Pursuant to Article 11 of the Law on Medicines („Official Gazette of Montenegro", No 56/11 and 6/13), the Agency for Medicines and Medical Devices has passed

DECISION ON THE PAYMENT METHOD AND FEES FOR ISSUANCE OF AUTHORISATIONS, CERTIFICATES AND APPROVALS FOR MANUFACTURE AND MARKETING OF MEDICINES

Article 1

Payment method and fees corresponding to actual costs of performed tasks in the procedure of issuance of authorisations, certificates and approvals from the Article 8 of the Law on Medicines, are determined by this Decision.

Article 2

Applicant shall submit evidence on payment of prescribed fee, along with the application for issuance of authorisations, certificates and approvals referred to in Article 1 of this Decision.

Article 3

Applicant who, within seven days from the receipt of the confirmation of formal assessment of the documentation, informs the Agency for Medicines and Medical Devices (hereinafter: Agency) in writing, on withdrawing the application, shall be returned the fee reduced by 30% compared to the amount paid.

Applicant who, within seven days from the submission of the application for issuance of authorisations, certificates and approvals referred to in Article 1 of this Decision for which formal assessment is not prescribed, informs the Agency in writing, on withdrawing the application, shall be returned the fee reduced by 30% compared to the amount paid.

If the applicant withdraws in writing the application for the issuance authorisations, certificates and approvals after the expiry of time limit referred to in paragraphs 1 and 2 of this Article shall bear the costs in the amount determined by this Decision for that kind of act.

Article 4

1. Fee for issuance of marketing authorisation for human medicine based on complete documentation in accordance with Article 31 of the Law is as follows:

1) for applications submitted to the Agency the same time	EUR
- one pharmaceutical form, strength and packaging of the medicine	2.000
- additional pharmaceutical form	1.200
- additional strength of the same pharmaceutical form	900
- additional type of packaging of the same pharmaceutical form and strength	400
- additional packaging size of the same pharmaceutical form and strength	400
2) for applications submitted to the Agency subsequently	
- additional pharmaceutical form	1.300
- additional strength of the same pharmaceutical form	1.000
- additional type of packaging of the same pharmaceutical form and strength	500
- additional packaging size of the same pharmaceutical form and strength	500

2. Fee for issuance of marketing authorisation for veterinary medicine based on complete documentation in accordance with Article 31 of the Law is as follows:

1) for applications submitted to the Agency the same time	EUR
- one pharmaceutical form, strength and packaging of the medicine	800
- additional pharmaceutical form	500
- additional strength of the same pharmaceutical form	400
- additional type of packaging of the same pharmaceutical form and strength	300
- additional packaging size of the same pharmaceutical form and strength	300
2) for applications submitted to the Agency subsequently	
- additional pharmaceutical form	600
- additional strength of the same pharmaceutical form	500
- additional type of packaging of the same pharmaceutical form and strength	400
- additional packaging size of the same pharmaceutical form and strength	400

3. Fee for issuance of marketing authorisation for human medicine based on documentation in accordance with Articles 32 and 34 of the Law on Medicines is as follows:

1) for applications submitted to the Agency at the same time	EUR
- one pharmaceutical form, strength and packaging of the medicine	1.700
- additional pharmaceutical form	1.200
- additional strength of the same pharmaceutical form	900
- additional type of packaging of the same pharmaceutical form and strength	400
- additional packaging size of the same pharmaceutical form and strength	400
2) for applications submitted to the Agency subsequently	
- additional pharmaceutical form	1.300
- additional strength of the same pharmaceutical form	1.000
- additional type of packaging of the same pharmaceutical form and strength	500
- additional packaging size of the same pharmaceutical form and strength	500

4. Fee for issuance of marketing authorisation for veterinary medicine based on documentation in accordance with Articles 32 and 34 of the Law on Medicines is as follows:

1) for applications submitted to the Agency at the same time	EUR
- one pharmaceutical form, strength and packaging of the medicine	700
- additional pharmaceutical form	500
- additional strength of the same pharmaceutical form	400
- additional type of packaging of the same pharmaceutical form and strength	300
- additional packaging size of the same pharmaceutical form and strength	300
2) for applications submitted to the Agency subsequently	
- additional pharmaceutical form	600
- additional strength of the same pharmaceutical form	500
- additional type of packaging of the same pharmaceutical form and strength	400
- additional packaging size of the same pharmaceutical form and strength	400

5. Fee for entering traditional herbal medicine into the Register is as follows:

	EUR
- one pharmaceutical form, strength and packaging of the medicine	900
- additional pharmaceutical form	450
- additional strength of the same pharmaceutical form	350
- additional type of packaging of the same pharmaceutical form and strength	250

- additional packaging size of the same pharmaceutical form and strength	250

6. Fee for entering homeopathic medicine into the Register is as follows:

- one pharmaceutical form, strength and packaging of the medicine	900
- additional pharmaceutical form	450
- additional strength of the same pharmaceutical form	350
- additional type of packaging of the same pharmaceutical form and strength	250
- additional packaging size of the same pharmaceutical form and strength	250

Article 5

Fee for amendments to the marketing authorisation (hereinafter: variations) is as follows:

	EUR
- variations type IA and IB	150
- variations type II	250
- variations for which new marketing authorisation is issued:	
- for active substance	700
- change of pharmaceutical form	600
- change of administration route	600
- change of strength	500

If the application for variation from paragraph 1 of this Article refers to more marketing authorisations, the amount of fee is 50 euros for additional pharmaceutical form, strength or packaging of the medicine.

Article 6

1. Fee for renewal of marketing authorisation for human medicine is as follows:

	EUR
- one pharmaceutical form, strength and packaging of a medicine	1.300
- additional pharmaceutical form	1.000
- additional strength of the same pharmaceutical form	700
- additional packaging type of the same pharmaceutical form and strength	300
- additional packaging size of the same pharmaceutical form and strength	300

2. Fee for renewal of marketing authorisation for veterinary medicine is as follows:

	EUR
- one pharmaceutical form, strength and packaging of a medicine	500
- additional pharmaceutical form	300
- additional strength of the same pharmaceutical form	300
- additional packaging type of the same pharmaceutical form and strength	200
- additional packaging size of the same pharmaceutical form and strength	200

3. Fee for renewal of Register entry of traditional herbal medicine is as follows:

	EUR
- one pharmaceutical form, strength and packaging of a medicine	600
- additional pharmaceutical form	400
- additional strength of the same pharmaceutical form	400
- additional packaging type of the same pharmaceutical form and strength	350
- additional packaging size of the same pharmaceutical form and strength	350

4. Fee for renewal of Register entry of homeopathic medicine is as follows:

	EUR
- one pharmaceutical form, strength and packaging of a medicine	600
- additional pharmaceutical form	400
- additional strength of the same pharmaceutical form	400
- additional packaging type of the same pharmaceutical form and strength	350
- additional packaging size of the same pharmaceutical form and strength	350

Article 7

Fee for transfer of the marketing authorisation to a new marketing authorisation holder is 150 euros.

Article 8

Fee for issuance of manufacturing authorisation for medicines is as follows:

	EUR
- requirements assessment and issuance of manufacturing authorisation for a specific manufacturing site, each manufacturing line and finished medicinal product	1.500
- requirements assessment and issuance of manufacturing authorisation for traditional herbal or homeopathic medicine	1.000
- extension of the manufacturing authorisation for medicines that are drugs	500
- authorisation amendment due to change of space	900
- authorisation amendment due to change of manufacturing equipment	750
- authorisation amendment due to change/addition of finished medicinal product	500
- authorisation amendment due to change of responsible persons	250
- administrative changes	100.

Article 9

Fee for issuance of wholesale authorisation for medicines is as follows:

	EUR
- requirements assessment and issuance of wholesale authorisation	1.250
- extension of wholesale authorisation for medicines which are drugs	500
- wholesale authorisation amendment due to change of space	750
- wholesale authorisation amendment due to change/addition groups of medicines	500
- wholesale authorisation amendment due to change of person responsible for storage and distribution of medicines	250
- wholesale authorisation amendment due to change of transport vehicle	100
- administrative changes	100

Article 10

Fee for keeping record of legal persons performing import/export of medicines is 250 euros.

Article 11

Fee for issuance of approval of clinical trial of medicines is as follows:

	EUR
- clinical trial of a medicine which does not have a marketing authorisation	1.500
- clinical trial of a medicine which has a marketing authorisation	1.000
- substantial amendments to the approval of clinical trial of a medicine	700
- administrative amendments to the clinical trial of a medicine	100

Article 12

Fee for:
- notification of the clinical trial is 400 euros,
- notification of amendments to the clinical trial is 100 euros.

Article 13

Annual fee for the system of pharmacovigilance for marketing authorisation is 100 euros.

Article 14

Fees for:

	EUR
- requirements assessment and issuance of the first certificate of Good Manufacturing Practice (GMP)	2.000
- issuance of GMP certificate for additional pharmaceutical forms	1.000
- extension of the GMP certificate	500
- issuance of the certificate of Good Clinical Practice (GCP)	500
- requirements assessment and issuance of the first certificate of Good Distributing Practice (GDP)	500
- extension of the GDP certificate	300

Article 15

Fee for issuance of the certificate for export of a medicine prepared in accordance with recommendations of the World Health Organization is 50 euros.

Article 16

Fee for issuance of the approval for the procurement i.e. import of medicines that do not have a marketing authorisation, according to the total value of the import is as follows:

	EUR
up to 5 000 EUR	60
from 5 000 to 50 000 EUR	125
from 50 000 to 250 000 EUR	250
from 250 000 to 500 000 EUR	500
from 500 000 to 1.000 000 EUR	1.000

Article 17

Fee for issuance of the approval for import of each batch of the medicine that has a marketing authorisation is 50 euros.

Article 18

Fee for issuance of the approval for import and export of immunological medicine, medicine derived from blood and plasma and radiopharmaceutical medicine that has a marketing authorisation is 50 euros.

Article 19

Fee for issuance of the approval for the procurement or import of medicines intended for scientific and medical research for one-year needs is 100 euros.

Article 20

Fee for issuance of the approval for import, export or transit of medicines which are, or contain drugs and psychotropic substances, is in accordance with international conventions, 1% of the total value of import, export or transit of medicines.

Article 21

Fee for issuance of the approval for import, export or transit of substances which can be used for the manufacture of drugs and psychotropic substances (precursors) is, in accordance with international conventions, 50 euros.

Article 22

Approval for the possession of drugs on ships and airplanes in the international traffic for the purposes of first aid provision is 500 euros.

Article 23

Registration fee for the expert and educational trainings from the scope of the Agency's work is as follows:

	EUR
- half-day training	50
- one-day training	70
- two-day training	100
- one-day training with international guest lecturers	200
- two-day training with international guest lecturers	300

Article 24

Fee for issuance of documents from the Agency's registers is as follows:

	EUR
- duplicate of decisions, certificates and opinions	20
- confirmations from the Agency's registers	10.

Article 25

Fee for issuance of decisions on the termination of authorisations, certificates and approvals is 100 euros.

Article 26

Fee for issuance of the expert opinion on classification of a product into a medicine or group of medicines, as well as other expert opinions, is 100 euros.

Article 27

Fee for setting maximum price for a human medicine is 40 euros.

Article 28

Fee for laboratory controls paid by the applicant for a marketing authorisation or marketing authorisation holder, is not included in the amount of fees established by this Decision.

Article 29

Decision on the manner of payment and amount of fees for issuance of authorisations, certificates and approvals for the manufacture and marketing of medicines (Official Gazzete of Montenegro No 6/09 and 83/09) shall cease to be valid on the day of entry into force of this Decision.

Article 30

This Decision shall be published in the "Official Gazzete of Montenegro" after obtaining consent from the Government of Montenegro.

Article 31

This Decision shall enter into force on the eight day of its publication in the "Official Gazette of Montenegro".

No: 3020-6306/1
Podgorica, 10 May 2013

General Manager,
dr Milorad Drljević, m.p.