



Year XIII Monday, September 7th / September 2009	number 70	Година XIII Понедељак, 7. септембра 2009. године
		ISSN 1512-7486 -English language

Based on Article 17 of the Law on Council of Ministers of Bosnia and Herzegovina ("Official Gazette of BiH", No. 30/03, 42/03, 81/06, 76/07, 81/07, 94/07 and 24/08) and Article 45, Article 56, paragraph (4), Article 65, paragraph (2), Article 81 (5), Article 106, paragraph (5), Article 112, paragraph (3) and Article 120, paragraph (6) of the Medicinal Products and Medical Devices Act of Bosnia and Herzegovina ("Official Gazette of BiH", no. 58/08), the Council of Ministers of Bosnia and Herzegovina, at the proposal of the Direktor of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, at the 94th session held on July 16th, 2009, adopted

ORDINANCE

on the type, amount and method of payment of costs for the activities conducted by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina

PART ONE - INTRODUCTION

Article 1 (Subject of the Ordinance)

This Ordinance shall establish the type, the amount of expenses, as well as the method of payment of costs for the conducted activities of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina prescribed by Medicinal Products and Medical Devices Act of Bosnia and Herzegovina ("Official Gazette of BiH", no. 58/08), hereinafter: Act, paid by the applicant. The amount of costs is expressed in BAM without VAT.

PART TWO - TYPE AND AMOUNT OF EXPENSES

TITLE I - MEDICINES

Subtitle A. Marketing authorization, Article 45 of the Act

Article 2

(The costs regarding the granting, renewal and changes of marketing authorization)

(1) The costs relating to the granting of marketing authorization, are determined in the amount:

- a) for each pharmaceutical form, dose and packaging of a medicine.....5.000,00 BAM;
- b) for each additional pharmaceutical form of the same medicine of the simultaneously submitted request 1,500.00 BAM;
- c) for each additional dose of the same pharmaceutical form of the simultaneously submitted request 1,000.00 BAM;
- d) for each additional packaging size of the same pharmaceutical form and dose of the simultaneously submitted request..... 1,000.00 BAM;
- e) for each additional type of primary packaging of the same pharmaceutical form, dose and packaging size of the simultaneously submitted request..... 500, 00 BAM.

(2) The costs for not submitting request simultaneously for the granting of marketing authorization, that is, for subsequently submitted requests, the costs of issuing a permit, are determined in the amount:

- a) for each additional pharmaceutical form of the same medicine 2,000.00 BAM;
- b) for each additional dose of the same pharmaceutical form1,500.00 BAM;
- c) for each additional packaging size of the same pharmaceutical form and the same dose1,500.00 BAM;
- d) for each additional type of primary packaging of the same pharmaceutical form, dose and package size 600,00 BAM.

(3) The costs of renewal of marketing authorization, are determined in the amount:

- a) for each pharmaceutical form, dose and packaging of a medicine 3,000.00 BAM;
- b) for each additional pharmaceutical form of the same medicine 1,200.00 BAM
- c) for each additional dose of the same pharmaceutical form 800,00 BAM;
- d) for each additional packaging size of the same pharmaceutical form and dose 800,00 BAM;
- e) for each additional type of primary packaging of the same pharmaceutical form, dose and packaging size 300,00 BAM.

(4) The costs for changes of a permit or changes of submitted documentation for marketing authorization, are determined in the amount:

- a) the costs of changes of marketing authorization or changes of submitted documentation of a medicine (change type IA and type IB) 500,00 BAM;
- b) the costs of changes of marketing authorization or changes of submitted documentation (change type II) 500,00 BAM;
- c) the costs of changes of a permit in terms of transfer of ownership of marketing authorization to another legal entity 300,00 BAM;
- d) the costs of amendment of marketing authorization 500,00 BAM;
- e) the costs of other changes that do not require granting of a new marketing authorization 500,00 BAM.

(5) The costs regarding the provision of expert opinion regarding the medicines..... 100,00 BAM.

Article 3

(The costs related to the preparation of reports on the pharmaceutical quality of a medicine)

(1) The costs of the preparation of reports on the pharmaceutical quality of a medicine at the request

of the manufacturer or legal representative, are determined in the amount:

- a) for one pharmaceutical form, dose and packaging 3,000.00 BAM;
- b) for other pharmaceutical form of the same medicine of the simultaneously submitted request 1,000 00 BAM;
- c) for each additional dose of the same pharmaceutical form of the simultaneously submitted request..... 1.500,00 BAM;
- d) for each additional packaging size of the same pharmaceutical form and dose of the simultaneously submitted request..... 500 00 BAM;
- e) for each additional type of the primary packaging of the same pharmaceutical form, dose and packaging size of the simultaneously submitted request 800,00 BAM.

2) The costs for changes of a permit or changes of submitted documentation for marketing authorization, are determined in the amount:

- a) the costs of changes of marketing authorization or changes of submitted documentation of a medicine (change type IA and type IB) 500,00 BAM;
- b) the costs of changes of marketing authorization or changes of submitted documentation (change type II) 500,00 BAM;
- c) the costs of changes of a permit in terms of transfer of ownership of the permit for marketing authorization to another legal entity 300,00 BAM;
- d) the costs of amendment of marketing authorization 500,00 BAM;
- e) the costs of other changes that do not require granting of a new permit for marketing authorization 500,00 BAM.

Article 4

(The costs relating to the granting, renewal and changes of marketing authorization of a traditional medicine)

(1) The cost of granting of marketing authorization of a traditional medicine, are determined in the amount:

- a) for the pharmaceutical form, dose and packaging 2000, 00 BAM;
- b) for additional pharmaceutical form of the simultaneously submitted request..... 1,000.00 BAM;
- c) for an additional dose of the same pharmaceutical form of the simultaneously submitted request..... 500,00 BAM;
- d) for the additional packaging size of the same pharmaceutical form and dose of the simultaneously submitted request..... 500 00 BAM;
- e) for each additional type of the primary packaging of the same pharmaceutical form, dose and packaging size 200,00 BAM;

(2) Costs if the request for the granting of marketing authorization of a traditional medicine is not submitted simultaneously, ie for subsequently submitted requests, shall be determined in the amount:

- a) for additional pharmaceutical form of the same traditional medicine 1,500.00 BAM;
- b) for an additional dose of the same pharmaceutical form 1,000.00 BAM;
- c) for additional packaging size of the same pharmaceutical form and dose 1,000.00 BAM.

(3) The costs of change and renewal of marketing authorization of traditional medicine, are determined in the amount:

- a) for the change of marketing authorization of a traditional medicine or changes of the submitted

- documentation of the medicine 300,00 BAM;
- b) for the renewal of marketing authorization of a traditional medicine for each pharmaceutical form, dose and packaging 1,500.00 BAM;
- c) for the renewal of marketing authorization of a traditional medicine for each additional pharmaceutical form 400.00 BAM;
- d) for the renewal of marketing authorization of a traditional medicine for every additional dose of the same pharmaceutical form 400,00 BAM;
- e) for each additional packaging size of the same pharmaceutical form and dose 400,00 BAM.

Article 5

(The costs in connection with the granting, renewal and changes of marketing authorization of a homeopathic medicine)

The costs of granting of marketing authorization of a homeopathic medicine are determined in the amount:

- a) for granting of marketing authorization of a homeopathic medicine..... 1.500,00 BAM;
- b) for the renewal of marketing authorization of a homeopathic medicine..... 1,000.00 BAM;
- c) for change of a permit or submitted documentation for marketing authorization of a homeopathic medicine 300,00 BAM.

Article 6

(The costs for issuing conclusion on categorization)

The costs for issuing conclusion on product categorization for each product individually are determined in the amount of300,00 BAM.

Article 7

(The cost of the records book verification)

The cost of the records book verification for each verification of the book individually 20.00 BAM.

Article 8

(The annual costs for the maintenance of registration dossier)

The annual costs for the maintenance of documentation, are determined in the amount:

- a) for the medicinal product.....300,00 BAM;
- b) for the homeopathic medicine.....100,00 BAM;
- c) for medical device 50,00 BAM.

Article 9

(The costs of issuing approval and permit for import-export of medicinal products and medical devices)

The costs relating to the granting of approvals or permits for import-export of medicinal products and medical devices shall be determined according to the financial amount of the requirements:

- a) up to 10,000, 00 BAM..... 50,00 BAM;
- b) from 10.000, 00 BAM to100,000.00 BAM 250,00 BAM;
- c) from 100,000.00 BAM to 500,000.00 BAM 500,00 BAM;
- d) more than 500,000.00 BAM..... 1,000.00 BAM.

Article 10

(The costs of issuing the certificate on the existence and duration of the entity permit)

The costs of issuing the certificate on the existence of a permit, as well as its duration to the individual holders of marketing authorization, wholesale of the medicines, production of medicines and import of medicines, are determined in the amount.....200,00 BAM.

Article 11

(The costs related to the advertising of medicines to professional and general public)

The costs related to advertising of medicines to professional and general public, are determined in the amount:

- a) the costs of issuing a permit for the advertisement of medicines to professional and general public 1,000.00 BAM;
- b) the costs of renewal of a permit for advertising of medicines to professional and general public 800,00 BAM;
- c) the cost of amendments of a permit for advertising of medicines to professional and general public 500.00 BAM

Subtitle B. Clinical trials of medicines, Article 56, paragraph (4) of the Act

Article 12

(The costs related to the application procedure and permit granting for clinical trials of medicines)

The costs related to the application procedure and permit granting for clinical trials of medicines, are determined in the amount:

- a) the costs of permit granting for clinical testing of medicines 8.000,00 BAM;
- b) the costs of permit granting for conducting bioequivalence tests3.500,00 BAM;
- c) the costs of the registration of the clinical trial of the medicine (when tested a drug that has a marketing authorization, the test is carried out according to the approved summary of medicine`s characteristics..... 2,000.00 BAM;
- d) the costs of obtaining the opinion of the central Ethics Committee for academic trials1.500,00 BAM;
- e) the costs of amendments of the permit for the clinical trial of medicine 1,000.00 BAM;
- f) the costs for minor administrative changes and amendments to the clinical trial of medicine 500 00 BAM;
- g) the costs for the granting of certificate of applying the guidelines of Good Clinical Practice 500,00 BAM;
- h) the costs of preparing reports on the side effects of the medicine for each individual form and dose, as an integral part of the documentation for renewal of a permit for marketing authorization 700,00 BAM.

Subtitle C. Wholesale distribution of medicines, the Article 65, Paragraph (2) of the Act

Article 13

(The costs related to the granting and amendments of the license for wholesale distribution of medicines)

The costs in connection with the granting and amendments of the license for wholesale distribution of medicines is determined in the amount:

- a) the costs of the procedure for establishing a quality system in accordance with good distribution practice, when issuing the license for wholesale distribution of medicines..... 1.500,00 BAM;
- b) the administrative costs of resolving the amendments of the licence for wholesale distribution of medicines..... 300,00 BAM;
- c) the costs of the amendments of the licenses for wholesale distribution of medicines if the investigation is done 500,00 BAM;
- d) the costs of verifying the implementation of good distribution and / or transport and / or storage conditions for medicines 500,00 BAM.

Article 14

(The costs related to the granting and amendments of the license for the manufacture of a medicine)

The costs related to the granting and amendments of the license for the manufacture of a medicine are determined in the amount:

- a) the costs of the procedure for establishing a quality system in accordance with good manufacturing practice, when issuing a license for the manufacture of a medicine for each pharmaceutical form and for each production site individually1.000,00 BAM;
- b) the administrative costs of resolving the amendments of the licence for the manufacture of a medicine 300.00 BAM;
- c) the costs of the amendments of the licenses for the manufacture of a medicine if the investigation is done..... 500,00 BAM;
- d) the costs of verifying the implementation of good manufacturing practices 500,00 BAM;
- e) the costs of verification of good manufacturing practice for the manufacturers outside of BiH 2,500.00 BAM.

Subtitle D. Quality control of medicines, Article 81, Paragraph (5) of the Act

Article 15

(The costs related to quality control of medicines)

The costs related to quality control of medicines, are determined in the amount:

- a) quality control of the first batch of medicines before they are marketed, in the process of renewal or changes of the permits that require quality control..... 2,000.00 BAM;
- b) quality control of each batch of imported medicine 500,00 BAM;
- c) control of the primary and secondary packaging of imported medicine 100.00 BAM;
- d) regular quality control of medicines in circulation in BiH 2 BAM / point;
- e) extraordinary quality control at the Agency's request while obtaining marketing authorization or after obtaining the permit due to unusual occurrences or suspicions of quality 2 BAM / point;

- f) extraordinary control, ie quality control of each batch of risky or other specific categories of medicines..... 2 BAM / point;
- g) quality control of medicine at the request of the pharmaceutical inspector 2 BAM / point;
- h) quality control of the intervening imported medicine.....2 BAM/ point.

TITLE II - MEDICAL DEVICES

Subtitle A. Registration of medical devices in the register of medical devices, registration of manufacturers of medical devices and registration of wholesalers of medical devices, Article 112, paragraph (3) of the Act

Article 16

(The costs relating to the registration, amendment and re-registration of medical devices in the register of medical devices)

(1) The costs related to the registration, amendment and re-registration of medical devices in the register of medical devices, are determined in the amount:

a) the costs for the registration of medical devices for each device from the request according to the number of protected or generic names of medical devices Class I:

- 1) up to 25 products 200.00 BAM;
- 2) up to 100 products 150.00 BAM;
- 3) over 100 products 100.00 BAM;

b) the costs for the registration of medical devices for each device from the request according to the number of protected or generic names of medical devices Class IIa and IIb:

- 1) up to 25 products 400.00 BAM;
- 2) up to 100 products 350,00 BAM;
- 3) over 100 products 300,00 BAM;

c) the costs for the registration of medical devices for each device from the request according to the number of protected or generic names of medical devices Class III:

- 1) up to 15 products 700,00 BAM;
- 2) over 15 products 500,00 BAM;

d) the costs for the registration of medical devices for each device from the request according to the number of protected or generic names of IN VITRO medical devices:

- 1) up to 25 products 200,00 BAM;
- 2) up to 100 products 150.00 BAM;
- 3) over 100 products 100,00 BAM;

e) the costs for the registration of medical devices for each device from the request according to the number of protected or generic names of ACTIVE IMPLATABLE medical devices:

- 1) up to 10 products 800,00 BAM;
- 2) up to 25 products 600,00 BAM;
- 3) over 25 500,00 BAM;

f) the costs for re-registration of medical devices in the register is 50% of the first

registration in the register;

- g) the costs for amendments of registration in the register of medical devices 200,00 BAM;
- h) the costs for the supplement of registration in the register of medical devices 200,00 BAM;
- i) the costs of expert opinion related to medical devices 100,00 BAM;
- j) the costs for the granting of a certificate of compliance for medical devices 1,000.00 BAM;
- k) the costs of resolving requests for the classification of medical devices 200,00 BAM.

Article 17

(The costs related to advertising of medical devices to professional and general public)

The costs related to advertising of medical devices to profesional and the general public, are determined in the amount:

- a) the costs of issuing a permit for the advertisement of medical devices to professional and general public 1,000.00 BAM;
- b) the costs of renewal of a permit for the advertisement of medical devices to professional and general public..... 800,00 BAM;
- c) the costs of amendments of a permit for the advertisement of medical devices to professional and general public..... 500,00 BAM.

Article 18

(The costs related to registration and amendment of registration of legal entities in the register of manufacturers of medical devices)

The costs related to registration and amendment of registration of legal entities in the register of manufacturers of medical devices are determined in the amount:

- a) the cost of the procedure for establishing a quality system when registering legal entities in the register of manufacturers of medical devices 1.000, 00 BAM;
- b) the costs of administrative resolving of registration amendment of manufacturers of medical devices 300,00 BAM;
- c) the costs of registration a of manufacturers of medical devices, if an investigation is done..... 500,00 BAM;
- d) the costs of verifying the implementation of good manufacturing practices 500,00 BAM.

Article 19

(The costs related to registration and amendment of registration of legal entities in the register of wholesalers of medical devices)

The costs related to registration and amendment of registration of legal entities in the register of wholesalers of medical devices, are determined in the amount:

- a) the cost of the procedure for establishing the conditions for registration of wholesalers of medical devices 700,00 BAM;
- b) the costs of administrative resolving of registration amendment of wholesalers of medical devices 300,00 BAM;
- c) the cosst of registration amendment of manufacturers wholesalers of medical devices, if an investigation is done..... 500,00 BAM;

d) the costs of verifying the implementation of good distribution and / or transport and / or storage practices for medical devices 300.00 BAM.

Article 20

(The costs of issuing the certificate of existence and duration of the entity licence)

The costs of issuing the certificate of existence of a license, as well as its duration to the individual holders of licenses related to the registration of medical devices in the register of medical devices, the register of manufacturers of medical devices, the register of wholesalers of medical devices and import of medical devices, are determined in the amount 300, 00 BAM.

Subtitle B. The clinical testing of medical devices, Article 120, paragraph (6) of the Act

Article 21

(The costs related to the application procedure and issuing of permit for clinical trial of medical devices)

The costs related to the application procedure and issuing of permit for clinical trial of medical devices are determined in the amount:

- a) the costs of permit granting for clinical trials of medical devices3.000,00 BAM;
- b) the costs of the application for clinical trial of medical devices that are registered in the register of medical devices 1,000.00 BAM;
- c) the costs for amendments of a permit for the clinical trial of medical devices 400.00 BAM;
- d) the costs for smaller administrative changes and amendments to the clinical trial medical devices 200,00 BAM;
- e) the costs of preparing the reports on adverse effects of medical device as an integral part of the documents for re-registration of medical device in the register of medical devices 300,00 BAM.

PART III - PAYMENT METHODS

Article 22 (Payment of funds)

The applimayt shall pay the costs of the proceedings according to the established fees specified in this Ordinance, by depositing the money to the sub-account of the Agency in the framework of the Budget of the institutions of Bosnia and Herzegovina and international obligations of Bosnia and Herzegovina.

PART FOUR - FINAL PROVISIONS

Article 23

(Amendments to Ordinance)

Amendments to this Ordinance shall be conducted in a manner of and according to the procedure for its adoption.

Article 24

(Entry into Force and Publication)

This Ordinance shall enter into force on the day of granting and shall be published in the "Official Gazette of BiH".

SM No. 196/09
July 16th, 2009
Sarajevo

Chairman of
the Council of Ministers
Dr. Nikola Spiric.