Pursuant to articles 93 and 107 of the Law on Medicines ("Official Gazette of Montenegro", No 56/11), Ministry of Health passes the following:

RULEBOOK ON THE FORM, CONTENT, MANNER AND PERIOD OF REPORTING ON SALE OF MEDICINES

Article 1

Report on total value of sale of all medicines, as well as on the amount of sale of all medicines separately (per packaging) in Montenegro and period for which the report is submitted (hereinafter: Report), shall be submitted in the form and content determined by this Rulebook.

Article 2

The report from article 1 of this Rulebook shall be, in accordance to the Law, submitted to the Agency for Medicines and Medical Devices (hereinafter: Agency) by manufacturers of medicines, marketing authorization holders and by pharmacies and veterinary facilities.
Manufacturers of medicines, marketing authorization holders, pharmacies and veterinary facilities shall submit the report to the Agency according to the Anatomical Therapeutic Chemical classification code of medicines (ATC), i.e. to the ATC veterinary classification code (ATC vet) for the medicine used in veterinary medicine, prescribed by World Health Organisation and which is valid for the year which the report refers to.

Article 3

The report from article 1 of this Rulebook shall be submitted for medicines used both in human and veterinary medicine.
Reports from article 1 of this Rulebook shall be submitted on templates (Templates 1 and 2) which are constituent part of this Rulebook.

Article 4

The report for medicines used in human medicine contains:
1) code of the medicine;
2) code in health information system ;
3) ATC classification;
4) international nonproprietal name of the medicine (INN);
5) name of finished medicine;
6) pharmaceutical form;
7) quantity of pharmaceutical form in packaging;

8) strength of the medicine;
9) total volume;
10) name of the manufacturer;
11) data on registration of the medicine (whether it has been granted marketing authorisation or not);
12) mode of dispensing of the medicine: with or without perscription;
13) data on whether dispensing of the medicine is covered by Health Insurance Fund;
14) number of packagings dispensed/sold to patients;
15) number of packagings delivered to pharmacies;
16) number of packagings delivered to other wholesalers;
17) number of packagings delivered to Clinical Centre of Montenegro;
18) number of packagings delivered to hospitals;
19) number of packagings delivered to other health institutions;
20) unit of measure of packaging-code;
21) unit of measure of packaging-name;
22) wholesale price for each finished medicine in euros;
23) retail price for each finished medicine in euros;
24) site of delivery (municipality) of finished medicine in wholesale.

The report for medicines used in veterinary medicine contains:
1) code of the medicine;
2) ATC vet classification;
3) international nonproprietal name of the medicine (INN);
4) name of finished medicine;
5) pharmaceutical form;
6) quantity of pharmaceutical form in packaging;
7) strength of the medicine;
8) total volume;
9) name of the manufacturer;
10) data on registration of the medicine (whether it has been granted marketing authorisation or not);
11) mode of dispensing of the medicine: with or without perscription;
12) number of packagings dispensed/sold to users;
13) number of packagings delivered to other wholesalers;
14) number of packagings delivered to the Veterinary Administration;
15) number of packagings delivered toveterinary ambulances;
16) number of packagings delivered to other veterinary facilities;
17) unit of measure of packaging-code;
18) unit of measure of packaging-name;
19) wholesale price for each finished medicine in euros;
20) retail price for each finished medicine in euros;
21) site of delivery (municipality) of finished medicine in wholesale.

Article 5

Manufacturers of medicines, marketing authorization holders, pharmacies and veterinary facilities shall submit the report to the Agency at least once a year, not later than 1 February of current year for medicines for veterinary use, and not later than 1 March of current year for medicines for human use for previous year, or even more often, if required by the Agency.

Article 6

The report shall be submitted to the Agency in both written and electronic form.
The report shall be accompanied by cover letter contaning:
- logo, name, register number and address of legal person;
- date and signature of the person responsible for data from the report.

Article 7

On the basis of submitted reports, the Agency shall process data on total sale of medicines in Montenegro, namely:
1) total consumption by ATC classification of medicines expressed in number of defined daily doses per 1000 inhabitants per day (hereinafter: DDD/1000/day);
2) total consumption by ATC classification or ATC vet classification expressed in total amount in eurous according to wholesale and retail prices;
3) in-patient consumption expressed in number of DDD/1000/day;
4) in-patient consumption expressed in total amount in eurous according to wholesale prices;
5) out-patient consumption expressed in number of DDD/1000/day;
6) out-patient consumption expressed in total amount in euros according to wholesale prices;
7) consumption of finished medicines covered by Health Insurance Fund;
8) consumption of finished medicines which are not covered by Health Insurance Fund.

Daily defined dose established by the World Health Organization for the year which the report refers to is used to calculate number of DDD/1000/day

In the event that there are no data for defined daily dose prescribed by the World Health Organization, only medicine consumption in euros shall be stated.

Article 8

The Agency shall process data not later than 31 December of current year, for previous year.

Article 9

This Rulebook shall come into force on the 8th after being published the "Official Gazette of Montenegro."

No: 03-3463/2
Podgorica, 27 December 2012

Minister,
prof. dr Miodrag Radunović, m.p.

Table presenting marketing of medicines for human use, Template 1, page 1/3

Code of the medicine	Code in Health Information System	ATC Classification	International nonproprietary name (INN)	Name of the finished medicine	Pharmaceutical form of the medicine	Quantity of pharmaceutical form per packaging	Strength of the medicine	Total volume	Name of the manufacturer	Data on the registration of the medicine (yes/no)	Mode of dispensing medicine	Data on whether the medicine is covered by HIF

Template 1, page 2/3

Number of packagings dispensed/sold to the patients	Number of packagings delivered to the pharmacies	Number of packagings delivered to other wholesalers	Number of packagings delivered to Clinical Cenre	Number of packagings delivered to hospitals	Number of packagings delivered to other health institutions	Unit of measure of packaging - code	Unit of measure of packaging - name	Whole sale price – in euros for each finished medicine	Retail price – in euros for each finished medicine	Andrijevica	Bar	Berane	Bijelo Polje	Budva

Template 1, page 3/3

Cetinje	Danilovgrad	Herceg Novi	Kolašin	Kotor	Mojkovač	Nikšić	Plav	Plužine	Pljevlja	Podgorica	Rožaje	Tivat	Ulcinj	Šavnik	Žabljak

Table presenting marketing of medicines for veterinary use, Template 2, page 1/3

Code of the medicine	ATC vet classification	International nonproprietary name	Name of finished medicine	Pharmaceutical form	Quantity of pharmaceutical form per packaging	Strength of the medicine	Total volume	Name of the manufacturer	Data on the registration of the medicine (yes/no)	Mode of dispensing medicine

Template 2, page 2/3

Number of packagings dispensed/sold to the users	Number of packagings delivered to other wholesalers	Number of packagings delivered to Veterinary Administration	Number of packagings delivered to veterinary ambulances	Number of packagings delivered to other veterinary facilities	Unit of measure of packaging - code	Unit of measure of packaging - name	Wholesale price – in euros for each finished medicine	Retail price – in euros for each finished medicine	Andrijevica	Bar	Berane	Bijelo Polje	Budva

Template 2, page 3/3

Cetinje	Danilovgrad	Herceg Novi	Kolašin	Kotor	Mojkovač	Nikšić	Plav	Plužine	Pljevlja	Podgorica	Rožaje	Ti vat	Ulcinj	Šavnik	Žabljak