INSTITUTE FOR MEDICINES AND MEDICAL DEVICES OF MONTENEGRO

Consolidated text of the 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 shall include following regulations:

1. 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, No 3020/22/113/8-2456 from 25.03.2022.,
2. Desision on amendment to the 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, No 1010/22/4/6-349 from 01.07.2022.,
3. Desision on amendment to the 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, No 1010/22/4/7-349 od 10.10.2022., with an indicated date of entry into force.

Pursuant to the Article 24 paragraph 2 of the Law on medicines („Official Gazette of Montenegro“, No 80/20), Institute for medicines and medical devices hereby adopts

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

General provisions

Article 1

This Decision shall determine the payment method and the amount of fees that correspond to actual costs of carried out assignments referred to in the Article 22 of the Law on medicines (hereinafter: services provided by the Institute).

Article 2

After receiving the invoice from the Institute for Medicines and Medical Devices (hereinafter: Institute), the applicant is obliged to pay a certain fee to the Institute's account, within a maximum of 30 days from the date of receipt.

Applicant is obliged to submit evidence of payment of prescribed fee along with the application for a service provided by the Institute for Medicines and Medical Devices for which no invoice is issued.

Article 3

Applicant who, within seven days from the date of submission of the application for the service provided by the Institute, notifies the Institute in writing on withdrawing the application, will be able to recover the amount of paid fee reduced by 30%.

Regarding applications for which formal assessment of the documentation is prescribed, the applicant who notifies the Institute in writing on withdrawing the application prior to determining the formal completeness of the application, will be able to recover the amount of paid fee reduced by 30%.

If the applicant withdraws in writing the application for the issuance of authorisations, certificates and approvals after the expiration of the period referred to in paragraphs 1 and 2 of this Article shall bear costs in the amount determined by this Decision for that type of the document.

Article 4

Amount of the fee for issuance of the decision on termination of validity of authorisations, certificates and approvals is 150 EUR.

Expert opinions and advice, educational, publishing and other services

Article 5

Amount of the fee for issuance of expert opinion is as follows:

Name of the service	**Price (EUR)**
– simple expert opinion/opinion on the application of regulations	100,00
– complex expert opinion	300,00
– highly complex expert opinion	500,00
– expert opinion on the translation of the package leaflet and labeling of a medicine	150,00

Applicant shall propose the level of complexity of the expert opinion referred to in paragraph 1 of this Article.

Decision on the level of complexity of the expert opinion referred to in paragraph 1 of this Article is made by the Institute.

Article 6

Fee for providing oral expert advice by employees of the Institute at the proposal of the applicant (consultation in the premises of the Institute) is EUR 50 per hour.

The Institute shall prepare an invoice based on the assessment of complexity of the submitted application for expert advice.

Applicant shall pay at least half of the amount referred to in paragraph 2 of this Article before the day set for the provision of expert advice, and the rest of the fee after recieving the invoice issued by the Institute.

After providing expert advice, the Institute shall issue the invoice with actual hours of provided service referred to in paragraph 1 of this Article.

Article 7

Amount of costs for educational services (professional meetings, seminars, workshops, etc.) organized by the Institute, or in which the Institute participates is as follows:

Name of the service	Price (EUR)
Half-day education	
– for healthcare professionals and scientific workers	100,00
– for regulatory bodies	200,00
– for MAHs/wholesalers, manufacturers, etc.	300,00
Education lasting up to 3 days	
– for healthcare professionals and scientific workers	300,00
– for regulatory bodies	600,00
– for MAHs/wholesalers, manufacturers, etc.	900,00
Each additional day for education lasting longer than 3 days	
– for healthcare professionals and scientific workers	100,00
– for regulatory bodies	200,00
– for MAHs/wholesalers, manufacturers, etc.	300,00
Education with international participation lasting up to 2 days	
– for healthcare professionals and scientific workers	300,00
– for regulatory bodies	600,00
– for MAHs/wholesalers, manufacturers, etc.	900,00
Each additional day for educations with international participation lasting longer than 3 days	
– for healthcare professionals and scientific workers	100,00
– for regulatory bodies	200,00
– for the representative of MAHs/wholesalers, manufacturers, etc.	300,00

Fee referred to in paragraph 1 of this Article may be increased for the costs of renting facilities, preparation of expert materials, travel and accommodation costs for lecturers who are not employed in the Institute, as well as for other costs incurred during the implementation of the education.

Amount of the fee referred to in paragraph 1 of this Article shall be published by the Institute on its portal, or in the application for education.

Fee referred to in paragraph 1 of this Article shall not be charged to students from health-oriented faculites.

Article 8

Fee for printed publications is up to EUR 50 per copy.

Issuance of additional copies, transcripts and more

Article 9

Fee for issuance of additional copies, transcripts, etc. of certain administrative acts is as follows:

Name of the service	Price (EUR)
– each additional copy of an individual administrative act (decision, authorisation, certificate, etc.)	30,00
– issuance of copies of certain administrative acts (decision, authorisation, certificate, etc.)	75,00
– confirmation of finality of certain administrative acts (decision, authorisation, certificate, etc.)	30,00

Other expert services

Article 10

Institute may also charge a fee for other services provided by the Institute, which are not prescribed by this Decision, based on actual costs.

Placing a medicine onto the market

Article 11

Amount of the fee for issuance of marketing authorisation for a medicine for human use based on complete documentation is as follows:

1) for applications submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	2500,00
– next pharmaceutical form	1500,00
– next strength of the same pharmaceutical form	1100,00
– next package type of the same pharmaceutical form and strength	400,00
– next package size of the same pharmaceutical form and strength	200,00

2) for applications that were not submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– next pharmaceutical form	1800,00
– next strength of the same pharmaceutical form	1400,00
– next package type of the same pharmaceutical form and strength	400,00
– next package size of the same pharmaceutical form and strength	200,00

Amount of the fee for issuance of a marketing authorisation for a veterinary medicine, based on complete documentation, is as follows:

1) for applications submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	1400,00
– next pharmaceutical form	900,00
– next strength of the same pharmaceutical form	600,00
– next package type of the same pharmaceutical form and strength	300,00

- next package size of the same pharmaceutical form and strength 150,00

2) for applications that were not submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– next pharmaceutical form	1000,00
– next strength of the same pharmaceutical form	750,00
– next package type of the same pharmaceutical form and strength	300,00
– next package size of the same pharmaceutical form and strength	150,00

The amount of the fee for issuance of marketing authorisation for a medicine for human use based on abridged documentation is as follows:

1) for applications submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	2200,00
– next pharmaceutical form	1300,00
– next strength of the same pharmaceutical form	900,00
– next package type of the same pharmaceutical form and strength	400,00
– next package size of the same pharmaceutical form and strength	200,00

2) for applications that were not submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– next pharmaceutical form	1800,00
– next strength of the same pharmaceutical form	1300,00
– next package type of the same pharmaceutical form and strength	400,00
– next package size of the same pharmaceutical form and strength	200,00

The amount of the fee for issuance of marketing authorisation for a veterinary medicine based on abridged documentation is as follows:

1) for applications submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	1200,00
– next pharmaceutical form	900,00
– next strength of the same pharmaceutical form	600,00
– next package type of the same pharmaceutical form and strength	300,00
– next package size of the same pharmaceutical form and strength	150,00

2) for applications that were not submitted to the Institute at the same time, for:

Name of the service	Price (EUR)
– next pharmaceutical form	1000,00

- next strength of the same pharmaceutical form 750,00
- next package type of the same pharmaceutical form and strength 300,00
- next package size of the same pharmaceutical form and strength 150,00

Amount of the fee for entering traditional herbal medicine into the register is as follows, for:

Name of the service	**Price (EUR)**
- one pharmaceutical form, strength and package of the medicine	
- in case there is EU monograph	1200,00
- in case there is no EU monograph	1600,00
- next pharmaceutical form	
- in case there is EU monograph	800,00
- in case there is no EU monograph	1200,00
- next strength of the same pharmaceutical form	500,00
- next package type, or size of the same pharmaceutical form and strength	200,00

Amount of the fee for entering a homeopathic medicine into the register is as follows, for:

Name of the service	**Price (EUR)**
- one pharmaceutical form, strength and package of the medicine	1600,00
- next pharmaceutical form	1200,00
- next strength of the same pharmaceutical form	500,00
- next package type, or size of the same pharmaceutical form and strength	200,00

Article 12

Amount of the fee related to the Register of traditional herbal and homeopathic medicines is as follows, for:

Name of the service	**Price (EUR)**
- transfer of the holder of entry in the Register of traditional herbal and homeopathic medicines	200,00
- amendments to the entry in the Register of traditional herbal and homeopathic medicines	200,00
- removal from the Register of traditional herbal and homeopathic medicines	150,00

Article 13

Amount of the fee for the transfer of the authorisation to a new marketing authorisation holder is 200 EUR.

Amendment to marketing authorisation

Article 14

Amount of the fee for the amendment to marketing authorisation for a medicine for human use (hereinafter: variations) is as follows, for:

Name of the service	Price (EUR)
– variations type IA, IAin	150,00
– variations type IB	250,00
– variations type II	350,00
– same variation for additional strength, pharmaceutical form, or package – type IA, IAin, IB	60,00
– same variation for additional strength, pharmaceutical form, or package – type II	100,00

Amount of the fee for variation line extension is 800 EUR.

Amount of the fee for the amendment to marketing authorisation for a veterinary medicine (hereinafter: variations) is as follows, for:

Name of the service	Price (EUR)
– variations type IA, IAin	70,00
– variations type IB	130,00
– variations type II	200,00
– same variation for additional strength, pharmaceutical form, or package – type IA, IAin, IB	30,00
– same variation for additional strength, pharmaceutical form, or package – type II	50,00

Amount of the fee for variation line extension is 500 EUR.

Renewal of marketing authorisation

Article 15

Amount of the fee for the renewal of marketing authorisation for a medicine for human use is as follows, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	1500,00
– next pharmaceutical form	1100,00
– next strength of the same pharmaceutical form	800,00
– next package type of the same pharmaceutical form and strength	350,00
– next package size of the same pharmaceutical form and strength	300,00

Amount of the fee for the renewal of marketing authorisation for a veterinary medicine is as follows, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	1000,00
– next pharmaceutical form	600,00
– next strength of the same pharmaceutical form	600,00
– next package type of the same pharmaceutical form and strength	300,00
– next package size of the same pharmaceutical form and strength	200,00

Amount of the fee for the renewal of entry in the Register of tradicional herbal medicine is as follows, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	800,00
– next pharmaceutical form	550,00
– next strength of the same pharmaceutical form	500,00
– next package type, or size of the same pharmaceutical form and strength	400,00

Amount of the fee for the renewal of entry in the Register of homeopathic medicine is as follows, for:

Name of the service	Price (EUR)
– one pharmaceutical form, strength and package of the medicine	800,00
– next pharmaceutical form	550,00
– next strength of the same pharmaceutical form	500,00
– next package type, or size of the same pharmaceutical form and strength	400,00

Manufacture, wholesale and inspection of medicines

Article 16

Amount of the fee for issuance of manufacturing authorisation for medicines is as follows, for::

Name of the service	Price (EUR)
– issuance of manufacturing authorisation for medicines for a specific manufacturing site, i.e. manufacturing plant, pharmaceutical form and specific finished medicine (per day)	1000,00

– amendment to manufacturing authorisation for medicines when inspection is carried out (per day)	600,00
– amendment to manufacturing authorisation for medicines if inspection is not carried out	600,00
– administrative amendments	200,00

Article 17

Amount of the fee for issuance of wholesale authorisation for medicines is as follows, for:

Name of the service	**Price (EUR)**
– issuance of wholesale authorisation for medicines (per day)	800,00
– amendment to wholesale authorisation for medicines when inspection is carried out (per day)	500,00
– amendment to wholesale authorisation for medicines if inspection is not carried out	500,00
– administrative amendments	200,00

Article 18

Fee for entering manufacturers, importers, or wholesalers of active substances into the Register is 500 EUR.

Fee for amendments to the entry into the Register of manufacturers, importers, or wholesalers of active substances is 250 EUR.

Article 19

Amount of the fee is as follows, for:

Name of the service	**Price (EUR)**
– Issuance of Good Manufacturing Practice (GMP) certificate	500,00
– GMP inspection in Montenegro (per day)	1000,00
– GMP inspection outside of Montenegro (per day)	1500,00 + travel and accommodation costs
– GCP inspection (per day)	1000,00
– Issuance of Good Distribution Practice (GDP) certificate	500,00
– GDP inspection (per day)	800,00
– Verifying of the pharmacovigilance system of the marketing authorisation holder, GVP inspection (per day)	1000,00
– GMP, GDP, GCP and GVP inspection reports in English	1000,00

Marketing of medicines

Article 20

Amount of the fee for issuance of a certificate for the purpose of exporting medicines in accordance with the recommendations of the World Health Organization (WHO) is 100 EUR.

Article 21

Amount of the fee for issuance of approval for the procurement, i.e. the import of medicines for human use that do not have marketing authorisation is 150 EUR.

Amount of the fee for issuance of approval for the procurement, i.e. 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

Article 22

Amount of the fee for issuance of approval for import and export of immunological medicines and medicines for human use derived from blood and plasma which have marketing authorisation is 70 EUR.

Amount of the fee for issuance of approval for import and export of immunological medicines and medicines for human use derived from blood and plasma which do not have marketing authorisation is 70 EUR.

Amount of the fee for issuance of approval for import and export of immunological veterinary medicines is 70 EUR.

Article 23

Amount of the fee 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 EUR.

Article 24

Authorization for the possession of drugs in ships and airplanes in international traffic for the provision of first aid is 500 EUR.

Article 25

Amount of the fee for issuance of reports on the consumption of medicines for one calendar year is 100 EUR.

Article 26

Amount of the fee for setting maximum price of a medicine for human use is 60 EUR.

Article 27

Amount of the fee for setting maximum price of a medicine for human use based on indicators of pharmacoeconomic study is 100 EUR.

Article 28

Amount of the fee for issuance of an authorization for use of precursors is 100 EUR.

Clinical trials of medicines

Article 29

Amount of the fee for issuance of approval for a clinical trial of a medicine is as follows, for:

Name of the service	Price (EUR)
– clinical trial of a medicine that does not have marketing authorization	2000,00
– clinical trial of a medicine that has marketing authorization	1000,00
– substantial amendment to the approval of clinical trial of a medicine	500,00
– recording of a non-interventional clinical trial	500,00

Pharmacovigilance

Article 30

Amount of the fee for the assessment of additional risk minimization measures - educational materials, when they are not available in the language that is in official use in Montenegro, is 500 EUR.

Amount of the fee for the assessment of amendments to additional risk minimization measures 170 EUR.

Annual fees

Article 31

Annual fee is as follows, for:

Name of the service	Price (EUR)
– marketing authorisation for a medicine for human use issued for an indefinite period	250,00
– marketing authorisation for a veterinary medicine issued for an indefinite period	100,00
– pharmacovigilance system for marketing authorisation for a medicine for human use	100,00

– pharmacovigilance system for marketing authorisation for a veterinary medicine	50,00
– wholesale authorisation for medicines for human use	200,00
– manufacturing authorisation for medicines for human use	300,00

Laboratory services

Article 32

Amount of the fee for analyses conducted in the laboratory of the Institute, based on X-ray diffraction, or fluorescence:

1) XRD technique, for:

Name of the service	**Price (EUR)**
– sample preparation (in case the sample is not in powder form)	10,00
– analysis of the sample according to defined parameters of the client's analysis (client submits recording method in a time duration up to 1 hour), without interpretation of results	50,00
– sample analysis using the method of the Institute without interpretation of results (diffractogram)	80,00
– sample analysis with identification of stages - qualitative presentation of results (depending on complexity of the sample)	100,00-150,00
– sample analysis with identification of stages - qualitative and semi-quantitative presentation of results (depending on complexity of the sample)	150,00-200,00
– detection of substandard and falsified medicines	300,00

2) XRF technique, for:

Name of the service	**Price (EUR)**
– sample analysis with qualitative presentation of results for up to 3 elements (elements with atomic number ≥ 11)	15,00
– sample analysis with qualitative presentation of results (all elements with atomic number ≥ 11)	30,00
– sample analysis with semi-quantitative presentation of results for up to 3 elements (elements with atomic number ≥ 11)	30,00
– sample analysis with semi-quantitative presentation of results (all elements with atomic number ≥ 11)	50,00
– samples analysis of solid form of a medicine, or supplement with quantitative presentation of results for up to 3 elements (elements with atomic number ≥11)	50,00
	80,00

- samples analysis of the solid form of the medicine, or supplement with a quantitative presentation of the results (all elements with an atomic number ≥11)

Amount of fees for batches of more than 5 samples is 90% of prescribed service prices.

Amount of fees for batches of more than 10 samples is 80% of prescribed service prices.

Amount of fees for needs of faculties, institutes and health institutions is 50% of prescribed service prices, unless analyzes are an integral part of a scientific research project for which funding has been ensured.

Article 33

Amount of the fee for conducted laboratory controls paid by the applicant for the issuance of marketing authorisation, i.e. the marketing authorisation holder, is not included in the amount of fees determined by this Decision.

Article 34

Institute shall not charge fees determined by this Decision for medicines used for the treatment of rare diseases in humans (orphan medicines), for the treatment of rare diseases in less common animal species, medicines from humanitarian aid and medicines for medically justified needs, in case of epidemics, epizootics, natural disasters, or other emergency situations, for health protection, when the import is carried out by a state-owned wholesaler, or on the basis of a contract concluded by a state administration body.

Article 35

Decision on the payment method and the amount of fees for the issuance of authorisations, certificates and approvals for the manufacture and marketing of medicines ("Official Gazette of Montenegro", No 22/13) shall be repealed with effect from the date of entry into force of this Decision.

Notwithstanding the paragraph 1 of this Article, the fee for application submitted by the date of entry into force of this Decision, shall be charged in accordance with Decision on the payment method and the amount of fees for the issuance of authorisations, certificates and approvals for the manufacture and marketing of medicines ("Official Gazette of Montenegro", No 22/13) and the Decision of the Steering Board No 3020/21/107/12-2570 from 20.04.2021. and No 3020/21/312/2-7255 from 05.11.2021., which was valid until the date of entry into force of this Decision.

Article 36

This decision shall enter into force and be applied on the day of approval by the Steering Board of the Institute.

MANAGING DIRECTOR

Doc. dr med. spec. Snežana Mugoša