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Pursuant to Article 20 paragraph 2 and Article 29 paragraph 4 of 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", number 83/09), the Ministry of Health hereby issues the

RULEBOOK

ON THE CONTENTS AND MANNER OF KEEPING RECORDS OF LEGAL ENTITIES ENGAGED IN MANUFACTURE AND/OR TRADE OF PRECURSOR AND THE REGISTER OF LEGAL ENTITIES PERFORMING MANUFACTURE, TRADE, IMPORT, EXPORT, TRANSIT AND TRANSPORT OF PRECURSORS, AS WELL AS THE SPECIAL REGISTER OF ISSUED AUTHORIZATIONS

Article 1

This Rulebook shall lay down the contents and manner of keeping records of legal entities engaged in manufacture and/or trade of precursors, register of legal entities performing manufacture, trade, import, export, transit and transport of precursors (hereinafter referred to as: Register of legal entities), as well as the special register of issued authorizations (hereinafter referred to as: Register of issued authorizations).

Article 2

Records of legal entities engaged in manufacture and/or trade of precursors shall contain the following:

- 1) name and address of legal entity (phone, fax, e-mail);
- 2) full name of a responsible person;
- 3) authorization title;
- 4) number and date of the authorization;
- 5) period of authorization validity;
- 6) activities of legal entity (manufacture, trade);
- 7) address of manufacturing site, that is, of storing site;
- 8) trade name of preparation;
- 9) name of precursor in accordance with the regulation governing the list of precursors, number from the International Register of Chemicals (CAS number) and HS number;
- 10) anhydrous base content in percentages (%);
- 11) total quantity of precursors given in appropriate unit of measurement (kg, l, etc.) manufactured by a legal entity inyear;
- 12) total quantity of imported precursors given in appropriate unit of measurement (kg, l, etc.) inyear;
- 13) total quantity of exported precursors given in appropriate unit of measurement (kg, l, etc.) inyear;
- 14) total quantity of precursors given in appropriate unit of measurement (kg, l, etc.) that a legal entity delivered to legal entities in Montenegro inyear;
- 15) total quantity of precursors given in appropriate unit of measurement (kg, l, etc.) that a legal entity traded inyear;

Article 3

Records referred to in Article 2 of this Rulebook shall be kept in writing or in electronic form provided in Annex 1, which make an integral part of this Rulebook.

Article 4

Register of legal entities shall contain:

- 1) ordinal number of registration;
- 2) registration date;
- 3) name and address of legal entity (phone, fax, e-mail);
- 4) full name of a responsible person;
- 5) authorization title;
- 6) number and date of authorization;
- 7) authorization validity period;
- 8) activities of legal entity (manufacture, trade, import, export, transit, transport);
- 9) address of manufacturing site, that is, storing site;
- 10) name of precursor in accordance with the regulation governing the list of precursors, number from the International Register of Chemicals (CAS number) and HS number;
- 11) anhydrous base content in percentages (%);
- 12) total quantity of precursors given in appropriate unit of measurement (kg, l, etc.);
- 13) changes and date of changes;
- 14) notes.

Article 5

Register of issued authorizations shall contain:

- 1) ordinal number of registration;
- 2) registration date;
- 3) type of authorization (manufacture, trade, import, export, transit, transport);
- 4) number and date of the application for issuing the authorization;
- 5) number and date of the authorization;
- 6) authorization validity period;
- 7) name and address of a legal entity the authorization has been issued to;
- 8) trade name of the preparation;
- 9) name of precursor in accordance with the regulation governing the list of precursors, number from the International Register of Chemicals (CAS number) and HS number;
- 10) precursors' anhydrous base content in percentages (%);
- 11) total quantity of precursors given in appropriate unit of measurement (kg, l, etc.);
- 12) name of the authority issuing the authorization;
- 13) name and address of exporter and name of the country the precursor is exported from;
- 14) name and address of importer and name of the country the precursor is imported to;
- 15) number and date of a authorization renewal request;
- 16) number and date of a renewed authorization;
- 17) number and date of the decision on revoking the authorization;
- 18) changes and date of changes;
- 19) notes.

Article 6

Register of legal entities and Register of issued authorizations (hereinafter referred to as: Register) shall be kept in writing or in electronic form.

Article 7

Register, in writing, shall be kept in a form of a hard binding book composed of registration sheets whose pages shall be enumerated.

On the front side of the cover of the Register of Legal Entities there shall be the coat of arms of Montenegro, with the Ministry of Health inscribed below it, that is, the Agency for Medicines and Medical Devices, and in the middle there shall be the name of "**Register of legal entities**"

performing manufacture, trade, import, transit and transport of precursors” and ordinal number of _____Register.

On the front side of the cover of the Register of Issued Authorizations there shall be the coat of arms of Montenegro, with the Ministry of Health inscribed below it, that is, the Agency for Medicines and Medical Devices and in the mid part there shall be the name of “**Register of Issued Authorizations**” and ordinal number of _____Register.

Article 8

Data shall be entered into the Register on the basis of authorizations for manufacture, trade, import, export, transit and transport of precursors.

Article 9

Data in the Register should be clear and readable and cannot be deleted.

Errors shall be corrected in a way that wrongly entered word or data should be strike through with two horizontal lines in a way that a wrongly entered word or data remain readable, and a new entry shall be provided next to it or above the one that has been strike through.

In case of a major error, the whole entry shall be annulled by striking it through by red slash and entry shall be made on the first available registration sheet.

A new entry shall be certified by signature of an authorized officer and affixed stamp of the state administration authority competent for health issues, that is, of administrative authority competent for medicines and medical devices.

Article 10

Changes incurred after the first entry into the Register shall be registered into the column “changes” according to the date of the change, with designation of a number and date of the decision of authority competent for making the decision about the change.

Following the entry of new data, the column containing the old data shall be stroke through by slash.

Article 11

This Rulebook shall enter into force on the eight day of its publication in the “Official Gazette of Montenegro”.

Number: 011-152/2015

Podgorica, 19 June 2015

Minister

Prof.dr Budimir Segrt, handwritten signature

Annex 1

RECORDS OF LEGAL ENTITIES ENGAGED IN MANUFACTURE AND/OR TRADE OF PRECURSORS

1. Name and address of legal entity (phone, fax, e-mail)	
2. Full name of a responsible person	
3. Name of authorization	
4. Number and date of authorization	
5. Period of authorization validity	
6. Activity (manufacture, trade)	
7. Address of the manufacturing site, that is, storing site	
8. Trade name of preparation	
9. Name of precursor in accordance with the regulation governing the list of precursors, number from the International Register of Chemicals (CAS number) and HS number	
10. anhydrous base content in percentages (%);	
11. total quantity of precursors given in appropriate unit of measurement (kg, l, etc.) manufactured by a legal entity in ____year;	
12. total quantity of imported precursors given in appropriate unit of measurement (kg,l, etc.)in ____year;	
13. total quantity of exported precursors given in appropriate unit of measurement (kg,l, etc.)in ____year;	
14. total quantity of precursors given in appropriate unit of measurement (kg, l, etc.) that a legal entity delivered to legal entities in Montenegro in ____year;	
15. total quantity of precursors given in appropriate unit of measurement (kg, l, etc.) that a legal entity traded in ____year;	