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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

LITHUANIA

Communicated by the Government of Lithuania

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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*Note by the Secretariat: This document is a direct reproduction of the texts translated from Lithuanian into English, communicated to the Secretariat by the Government of Lithuania.

V.97-26088

GOVERNMENT OF THE REPUBLIC OF LITHUANIA

RESOLUTION No.1630

On the Approval of the Regulations of Issuing Licences to Produce, Import into the Republic of Lithuania and Export from the Republic of Lithuania Narcotic and Psychotropic Substances, to Engage in their Wholesale and Retail trade in the Republic of Lithuania. [, 1995]

Vilnius, 28 December 1995

The Government of the Republic of Lithuania r e s o l v e s:

1. To approve the Regulations of issuing Licences to produce, import into the Republic of Lithuania, export from the Republic of Lithuania narcotic and psychotropic substances , to engage in their wholesale and retail trade in the Republic of Lithuania (enclosed)

2. To charge the State Medicines Control Agency under the Ministry of Health Care with the issuance of licences to produce, import into the Republic of Lithuania, export from the Republic of Lithuania narcotic and psychotropic substances, to engage in their wholesale and retail trade in the Republic of Lithuania.

Prime Minister Adolfas Šleževičius

Minister of Health Care Antanas Vinkus

E/NL.1997/45

APPROVED

by Resolution No. 1630
of 28 December 1996
of the Government
of the Republic of Lithuania

Regulations of Issuing Licences to Produce, Import in to the Republic of Lithuania and Export from the Republic of Lithuania Narcotic and Psychotropic Substances, to Engage in their Wholesale and Retail Trade in the Republic of Lithuania[, 1996]

General Provisions

1. These Regulations establishes the procedure according to which the enterprises registered and incorporated in the Republic of Lithuania (hereinafter referred to as enterprises) may produce, import into the Republic of Lithuania, export from the Republic of Lithuania, engage in their wholesale and retail trade in the Republic of Lithuania.

The list of narcotic and psychotropic substances shall be approved by the Ministry of Health Care.

Types of Licences

2. In accordance with these Regulations the following types of licences shall be issued:

2.1. to produce narcotic and psychotropic drugs and medicinal substances;

2.2. to produce psychotropic drugs and medicinal substances;

2.3. to engage in the wholesale trade, import and export of narcotic and psychotropic drugs and medicinal substances;

2.4. to engage in the wholesale trade, import and export of psychotropic drugs and medicinal substances;

2.5. to engage in the retail trade of narcotic and psychotropic drugs and medicinal substances;

2.6. to engage in the retail trade of psychotropic drugs and medicinal substances.

Licence Issuing Institution

3. The State Medicines Control Agency under the Ministry of Health Care (hereinafter referred to as the State Medicines Control Agency) has the right to issue, refuse to issue licences of the type specified in Article 2 of the said Regulations, suspend or abrogate the validity of the licence.

Documents Necessary for Obtaining the Licence

4. To obtain a licence an application and the following supplementary documents shall be presented to the State Medicines Control Agency:

4.1. A copy of the enterprise registration certificate (enterprises under incorporation submit appropriate incorporation documents or their drafts according to the types of enterprises or other legal acts: the incorporation agreement, the act of foundation, joint activities agreement, the draft of articles of association);

4.2. A copy of the permit granted by the Ministry of Health Care to the enterprise to engage in pharmaceutical activities;

4.3. A copy of the licence issued by the Ministry of Health Care to the executive pharmaceutical chemist to engage in pharmaceutical activities;

4.4. A copy of the decree of the enterprise authority concerning the appointment of the executive pharmaceutical chemist;

4.5. Description of the premises and facilities assigned for the licensed activities (indicating their address, plan, equipment, safety measures)

4.6. Certificate granted by the Ministry of Internal Affairs officials concerning the suitability of the equipment of the premises assigned for the storage of narcotic drugs and medicinal substances as well as the safety measures;

4.7. Certificate on the suitability of the equipment of the premises assigned for the storage of psychotropic drugs and medicinal substances as well as the safety measures, granted by the control institutions of the State Medicines Control Agency;

4.8. Nomenclature of narcotic or psychotropic drugs and medicinal substances and the data on their projected annual turnover (if engaged in wholesale trade), the nature of the import and export operations, the countries that will be traded with (if export or import is performed).

5. The form of application shall be determined by the State Medicines Control Agency. The application must include the following data:

5.1. Code of the enterprise (if a registered enterprise applies for a licence. If the licence is being issued to an enterprise under incorporation, the code shall be entered after the enterprise presented the registration certificate. The licence issuing institution shall enter the code), its name and address;

5.2. The type of the licence applied for (according to Article 2 of these Regulations);

5.3. Application submission date.

6. The application and other submitted documents shall be reviewed by the Commission set up by the State Medicines Control Agency.

Time Schedule for Reviewing Documents Submitted for Licensing

7. After the reviewing of the application and other presented documents by the Commission, specified in Article 6 of these Regulations, within 30 days after their submission, the State Medicines Control Agency issues a licence to the applicant or provides him with a motivated refusal to issue a licence.

8. A licence shall be issued only after the applicant pays the appropriate stamp duty and presents the document confirming the payment.

Licence Validity Period and Repetitive Issuance of a Licence

9. The licence shall be issued for the period required by the enterprise, but not exceeding a 5 years' period.

10. Upon the expiration of the licence validity period, it may be issued repeatedly only after presenting documents specified in Article 4 of these Regulations, and keeping to the requirements set in these Regulations.

Requisites of the Licence Form

11. The following requisites have to be specified in the licence:

11.1. the name of the institution which has issued the licence;

11.2. the number of the licence;

11.3. the code of the enterprise, its name, its address;

11.4. the type of the licensed activities (according to Article 2 of these Regulations);

11.5. the date of the issuance of the licence;

11.6. the validity period of the licence.

12. The State Medicines Control Agency shall establish the form of the licence.

Registration Procedure of the Licences Issued

13. The licences issuing institution shall administer the Register of licences. The following requisites have to be included in the Register:

13.1. the number of the licence;

13.2. the code of the enterprise, its name, its address;

13.3. the type of the licensed activities (according to Article 2 of these Regulations);

13.4. the date of the issuance of the licence;

13.5. licence validity period;

13.6.the date of the suspension of the licence validity;

13.7.the abrogation date of the suspension of licence validity;

13.8.the date of abrogation of the licence validity.

Refusal to Issue the Licence

14. Licences shall not be issued if:

14.1. not all necessary documents are presented;

14.2. the presented documents do not conform to the requirements and are officially incorrectly registered;

14.3. the presented data are misleading;

14.4. the holder of the previously issued licence had violated the conditions of the activities under licencing and did not eliminate the causes that predetermined the violation;

15. Upon elimination of the causes interfering with obtaining of a licence it is possible to reapply to the State Medicines Control Agency in accordance with the established procedure.

Suspension of the Licence Validity and its Abrogation

16. The licence validity may be suspended, if:

16.1. the conditions of licensed activities, specified in Article 2 of these Regulations, are not observed;

16.2. it becomes evident that the data presented for the issuance of the licence was misleading;

16.3. the validity of the licence (authorisation) to engage in pharmaceutical activities is suspended or this licence (authorisation) is abrogated;

17. The suspension of the licence shall be abrogated after the violations are eliminated.

18. The licence may be abrogated, provided:

18.1. the licence holder discontinues the licensed activities and submits to the State Medicines Control Agency the application to abrogate the licence;

18.2. the State Medicines Control Agency makes a decision to abrogate the licence provided the enterprise fails to eliminate the violations after the suspension of the licence validity in 2 months' time;

18.3. the notification has been received concerning the reorganization or liquidation of the enterprise when the enterprise discontinues its activities as an independent economic entity.

19. The State Medicines Control Agency, upon issuing the licence, upon suspending the licence issuance, upon abrogating the suspension of the licence validity, upon abrogation of the licence, places an announcement in "Valstybės žinios". The announcement about the issued licence shall provide the following data:

19.1. the code of the enterprise, its name and address;

19.2. the type of the activities to engage in which the licence has been issued;

19.3. the number of the licence;

19.4. the date of the licence issuance (when the validity of the licence is suspended, the suspension of its validity is abrogated, or the licence is abrogated; all the data about the issued licence and appropriate date must be submitted).

Terms of Licensed Activities

20.The main terms of the licensed activities shall be as follows:

20.1 to produce, store, sell the narcotic and psychotropic drugs and medicinal substances, to engage in their wholesale and retail trade it is obligatory to observe the requirements set by the Ministry of Health Care concerning production, storage, prescription, dispensing, accounting, wholesale and retail trade, import and export of narcotic and psychotropic drugs and medicinal substances;

20.2. for the import, export, transfer of narcotic and psychotropic drugs and medicinal substances from one to another location it is obligatory to observe the rules of transportation, packaging and marking;

20.3. during the licence validity period the warehouse and the safety facilities have to conform to the requirements, established by the Rules for storing of the narcotic and psychotropic drugs and medicinal substances.

The Control of the Observance of the Licensed Activities Terms

21. The State Medicines Control Agency must supervise and control the observance of the licensed activities conditions paying particular attention to the way of keeping to the established requirements of production, storage, prescription, dispensing, accounting, wholesale and retail trade, import and export of narcotic and psychotropic drugs and medicinal substances as well as to the rules of their storage conditions and safe transportation.