

Law on control of manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances

Published in ("Official Gazette of Montenegro", No. 83/09)

I. GENERAL PROVISIONS

Article 1

This Law shall regulate monitoring and control of the manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances (hereinafter referred to as "precursors"), for the purpose of preventing their abuse or use for illegal purposes, as well as protecting human life and health and environmental protection from harmful effects of precursors.

Article 2

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

- 1) Precursor** shall mean a substance determined by the List of Precursors, including a mixture of substances or a natural product that the precursor contains, and which can be used for the illicit manufacturing of narcotic drugs and psychotropic substances. Precursors shall not mean pharmaceuticals and other preparations containing precursors, which are combined in a way that they cannot be isolated and used easily, simply and in a cost-effective manner;
- 2) Manufacture** of precursors shall mean preparation, processing, mixing, refining or any other activity by which the manufacture of narcotic drugs, psychotropic substances and their preparations is obtained or which can contribute to it;
- 3) Trade** of precursors shall include: import, export, transit, transport, storage, delivery, sale, purchase, mediation in the purchase or sale of precursors, as well as any handling of precursors, and which is performed by a legal entity with financial compensation or free of charge;
- 4) Transit** of precursors shall mean transport of precursors through the territory of Montenegro, without reloading, unloading or replacement of shipment, from entry to exit from the territory of Montenegro;
- 5) Transport** of precursors shall mean transfer of precursors from one place to another in Montenegro, without reloading, unloading or replacement of shipment, to the final destination of transport of precursors in Montenegro, and which is performed by a carrier;
- 6) End customer** shall mean any natural person or legal entity to which the precursor is delivered in the country which is the final destination;
- 7) Importer** shall mean any legal entity that is responsible for import activities of precursors and that submits the customs declaration or on whose behalf the customs declaration is submitted;
- 8) Exporter** shall mean any legal entity that is responsible for export activities of precursors and that submits the customs declaration or on whose behalf the customs declaration is submitted;

9) International authority for control of narcotics shall mean the International Narcotics Control Board (INCB).

Article 3

Manufacture and trade of precursors, as well as agents for their manufacturing and processing, contrary to the provisions of this Law, shall be prohibited.

Article 4

Precursors are divided into first, second and third category.

The first category consists of precursors that are used as the main and most important raw material in the manufacture of narcotic drugs and psychotropic substances.

The second category consists of precursors that are used as auxiliary raw materials in the manufacture of narcotic drugs and psychotropic substances.

The third category consists of precursors that are used as auxiliary raw materials in the manufacture of narcotic drugs and psychotropic substances, and which, in this process, can be replaced by other appropriate raw materials.

The List of Precursors classified into categories under paragraphs 2, 3 and 4 of this Article shall be adopted by state administration authority competent for health affairs (hereinafter referred to as "the Ministry") at the proposal of the Agency for Pharmaceuticals and Medical Devices (hereinafter referred to as "the Agency") and state administration authority competent for police affairs (hereinafter referred to as "the Police Directorate").

The List of Precursors shall be determined in accordance with ratified international agreements, standards and regulations of the European Union and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

The List of Precursors shall be published in the "Official Gazette of Montenegro".

II. MANUFACTURE OF PRECURSORS

Article 5

Manufacture of precursors may be performed by a legal entity to which the Ministry, i.e. the Agency, has issued a license for the manufacture of precursors.

Manufacturer of precursors that are toxins must meet the requirements in terms of space, staff and equipment, in accordance with regulations governing the manufacture of toxins.

Manufacturer of first category precursors that are pharmacologically active substances used for the manufacture of pharmaceuticals must meet requirements in terms of space, staff and equipment, in accordance with regulations governing the manufacture of pharmaceuticals.

The license for the manufacture of precursors under paragraph 2 of this Article shall be issued by the Ministry, within 60 days of the receipt of the complete documentation prescribed by this Law and regulations for implementation of this Law.

The license for the manufacture of precursors under paragraph 3 of this Article shall be issued by the Agency, within 60 days of the receipt of the complete documentation prescribed by this Law and regulations for implementation of this Law.

In addition to the evidence on fulfilment of the requirements for the manufacture of precursors under paragraphs 2 and 3 of this Article, which is attached by the legal entity with the request, the Ministry, i.e. the Agency, shall obtain the evidence from the competent authority for keeping criminal records that the legal entity, the founder and the responsible person have not been convicted, and that no criminal proceedings for illegal activities with narcotic drugs and psychotropic substances is conducted against them.

Manufacturer of precursors shall designate a person responsible for the preservation, storage, trade and keeping records on trade of precursors, pursuant to this Law, as well as report a change of this person to the Ministry, i.e. the Agency.

The contents of the license for the manufacture of precursors, as well as the contents of the request for obtaining the license for manufacture, shall be prescribed by the Ministry.

Article 6

Legal entity performing the manufacture of precursors shall keep and preserve records on the trade of manufactured and sold precursors on domestic and international market, as well as data on customers.

Legal entity under paragraph 1 of this Article shall preserve the entire business and customs documentation on trade of precursors for at least five calendar years, in accordance with a special law.

Documentation under paragraph 2 of this Article shall contain the following data:

- Name and category of precursor, and in the case of a mixture or natural product, also name of the mixture or natural product and name of precursor, pursuant to the List of Precursors;
- Quantity and weight of precursor, and in the case of a mixture or natural product, quantity, weight, name and percentage prevalence of precursor which the final product contains;
- Name and address of the importer, exporter, end customer and, if possible, name of the person who is directly involved in the trade activities.

Article 7

Legal entities that have the license for the manufacture of precursors may also perform their trade.

Retail trade of precursors shall be prohibited.

III. TRADE OF PRECURSORS

Article 8

Trade of precursors may be performed by a legal entity to which the Ministry, i.e. the Agency, has issued a license for the trade of precursors.

Legal entity may perform trade of precursors that are toxins, if it meets the requirements in terms of space, staff and equipment, in accordance with regulations governing the trade of toxins.

Trade of first category precursors that are pharmacologically active substances used for the manufacture of pharmaceuticals may be performed by a legal entity that meets requirements in terms of space, staff and equipment, in accordance with regulations governing the trade of pharmaceuticals.

The license for the trade of precursors under paragraph 2 of this Article shall be issued by the Ministry, within 60 days of the receipt of the complete documentation prescribed by this Law and regulations for implementation of this Law.

The license for the trade of precursors under paragraph 3 of this Article shall be issued by the Agency, within 60 days of the receipt of the complete documentation prescribed by this Law and regulations for implementation of this Law.

In addition to the evidence on fulfilment of the requirements under paragraphs 2 and 3 of this Article, which is attached by the legal entity with the request for obtaining the license for the trade of precursors, the Ministry, i.e. the Agency, shall obtain the evidence from the competent authority for keeping criminal records that the legal entity, the founder and the responsible person have not been convicted, and that no criminal proceedings for illegal activities with narcotic drugs and psychotropic substances is conducted against them.

Article 9

The license for the trade of precursors shall be issued at the written request of the legal entity, for trade of exactly specific first and second category precursors, for a period of three years, and for the trade of third category precursors, for a period of five years.

The contents of the license for the trade of precursors, as well as the contents of the request for obtaining the license for trade, shall be prescribed by the Ministry.

Article 10

The request for renewal of the license for the trade of precursors shall be submitted at least six months prior to the expiry of the period for which the license for trade has been issued.

Article 11

The license for the trade of precursors shall not be required for legal entities that, during one calendar year, use precursors in amounts that do not exceed the following limits: acetone - 50 kg, ethyl ether - 20 kg, methyl ethyl ketone - 50 kg, toluene - 50 kg, sulphuric acid 100 kg and hydrochloric acid 100 kg, as well as certain salts of these substances when their existence is not possible.

Article 12

The Ministry, i.e. the Agency, shall issue the approval for the use of precursors to pharmacies, veterinary facilities, police, customs, laboratories, Army of Montenegro, institutions engaged in educational activities and scientific and research work and other legal entities that need the precursors for conducting business activities, in accordance with their needs.

The approval for the use of first category precursors shall be issued for a period of three years, and for second category precursors, for a period of five years.

The contents of the approval for the use of precursors, as well as the contents of the request for obtaining the approval for the use of precursors, shall be prescribed by the Ministry.

Article 13

The license for the trade of precursors may be revoked for a legal entity prior to the expiry of the period for which it is issued, if:

- It does not meet one of the requirements for trade under Article 8 of this Law;
- In the period of three years from the issuance of the license for trade, it does not begin conducting the business activity;
- A temporary measure of prohibition of conducting the business activity has been imposed by the final decision of the competent authority.

Legal entity performing the trade of precursors shall report to the Ministry, i.e. the Agency, any change in terms of space, staff, equipment, seat and substances with which it performs the trade, within 10 days of such change.

For any change in terms of space, equipment, staff and substances with which it performs the trade, the legal entity shall submit to the Ministry, i.e. the Agency, a new request for establishing the conditions for performing the trade of precursors.

The Ministry, i.e. the Agency, shall decide upon the submitted request, within 60 days of the receipt of the request for issuance of license for the trade of precursors, i.e. within 30 days upon the request for renewal of the license for the trade.

Article 14

Legal entity to which the license has been revoked in accordance with Article 13, paragraph 1, indents 1 and 3, of this Law shall, upon prior written notification of the Ministry, i.e. the Agency, give the remaining amount of precursors to a legal entity that has the license for the manufacture, i.e. the trade of precursors.

Article 15

Legal entity performing the trade of precursors shall keep and preserve records on all activities related to import, export, transport and transit of precursors.

Documentation regarding import, export, transport and transit (invoices, bills of lading, customs declarations, documentation on transport and shipping services) shall contain data on:

- Name and category of precursor, in accordance with this Law;
- Quantity and weight of precursor, in the case of a mixture or natural product;
- Quantity and weight of each individual precursor in the mixture;
- Name and address of the importer, exporter, distributor and end customer.

Declaration of the end customer on the intended use of precursor shall be an integral part of the documentation under paragraph 1 of this Article.

The form and contents of the declaration of the end customer shall be prescribed by the Ministry.

Legal entity performing the trade of precursors shall preserve the documentation under paragraph 1 of this Article for at least five calendar years, in accordance with a special law.

Article 16

Legal entity under Article 8 of this Law shall designate a person responsible for the trade, preservation, storage, keeping records and reporting, as well as for the prevention of abuse, in accordance with this Law, and report a change of this person to the Ministry, i.e. the Agency.

Legal entity performing the trade of precursors shall obtain the declaration of the end customer on the intended use of precursor whose trade is performed and preserve it in the documentation.

Legal entity under paragraph 1 of this Article shall give one copy of the declaration of the end customer to persons performing any activity for the seller or the end customer (transport, storage and similar), who shall preserve it in their documentation.

Legal entity performing the trade and transit of precursors shall, in the event of change of the end customer regarding the trade or change of the intended use of precursors, notify the Ministry, i.e. the Agency, about this.

The form, contents, manner of use and preservation of the declaration of the end customer shall be prescribed by the Ministry.

Article 17

Legal entity performing the manufacture, i.e. the trade of precursors, shall immediately notify the Ministry, i.e. the Agency, and the Police Directorate of all facts that indicate suspicion of abuse of precursors in manufacture, i.e. trade, as well as unusual orders, theft of precursors or other illicit activities relating to the manufacture, i.e. the trade of precursors.

Competent authorities, institutions and legal entities shall collaborate in order to prevent illicit trade of precursors and their use in the manufacture of narcotic drugs and psychotropic substances.

Legal entity that has the license for the manufacture, i.e. the trade of precursors, shall submit annual report on manufacture and trade of precursors to the Ministry, i.e. the Agency, until 31st January of the current year for the previous year, and earlier upon request.

More detailed data and contents of the report under paragraph 3 of this Article shall be prescribed by the Ministry.

Article 18

Annual needs for precursors shall be determined by the Ministry.

The Ministry shall determine the annual needs for precursors that are pharmacologically active substances used for the manufacture of pharmaceuticals, at the proposal of the Agency.

Legal entities performing the manufacture and trade of precursors, as well as legal entities under Article 12, paragraph 1, of this Law, shall submit the annual needs for precursors to the Ministry, and for precursors that are pharmacologically active substances, to the Agency, until 31st January of the current year for the following year.

After processing of data, the Agency shall submit the report to the Ministry, which shall include data on the needs submitted to it, with data received by the Agency, and it shall, by the end of March, adopt the decision under paragraph 1 of this Article.

Article 19

Legal entities performing the manufacture and trade of precursors, i.e. which use the precursors, shall submit to the Ministry, i.e. the Agency, reports on import and export of precursors for the previous year, until 31st January of the current year.

The Police Directorate shall submit the report on the amount of precursors seized for the previous year to the Ministry, until 31st January of the current year.

The Ministry shall submit the collective report under paragraphs 1 and 2 of this Article to the International Narcotics Control Board, in accordance with international regulations and conventions on control of narcotics.

Article 20

The Ministry shall keep records of legal entities engaged in the manufacture and/or trade of precursors, and which shall contain the name of legal entity, type and quantity of precursors.

The contents and manner of keeping records under paragraph 1 of this Article shall be prescribed by the Ministry.

Data under paragraph 1 of this Article are a business secret and may be made available to the competent authorities, in accordance with the law.

Article 21

Packaging used for trade of precursors must contain data on: manufacturer, name of precursor from the List of Precursors, chemical composition (in the case of a mixture or natural product), contents, quantity, as well as instructions on storage and expiration date.

Safety data sheet shall be enclosed with the shipment (international name - MSDS).

IV. IMPORT, EXPORT, TRANSIT AND TRANSPORT OF PRECURSORS

Article 22

Legal entities may perform import, export, transit and transport of precursors based on the license issued by the Ministry, i.e. the Agency.

The license for import, export, transit and transport of precursors that are toxins shall be issued by the Ministry, and for first category precursors that are pharmacologically active substances used for the manufacture of pharmaceuticals, by the Agency.

The license for import shall be issued to legal entities under Articles 11 and 12, paragraph 1, of this Law.

The license under paragraph 1 of this Article shall be issued at the written request of the legal entity, within 15 days of the receipt of the complete request.

Exceptionally from paragraph 4 of this Article, the license may be issued within 30 days of the receipt of the request, if additional verification of data from documentation is required or if it is necessary to verify the legitimacy of the transaction, especially when the certificate of the country which is marked as the final destination is necessary.

The contents of the request and form of the license under paragraph 1 of this Article shall be prescribed by the Ministry.

Legal entity performing the export of precursors in the country for which there are available data indicating that precursors in its territory are used for illicit manufacturing of narcotic drugs and psychotropic substances shall, with the request for obtaining the license, submit to the Ministry, i.e. the Agency, the appropriate import license issued by the competent authority of the country in which the precursor is exported and the declaration of the end customer, if prescribed by the laws of that country.

Article 23

The request for issuance of the license for import, export, transit and/or transport shall be denied if:

- The competent authority determines that the data submitted with the request are inaccurate;
- Necessary data and documentation have not been attached to the request;
- There is a reasonable suspicion that the precursor can be abused;
- The license for import of the country which is the final destination has not been attached to the request, in accordance with this Law.

Article 24

One copy of the license for import, export or transit of precursors shall be submitted by the Ministry, i.e. the Agency, to the applicant, as well as to the administrative authority competent for customs duties.

The authority competent for customs duties shall certify the license for import, export and transit of precursors for each import, export and transit of precursors and write the date and place of customs clearance and return the certified license to the Ministry, i.e. the Agency, within 15 days from the date of import, export or transit.

Article 25

The Ministry, i.e. the Agency, prior to issuing the license for export of precursors, shall submit to the competent authority of the country on whose territory the precursor is to be exported the following data:

- Name and address of the exporter, importer and other legal entities involved in the export business or transport, as well as end customer, if known;
- Name and category of precursor;
- Quantity and weight of precursor, i.e. in the case of a mixture, the quantity and weight of precursor in that mixture;
- Data on transport (expected time of implementation of customs procedures and route, if known).

Data under paragraph 1 of this Article are a business secret.

The form and contents, as well as the manner of submitting the notification under paragraph 1 of this Article, shall be prescribed by the Ministry.

Article 26

The Ministry, i.e. the Agency, may revoke the license for import, export, transit and transport, based on notification of the competent authority of the country on whose territory the precursor is to be exported, if there is a reasonable suspicion that the precursors are used for illicit manufacture of narcotic drugs or psychotropic substances.

Article 27

The legal entity shall, based on the obtained license, perform import, export or transit of precursors, within 30 days from the date of issuance of the license, and simultaneously.

The legal entity that has not performed import, export or transit of precursors based on the obtained license shall return the license to the Ministry, i.e. the Agency,

within seven days from the day of expiry of the deadline under paragraph 1 of this Article.

Article 28

Legal entity that has performed the export or import of precursors based on the obtained license shall submit to the Ministry, i.e. the Agency, a report on the actual quantities of exported or imported precursors, within 15 days from the date of such export or import.

The form and contents of the report under paragraph 1 of this Article shall be prescribed by the Ministry.

Article 29

The Ministry, i.e. the Agency, shall keep a registry of legal entities performing manufacture, trade, import, export, transit and transport of precursors, as well as a special registry on the issued licenses.

Central registry on records under paragraph 1 of this Article shall be kept by the Ministry, on the basis of its data and data that the Agency shall submit quarterly.

Data from the registries under paragraphs 1 and 2 of this Article are a business secret and shall be kept in accordance with the law.

The contents and manner of keeping registries under paragraph 1 of this Article shall be prescribed by the Ministry.

Article 30

Advertising the offer and demand of precursors, as well as the agents for their manufacturing and processing or mediation in these operations, in the media or in any other carrier of advertisement, shall be prohibited.

Article 31

Provisions of the law regulating general administrative procedure shall accordingly apply to issues that are not regulated by this Law.

V. MONITORING

Article 32

Monitoring over the implementation of this Law and regulations adopted pursuant to this Law shall be performed by the Ministry through health and sanitary inspection.

VI. PENALTY PROVISIONS

Article 33

A legal entity shall be punished for the offence by a fine of two hundredfold to three hundredfold amount of the minimum wage in Montenegro, if:

1) It fails to designate a person responsible for the preservation, storage, trade, reporting and keeping records on trade of precursors (Article 5, paragraph 7);

- 2) It fails to report a change of the person responsible for the preservation, storage, trade, reporting and keeping records on trade of precursors to the Ministry, i.e. the Agency (Article 5, paragraph 7);
- 3) It fails to keep records on the trade of manufactured and sold precursors on domestic and international market, as well as data on customers (Article 6, paragraph 1);
- 4) It fails to preserve the entire business and customs documentation on trade of precursors for at least five calendar years (Article 6, paragraph 2);
- 5) Documentation on trade of precursors does not contain any of the data prescribed by Article 6, paragraph 3, of this Law;
- 6) It fails to report to the Ministry, i.e. the Agency, any change in terms of space, staff, equipment, seat and substances with which it performs the trade, within 10 days of such change (Article 13, paragraph 2);
- 7) It fails to keep and preserve records on all activities related to import, export, transport and transit of precursors (Article 15, paragraph 1);
- 8) It fails to obtain the declaration of the end customer on the intended use of precursor whose trade is performed (Article 16, paragraph 2);
- 9) It fails to preserve in the documentation the declaration of the end customer on the intended use of precursor whose trade is performed (Article 16, paragraph 2);
- 10) It fails to give one copy of the declaration of the end customer to persons performing any activity for the seller or the end customer (Article 16, paragraph 3);
- 11) It fails to notify the Ministry, i.e. the Agency, about the change of the end customer regarding the trade or change of the intended use of precursors (Article 16, paragraph 4);
- 12) It fails to submit the annual report on manufacture and trade of precursors to the Ministry, i.e. the Agency, until 31st January of the current year for the previous year, and earlier upon request (Article 17, paragraph 3);
- 13) It fails to submit to the Ministry, i.e. the Agency, reports on import and export of precursors for the previous year, until 31st January of the current year (Article 19, paragraph 1);
- 14) It fails to use the packaging that contains data on manufacturer, name of precursor from the List of Precursors, data on chemical composition (in the case of a mixture or natural product), contents, quantity, as well as instructions on storage and expiration date (Article 21, paragraph 1);
- 15) It fails to enclose the safety data sheet with the shipment (international name - MSDS) (Article 21, paragraph 2);
- 16) It fails to return to the Ministry, i.e. the Agency, the license based on which it has not performed import, export or transit of precursors, within seven days from the day of expiry of the deadline under Article 27, paragraph 1 (Article 27, paragraph 2);
- 17) It fails to submit to the Ministry, i.e. the Agency, a report on the actual quantities of exported or imported precursors, within 15 days from the date of such export or import (Article 28, paragraph 1);
- 18) It advertises the offer and demand of precursors, as well as the agents for their manufacturing and processing, in the media or in any other carrier of advertisement (Article 30).

Responsible person in the legal entity shall also be punished for offences under paragraph 1 of this Article by a fine of tenfold to twentyfold amount of the minimum wage in Montenegro.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 34

Regulations for the implementation of this Law shall be adopted within six months from the date of entry into force of this Law.

Article 35

Legal entities engaged in the manufacture, trade, import, export, transit and transport of precursors shall harmonize their operations with this Law, within nine months from the date of entry into force of this Law.

Article 36

This Law shall enter into force on the eighth day as of its publication in the "Official Gazette of Montenegro".