number _____

3.6. e-mail address (if any) _____

4. I request to issue a permit for an activity involving the following plants, substances and medicinal products included in Schedules I, II or III:

No.	Name of the plants and substances	Medicinal products containing the substances included in Schedules I, II or III (name)	Quantity intended to be utilised within a year

5. Intended activities involving plants, substances and medicinal products included in Schedules I, II or III, the purpose of utilisation thereof or a justification for supplementation of the nomenclature of the plants, substances and medicinal products specified in the permit _____

6. Information indicated in the application, documents appended to the application and other information is true and conforms to the requirements specified in regulatory enactments:

6.1. given name, surname of the applicant (or authorised person) _____

6.2. position of the applicant (or authorised person) _____

6.3. address _____

6.4. telephone _____

6.5. fax _____

6.6. e-mail address (if any) _____

Signature of the applicant (or authorised person)* _____

Date* _____

Minister for Health

I. Eglītis

* The document details “signature” and “date” shall not be completed if the electronic document has been drawn up in conformity with the regulatory enactments regarding drawing up of electronic documents.

Strict Accountability Register of Plants, Substances and Medicinal Products Included in Schedules I, II or III

_____ (name of the permit holder)

_____ (year, month)

Name of the plants, substances or medicinal products _____

Name of the plants or substances and content of the substance included in Schedules I, II or III _____

The pharmaceutical form and content of the substance included in Schedules I, II or III _____

Remainder at the beginning of the month	Received				Dispensed or utilised			Remainder	Signature of the responsible official
	date	location received from, document number	quantity	in total (received + remainder)	date	to whom dispensed or utilised for what purpose	quantity		
1	2	3	4	5	6	7	8	9	10

Responsible official _____
(signature and full name)

Permit holder or his or her authorised person _____
(signature and full name)

Place for a seal

Minister for Health

I. Eglītis