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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT
ON IMPORT LICENSING PROCEDURES (2022)

MONTENEGRO

The following communication, dated 26 October 2023, is being circulated at the request of the delegation of Montenegro.

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1 MINISTRY OF ECONOMIC DEVELOPMENT AND TOURISM[1]

1.1 Arms and military equipment

Outline of system

1. Import licensing system is regulated by the Law on Foreign Trade in Arms and Military Equipment (OG MNE No. 40/16). Import licenses are required for weapons and military equipment listed in the National Control List for export and import.

[1] Since 6 May 2022, the Minister of Economy Development is now named the Ministry of Economic Development and Tourism.

Purposes and coverage of licensing

2. Imports of:

- Weapons and military equipment – specific tariff lines from Chapters 27, 28, 29, 31, 36, 38, 71, 88, 89, 93 are subject to licensing.

3. The import licensing system applies to goods originating in and coming from all countries.

4. Licenses are not intended to restrict the quantity or value of imports. In accordance with the Foreign Trade Law the Government may require import licenses only when it is necessary to:

- Protect national security.

5. The following laws and legal acts regulate issuance of licenses by the Ministry of Economic Development and Tourism:

- The Law on Foreign Trade in Arms and Military Equipment (OG MNE No. 40/16);
- The National Control List of Weapons and Military Equipment (OG MNE No. 58/21); and
- The Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 56/14; No. 20/15; No. 40/16 and No. 37/17).

Procedures

6. Not applicable.

7.(a) Licenses are issued in a period not exceeding 15 days, except for weapons and military equipment where licenses are issued in a period not exceeding 30 days, provided that all required documents are submitted. Licenses could be obtained in a shorter period.

(b) Yes.

(c) There are no limitations as to the period of the year during which application for license and/or importation may be made.

(d) An importer has to approach only one administrative organ as regards the application. Ministry of Economic Development and Tourism has to obtain positive opinion from the Ministry of Foreign Affairs, the Ministry of Defence and the Ministry of Internal Affairs in accordance with the Law on Foreign Trade in Arms and Military Equipment (OG MNE No. 40/16).

8. None, except in cases prescribed by international regulations including international sanctions, recommendations of OEBS, etc.

The reasons for any refusal are given to the applicant in writing. In the event of refusal to issue a license, the applicant has a right of appeal to the Administrative Court of Montenegro, as prescribed by the Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 56/14; No. 20/15; No. 40/16 and No. 37/17) and the Law on Administrative Dispute (OG MNE No. 54/16).

Eligibility of importers to apply for license

9. According to the Law on Foreign Trade in Arms and Military Equipment in order to be engaged in importation of arms and military equipment, legal persons have to be registered within the Ministry of Economic Development and Tourism. There is no published list of importers, with exception of the register of importers of weapon kept within the Ministry of Economic Development and Tourism.

Documentation and other requirements for application for license

10. Please see Exhibit I.[2]

[2] Available for consultation on the Import Licensing website "https://www.importlicensing.wto.org" (English only).

11. The importer must only provide a copy of a license or approval upon actual importation along with other required customs documents (declaration, invoice, bill of lading, certificates and, where required, other certificates - origin, conformity, veterinary, health, quality, phytosanitary).

12. Yes, there is a license fee. In accordance with the Law on Administrative Fees (RM OG No. 18/19) the Ministry of Economic Development and Tourism charges €100 for issuing licenses for weapons and military equipment from the National Control List for export and import.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Licenses are valid for one year from the date of issuance. If the realization of the activities related to foreign trade lasts longer than a year, the Ministry may determine the validity of the license until the deadline for completion of the work specified in the contract, but not longer than three years.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. Licenses are not transferable between importers.

17. There are no conditions attached to the issuance of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

1.2 Other goods

Outline of system

1. Import licensing system is regulated by the Foreign Trade Law (RM OG No. 28/04; No. 37/07 and OG MNE No. 73/10; No. 01/14; No. 14/14 and No. 57/14). Import licenses are required for other goods listed in the National Control List for export and import.

Purposes and coverage of licensing

2. Imports of:

- Other goods from National Control List for export and import Chapter 29 – 19 tariff lines (polyacetals)/Chapter 30 – 60 tariff lines Chapter 31 - 1 tariff line, Chapter 33 - 1 tariff line, Chapter 34 -1 tariff line, Chapter 36 - 20 tariff lines, Chapter 37-1 tariff line, Chapter 38 2 tariff lines, Chapter 39 - 3 tariff lines, Chapter 40 - 2 tariff lines, Chapter 48 -1 tariff line, Chapter 50 -1 tariff line, Chapter 61 -1 tariff line Chapter 63 - 4 tariff line, Chapter 65 – 2 tariff lines, Chapter 70 -1 tariff line Chapter 71 - 5 tariff lines, Chapter 83 - 1 tariff line, Chapter 84 - 9 tariff lines, Chapter 85 - 5 tariff lines, Chapter 88 - 6 tariff lines, Chapter 90 - 53 tariff lines, Chapter 93 - 24 tariff lines, Chapter 95 - 2 tariff lines, Chapter 96 – 1 tariff line are subject to licensing.

3. The import licensing system applies to goods originating in and coming from all countries.

4. Licenses are not intended to restrict the quantity or value of imports. In accordance with the Foreign Trade Law the Government may require import licenses only when it is necessary to:

- Protect human, animal or plant life or health;
- Protect environment or exhaustible natural resources;
- Protect public morals;
- Protect intellectual property rights; or
- Enforce any special rules related to gold and silver.

5. The following laws and legal acts regulate issuance of licenses by the Ministry of Economic Development and Tourism:

- The Foreign Trade Law (RM OG No. 28/04; 37/07 and OG MNE No. 73/10; No. 01/14; No. 14/14 and No. 57/14);
- The Law on Optical Discs (RM OG No. 2/07 and OG MNE No. 53/11);
- Decision to amend National Control list for export and import (OG MNE No.71/21).
- The Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 56/14; No. 20/15; No. 40/16 and No. 37/17).

Procedures

6. Not applicable.

7.(a) Licenses are issued in a period not exceeding 15 days, provided that all required documents are submitted. Licenses could be obtained in a shorter period.

(b) Yes.

(c) There are no limitations as to the period of the year during which application for license and/or importation may be made.

(d) An importer has to approach only one administrative organ as regards the application. The Ministry of Economic Development and Tourism has to obtain positive opinion from the Ministry of Internal Affairs (explosives, civil aircrafts, arms for sport and hunting etc.) Civil aircraft agency (civil aircrafts, drones) in accordance with The Foreign Trade Law (RM OG No. 28/04; No. 37/07 and OG MNE No. 73/10; No. 01/14; No. 14/14 and No. 57/14).

8. None, except in cases prescribed by international regulations including international sanctions, recommendations of OEBS, etc.

The reasons for any refusal are given to the applicant in writing. In the event of refusal to issue a license, the applicant has a right of appeal to the Administrative Court of Montenegro, as prescribed by the Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 56/14; No. 20/15; No. 40/16 and No. 37/17) and the Law on Administrative Dispute (OG MNE No. 54/16).

Eligibility of importers to apply for license

9. All persons having the right to engage in import activities are eligible to apply for licenses which are issued by the Ministry of Economic Development and Tourism. There is no published list of importers.

Documentation and other requirements for application for license

10. Please see Exhibit I.[3]

11. The importer must only provide a copy of a license or approval upon actual importation along with other required customs documents (declaration, invoice, bill of lading, certificates and, where required, other certificates - origin, conformity, veterinary, health, quality, phytosanitary).

12. Yes, there is a license fee. In accordance with the Law on Administrative Fees (RM OG No. 18/19) the Ministry of Economic Development and Tourism charges €10 for goods from the National Control List for export and import.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

[3] Available for consultation on the Import Licensing website "https://www.importlicensing.wto.org" (English only).

Conditions of licensing

14. Licenses are valid for one year from the date of issuance. If the realization of the activities related to foreign trade lasts longer than a year, the Ministry may determine the validity of the license until the deadline for completion of the work specified in the contract, but not longer than three years.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. Licenses are not transferable between importers.

17. There are no conditions attached to the issuance of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

1.3 Goods which may be used for the execution of a death penalty and whose application may be subject to torture

Outline of system

1. Import licensing system is regulated by the Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No. 2/18).

Purposes and coverage of licensing

2. Imports of:

- goods which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment – specific tariff lines from Chapters 29, 30, 33, 38, 39, 42, 62, 84, 93 are subject to licensing.

3. The import licensing system applies to goods originating in and coming from all countries.

4. Licenses are not intended to restrict the quantity or value of imports. In accordance with the Foreign Trade Law the Government may require import licenses only when it is necessary to:

- Protect national security.

5. The following laws and legal acts regulate issuance of licenses by the Ministry of Economic Development and Tourism:

- Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No. 2/18);
- The Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 56/14; No. 20/15; No. 40/16 and No. 37/17).

Procedures

6. Not applicable.

7.(a) Licenses are issued in a period not exceeding 30 days, except in case the additional checks are to be performed in a period not exceeding 45 days, provided that all required documents are submitted. Licenses could be obtained in a shorter period.

(b) Yes.

(c) There are no limitations as to the period of the year during which application for license and/or importation may be made.

(d) An importer has to approach only one administrative organ as regards the application. The Ministry of Economic Development and Tourism has to obtain positive opinion from the Ministry of Foreign Affairs, the Ministry of Internal Affairs and Ministry of Culture and Media in cases where these goods will be used for exposure to museums in accordance with the Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No. 2/18).

8. None, except in cases prescribed by international regulations including international sanctions, recommendations of OEBS, etc.

The reasons for any refusal are given to the applicant in writing. In the event of refusal to issue a license, the applicant has a right of appeal to the Administrative Court of Montenegro, as prescribed by the Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 56/14; No. 20/15; No. 40/16 and No. 37/17) and the Law on Administrative Dispute (OG MNE No. 54/16).

Eligibility of importers to apply for license

9. According to the Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No. 2/18), natural and legal persons. There is no published list of importers.

Documentation and other requirements for application for license

10. Please see Exhibit I.[4]

11. The importer must only provide a copy of a license or approval upon actual importation along with other required customs documents (declaration, invoice, bill of lading, certificates and, where required, other certificates - origin, conformity, veterinary, health, quality, phytosanitary).

12. Yes, there is a license fee. In accordance with the Law on Administrative Fees (RM OG No. 18/19) the Ministry of Economic Development and Tourism charges €100 for issuing licenses goods which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Licenses are valid for one year from the date of issuance. If the realization of the activities related to foreign trade lasts longer than a year, the Ministry may determine the validity of the license until the deadline for completion of the work specified in the contract, but not longer than one year.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. Licenses are not transferable between importers.

17. There are no conditions attached to the issuance of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

[4] Available for consultation on the Import Licensing website "https://www.importlicensing.wto.org" (English only).

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

2 INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

2.1 Human and veterinary medicines, and medical devices

Outline of System

1. Institute for Medicines and Medical Devices (hereinafter: Institute) issues authorisations for the import of: human and veterinary medicines, and medical devices. Authorisations are issued in accordance with the following legislation:

- Law on Medicines ("Official Gazette of Montenegro", No. 080/20);
- Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19);
- Law on administrative procedure ("Official Gazette of Montenegro", No. 056/14, No. 020/15, No. 040/16 and No. 037/17); and
- Rulebook on more detailed conditions for import of medical devices that are not registered ("Official Gazette of Montenegro", No. 073/22 and No. 126/22).

Purposes and Coverage of Licensing

2. The Institute issues import licenses for the following products:

- human and veterinary medicines; and
- medical devices.

3. The system is related to the goods originating/coming from any country.

4. The purpose of issuing authorisations for the import of medicines and medical devices is not to limit the quantity or value of the import, but to check the documentation on the quality, safety and efficacy of the products imported. Alternative methods for meeting the goals are not considered, because the issuance of import licenses is in accordance with the national legislation which is to a great extent harmonized with the EU legislation in the area.

5. The issuance of import licenses is conducted in accordance with:

- Law on Medicines ("Official Gazette of Montenegro", No. 080/20);
- Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19);
- Law on administrative procedure ("Official Gazette of Montenegro", No. 056/14, No. 020/15, No. 040/16 and No. 037/17);
- Rulebook on more detailed conditions for import of medical devices that are not registered ("Official Gazette of Montenegro", No. 073/22 and No. 126/22).

The issuance of import licenses is obligatory and there is no possibility to issue the license based on administrative discretion.

The Article 8 of Law on Medicines ("Official Gazette of Montenegro", No. 080/20) envisages that Government of Montenegro may determine alternative procedures and conditions for the issuance of marketing authorisation for a medicine.

Procedures

6.I-XI. Not applicable.

7.(a) The application for import for these products may be submitted at any time according to the opinion of the importer. The time-limit for issuing license is 30 days. This term is most often seven days, or if the goods have already arrived at the customs and at the request of the importer, it may be even shorter, i.e., be done by priority (providing all necessary documentation is still obligatory).

(b) In case of emergency, if the documentation is correct, the license may be issued in less than 30 days or shorter than the average period (see answer to question a).

(c) There are no limitations regarding the period of the year during which the application may be submitted and/or import be done.

(d) Processing of applications for import is performed only by one administrative body - Institute for Medicines and Medical Devices.

8. An application for a license may be rejected due to inadequate documentation on the product or the applicant and in other cases in accordance with relevant laws. Reasons for rejection of any kind are given to the applicant in the form of an appropriate legal act.

In case of rejection, the applicants have the right to appeal to the Administrative Court, in accordance with:

- Law on Medicines ("Official Gazette of Montenegro", No. 080/20);
- Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19);
- Law on administrative procedure ("Official Gazette of Montenegro", No. 056/14, No. 020/15, No. 040/16 and No. 037/17).

Eligibility of Importers to Apply for License

9. There is a system of registration of legal persons that may perform import and marketing.

Import or marketing of medicines may be performed by legal persons seated in Montenegro, which possess wholesale authorisation (wholesalers), issued by the Institute or authority in charge of veterinary affairs for veterinary medicines.

Wholesale of medical devices may be performed by legal persons seated in Montenegro, which are registered in accordance with decision on wholesale registration by the Institute.

Fees for issuance of licenses for the import and wholesale of all these products are defined by:

- Decision on the payment method and amount of fees for the exercise of competences of the Institute for Medicines and Medical Devices that are determined by the law; and
- Decision on the mode of payment and amount of fees for entering and removing medical devices, manufacturers and legal persons that market and import medical devices into and from the Register, as well as keeping the Register (Official Gazette of Montenegro No. 78/2009).
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A list of all legal persons that are authorised to perform import and marketing on the basis of authorisations issued by the Institute, is published on the website of the Institute https://www.cinmed.me/ and is regularly updated.

Documentational and Other Requirements for Application for License

10. The Institute's portal https://www.cinmed.me/ contains all the data that must be listed on the application for import all product groups.

Documentation required for obtaining authorisation for import of medicines for human use:

1) Cover letter;
2) Table containing list of medicines to be imported/exported;
3) Invoice or pro-forma invoice from a supplier;
4) Evidence from the competent authority that a medicine has been granted marketing authorisation in the country of a manufacturer, European Union Member States, or in countries having the same standards for issuing marketing authorisation (marketing authorisation, or CPP certificate in English language, or translated into Montenegrin) - for first import or at the request of the Institute;

5) Evidence from the competent authority that a medicine has been manufactured in accordance with Guidelines on Good Manufacturing Practice (GMP certificate issued by competent authority of one of the EEA Member States or countries that have signed mutual recognition agreements (MRA) with European Union concerning recognition of GMP inspections) - for first import or at the request of the Institute;
6) Summary of Product Characteristics (SmPC) and Package Leaflet (PL) approved in one of the countries referred to in point 4 (in English, or translated into Montenegrin). It is also necessary to submit Mock-up, approved along with the SmPC and PL or developed in line with the approved labelling for immediate and outer packaging - for first import or at the request of the Institute;
7) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch the import of which is applied for;
8) In case of import/export of blood products and immunological products a certificate of analysis for every batch is required, from a manufacturer and from one of the laboratories that are OMCL members, or countries that have signed agreements with European Union on recognition of batch certification;
9) Manufacturing and control summary protocol (for vaccines only), for batch(es) for which certificates are submitted;
10) Justified request of the health institution, i.e., opinion of medical specialist on the need for import of the particular medicine;
11) Statement of the applicant for obtaining import authorisation that medicine will be labelled in accordance with the provisions of the Rulebook on the contents and method of labelling the outer and immediate packaging of a medicine and contents of the package leaflet ("Official Gazette of Montenegro" No. 21/16) before placing on the market in Montenegro. Statement must contain batch number(s) of the medicine.
12) Proof of payment of prescribed fees.

Documentation required for obtaining authorisation for import of veterinary medicines:

1) Cover letter;
2) Table containing list of medicinal products to be imported;
3) Evidence from the competent authority that a medicinal product has been granted marketing authorization in country of a manufacturer, European Union Member States, or in countries having the same standards for issuing marketing authorization;
4) Evidence from the competent authority that a medicinal product has been manufactured in accordance with Guidelines on Good Manufacturing Practice (GMP certificate)
5) Approved Summary of product characteristics and Package leaflet from one of countries referred to in item 3 (in English, or translated into Montenegrin) and Mock- up approved along with the summary and package leaflet, i.e., developed according to the approved text of the packaging (Labelling)
6) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of medicinal product to be imported
7) In case of import/export of immunological products a certificate of analysis for every batch is required, from a manufacturer and from one of the laboratories that are OMCL members, or countries that have signed agreements with European Union on recognition of batch certification;
8) Pro-forma invoice, or invoice of the distributor;
9) Evidence of payment of prescribed fees.

Documentation required for obtaining authorisation for import of medical devices:

- Wholesaler shall submit the following documentation along with the application:

    1) Form for issuance of import authorization for medical devices that are not registered (available on CInMED portal);
    2) Justification, or statement of the proposer of an unregistered medical device import (available on CInMED portal);
    3) declaration of conformity and/or certificate of conformity of an unregistered medical device or proof that equivalent safety and performance assessment has been carried out for unregistered medical device for which no conformity assessment was carried out by a notified body, i.e. a manufacturer seated in the EEA member state;

4) Free sale certificate, or certificate issued by an authorized body ISO 13485 for class I medical devices, other in vitro diagnostic medical devices and class A in vitro diagnostic medical devices;
5) translation of instructions for use of unregistered medical device into Montenegrin and into languages that are in official use in Montenegro, signed by a medical doctor of appropriate specialty for the medical device that the patient uses independently;
6) pro-forma invoice of the supplier;
7) other information at the request of the Institute, in accordance with the Law.

Certificate of conformity for an unregistered medical device shall not be submitted for medical devices of class I, Other-In vitro diagnostic medical devices and in vitro diagnostic medical devices of class A.

Equivalent safety and performance assessment implies that a conformity assessment is carried out in a member state of the International Medical Device Regulators Forum.

Justified proposal for import and the statement of the responsible person shall be submitted on forms published on the portal of the Institute.

11. Documents required are related to the quantity of the imported products and the date of the import. For medicines and medical devices additional documentation upon import is not required.

12. The fees for issuing import licenses are defined by following Decisions:

- Decision on the payment method and amount of fees for the exercise of competences of the Institute for Medicines and Medical Devices that are determined by the law; and
- Decision on the mode of payment and amount of fees for entering and removing medical devices, manufacturers and legal persons that market and import medical devices into and from the Register, as well as keeping the Register (Official Gazette of Montenegro No. 78/2009).

In line with Decision on the payment method and amount of fees for the exercise of competences of the Institute for Medicines and Medical Devices that are determined by the law:

- Fee for import licenses for human medicines that do not have marketing authorisation is €150.
- Amount of the fee for issuance of approval for the import of veterinary medicines that do not have marketing authorisation is, for:

Name of the service	**Price (EUR)**
– up to 6 medicines	60,00
– from 7 to 10 medicines	100,00
– from 11 to 20 medicines	150,00
– more than 20 medicines	200,00

In line with Decision on the mode of payment and amount of fees for entering and removing medical devices, manufacturers and legal persons that market and import medical devices into and from the Register, as well as keeping the Register (Official Gazette of Montenegro No. 78/2009) fees for import licences for medical devices is determined based on the total value of the requested import:

Import value	**Fees (EUR)**
up to 5,000 EUR	60
from 5,000 up to 50,000 EUR	125
from 50,000 up to 250,000 EUR	250
from 250,000 up to 500,000 EUR	500
from 500,000 up to 1,000,000 EUR	1,000

13. No.

Conditions of Licensing

14. Period of validity of an import license for medicines is until the end of the import of the quantities indicated in the import license and it is valid for a multiple import.

Period of validity of an import license for veterinary medicines is three months from the date of issuance and is valid for a multiple import.

Period of validity of an import license for medical devices is three months from the date of issuance and is valid for a multiple import.

Licenses could not be extended but request for a new license can be submitted.

15. No, there is not a penalty for the non-utilization of a license or a portion of a license.

16. Licenses are not transferable between importers.

17.(b)No other conditions attached.

Other Procedural Requirements

18. No.

19. N/A.

2.2 Controlled substances (drugs, precursors and medicines containing precursors)

Outline of System

1. Institute for Medicines and Medical Devices (hereinafter: Institute) issues authorisations for the import of: medicines classified as drugs (hereinafter: drugs), precursors and medicines containing precursors. Authorisations are issued in accordance with the following legislation:

- Law on Medicines ("Official Gazette of Montenegro", No. 080/20);
- 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 and No. 40/11);
- Law about preventing of drug abuse ("Official Gazette of Montenegro", No. 28/11 and No. 35/13);
- Law on administrative procedure ("Official Gazette of Montenegro", No. 056/14, No. 020/15, No. 040/16 and No. 037/17).

Purposes and Coverage of Licensing

2. Institute issues import licenses for the following products:

- controlled substances (drugs, precursors and medicines containing precursors).

3. The system is related to the goods originating/coming from any country.

4. There is an annual quota for drugs, precursors and medicines containing precursors, such as pseudoephedrine, ephedrine and norephedrine in terms of quantity at the national level that cannot be exceeded. This quota, for each calendar year, is determined by the International Narcotics Control Board in Vienna (INCB), and authorisations for the import of mentioned controlled substances are issued according to it.

5. Issuance of import licenses is conducted in accordance with:

- Law on Medicines ("Official Gazette of Montenegro", No. 080/20);

- 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 and No. 40/11);
- Law about preventing of drug abuse ("Official Gazette of Montenegro", No. 28/11 and No. 35/13);
- Law on administrative procedure ("Official Gazette of Montenegro", No. 056/14, No. 020/15, No. 040/16 and No. 037/17).

Issuance of import licenses is obligatory and there is no possibility to issue the license based on administrative discretion.

The Article 8 of Law on Medicines ("Official Gazette of Montenegro", No. 080/20) envisages that Government of Montenegro may determine alternative procedure and conditions for the issuance of marketing authorisation for a medicine.

Procedures

6.I. Information on permitted annual quotas for import of drugs are published on the website of the International Narcotics Control Board (www.incb.com). Quotas are formed on the basis of needs for drugs, precursors and medicines containing precursors, such as pseudoephedrine, ephedrine and norephedrine individually on annual level that importers submit to the Institute. After processing these data, the Institute sends data to the Ministry of Health, which forward these data for the approval to the International Narcotics Control Board (INCB).

In cases where needs for controlled substances are increased in relation to the required annual quota, the Institute, through the Ministry of Health may, with an explanation, ask for an increase in quotas for certain drug, precursor and medicine containing precursors, such as pseudoephedrine, ephedrine and norephedrine.

All the information needed to obtain import authorisation for drugs (regulations, instructions and forms) the importer can find on the website of the Institute https://www.cinmed.me/.

II. The amount of quotas is determined annually by the International Narcotics Control Board. Application for an import may be submitted by necessity, with the condition not to exceed the quota, and the validity period of import authorisation for drugs is six months and for precursors and medicines containing precursors is 30 days, which are intended for single import.

III. The Institute sends one copy of the import license for drugs, precursors and medicines containing precursors to the Customs Administration, and after customs clearance of the goods, Customs returns this copy of the license to the Institute, which contain details of the realisation of imported products. The amount that has not been imported is not counted into the allowed quota. One copy of import authorisations for drugs is intended for importer, and one for the competent authority of the exporting country.

IV. Applications may be submitted immediately after publishing quotas.

V. The period needed for processing applications and issuing license for the import of drugs is up to 30 days but usually within seven days.

VI. Import can be done immediately after obtaining import license (date of issuance of the license is stated on the license).

VII. Processing of applications for import of drugs, precursors and medicines containing precursors is performed only by one administrative body – Institute for Medicines and Medical Devices.

VIII. If the demand for licenses cannot be completely fulfilled i.e., if a small amount is missing for fulfilling an annual quota, the applicant which did not import his stated year demand takes precedence over others for obtaining import license for a certain drug, precursor or medicines containing precursors such as pseudoephedrine, ephedrine and norephedrine (see answer to question I). Applications for import are processed according to the date of receipt, chronologically. The new importer who obtained wholesale license for marketing of drugs and precursors must submit annual demand for drugs before submitting an application for import.

IX. Import licenses are always needed, regardless of the fact that exporting countries issues export licenses. Import licenses are not issued automatically.

X. Not applicable.

XI. There have been no such cases so far. Legal provisions provide that the procedure for approving the import of drugs, precursor or medicines containing precursors is identical regardless of whether the product will be marketed in Montenegro or exported to other countries (which requires a special export license).

7.(a) - (d) Not applicable.

8. An application for a license may be rejected due to inadequate documentation on the product or the applicant and in other cases in accordance with relevant laws. Reasons for rejection of any kind are given to the applicant in the form of an appropriate legal act.

In case of rejection, the applicants have the right to appeal to the Administrative Court, in accordance with:

- Law on Medicines ("Official Gazette of Montenegro", No. 080/20);
- 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 and No. 40/11);
- Law about preventing of drug abuse ("Official Gazette of Montenegro", No. 28/11 and No. 35/13);
- Law on administrative procedure ("Official Gazette of Montenegro", No. 056/14, No. 020/15, No. 040/16 and No. 037/17).
-

Eligibility of Importers to Apply for License

9. There is a system of registration of legal persons that may perform import and marketing. Legal persons that import and market drugs and precursors additionally require a separate authorisation for wholesale of drugs or precursors.

Fees for issuance of licenses for the import and wholesale of all these products are defined by:

- Decision on the payment method and amount of fees for the exercise of competences of the Institute for Medicines and Medical Devices that are determined by the law.

A list of all legal persons that are authorised to perform import and marketing on the basis of authorisations issued by the Institute, is published on the website of the Institute https://www.cinmed.me/ and is regularly updated.

Documentational and Other Requirements for Application for License

10. The portal Institute https://www.cinmed.me/ contains all the data that must be listed on the application for import all product groups.

Documentation required for obtaining authorisation for import of narcotic drugs is consisted of the following:

1) The application cover letter;
2) Completed Application form for issuance of the import, export and transit authorisation for drugs (available on the CInMED web portal);
3) User's (applicant's) statement of the purpose;
4) Pro forma or forma invoice;
5) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine whose import is required.

Documentation required for obtaining authorisation for import of precursors and medicines containing precursors is consisted of the following:

1) The application cover letter;
2) Completed Application form for issuance of the import, export and transit authorisation for precursors and medicines containing precursors (available on the CInMED web portal);
3) User's (applicant's) statement of purpose;
4) Pro-forma invoice or forma invoice;
5) End user's statement of purpose of precursors, in accordance with the Rulebook on the form and content of statement of end user on the purpose of precursors ("Official Gazette of Montenegro", No. 4/2015) (applies only to precursors);
6) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine whose import is required.

11. Upon actual importation, additional documentation is required only for the products belonging to the group of controlled substances i.e. drugs and precursors and medicines containing precursors. Documents required are related to the quantity of the imported products and the date of the import.

12. The fees for issuing import licenses are defined by:

- Decision on the payment method and amount of fees for the exercise of competences of the Institute for Medicines and Medical Devices that are determined by the law.

In line with this Decision, fees for issuance of approval for import, transit or export of medicines containing drugs and import, transit, export or transport of precursors, in accordance with the regulations governing these areas, is €80.

13. No.

Conditions of Licensing

14. Period of validity of an import license for drugs is six months and is valid for a single import.

Period of validity of an import license for precursors and medicines containing precursors is 30 days and is valid for a single import.

Licenses could not be extended but request for a new license can be submitted.

15. No, there is not a penalty for the non-utilization of a license or a portion of a license.

16. Licenses are not transferable between importers.

17.(a) No other conditions attached.

Other Procedural Requirements

18. No.

19. N/A.

3 NATURE AND ENVIRONMENTAL PROTECTION AGENCY

3.1 Waste

Outline of System

1. Licenses for the transboundary movement of waste (import, export and transit) are issued in accordance with the Law on waste management (OG MNE, No. 64/11, No. 39/16) and Basel Convention on the Control of Transboundary movements of hazardous waste and their disposal (OG FRY-International agreements, No. 2/99). The import of hazardous waste is forbidden. The import of non-hazardous waste to remove and use as fuel or other means to generate energy is forbidden as well.

Purposes and coverage of licensing

2. Import licenses are required for:
- Transboundary movement of waste (import, export and transit of waste);

3. The system applies to goods originating and coming from all countries.

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. For waste management the licensing intends to control the quantity of imports because it is related to the protection of the environment and fulfilling the obligation in accordance with the international agreement: Basel Convention. No alternative methods were considered.

5. The licensing is maintained in accordance with:

- The Law on waste management ("OG MNE", No. 64/11, No. 39/16);
- The Law on Confirmation of the Basel Convention on the Control of Transboundary Movements of Dangerous Waste and Their Disposal ("OG FRY"-International agreements, No. 2/99);
- The Rulebook on the content of documentation submitted in support of the application for the permit for import, export and transit of waste, as well as lists of waste classification and the content and manner of keeping a register of issued licenses ("OG MNE", No. 83/16, No. 76/16).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.a) There is no fixed time-limit for submitting an application before importation. In accordance with the Law on Administrative Procedure length of time for processing application is 30 day from the day of receipt of the official request. License could be obtained in a shorter period than 30 days if all required documents are submitted.

(b) There is no such possibility.

(c) There are no such limitations.

(d) NEPA is a Single administrative body in charge of consideration of license applications.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Economic Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for license

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licenses. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for licence

10. The application for permit for import of non-hazardous waste, only for the purpose of its processing, must contain the following:

- Documentation of signs and types of waste from the list of non-hazardous waste;
- An agreement between importers and exporters of waste with validity period until the completion of delivery of waste and with financial guarantees or insurance policy or other form of insurance in the case of return in the country of export;
- An agreement between importers and processors of waste, in case that the importer is not the waste processor;
- Proof that the importer of waste is registered for import activities;
- Information on methods for transport and shipment of waste (at once or in several shipments);
- Information on the border crossing point on which imports will be made, the time of arrival of waste on border crossing point, route of waste movement from the border customs office to processors; and,
- Proof of the administrative fee payment.

11. Importer must present valid license issued by NEPA along with standard customs documentation.

12. There are administrative fees as follows:

- Administrative fee in the amount of €2 for non-hazardous waste.

13. There is no deposit or advance payment associated with the issue of licenses.

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. The licenses are not transferable between importers.

17. There are no other conditions attached to the issue of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

3.2 Ozone depleting substances and alternative substances

Outline of System

1. Permits for import/export of ozone depleting substances and alternative substances are issued in accordance with the Law on the Protection against Adverse Impacts of Climate Change (Official Gazette of MNE, No. 073/19, dated 27 December 2019). and the Decree on ozone depleting substances and alternative substances (OG MNE, No. 5/11). Also, on 23 October 2006 Montenegro ratified by means of succession the Vienna Convention on ozone layer protection, the Montreal Protocol on ozone depleted substances and the Amendments to the Montreal Protocol. One of the obligations under the Montreal protocol was to establish import/export Montenegro to control consumption of ozone depleting substances. Montenegro operated under Article 5 of Montreal protocol and it is in compliance with the provisions of the Protocol.

Purposes and coverage of licensing

2. Import licenses are required for:

- Ozone depleting substances and alternative substances;

3. The system applies to goods originating and coming from all countries. Import is forbidden for countries that are not parties to the Montreal protocol on ozone depleting substances.

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. In the case of ozone depleting substances, the licensing intends to control the quantity of imports because it is related to the protection of the environment and fulfilling the obligation in accordance with the international agreements: the Vienna Convention and the Montreal Protocol. No alternative methods were considered.

5. The licensing is maintained in accordance with:

- Law on the Protection against Adverse Impacts of Climate Change (Official Gazette of MNE, No. 073/19, dated 27 December 2019);
- The Decree on ozone depleting substances and alternative substances ("OG MNE", No. 5/11);
- The Law on ratification of The Vienna Convention for the Protection of the Ozone Layer with Annexes I and II ("Official Gazette of SFRJ" – International agreements, No. 1/90);
- The Law on ratification of The Montreal Protocol on Substances that Deplete the Ozone Layer ("Official Gazette of SFRJ" – International agreements, No. 16/90);
- The Law on ratification of the Amendments to The Montreal Protocol on Substances that Deplete the Ozone Layer ("Official Gazette of Serbia and Montenegro" - International agreements, No. 24/04).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6.I. Imports of ozone depleting substances (ODS) are under the quota system. Procedure for quota system for import of the ozone depleting substances are prescribed by the Decree on ozone depleting substances and alternative substances ("OG MNE", No. 5/11).

II. A quota for import of ozone depleting substances is determined on an annual basis and written application of importer for setting annual quota have to be submitted to the NEPA not later than 1 December of the current year for the following year. The licenses for import are issued for each import separately.

III. The licenses are not allotted for certain goods partly or only to domestic procedures of like goods. Legal person or entrepreneur performing the imports of ODS are obligated to submit proof to the NEPA Unified Customs Document of imported or exported amounts of ODS for each issued permit, not later than three days after the performed import or export of such substances. Unused allocations are not added to quotas for the next year. Also, all issued licenses are published on the NEPA web site.

IV. Written application of importer for setting annual quota for ODS imports, have to be submitted to the NEPA not later than 1 December of the current year for the following year. An application for obtaining import permit for import of ODS could be submitted as soon as quotas are allocated for the year for which the quota is allocated.

V. Length of time for processing application is prescribed by the Law on Administrative Procedure. Processing time is up to 30 days.

VI. Import can be done immediately after obtaining import license (date of issuance of the license is stated on the license).

VII. NEPA is a Single administrative body for consideration of license applications.

VIII. Quotas usually satisfy demand, as they are referred to substances whose consumption is phasing out. All applications are examined simultaneously and allocation of quota is made on the past performance. In the case of new importers of ODS, they will be given 10% from total annual quota. This is in accordance with the recommendation and experience from EU and region countries.

IX. Not applicable.

X. Through the communication between country authorities in charge of the implementation of the Montreal Protocol.

XI. There are no such products.

7.(a)-(d) Not applicable.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Sustainable Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for license

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licenses. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for license

10. The application for import of ozone depleting substances and alternatives substances must contain the following:

- Written request for permits for import/export of ozone depleting substances and alternatives substances which contains the following information: name and type of goods; heading tag or label of goods tariff; the amount of goods in units of measure; information about the person who imports and exports the goods (name, address, registration, and registration number); indication of the state of origin of goods; the name of the company that supplied the goods and the country from which goods are supplied; border crossing;
- A copy of the invoice or pro-invoice companies that supplied goods; and
- Evidence that the importer / exporter is registered to carry out these activities;
- Proof of the administrative fee payment.

11. Importer must present valid license issued by NEPA along with standard customs documentation.
12. There are administrative fees as follows:

- Administrative fee in the amount of €40 for each imported consignment of ozone depleting substances;

13. There is no deposit or advance payment associated with the issue of licenses.

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year. In case of import of chemicals and ozone depleting substances and alternative substances the license is valid for the period specified in the license, or until the end of the current year.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. The licenses are not transferable between importers.

17. There are no other conditions attached to the issue of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

3.3 Endangered and protected species of flora and fauna

Outline of System

1. Permits for import of species and their products and derivates are issued in accordance with the Law on nature protection (OG MNE, No. 054/16) and the CITES Convention. By means of succession, on 3 June 2007, Montenegro ratified the CITES Convention. Montenegro operates under Articles 1 to 25 of the CITES Convention and it is in compliance with the CITES provisions.

Purposes and coverage of licensing

2. Import licenses are required for:

- Endangered and protected species of wild flora and fauna their products and derivates;
- Endangered and protected species of wild flora and fauna their products and derivates in accordance with the CITES Convention and protected plant, animal and fungus species (examples of wild plants, fungi and animals from free and their cultivated specimens; their development forms -eggs, seeds, fruits, mycelium, etc.; their parts and derivatives; therefrom easily recognizable products) in accordance with the Law of Nature Protection.

3. The system applies to goods originating and coming from all countries. Import is forbidden for countries that are not parties to the CITES Convention.

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. In case of CITES, the licensing intends to control the quantity of imports because it is related to the protection of the environment and fulfilling the obligation in accordance with the international agreements: CITES Convention. No alternative methods were considered.

5. The licensing is maintained in accordance with:

- The Law on Confirmation of the CITES Convention on International Trade of Endangered Species of Wild Fauna and Flora ("OG FRY", International agreements, No. 11/01);
- The Nature Protection Act ("OG MNE", No. 054/16);
- The Ordinance on closer conditions for the trade in protected wild species of plants, animals and fungi ("OG MNE", No. 109/17).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6.I. Information regarding CITES species quotas can be found at CITES website (http://www.cites.org/) and formalities of filing applications for licenses can be found at Nature and Environment Protection Agency (NEPA) website (http://www.epa.org.me/). Information regarding other questions is not applicable.

II. System of quotas for CITES permits is not established in Montenegro.

III. The licenses are not allotted for certain goods partly or only to domestic procedures of like goods. Also, all issued licenses are published on the NEPA web site. The copy of the CITES license with Customs Administration signature and seal.

IV. Not applicable.

V. Length of time for processing application is prescribed by the Law on Administrative Procedure. Processing time is up to 30 days.

VI. Import can be done immediately after obtaining import license (date of issuance of the license is stated on the license).

VII. NEPA is a Single administrative body for consideration of license applications.

VIII. Not applicable.

IX. Not applicable.

X. Through the communication between country authorities in charge of the implementation of the CITES Convention.

XI. There are no such products.

7.(a)-(d) Not applicable.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Economic Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for license

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licenses.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee;
- There is no published list of authorized operators.

Documentation and other requirements for application for license

10. The application for import of CITES listed species and their products and derivates has to contain the following:

- Application for issuance of CITES import permit;
- Copy of CITES export permit;

- Positive opinion of Montenegrin scientific authorities that import of species will not jeopardize survival of that species and sustainability of biodiversity in Montenegro;
- Positive opinion of Montenegrin scientific authorities that imported species will be properly accommodated;
- Statement by the importer regarding the mode of species transport and using purposes;
- Proof of administrative fee payment;
- Additional documents according to Law on nature protection and Law on foreign trade.

Written request for permits for plant, animal and fungus species has to contain the following information:

- Name and seat, or the name and address of the importer;
- The name of the input border crossing;
- Day and start time of importation;
- Quantity;
- Provider/supplier (quantity);
- A court certificate; and
- Proof of the administrative fee payment.

11. Importer must present valid license issued by NEPA along with standard customs documentation.

12. There are administrative fees as follows:

- Administrative fee in the amount of €50 for each imported consignment of CITES species/products/derivates (1 CITES import permit).

13. There is no deposit or advance payment associated with the issue of licenses.

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. The licenses are not transferable between importers.

17. There are no other conditions attached to the issue of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

3.4 Hazardous chemicals

Outline of System

1. Permits for free movement of hazardous chemicals and adding biocide into a temporary list of biocides are issued in accordance with the Law on chemicals (OG MNE, No. 51/17) and the Law on biocidal products ("OG MNE", No. 54/16).

Purposes and coverage of licensing

2. Import licenses are required for:

- Free movement of hazardous chemicals and adding biocide into a temporary list of biocides.

3. The system applies to goods originating and coming from all countries.

The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. No alternative methods were considered.

The licensing is maintained in accordance with:

- The Law on chemicals ("OG MNE", No. 51/17);
- The Law on biocidal products ("OG MNE", No. 54/16);
- The Rulebook on detailed conditions for storage and measures for safe keeping and use of hazardous chemicals ("OG MNE", No. 61/18);
- The Decree on prohibition and restriction of the use, placing on the market and production of chemicals that presenting an unacceptable risk to human health and the environment ("OG MNE", No. 70/18);
- The Rulebook on detailed contents of prior notification for export of chemicals ("OG of MNE", No. 061/17);
- The Rulebook on list of dangerous chemicals and products which export is prohibited ("OG of MNE", No. 071/18);
- The Rulebook on conditions for placing biocidal products on the market and use ("OG MNE", No. 059/16);
- The Rulebook on content of the application for issuing permit for biocides ("OG MNE", No. 017/17);
- The Rulebook on the contents of the technical dossier and the basic data for biocides ("OG MNE", No. 005/17, 9/18);
- The Foreign Trade Law ("Official Gazette of Republic Montenegro (OG RMNE)", No. 28/04, No. 37/07 and "OG MNE", No. 57/14);
- Decision to amend National Control list for export and import (OG MNE No. 40/20);
- The Law on Administrative Procedure ("OG MNE", No. 56/14, No. 20/15, No. 40/16, No. 37/17);
- The Decree on the implementation of the Foreign Trade Law ("OG RMNE", No. 52/04, No. 44/07 and ("OG MNE", No. 78/2017).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.(a) There is no fixed time-limit for submitting an application before importation. In accordance with the Law on Administrative Procedure length of time for processing application is 30 day from the day of receipt of the official request. License could be obtained in a shorter period than 30 days if all required documents are submitted.

(b) There is no such possibility.

(c) There are no such limitations.

(d) NEPA is a Single administrative body in charge of consideration of license applications.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Economic Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for license

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licenses. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for license

10. Written request for permits for free movement of hazardous chemicals has to contain the following information:

- Name and seat, or the name and address of the supplier, trade name and chemical name and address of the manufacturers of chemicals;
- Information on the method of packaging and labelling of chemicals;
- Information on the purpose and use of chemicals;
- Data on the quantity of chemicals;
- Information on the method of storage (location, description of facilities);
- Measures to be implemented for the safe keeping and storage of chemicals;
- Other information requested by the NEPA;
- Contract of insurance against liability for any damage that may result from the use of chemicals;
- Proof of the administrative fee payment.

For the request to adding the biocide into a temporary list of biocides, the applicant has to submit the basic information about the biocide:

- The name of the biocide's manufacturer;
- Authorized representative of the biocide's manufacturer;
- Identity of biocides and active substances in the biocide;
- Effectiveness of biocides;
- The content of the declaration;
- The method of use;
- Classification, packaging and labelling of biocides;
- Annex 4 of Rulebook on the contents of the technical dossier and the basic data for the biocide; and
- Proof of the administrative fee payment.

11. Importer must present valid license issued by NEPA along with standard customs documentation.

12. There are administrative fees as follows:

- Administrative fee in in the amount of €40 for chemicals.

13. There is no deposit or advance payment associated with the issue of licenses.

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year. In case of import of chemicals and ozone depleted substances and alternative substances the license is valid for the period specified in the license, or until the end of the current year.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. The licenses are not transferable between importers.

17. There are no other conditions attached to the issue of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

3.5 Ionizing radiation generators and radioactive sources for spare parts for devices that produce ionizing radiation

Outline of System

1. Permits for importing ionizing radiation generators, for radioactive sources for spare parts for devices that produce ionizing radiation are issued in accordance with the Law on ionizing radiation protection and radiation safety (OG MNE, No. 56/09, 58/09).

Purposes and coverage of licensing

2. Import licenses are required for:

- Generators of ionizing radiation, radioactive sources and spare parts for devices that produce ionizing radiation.

3. The system applies to goods originating and coming from all countries.

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. No alternative methods were considered.

5. The licensing is maintained in accordance with:

- The Law on ionizing radiation protection and radiation safety ("OG RMNE", No. 56/09, No. 58/09).
- The Foreign Trade Law ("Official Gazette of Republic Montenegro (OG RMNE)", No. 28/04, No. 37/07 and "OG MNE", No. 57/14);
- Decision to amend National Control list for export and import (OG MNE No.40/20);
- The Decree on the implementation of the Foreign Trade Law ("OG RMNE", No. 52/04, No. 44/07 and ("OG MNE", No. 78/2017);
- The Law on Administrative Procedure ("OG MNE", No. 56/14, No. 20/15, No. 40/16, No. 37/17).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.(a) There is no fixed time-limit for submitting an application before importation. In accordance with the Law on Administrative Procedure length of time for processing application is 30 day from the day of receipt of the official request. License could be obtained in a shorter period than 30 days if all required documents are submitted.

(b) There is no such possibility.
(c) There are no such limitations.

(d) NEPA is a Single administrative body in charge of consideration of license applications.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Economic Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for license

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licenses. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee;
- There is no published list of authorized operators.

Documentation and other requirements for application for license

10. As regards the ionizing radiation, the request has to include basic information about the goods to be imported; a general application form does not exist. The importer must submit the following:

- Proof that the facilities and rooms where trading in ionizing radiation sources or radioactive material is performed in comply with technical, secure, safe, sanitary and other prescribed requirements ensuring health and protection of people and the environment against ionizing radiation;
- Proof that there is an employee in charge for protection against ionizing radiation;
- Proof that persons operating ionizing radiation sources are provided with adequate ionizing radiation protection equipment, as well as equipment for radiation measurements;
- Proof that all persons operating ionizing radiation sources have professional qualification required and satisfy prescribed health requirements for work with ionizing radiation sources;
- Certificate on technical/technological integrity of ionizing radiation source, obtained by the competent authority;
- Instruction for action in case of radiation accident;
- Proof that radioactive materials x-ray devices or other devices producing ionizing radiation are secured in accordance with prescribed requirements for their trading.

11. Importer must present valid license issued by NEPA along with standard customs documentation. When it comes to ionising radiation, in addition to above mentioned, complete technical documentation of the device is required.

12. There are administrative fees as follows:

- Administrative fee in the amount of €100 for ionising radiation.

13. There is no deposit or advance payment associated with the issue of licenses.

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year. When it comes to ionising radiation, the license is valid up to one year and cannot be extended.

15. There is no penalty for non-utilization of a license or a portion of a license.

16. The licenses are not transferable between importers.

17. There are no other conditions attached to the issue of a license.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.