

Pursuant to Article 95 item 3 of the Constitution of Montenegro I hereby pass

DECREE

PROMULGATING THE LAW ON THE SUPERVISION AND CONTROL OF MANUFACTURING AND MARKETING OF CERTAIN SUBSTANCES THAT MAY BE USED IN ILLICIT MANUFACTURING OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

("Official Gazette of Montenegro", No. 003/26 from 09 January 2026)

I hereby promulgate the Law on the supervision and control of manufacturing and marketing of certain substances that may be used in illicit manufacturing of narcotic drugs and psychotropic substances adopted by the Assembly of Montenegro at its 7th sitting of the 2nd annual regular (autumn) session in 2025 on 31 December 2025.

No: 01-009/25-2542/2

Podgorica, 31 December 2025

President of Montenegro,

Jakov Milatović, m.p.

Pursuant to Article 82 paragraph 1 item 2 and Article 91 paragraph 1 of the Constitution of Montenegro, the Assembly of Montenegro in its 28th legislature at the 7th sitting of the 2nd regular (autumn) session in 2025, on 31 December 2025 adopted

LAW

ON THE SUPERVISION AND CONTROL OF MANUFACTURING AND MARKETING OF CERTAIN SUBSTANCES THAT MAY BE USED IN ILLICIT MANUFACTURING OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES *

I. GENERAL PROVISIONS

Article 1

This Law regulates supervision and control of manufacturing and marketing of certain substances that may be used in illicit manufacturing of narcotic drugs and psychotropic substances (precursors for drugs), in order to prevent their misuse or illicit use, as well as other matters of significance for this area.

Article 2

Within the meaning of this Law, precursors shall not mean mixtures and natural products containing precursors which are combined in a manner that they cannot be easily used or extracted by easily applicable or cost-effective means. Medicines defined in the Law on medicines, except for medicines listed in the 4th category of precursors, shall not be considered precursors either.

Article 3

Precursors are classified into the first, second, third and fourth category.

The first category consists of precursors that are used as basic and most important substance in the manufacturing of narcotic drugs and psychotropic substances.

The second category consists of precursors used as auxiliary substances in the manufacturing of narcotic drugs and psychotropic substances and are classified into subcategories II.A and II.B.

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

The fourth category of precursors consists of medicines for human and veterinary use that contain ephedrine or ephedrine salts, pseudoephedrine or pseudoephedrine salts, or norephedrine or norephedrine salts.

Article 4

The list of precursors classified into categories referred to in Article 3, paragraphs 2 to 5 of this Law shall be adopted by the state administration body responsible for health affairs (hereinafter: Ministry) after obtaining the opinion of the Institute for Medicines and Medical Devices (hereinafter: Institute) and the administrative body responsible for police affairs (hereinafter: the Police Administration).

The list of precursors shall be established 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 concluded in 1988.

The list of precursors shall be published in the "Official Gazette of Montenegro".

Article 5

The Ministry shall establish the Commission for precursors, as an expert body (hereinafter: Commission).

The Commission shall be composed of experts from the field of chemistry, pharmacy and medicine, or experts for use of precursors, narcotic drugs and psychotropic substances, as well as of representatives of the Ministry, state administration body responsible for environmental protection, state administration body responsible for veterinary affairs, state administration body responsible for internal affairs and state administration body responsible for customs affairs.

The Commission shall include at least one representative from the relevant field or institution. The Commission is appointed for a four-year period. The Commission adopts rules of procedure that further regulate its work and voting methods.

The Commission shall perform the following tasks:

- 1) developing and updating Guidelines in accordance with the European Union regulations on the method and procedure for identifying suspected use of precursors from the List of precursors, as well as substances outside the List of precursors;
- 2) monitoring the use of substances outside the List of precursors and, in order to prevent misuse, proposing to the Ministry to classify them in accordance with Article 3 of this Law and include these substances in the List of precursors in accordance with Article 4 of this Law;
- 3) cooperating with competent state authorities in resolving identified issues related to the manufacture or marketing of precursors, as well as substances outside the List of precursors;
- 4) providing expert opinions to legal persons performing activities in the chemical or pharmaceutical industry;
- 5) carrying out other expert activities related to the manufacturing or marketing of precursors, by order of the Minister.

Article 6

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

Article 7

Terms used in this Law shall have the following meaning:

- 1) Precursor for drugs (hereinafter: precursor) shall mean a substance determined by the List of precursors, that may be used for illicit manufacturing of narcotic drugs and psychotropic substances, including a mixture of substances or a natural product containing such substances, but excluding mixtures and natural products containing precursors which are combined in a way that they cannot be easily used or extracted by easily applicable or cost-effective means, and also medicines defined in the Law on medicines, except for medicines listed in the 4th category of precursors.
- 2) Substance outside the List of precursors is any substance that can be used for the manufacturing of narcotic drugs and psychotropic substances if it is not determined by the List of precursors;
- 3) mixture is a combination or solution of two or more substances;
- 4) natural product is a substance found as such in nature, unprocessed or processed exclusively by manual, mechanical or gravitational means, by dissolution in water, flotation, extraction using water, steam distillation or water evaporation, or extracted from the air in any manner;
- 5) placing on the market is any delivery, for a fee or at no cost, of precursors or storage, manufacturing, production, processing, marketing, distribution or brokering of precursors, for the purpose of delivery to the market;
- 6) Final recipient shall mean any legal or natural person to whom a precursor is delivered in the country of final destination, not necessarily a user;

- 7) User shall mean a legal or natural person who is not the entity that places the precursor on the market, and who carries out activities related to processing, formulating, consuming, storage, preserving, further processing, packaging, transferring from one packaging to another, mixing, or other uses of precursor;
- 8) Entity is any legal or natural person who participates in placing precursors on the market;
- 9) import shall mean any entry of precursors that have the status of goods that are not goods of Montenegro into the customs territory of Montenegro, including temporary storage, placement in a free zone or a free warehouse, placement under a suspensive procedure and release for free marketing within that territory;
- 10) export shall mean any removal of precursors from the customs territory of Montenegro, including the exit of precursors for which a customs declaration is required and exit after their storage in a free customs zone;
- 11) brokering activities shall mean all activities related to the organisation of the purchase and sale or procurement of precursors carried out by any legal or natural person with a view to concluding a contract between two parties or acting on behalf of at least one of those parties, without taking possession of those substances or taking control over the implementation of such a transaction; this definition shall also cover any activity carried out by any legal or natural person established in the Union, which relates to the purchase and sale or procurement of precursors without bringing those substances into the customs territory of the Union;
- 12) importer shall mean any legal or natural person responsible for the import of precursors and who submits a customs declaration or on whose behalf a customs declaration is submitted;
- 13) exporter shall mean any legal or natural person responsible for the export of precursors and who submits a customs declaration or on whose behalf the customs declaration is submitted;
- 14) Business premises shall mean premises together with a land used by any legal or natural person at any individual location;
- 15) Pre Export Notification - PEN online shall mean a system intended for national authorities dealing with export and import to monitor and verify the legitimacy of individual shipments in international marketing of such precursors, identify suspicious transactions and prevent their diversion into illegal channels.
- 16) International Narcotics Control Board (INCB) is a body established by the Single Convention on Narcotic Drugs from 1961 (amended by the protocol from 1972), responsible for monitoring the implementation of conventions in the field of narcotic drugs and psychotropic substances, namely: the Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances (1971) and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

II. MANUFACTURING OF MEDICINES

Article 8

Manufacturing of precursors refers to their production by synthesis or isolation from a natural or synthetic mixture of substances, their modification, purification, processing, packaging and mixing to obtain semi-finished or finished products using chemical, physical and biological processes.

Article 9

Manufacturing of precursors of the first, second or third category may be carried out by a legal or natural person to whom the Ministry or the Institute has issued an authorisation for the manufacturing of precursors.

Manufacturing of precursors of the fourth category may be carried out by a legal person on the basis of manufacturing authorisation for medicines issued by the Institute, in accordance with the law regulating the manufacturing of medicines.

Manufacturing of the first category precursors, which are used for the manufacturing of medicines, may be carried out by a legal person that meets the requirements for the manufacture of medicines, in accordance with the law regulating the manufacture of medicines.

Manufacturing of the first category precursors that are not used for the manufacturing of medicines, as well as the second and third category precursors, may be carried out by a legal or natural person registered for the manufacturing of chemical products, and which meets special requirements in terms of premises, personnel and equipment.

Special conditions referred to in paragraph 4 of this Article shall be prescribed by the Ministry.

Article 10

The authorisation for the manufacturing of precursors shall be issued upon the application of a legal or natural person for a period of three years for the manufacturing of a certain precursor of the first, second and third category.

If the application referred to in paragraph 1 of this Article is incomplete, the Ministry or the Institute shall notify the applicant to supplement the application no later than 15 working days from the date of submission of the notification.

The Institute shall, within 60 working days from the date of receipt of the complete documentation prescribed by this Law, issue the manufacturing authorisation of a certain precursor referred to in Article 9, paragraph 3 of this Law.

The Ministry shall, within 60 working days from the date of receipt of the complete documentation prescribed by this Law, issue the manufacturing authorisation of precursor referred to in Article 9, paragraph 4 of this Law.

The time-limit referred to in paragraphs 3 and 4 of this Article shall stop running on the date when the Institute or the Ministry requests the supplement of the application and shall continue to run from the date of submission of the requested data.

In the procedure for issuance of the manufacturing authorisation for precursors, the Ministry or the Institute shall obtain the evidence from the administrative body competent for the enforcement of criminal sanctions that the legal or natural person, the founder and the responsible person has no criminal records, or that there are no ongoing criminal proceedings against these parties that involve illegal activities involving narcotic drugs and psychotropic substances.

The authorisation referred to in paragraph 1 of this Article may not be transferred to another legal or natural person.

The content of the application for the issuance of the manufacturing authorisation for precursors, the documentation attached to the application and the content of the manufacturing authorisation for precursors shall be prescribed by the Ministry.

Article 11

The Ministry or the Institute may reject the application for manufacturing authorisation for precursors if the applicant does not supplement the application in accordance with Article 10, paragraph 2 of this Law or if there is a reasonable doubt that the precursors will be used in illicit manufacturing of narcotic drugs and psychotropic substances.

The Ministry or the Institute shall issue a decision rejecting the application referred to in paragraph 1 of this Article no later than 60 working days from the date of submission of the application.

Article 12

If, after issuing manufacturing authorisation for a certain precursor, the data from the application are modified, the legal or natural person to whom the authorisation was issued shall notify the Ministry, or the Institute and submit a request for the amendment to the authorisation no later than ten days from the date of learning of the modification.

The Ministry or the Institute shall issue amended manufacturing authorisation for a certain precursor based on the verification of the data from the application referred to in paragraph 1 of this Article no later than 60 working days from the date of receipt of the complete application.

If the application referred to in paragraph 1 of this Article is incomplete, the Ministry or the Institute shall notify the applicant to supplement the application no later than 15 working days from the date of submission of the notification.

The time-limit referred to in paragraph 2 of this Article shall stop running on the date when the Institute or the Ministry requests the supplement of the application and shall continue to run from the date of submission of the requested data.

If the applicant does not supplement the application for the amendment to manufacturing authorisation for precursors within the period referred to in paragraph 3 of this Article, the Ministry or the Institute shall reject the application.

The content of the application and the documentation for the amendment to the manufacturing authorisation for precursors shall be prescribed by the Ministry.

Article 13

A legal or natural person who has been issued manufacturing authorisation for a certain precursor shall submit to the Ministry or the Institute an application for renewal of the authorisation no later than 60 working days before the expiry of the period for which the authorisation was issued.

The Ministry or Institute shall issue a new manufacturing authorisation for a certain precursor no later than 60 working days from the date of receipt of a complete application.

If the application referred to in paragraph 1 of this Article is incomplete, the Ministry or the Institute shall notify the applicant to supplement the application no later than 15 working days from the date of delivery of the notification.

The time-limit referred to in paragraph 2 of this Article shall stop running on the date when the Ministry or the Institute requests the supplement of the application and shall continue to run from the date of delivery of the requested data.

If the applicant does not supplement the application for renewal of manufacturing authorisation for precursors within the period referred to in paragraph 3 of this Article, the Ministry or the Institute shall reject the application.

The content of the application for renewal of the manufacturing authorisation for precursors shall be prescribed by the Ministry.

Article 14

The Ministry or the Institute may revoke or suspend a manufacturing authorisation for precursors before the expiry of the period for which it was issued:

1) if the data in the manufacturing authorisation for precursors are changed, and the legal or natural person does not submit an application for amendment to the authorisation in accordance with this Law;

2) if the legal or natural person ceases to meet the conditions for the manufacture of precursors prescribed by this Law;

3) if there is a reasonable doubt that there is a risk of misuse of precursors in the manufacturing of narcotic drugs and psychotropic substances; and

4) at the request of the legal or natural person.

The decision on the revocation or suspension of the manufacturing authorisation for precursors shall be issued by the Ministry or the Institute.

Article 15

If the period for which the manufacturing authorisation for precursors has expired, and the legal or natural person has not submitted an application for renewal of the authorisation, as well as when the authorisation has been revoked, the legal or natural person shall return the authorisation to the Ministry or to the Institute no later than ten days from the date of expiry of the period for which the authorisation was issued, or from the date of delivery of the decision on the revocation of the authorisation.

Article 16

Legal or natural person who possesses the manufacturing authorisation for precursors of the first, second or third category may also place them on the market.

Legal or natural persons who, on the basis of manufacturing authorisation for precursors of the first, second or third category, engages in marketing of these precursors may deliver precursors of the first and II.A category only to legal and natural persons who have the marketing authorisation for these precursors.

Article 17

A legal or natural person that carries out manufacturing of precursors shall have a full-time employee with a degree in chemistry, physical chemistry, biochemical, technological or pharmaceutical sciences who is responsible for the manufacturing, marketing, storage, and keeping records of the manufacturing and marketing of precursors of the first, second, third and fourth category in accordance with this Law.

The person referred to in paragraph 1 of this Article shall take into account all relevant data for the manufacturing, marketing, import and export of precursors, as well as inform the competent authority within the legal person without delay of all observed misuses in the manufacturing or marketing of precursors, of unusual orders, theft of precursors or other illegal actions related to the manufacturing or marketing of precursors, as well as in the event of reasonable doubt that there is a risk of misuse of precursors in the manufacturing of narcotic drugs and psychotropic substances.

Legal or natural person shall inform the competent authority about the name and contact details of the responsible person, as well as of all subsequent changes to such data.

The person referred to in paragraph 1 of this Article represents a legal or natural person and makes decisions necessary to perform all the duties referred to in paragraph 2 of this Article.

Article 18

Legal or natural person that carries out manufacturing of precursors shall keep records and keep documentation on marketing of manufactured and sold precursors on domestic and foreign markets.

Legal or natural person referred to in paragraph 1 of this Article shall keep all business and customs documentation on the manufacturing of precursors of the first, second, third and fourth category for at least three calendar years, in accordance with the law governing customs procedures.

The documentation referred to in paragraph 1 of this Article shall contain the following information:

- 1) name and category of the precursor, and in the case of a mixture or natural product, the name of the mixture or natural product and the name of the precursor;
- 2) quantity and weight of the precursor, and in the case of a mixture or natural product, the quantity, weight, name and percentage of the precursor contained in the finished product; and
- 3) name and address of the importer, exporter, user and, if possible, the name of the person carrying out brokering.

The documentation referred to in paragraph 3 of this Article may also be kept in the form of reproduction on a data storage medium, and shall be:

- 1) identical in appearance and content to the documentation in printed version;
- 2) easily accessible at all times; and
- 3) easily readable, and capable of being analyzed automatically, electronically for a period of three years.

III. MARKETING OF PRECURSORS

Article 19

Wholesale of precursors shall include the following: import, export, transportation, storage, delivery, sale, purchase, brokering in the purchase or sale of precursors, as well as any handling of precursors.

Article 20

Marketing of precursors of the first, second or third category may be carried out by a legal or natural person to whom the Ministry or the Institute has issued a marketing authorisation for precursors.

Marketing of precursors of the fourth category is carried out by a legal person on the basis of a wholesale authorisation for medicines for human use issued by the Institute or a wholesale authorisation for veterinary medicines issued by the administrative body competent for veterinary affairs in accordance with the law regulating the marketing of medicines.

Marketing of precursors of the first category, which are used for the manufacture of medicines, may be carried out by a legal person that meets the conditions prescribed by the law regulating marketing of medicines.

Marketing of precursors of the first category, which are not used for the manufacturing of medicines, as well as precursors of the second and third category, may be carried out by a legal or natural person registered for marketing of chemical products, and that meets special conditions in terms of premises, personnel and equipment.

Legal or natural persons who have the authorisation referred to in paragraph 1 of this Article may supply precursors of the first category and precursors of the II.A subcategory only to legal or natural persons or users who also have marketing authorisation, and must obtain from the buyer a statement on the intended use of the precursors - the End-use statement.

Special conditions from paragraph 4 of this Article shall be prescribed by the Ministry.

Article 21

Marketing authorisation for precursors shall be issued upon the application of a legal or natural person, for marketing of a precisely specified precursor of the first, second or third category for a period of three years.

If the application for marketing authorisation for precursors is incomplete, the Ministry or the Institute shall notify the applicant to supplement the application no later than 15 working days from the date of submission of the notification.

Marketing authorisation for a specific precursor referred to in Article 20, paragraph 3 of this Law shall be issued by the Institute within 60 working days from the date of receipt of a complete application.

Marketing authorisation for a specific precursor referred to in Article 20, paragraph 4 of this Law shall be issued by the Ministry within 60 working days from the date of receipt of a complete application.

The time-limit referred to in paragraphs 3 and 4 of this Article shall stop running on the date when the Ministry or the Institute requests the supplement of the application and shall continue to run from the date of submission of the requested data.

In the process of issuing marketing authorisation, the Ministry, or the Institute, shall obtain the evidence that the legal or natural person, the founder and the responsible person have no criminal records, or that there are no ongoing criminal proceedings against these parties that involve illegal activities with narcotic drugs and psychotropic substances.

The authorisation referred to in paragraph 1 of this Article may not be transferred to another legal or natural person.

The content of the application for marketing authorisation for precursors, the documentation attached to the application and the content of the marketing authorisation for precursors shall be prescribed by the Ministry.

Article 22

The Ministry or the Institute may reject the application for marketing authorisation of precursors if the legal or natural person does not supplement the application in accordance with Article 21, paragraph 2 of this Law or when there is a reasonable doubt that the precursors will be used in illicit manufacturing of narcotic drugs and psychotropic substances.

The Ministry or the Institute shall issue a decision rejecting the application referred to in paragraph 1 of this Article no later than 60 working days from the date of submission of the application.

Article 23

If, after the issuance of marketing authorisation for precursors, the data from the application for the issuance of the authorisation are changed, the legal or natural person to whom the authorisation was issued shall notify the Ministry or Institute no later than ten days from the date of learning about the change and submit an application for the amendment of the marketing authorisation.

The Ministry or Institute shall issue an amended marketing authorisation for a certain precursor based on the verification of the data from the application, no later than 60 working days from the date of receipt of the complete application.

If the application referred to in paragraph 1 of this Article is incomplete, the Ministry or Institute shall inform the applicant to supplement the application no later than 15 working days from the date of submission of the notification.

The time-limit referred to in paragraph 2 of this Article shall stop running on the date when the Ministry or Institute requests the supplement of the application and shall continue to run from the date of submission of the requested data.

If the applicant fails to supplement the application for the amendment to the marketing authorisation for precursors within the period referred to in paragraph 3 of this Article, the Ministry or Institute shall reject the application.

The content of the application for amendment of the marketing authorisation for precursors, the evidence attached to the application and the content of the marketing authorisation for precursors shall be prescribed by the Ministry.

Article 24

A legal or natural person who has been issued a marketing authorisation for a certain precursor shall submit to the Ministry or the Institute an application for renewal of the authorisation no later than 60 working days before the expiry of the period for which the authorisation was issued.

The Ministry or Institute shall, upon the application, issue a new marketing authorisation for a certain precursor no later than 60 working days from the date of receipt of a complete application.

If the application referred to in paragraph 1 of this Article is incomplete, the Ministry or Institute shall notify the applicant to supplement the application no later than 15 working days from the date of delivery of the notification.

The time-limit referred to in paragraph 2 of this Article shall stop running on the date when the Ministry or Institute requests the supplement of the application and shall continue to run from the date of delivery of the requested data.

If the applicant does not supplement the application for renewal of the marketing authorisation for precursors within the period referred to in paragraph 3 of this Article, the Ministry or Institute shall reject the application.

The content of the application and documentation for the renewal of the marketing authorisation for precursors shall be prescribed by the Ministry.

Article 25

Marketing authorisation for precursors may be revoked or suspended before the expiry of the period for which it was issued in following cases:

- 1) if the data from the marketing authorisation for precursors are changed, and the legal or natural person does not submit the application for amendment to the authorisation;
- 2) if the legal or natural person ceases to meet one of the conditions for marketing of precursors;
- 3) if there is a reasonable doubt that there is a risk of misuse of precursors in marketing of narcotic drugs and psychotropic substances; and
- 4) at the request of a legal or natural person.

Decision on revocation or suspension of the authorisation referred to in paragraph 1 of this Article shall be passed by the Ministry, or the Institute.

Article 26

If the period for which marketing authorisation for precursors was issued has expired, and the legal or natural person has not submitted the application for renewal of the authorisation, as well as when the authorisation has been revoked or suspended, the legal or natural person shall return the authorisation to the Ministry or the Institute no later than ten days from the date of expiration of the period for which it was issued, or from the date of delivery of the decision on the revocation or suspension of the authorisation.

Article 27

Marketing authorisation for the second category precursors is not required for a legal or natural person who, during one calendar year, places on the market of Montenegro quantities that do not exceed the following threshold: acetic anhydride - 100 l, potassium permanganate - 100 kg, anthranilic acid and its salts - 1 kg, phenylacetic acid and its salts - 1 kg and piperidine and its salts - 0.5 kg.

Marketing authorisation for precursors is not required for a legal or natural person who, during one calendar year, exports third category precursors in quantities that do not exceed the following threshold: acetone - 50 kg, ethyl ether - 20 kg, methyl ether ketone - 50 kg, toluene - 50 kg, sulfuric acid - 100 kg and hydrochloric acid - 100 kg, as well as salts of these precursors when their existence is possible.

Marketing authorisation for precursors is not required if the quantity of precursors in the mixture during the previous calendar year does not exceed the threshold referred to in paragraph 1 of this Article.

A legal or natural person who, in the course of a calendar year, carries marketing of precursors in quantities exceeding the thresholds referred to in paragraphs 1, 2 and 3 of this Article shall submit the application for obtaining marketing authorisation for specific precursor in advance.

Article 28

The Ministry may issue the authorisation for the use of precursors to pharmacies, police, customs, laboratories, and the Army of Montenegro, which require precursors of the first, second, and third category for the performance of their activities.

The authorisation referred to in paragraph 1 of this Article shall be issued for an indefinite period.

The Ministry may revoke or suspend the authorisation referred to in paragraph 1 of this Article when there is a reasonable doubt that the holder of the authorisation for use does not meet the conditions under which the authorisation was issued.

The content of the application for obtaining the authorisation referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Article 29

Legal or natural person who carries out marketing of precursors of the first, second and third category shall keep records and keep documentation on marketing of precursors on the domestic and foreign markets.

Legal or natural person referred to in paragraph 1 of this Article shall keep all business and customs documentation regarding marketing of precursors for at least three calendar years, in accordance with the law governing customs procedures.

The documentation referred to in paragraph 1 of this Article shall contain the data on:

- 1) buyers;
- 2) name of the precursors of the first, second and third category, in accordance with the regulation governing the List of precursors;
- 3) quantity and weight of the precursors, and in the case of a mixture or natural product, the quantity, weight, name and percentage of the precursor contained in the mixture or natural product;
- 4) Safety Data Sheet for precursors of the first, second and third category;
- 5) name and address of the supplier, distributor, recipient and, if possible, other entities directly involved in marketing activities.

Legal or natural person who carries out marketing of precursors shall obtain a End-user statement on the purpose of the precursors of the first and second category, which is an integral part of the documentation referred to in paragraph 2 of this Article.

The documentation referred to in paragraph 3 of this Article may also be kept in the form of reproduction on a data storage medium, and shall be:

- 1) identical in appearance and content to the documentation in printed version;
- 2) easily accessible at all times; and
- 3) easily readable, and capable of being analyzed automatically, electronically for a period of three years.

Article 30

Notwithstanding Article 29, paragraph 4 of this Law, if a legal or natural person that carries out marketing of the second category precursors regularly supplies an end user with the second category precursors, they may accept a single declaration for multiple transactions relating to those precursors for a period not exceeding one year, if:

- 1) they have supplied the end user with a certain precursor at least three times in the previous 12 months;
- 2) quantities ordered correspond to the usual consumption of that end user, and
- 3) there is no reason to suspect that the precursor will be used for illicit purposes.

Article 31

A legal or natural person who carries out marketing of precursors of the first and the second category shall have a full-time employed person responsible for marketing of precursors, keeping records and reporting, as well as for preventing misuses in accordance with this Law, as well as in case of reasonable doubt that there is a risk of misuse of precursors on the market.

A legal or natural person who transports precursors of the first or the second category - II.A subcategory shall provide the person that transports the precursor with a certified and signed copy of the End-user statement on the purpose of the precursor.

A legal or natural person that carries out marketing of precursors shall, in the event of a change of the user or change in the intended use of the precursor, notify the Ministry or the Institute in writing within five working days from the date of the change.

A legal or natural person shall inform the competent authority about the name and contact information of the responsible person, as well as about any subsequent changes to that information.

The person referred to in paragraph 1 of this Article represents a legal or natural person and makes decisions necessary to perform all the duties referred to in paragraph 2 of this Article.

The Ministry shall prescribe detailed content, method of use and keeping the End-user statement.

Article 32

A legal or natural person that carries out marketing of precursors shall, without delay, notify the Ministry or Institute and the Police Directorate of all facts indicating suspicion of misuse of precursors in the manufacturing or marketing, as well as of unusual orders, theft of precursors or other illegal actions related to the manufacturing or marketing of precursors, as well as in the case of reasonable doubt of misuse of substances outside the List of precursors on the market.

The notification referred to in paragraph 1 of this Article shall contain the following:

- 1) name of the precursor;
- 2) quantity and weight of the precursor;
- 3) name and address of the importer or exporter;
- 4) name and address of the final recipient, and where possible, the name of the person involved in brokering activities;
- 5) name of the person responsible for marketing; and
- 6) other data relevant to the prevention of misuse of precursors.

The information referred to in paragraph 2 of this Article may be used exclusively for the purpose of preventing misuse of precursors.

Competent authorities, institutions and legal entities cooperate with each other in order to prevent illicit marketing of precursors and their use in illicit manufacturing of narcotic drugs and psychotropic substances.

IV. REPORTS AND RECORD KEEPING

Article 33

Legal or natural person who has the manufacturing or marketing authorisation for the of precursors of the first category that are not used for the manufacturing of medicines of the second and third category shall submit an annual report on the manufacturing and marketing of precursors to the Ministry by 15 March of the current year for the previous year, as well as annual needs for the following year, or earlier, upon request.

Legal or natural person who has a manufacturing or marketing authorisation for precursors of the first category that are used for the manufacturing of medicines and of the fourth category shall submit an annual report on the manufacturing and marketing of precursors to the Institute by 15 March of the current year for the previous year, as well as the annual needs for the following year, and upon request, earlier.

Legal or natural person referred to in paragraphs 1 and 2 of this Article shall submit a report to the Ministry or the Institute even where no manufacturing or marketing of precursors during the previous year took place.

The detailed content of the report referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Article 34

The Ministry, or the Institute, shall keep records of the authorisations and approvals issued to legal or natural persons engaged in the manufacturing and/or marketing of precursors, as follows:

- 1) manufacturing authorisations for precursors, or legal or natural persons engaged in the manufacturing of precursors;
- 2) marketing authorisations for precursors, or legal or natural persons engaged in marketing of precursors;
- 3) authorisations for use of the first and the second category precursors,
- 4) authorisations for the import or export of precursors, or legal or natural persons engaged in the import or export of precursors.

The Ministry shall prescribe the detailed content and manner of keeping the records referred to in paragraph 1 of this Article.

Article 35

The data referred to in Article 33 of this Law are available to competent state bodies, institutions and international organizations, in accordance with international agreements and regulations of the European Union and may not be used for other purposes.

The data referred to in Article 33 of this Law are a business secret in accordance with the Law.

Article 36

The administrative body responsible for police affairs shall submit a report on seized quantity of precursors to the Ministry by the 15th of May of the current year for the previous year.

The Institute shall process and submit the report referred to in Article 32, paragraph 2 of this Law to the Ministry by the 15th of April of the current year for the previous year.

The summary report referred to in paragraphs 1 and 2 of this Article shall be submitted by the Ministry to the International Narcotics Control Board in accordance with international regulations and conventions in the field of control of narcotic drugs and psychotropic substances.

Article 37

Packaging used for marketing of the first category precursors that are not used for the manufacturing of medicines, as well as of the second or the third category precursors, shall contain the information on: the manufacturer, the name of the precursor from the List of precursors, the chemical composition (if it is a mixture or a natural product), content, quantity, as well as instructions on storage and shelf life.

Packaging for the first category precursors used for the manufacturing of medicines, as well as for the fourth category precursors, shall contain information in accordance with the regulations governing the labelling of medicines.

V. IMPORT AND EXPORT OF PRECURSORS

Article 38

Import and export of precursors may be carried out by legal persons on the basis of the authorisation issued by the Ministry or the Institute.

Import and export authorisation for the first category precursors not used for the manufacturing of medicines, as well as for the second or the third category precursors, shall be issued by the Ministry, and for the first category precursors used for the manufacturing of medicines and fourth category precursors, shall be issued by the Institute.

The Ministry shall issue the authorisation for import or export of the first category precursors not used for the manufacturing of medicines, as well as for the second and third category precursors also to the administrative authorities referred to in Article 28 of this Law.

The authorisation referred to in paragraph 1 of this Article shall be issued upon submitted application no later than 15 working days from the date of receipt of a complete application.

If the application referred to in paragraph 4 of this Article is incomplete, the Ministry or the Institute shall notify the applicant to supplement the application no later than five working days from the date of delivery of the notification.

The time-limit referred to in paragraph 4 of this Article shall stop running from the date when the Ministry or the Institute requests the supplement of the application and shall continue to run from the date of delivery of the required data.

Notwithstanding paragraph 4 of this Article, the authorisation may be issued within 30 working days from the date of receipt of the application, if additional verification of the data from the documentation is required or if it is necessary to verify the legitimacy of the transaction, especially in the case when confirmation from the country designated as the final destination is required.

The detailed content of the application, documentation and content of the authorisation referred to in paragraph 4 of this Article shall be prescribed by the Ministry.

Article 39

To obtain the authorisation for the export of precursors of the first, second and fourth category, the legal or natural person exporting that precursor shall submit to the Ministry, or the Institute, the appropriate import authorisation issued by the competent authority of the country to which the precursor is imported.

To obtain the authorisation for the export of precursors of the third category, the marketing authorisation holder of precursors that carries out export of the precursor in question shall submit to the Ministry the appropriate import authorisation issued by the competent authority of the country to which the import is made, only when this is the request of that country and which is on the list of countries established by the Commission on Narcotic Drugs in accordance with the UN Convention (1988).

The export authorisation referred to in paragraphs 1 and 2 of this Article shall be issued after obtaining a pre-export notification (PEN online).

If the competent authority of the country to which the precursor is imported does not respond to the request for verification (Pre Export Notification - PEN online) referred to in paragraph 3 of this Article within 15 working days, the Ministry, or the Institute shall issue the authorisation for the export of precursors.

Article 40

The Ministry, or the Institute, before issuing the authorisation for the export of precursors, shall submit the following information to the competent authority of the country to which the precursor is imported:

- 1) name and address of the exporter, importer and other legal or natural persons involved in export operations or transport, as well as the final recipient;
- 2) name and category of the precursors, or in the case of a mixture or natural product, their name, CAS number and HS number, as well as the name of each precursor contained in the mixture or natural product;
- 3) quantity and weight of precursors, and in the case of a mixture or natural product, the quantity and weight and, if any, the percentage of each precursor contained therein;
- 4) information on the organization of transport, such as expected date of shipment, means of transport, name of the customs office where the customs declaration is submitted, the itinerary, expected point of exit from the customs territory and the point of entry into the country of the importer;
- 5) import authorisation issued by the country of final destination, in cases referred to in Article 39 of this Law;
- 6) authorisation number.

All persons who come into possession of the data referred to in paragraph 1 of this Article shall keep them as a business secret.

In the event of a breach of the obligation referred to in paragraph 2 of this Article, the regulations governing the confidentiality of data shall apply.

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

The form and content, as well as the manner of submitting the notification referred to in paragraph 1 of this Article, shall be prescribed by the Ministry.

Article 41

The Ministry or Institute shall reject the application for import and export authorisation for precursors if:

- 1) it determines that incorrect data has been submitted along with the application;
- 2) required data and documentation have not been attached to the application;
- 3) there is a reasonable doubt that the precursor may be misused;
- 4) application is not accompanied by an import authorisation from the country of final destination, in accordance with this Law; or
- 5) if suspicious transactions are identified based on the Pre Export Notification (PEN online).

Article 42

The import authorisation for precursors is issued in four copies marked with numbers 1 to 4.

Copy of the authorisation number 1 is retained by the Ministry or the Institute.

Copy of the authorisation number 2 is sent to the competent authority of the exporting country.

Copy of the authorisation number 3 accompanies the consignment of precursors from the point of entry of the shipment into the customs area of Montenegro to the competent customs office where the precursors are released into free circulation, and the legal or natural person who carries out the import is obliged to return copy of the authorisation number 3 to the Ministry, or to the Institute within 15 working days from the day of the import.

Copy of the authorisation number 4 is kept by the legal or natural person who carries out the import.

Article 43

The export authorisation for precursors is issued in four copies marked with numbers 1 to 4.

Copy of the authorisation number 1 is retained by the Ministry, or the Institute.

Copies of the authorisations no. 2 and 3 are submitted to the competent customs office to which the declaration for export is submitted and follow the shipment of precursors to the point of exit from the customs territory of Montenegro.

The competent customs office at the point of exit of precursors is obliged to return the certified copy of the authorisation number 2 to the Ministry, i.e., the Institute, within 15 working days from the day of export.

Copy of the authorisation number 3 accompanies the precursor to the competent authority of the importing country.

Copy of the authorisation number 4 is retained by legal or natural person who carries out the export.

Article 44

A legal or natural person shall import or export precursors on the basis of the obtained authorisation within six months from the date of issuance of the authorisation.

A legal or natural person who has not imported or exported precursors on the basis of the obtained authorisation shall return the authorisation to the Ministry or the Institute within ten working days from the date of expiry of the time-limit referred to in paragraph 1 of this Article.

Article 45

The Ministry or Institute may revoke or suspend the import and export authorisation for precursors based on the notification from the competent authority of the country from which the precursor is imported, or to whose territory the precursor is exported, or if there is a reasonable doubt that the precursors are being used for illicit manufacturing of narcotic drugs or psychotropic substances.

VI. SUPERVISION

Article 46

Supervision of the implementation of this Law and regulations adopted on the basis of this Law shall be carried out by the Ministry.

Inspection supervision shall be carried out by the sanitary and health inspection and the Inspectorate of the Institute for Medicines and Medical Devices.

Article 47

In conducting the supervision referred to in Article 46, paragraph 2 of this Law, the competent inspection shall have the authority and obligation to:

- 1) review general and individual acts, records and other documentation relating to the manufacturing, marketing, import or export of precursors as well as substances outside the List of precursors;
- 2) hear and take a statement from the responsible person in the legal person referred to in Article 17, paragraph 1 and Article 31, paragraph 1 of this Law;
- 3) order the legal or natural person to harmonise its operations, or eliminate deficiencies in terms of the conditions prescribed by this Law and the regulations for the implementation of this Law;
- 4) suspend the manufacturing and marketing of precursors, if the legal or natural person carries out these activities contrary to this Law and the regulations for the implementation of this Law;
- 5) prohibit the manufacturing or marketing of precursors, if the legal or natural person carries out these activities contrary to this Law and the regulations for the implementation of this Law;
- 6) order other measures to prevent illicit use of precursors.

VII. PENALTY PROVISIONS

Article 48

A legal person shall be fined from 1,500 euros to 20,000 euros for a misdemeanor if:

- 1) it fails to report to the Ministry or Institute, within ten working days from the date of the change, any change in relation to the data from the application on the basis of which the authorisation was issued (Article 12, paragraph 1);
- 2) it does not have a full-time employee responsible for the manufacturing, marketing, storage and keeping records of the manufacturing and marketing of precursors of the first, second, third, and fourth category (Article 17, paragraph 1);
- 3) it fails to keep the entire business and customs documentation on the manufacturing of precursors of the first, second, third, and fourth category for at least three calendar years, in accordance with the law governing customs procedures (Article 18, paragraph 2);
- 4) it fails keep records and documentation on marketing of manufactured precursors, marketing of precursors sold on domestic and foreign markets, as well as data on buyers (Article 18, paragraph 3);
- 5) the period for which the marketing authorisation for precursors has expired, and the legal person has not returned the authorisation to the Ministry or the Institute within a maximum of ten days from the date of expiry of the period for which it was issued, or from the date of delivery of the decision on the revocation or suspension of the authorisation (Article 26):
- 6) it carries out marketing of precursors of the first and second category and does not have a full-time employed person responsible for marketing of precursors, keeping records and reporting, as well as for preventing misuse in accordance with this law (Article 31 paragraph 1);
- 7) it carries out marketing of precursors of the first or second category - II.A sub-category and fails to provide a certified and signed copy of the End-user statement on the purpose of the precursor to the person transporting the precursor a (Article 31 paragraph 2);
- 8) it carries out marketing of precursors, and in the event of a change of end user or change in purpose of the precursor, fails to notify the Ministry or the Institute in writing within five working days from the date of the change (Article 31 paragraph 3);
- 9) it carries out marketing of precursors and fails to promptly notify the Ministry, or the Institute and the administrative body responsible for police affairs of all facts indicating suspicion of misuse of precursors in manufacturing or marketing, as well as of unusual orders, theft of precursors or other illegal actions related to the manufacturing or marketing of precursors (Article 32, paragraph 1);
- 10) it holds the authorisation for the manufacturing or marketing of precursors of the first, second and third category and fails to submit an annual report on the manufacturing and marketing of precursors to the Ministry by 15 March of the current year for the previous year, as well as annual needs for the following year, and earlier upon request (Article 33, paragraph 1);
- 11) it holds the authorisation for manufacturing and marketing of precursors of the first category used in the manufacturing of medicines or of the fourth category, and fails to submit an annual report on the manufacturing and marketing of precursors to the Institute by 15 March of the current year for the previous year, as well as annual needs for the following year, and earlier upon request (Article 33, paragraph 2);
- 12) it fails to submit a report to the Ministry or the Institute even when no manufacturing or marketing of precursors during the previous year took place (Article 33, paragraph 3);

13) it uses packaging for marketing of first, second or third category precursors which does not contain data on: the manufacturer, the name of the precursor from the List of precursors, chemical composition (if it is a mixture or natural product), content, quantity, as well as instructions on storage and shelf life (Article 37, paragraph 1);

14) it uses packaging for first category precursors used in the manufacturing of medicines and for fourth category precursors which does not contain data in accordance with the regulations governing the labelling of medicines (Article 37, paragraph 2);

15) it fails to import or export precursors on the basis of obtained authorisation and fails to return the authorisation to the Ministry or the Institute within ten working days from the expiry date of the time-limit referred to in Article 44, paragraph 1 of this Law (Article 44, paragraph 2).

Also the responsible person in the legal person shall be fined in the amount of 1,000 to 2,000 euros for the violation referred to in paragraph 1 of this Article.

The natural person shall be fined in the amount of 1,000 to 2,000 euros for the violation referred to in paragraph 1 of this Article.

Article 49

A natural person referred to in Article 17 shall be fined between EUR 1,000 and EUR 2,000, if he/she fails to notify the competent authority in the legal person without delay of all observed misuses in the manufacturing or marketing of precursors, of unusual orders, theft of precursors or other illegal actions related to the manufacturing or marketing of precursors, as well as in the case of reasonable doubt that there is a risk of misuse of precursors in the manufacturing of narcotic drugs and psychotropic substances.

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 50

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

Article 51

Legal or natural persons engaged in the manufacturing, marketing, import and export of precursors shall harmonise their business operations with this Law within one year from the date of entry into force of this Law.

Article 52

On the date of entry into force of this Law, the Law on control of manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro", No. 83/09) shall cease to be valid.

Article 53

This Law enters into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro".

No: 24-7/25-1/9

EPA 737 XXVIII

Podgorica, 31 December 2025

Assembly of Montenegro in its 28th legislature

Speaker of the Assembly,

Andrija Mandić, m.p.

*This Law transposes the following:

- Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors;

- Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005;

- Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 amending Regulation (EC) No 273/2004 on drug precursors;

- Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors;
- Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015 laying down rules in respect of Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors;
- Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors;
- Commission Delegated Regulation (EU) 2016/1443 of 29 June 2016 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances;
- Commission Delegated Regulation (EU) 2018/729 of 26 February 2018 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances;
- Commission Delegated Regulation (EU) 2020/1737 of 14 July 2020 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances;
- Commission Delegated Regulation (EU) 2022/1518 of 29 March 2022 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances;
- Commission Delegated Regulation (EU) 2023/196 of 25 November 2022 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances;
- Commission Delegated Regulation (EU) 2024/1331 of 28 February 2024 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of the drug precursor Isopropylidene (2-(3,4-methylenedioxyphenyl)acetyl)malonate (IMDPAM) and other substances in the list of scheduled substances.