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UNITED NATIONS

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 text / texts

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Communicated by the Government of the Former Yugoslav Republic of Macedonia

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 [...].

LAW ON PRECURSORS

V.05-87976 (E)

LAW ON PRECURSORS

I. GENERAL PROVISIONS

Article 1

This Law shall regulate the system of monitoring and control of the manufacture and trade with precursors with view of (i) preventing the abuse of precursors for illegal manufacture of narcotic drugs and psychotropic substances, and (ii) protecting the life and health of the population and the environment from the adverse impact of precursors.

Article 2

Certain terms used in this Law shall have the following meaning:

a) "Precursor" shall mean any substance listed in Article 3 of this Law, including mixtures containing such substances, as well as natural products from which precursors can be easily extracted, excluding medicaments, pharmaceutical preparations or other preparations containing precursors that are compounded in such a way that these substances cannot be easily used or recovered by readily applicable or economically viable means;
b) "Manufacture" shall mean preparation, making, processing, packaging and/or storage of precursors;
c) "Trade" shall mean import, export, transport, transit, storage, sale and/or handling of precursors;
d) "Import" shall mean any physical introduction of precursors into the country;
e) "Export" shall mean any physical departure of a precursor from the country;
f) "Transit" shall mean any transport of precursors between third countries through the territory of the Republic of Macedonia, without any transshipment, unloading or replacement of the load;
g) "Transport" shall mean the moving of the precursors through the territory of the Republic of Macedonia;
h) "Operator" shall mean any legal person engaged in the manufacture, storage, processing, trade or distribution of precursors in the Republic of Macedonia, or involved in other related activities such as import, export, transit, and broking of precursors, as well as any natural or legal person pursuing the activity of making customs declarations;
i) "Ultimate consignee" shall mean any natural or legal person to which the precursors are delivered in the country of final destination. This person may be different from the end-user;
j) "International narcotic control body" shall mean the International Narcotic Control Board (INCB), established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.

Article 3

The precursors, according to the ratified international agreements and the international norms and standards, shall be grouped in three categories:

1) The following substances belong to Category 1:
   - 1-Phenyl-2-Propanon, which may also be designated as Phenylacetone;
   - N-acetylanthranilic acid, which may also be designated as 2-Acetamidobenzoic acid;
   - Isosafrol (cis +trans);
   - 3,4-Methylenedioxyphenylpropane-2-on, which may also be designated as 1-(1,3-Benzodioxol-5-yl)propan –2-one);
   - Piperonal;
   - Safrol;
   - Ephedrine;
   - Pseudoephedrine;
   - Norephedrine;
   - Ergometrine
   - Ergotamine;
   - Lysergic acid; and
   - The salts of the substances listed in this category when the existence of those salts is possible.

2) The following substances belong to Category 2:
- Acetic anhydride;
- Phenylacetic acid;
- Anthranilic acid;
- Pottasium permanganate;
- Piperidine; and
- The salts of the substances listed in this category when the existence of those salts is possible.

3) The following substances belong to Category 3:
- Hydrochloric acid, which may also be designated as Hydrogen chloride;
- Sulphuric acid;
- Toluene;
- Ethyl ether, which may also be designated as Diethyl ether;
- Acetone; and
- Methylethylketone (MEK), which may also be designated as Butanone.

The precursors referred to in Paragraph 1, Sub-Paragraph 2, Indents 1, 2 and 4, and Sub-Paragraph 3, Indents 1, 2, 3, 4 and 5 of this Article, are also classified in the group of poisons in accordance with the regulations on poisons.

II. MANUFACTURE

Article 4

As regards the technical and sanitary-hygienic conditions, the operators engaged in the manufacture of precursors classified in the group of poisons according to the regulations on poisons, and/or in manufacture of other precursors referred to in Article 3 of this Law, should fulfill the conditions prescribed by the regulations on manufacture of poisons.

The operators engaged in the manufacture of precursors referred to in Category 1 of Article 3 of this Law, which are pharmacologically active substances that are used in the manufacture of medicaments, should fulfill the conditions for manufacture of medicaments as prescribed by the regulations on medicaments.

Article 5

The operators engaged in the manufacture of precursors are obliged to keep records on the quantities of precursors produced, the quantities of precursors sold on the domestic and the international market, as well as data on the purchaser.

The operators engaged in the manufacture of precursors are obliged to enable the competent authorities to inspect the records and the documentation referred to in Paragraph 1 of this Article.

The Minister of Health shall prescribe the contents and the manner of keeping of the records referred to in Paragraph 1 of this Article.

III. TRADE

Article 6

As for the conditions regarding space, equipment and staff, the operators engaged in the trade with precursors classified in the group of poisons according to the regulations on poisons, and/or trade with other precursors referred to in Article 3 of this Law, should fulfill the requirements prescribed by the regulations on trade with poisons.

The operators engaged in the trade with precursors being pharmacologically active substances that are used for manufacture of medicaments should fulfill the requirements for trade with medicaments at wholesale, prescribed by the regulations on medicaments.

Article 7

Precursors must not be temporarily kept and stored in bonded warehouses in the framework of the procedures conducted in accordance with the regulations on customs operations.

Article 8

The operator referred to in Article 6 of this Law may trade in precursors on condition that the Ministry of Health had issued a license for trading in precursors to it.

The license referred to in Paragraph 1 of this Article shall be issued upon a written application of the legal entity that will be trading in precursors, for specific precursors, for a period of 5 years.

The license referred to in Paragraph 1 of this Article shall be issued upon a previous check of the situation regarding the requirements for trading in poisons or in medicaments at wholesale.

The Minister of Health shall prescribe the contents of the application and the license, as well as the manner in which the license shall be issued.

The application for renewal of the license shall be submitted at least six months before the expiry of the validity period of the existing license.

Article 9

Upon request of the operator, the license referred to in Article 8, Paragraph 1 of this Law, may be revoked before the expiry of the period for which it had been issued.

The operator referred to in Paragraph 1 of this Article is obliged, upon a previous written notice to the Ministry of Health, to concede the remaining quantity of the precursor to a legal entity holding a license for working with precursors.

Article 10

The license for trading in precursors may be revoked even before the expiry of the period for which it had been issued, if:

1) The operator failed to fulfill any of the conditions referred to in Article 6 of this Law, and

2) The operator has been pronounced a security measure “prohibition of engaging in a business” by means of a final sentence.

The operator engaged in trade with precursors is obliged to notify the Ministry of Health of any alteration regarding the space, equipment and staff immediately after the alteration has occurred.

Article 11

The operators engaged in trade with precursors are obliged to keep records on all activities associated with the import, export, transport and transit of precursors, and to possess documentation on these issues.

The commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents shall contain sufficient information positively to identify: the name of the precursor as given in Article 3 of this Law; the quantity and weight of the precursor, and where it is a mixture - the quantity and weight of each individual precursor in the mixture; the name and the address of the importer, exporter, distributor and ultimate consignee.

The statement on the specific purpose of the precursor provided by the end user shall be an integral part of the documentation referred to in Paragraph 1 of this Article.

The operator engaged in trade with precursors is obliged to keep the documentation for at least five years from the day of the issuing thereof, and to enable the competent authorities to inspect it.

Article 12

The operators shall be obliged to notify the Ministry of Health in writing of any unusual order or transaction of precursors, which suggests that the imported/exported quantities may be diverted for illegal trade with narcotic drugs and psychotropic substances.

The operators are obliged to submit written reports on the trade with precursors upon request of the Ministry of Health.

Article 13

The operator engaged in manufacture and/or trade with precursors is obliged to designate the precursors with the names as indicated by Article 3 of this Law.

The provisions on labeling, warning and reporting included in the regulations on trade with poisons shall also apply to the precursors classified in the group of poisons in accordance with the regulations on poisons.

Article 14

The operators can engage in import, export, transport and transit of precursors as referred to in Article 3 of this Law provided that they had been issued an authorization by the Ministry of Health.

The authorization referred to in Paragraph 1 of this Article shall be issued upon written request of the operator within 15 days from the day of completion of the documentation.

As an exception to Paragraph 2 of this Article, the authorization may be issued within 30 days from the day of completion of the documentation if it is necessary to make an additional check of the data in the documentation.

The Minister of Health shall prescribe the content of the requests and the forms of the authorizations referred to in Paragraphs 1 and 2 of this Article.

Article 15

The operator is obliged to submit, attached to the request for obtaining export authorization, an import authorization issued by the country designated as the final destination, if such an authorization is provided for in the destination country.

Article 16

The Ministry of Health can order that special security measures be also undertaken during the transport and transit of a particular precursor referred to in Article 3 of this Law, in accordance with the regulations on the transport of hazardous matters.

The costs associated with the undertaking of the special security measures referred to in Paragraph 1 of this Article shall be borne by the operator.

Article 17

The application for obtaining import, export, transit and/or transport authorization shall be refused if:

1) Established by a competent authority that false or incorrect data have been attached to the application, and

2) No import authorization issued by the country designated as the final destination has been attached to the application, if such an authorization is provided for in the destination country.

Article 18

The import, export, transport and transit authorizations shall also be submitted to the customs authorities when the customs declaration is lodged.

A copy of the authorizations referred to in Paragraph 1 of this Article shall further accompany the consignment until the customs office at the point of entry and/or exit of the precursor from the country customs territory.

The customs office shall confirm the realization of the authorization by way of applying its stamp to the copy of the authorizations before returning it to the issuing authority.

Article 19

Before issuing an export authorization for a precursor referred to in Article 3 of this Law, the Ministry of Health shall submit the following information to the competent authority of the country that the precursor should be exported to:

- name and address of the exporter, importer and other operators involved in the export operations or in the transport, as well as of the end user if known;
- name of the precursor;
- the quantity and the mass of the precursor, and if it is a mixture - the quantity and the mass of the precursor in the mixture with a name as listed in Article 3 of this Law; and
- data on the transport: expected time of delivery, customs house where the customs procedure is expected to be carried out, as well as the itinerary if known.

The data referred to in Paragraph 1 of this Article shall constitute a business secret.

The list of countries requesting to be notified of the planned export of precursors referred to in Article 3 of this Law onto their territory shall be published in the "Official Gazette of the Republic of Macedonia".

Article 20

The Ministry of Health may revoke or annul import, export, transport and transit authorizations on the basis of a document from a competent authority indicating that the precursors might be used for illegal manufacture of narcotics or psychotropic substances.

Article 21

The Ministry of Health shall maintain a Register of the legal entities engaged in the manufacture and/or trade with precursors, which shall contain in particular data on the type and the quantity of the precursor and the name of the operator.

The Minister of Health shall prescribe the content and the manner of maintenance of the Register referred to in Paragraph 1 of this Article.

Article 22

Within the monitoring of the trade and manufacture of precursors and with the view of preventing illegal manufacture and trade, the Ministry of Health shall cooperate with the competent authorities responsible for internal affairs and with the customs authorities, as well as with the International Narcotic Control Body and with other bodies and institutions for the purpose of fulfilling the obligations assumed with the international agreements.

IV. SUPERVISION

Article 23

The Ministry of Health shall supervise the enforcement of this Law and of the regulations adopted on the basis thereof.

The State Sanitary and Health Inspectorate shall carry out inspection-based supervision of the enforcement and the application of this Law and of the regulations adopted on the basis of it with regard to the manufacture and trade with precursors classified in the group of poisons in accordance with the regulations on poisons and/or other precursors referred to in Article 3 of this Law.

Inspectors for medicaments shall carry out inspection-based supervision of the enforcement and the application of this Law and of the regulations adopted on the basis of it with regard to the manufacture and trade with precursors that are pharmacologically active substances used for manufacture of medicaments.

The State Inspectorate for Environment shall carry out inspection-based supervision of the enforcement and the application of this Law as well as of the regulations adopted on the basis of it with regard to the protection of the environment.

Article 24

The state sanitary and health inspectors, the inspectors for medicaments and the inspectors for the environment shall, while carrying out inspections, undertake measures and procedures as prescribed by the regulations on the sanitary and the health inspectorate, on medicaments, on remedial medicines and medical devices and on protection and promotion of the environment and nature.

Article 25

If the license for trading in precursors is taken away or a procedure is initiated for pronouncing the measure “prohibition of engaging in a business” during an inspection, the state sanitary and health inspector and the inspector for medicaments may temporarily take precursors away and order that they be stored in premises of another operator that fulfils the conditions of this Law - as a security measure until a court verdict is reached.

V. PENAL PROVISIONS

Article 26

The legal entity shall be fined with a fine ranging from 150.000 Denars to 300.000 Denars for misdemeanor, if:

1) it temporarily keeps and stores precursors in bonded warehouses (Article 7);

2) it trades in precursors without a license of the Ministry of Health (Article 8, Paragraph 1);

3) it failed to concede the remaining quantity of the precursor to a legal entity holding a license for working with precursors (Article 9, Paragraph 2);

4) it failed to give notice of a change with regard to space, equipment and staff (Article 10, Paragraph 2);

5) it failed to designate the precursors with the names as indicated by Article 3 of this Law and/or failed to apply the provisions on labeling, warning and reporting included in the regulations on trade with poisons (Article 13);

6) it carries out import, export, transport and transit of precursors referred to in Article 3 of this Law without an authorization issued by the Ministry of Health (Article 14, Paragraph 1).

For the actions referred to in Paragraph 1 of this Article, the legal entity shall also be pronounced a security measure "prohibition of engaging in a certain business" for a period from six months up to two years.

The responsible person in the legal entity shall be fined for misdemeanor for the actions referred to in Paragraph 1 of this Article with a fine ranging from 40.000 Denars to 50.000 Denars, and he/she shall also be pronounced a security measure "prohibition of performing a duty" for a period from three months up to one year.

Article 27

The legal entity shall be fined with a fine ranging from 80.000 Denars to 200.000 Denars for misdemeanor if:

1) it failed to keep records of the quantities of precursors produced, the quantities of precursors sold, the quantities of precursors sold on the domestic and the international market, as well as data on the purchaser, and failed to enable the competent authorities to inspect the records and the documentation (Article 5, Paragraphs 1 and 2);

2) it failed to keep records on all activities associated with the import, export, transport and transit of precursors, and possesses no documentation on these issues (Article 11, Paragraph 1);

3) it failed to keep the documentation referred to in Article 11 of this Law for at least five years, and failed to enable the competent authorities to inspect it (Article 11, Paragraph 4);

4) it failed to notify the Ministry of Health in writing of any unusual order or transaction involving precursors suggesting that the imported/exported quantities might be diverted for illegal trade with narcotic drugs and psychotropic substances (Article 12, Paragraph 1); and

5) it failed to submit a report on the trade with precursors upon request of the Ministry of Health (Article 12, Paragraph 2).

The responsible person in the legal entity shall also be fined for the actions referred to in Paragraph 1 of this Article with a fine ranging from 20.000 Denars to 40.000 Denars.

VI. TRANSITIONAL AND FINAL PROVISIONS

Article 28

Until the day of entry into force of this Law, legal entities engaged in trade with poisons shall continue to trade in precursors listed in Article 3 of this Law, continuing to do so until the harmonization of their operations with the provisions of this Law and the regulations adopted on the basis thereof.

Legal entities referred to in Paragraph 1 of this Article are obliged to make their operations compliant with this Law within six months from the day of entry into force of this Law.

Legal entities referred to in Paragraph 1 of this Article are obliged to submit an application for issuing of a license for trading in precursors within the time limit specified in Paragraph 2 of this Article.

Unless the legal entity submits an application as per Paragraph 3 of this Article, it shall be considered as not having a license for trading in precursors in accordance with this Law.

Article 29

The Ministry of Health shall adopt the regulations provided for in this Law within 3 months from the day of entry into force of this Law.

Article 30

The unresolved applications for import, export, transport or transit of precursors submitted prior to the day of entry into force of this Law shall be resolved in accordance with the provisions of this Law.

Article 31

This Law shall come into force on the eighth day from the day of the publication thereof in the "Official Gazette of the Republic of Macedonia."