DECISION

ON DETERMINATION OF THE AMOUNTS AND METHODS OF PAYMENT OF FEES FOR SERVICES OF THE MEDICINES AND MEDICAL DEVICES AGENCY OF SERBIA

("Official Gazette of the Republic of Serbia", No 95/2017)

1. Basic provision

Article 1

This decision stipulates the amount and method of payment of fees for the services of the Medicines and Medical Devices Agency of Serbia (hereinafter: the Agency).

2. Amounts of fees for issuing a marketing authorization for medicinal products

Article 2

Amounts of fees for issuing a marketing authorization for medicinal products:

	(RSD)
1) Issuance of the marketing authorization for medicinal product on the basis of complete documentation for:	
a) pharmaceutical form, strength, and package of the medicine	460.000,00
b) each additional pharmaceutical form	240.000,00
c) each additional strength of the same pharmaceutical form of the medicine	150.000,00
d) each type of additional inner package of the same pharmaceutical form and strength	30.000,00
e) each additional package size	30.000,00
2) Issuance of the marketing authorization for medicinal product on the basis of reduced documentation for:	
a) pharmaceutical form, strength, and package of the medicine	325.000,00
b) each additional pharmaceutical form	210.000,00
c) each additional strength of the same pharmaceutical form of the medicine	120.000,00
d) each type of additional inner package of the same pharmaceutical form and strength	30.000,00
e) each additional package size	30.000,00

3. Amounts of fees for issuing a conditional marketing authorization for medicinal product, marketing authorization under exceptional circumstances and temporary marketing authorization for medicinal product

Article 3

Amounts of fees for issuing a conditional marketing authorization for medicinal product, marketing authorization under exceptional circumstances and temporary marketing authorization:

a) pharmaceutical form, strength, and package of the medicine	460.000,00
b) each additional pharmaceutical form	240.000,00
c) each additional strength of the same pharmaceutical form of the medicine	150.000,00
d) each type of additional inner package of the same pharmaceutical form and strength	30.000,00
e) each additional package size	30.000,00

4. Amounts of fees for renewal of the marketing authorization for medicinal product

Article 4

Amounts of fees for renewal of the marketing authorization for medicinal product:

a) pharmaceutical form, strength, and package of the medicine	265.000,00
b) each additional pharmaceutical form	160.000,00
c) each additional strength of the same pharmaceutical form of the medicine	100.000,00
d) each type of additional inner package of the same pharmaceutical form and strength	20.000,00
e) each additional package size	20.000,00

Article 5

Fees for issuing an authorization for an unlimited period of time:

a) pharmaceutical form, strength, and package of the medicine	265.000,00
b) each additional pharmaceutical form	160.000,00
c) each additional strength of the same pharmaceutical form of the medicine	100.000,00
d) each type of additional inner package of the same pharmaceutical form and strength	20.000,00
e) each additional package size	20.000,00
The annual fee for maintenance of the marketing authorization for medicinal product, issued for an unlimited period of time	50.000,00

The annual fee for maintenance of the marketing authorization for medicinal product issued for an unlimited period of time, for the current year, shall be paid no later than 31 March of the current year, for marketing authorizations to be valid on the 1 January of the current year.

Article 6

In the case of issuance and renewal of a marketing authorization for medicinal product for each additional pharmaceutical form, each additional strength of the same pharmaceutical

form of the medicine, each type of additional inner package of the same pharmaceutical form and strength and for each additional package size for which the requests were submitted to the Agency at the same time, or on a same day - fees defined in Articles 2 to 4 and Article 5, paragraph 1 of this Decision shall be paid

5. Amounts of fees for amendments to a marketing authorization for medicinal product

Article 7

Amounts of fees for amendments to a marketing authorization for medicinal product (hereinafter: variations):

1) Variations of type IA, IAin and IB	20.000,00
2) Variations of type II	47.000,00
3) Approval of the same variation in additional strength or pharmaceutical form or package for a variation type I	20.000,00
4) Approval of the same variation in additional strength or pharmaceutical form or package for a variation type II	47.000,00
5) Variations which require an issuance of a new authorization	
a) active substance	160.000,00
b) modification of pharmaceutical form	150.000,00
c) modification of the method of administration	150.000,00
d) modification of strength	140.000,00
e) new indication(s)	160.000,00
f) target species	160.000,00

Article 8

Amount of fee for a variation related to alteration of name or address of the holder of marketing authorization for medicinal product, if holder of the authorization remains the same legal entity, refers to all issued decisions, and will be charged as a single variation of type IAin. Amounts of fees for the variations related to alteration of the name or address of a manufacturer of the finished medicinal product, including sites of quality control, refer to one or more decisions considering the same authorized holder, and will be charged as a variation of type IA or IAin.

6. Amounts of fees for issuance of the decision on transfer of the marketing authorization for medicinal product

Article 9

1) Fee for issuance of the decision on transfer of the marketing authorization for medicinal product	19.000,00
2) Fee for issuance of the decision on transfer of the decision on entry into the Registry	15.000,00

7. Amount of fee for issuance of the decision on termination of the marketing authorization for medicinal product

Article 10

Amount of fee for issuance of the decision on termination of the marketing authorization for medicinal product	10.000,00

8. Amount of the fee for the issuance of the decision on entry into the Registry of traditional herbal medicinal products and homeopathic medicinal products

Article 11

1) Fee for the issuance of the decision on entry into the Registry of traditional herbal medicinal products and homeopathic medicinal products (hereinafter: Registry)	210.000,00
2) Renewal of the registration into the Registry	148.000,00
3) Amendments related to the entry into the Registry	25.000,00
4) Removal from the Registry	10.000,00

9. Amounts of fees for issuance of the decision on entry of the medical device into the Registry of medical devices and renewal of the registration

Article 12

Amounts of fees for issuance of the decision on entry of the medical device into the Registry of medical devices (hereinafter: Registry) shall be determined for each single medical device from the requests of the same class, or group of products of the same manufacturer.

Fees for issuance of the decision on entry into the Registry for medical devices, which are in compliance with EU Directives and which are "CE" marked:

1) Medical devices of the Class I	
a) Up to 25 products	11.400,00
b) From 26 to 100 products	9.120,00
c) Over 100 products	6.840,00
2) Medical devices of the Class IIa	
a) Up to 25 products	28.500,00
b) From 26 to 100 products	22.800,00
c) Over 100 products	17.100,00
3) Medical devices of the Class IIb	
a) Up to 25 products	34.200,00
b) Over 25 products	27.360,00
4) Medical devices of the Class III	
a) Up to 15 products	57.000,00
b) Over 15 products	45.600,00
5) Medical devices from the A i B lists ("In vitro" diagnostic medical devices)	
a) Up to 25 products	13.680,00
b) From 26 to 100 products	11.400,00
c) Over 100 products	10.000,00

6) Medical devices for self-testing ("In vitro" diagnostic medical devices)	
a) Up to 25 products	11.400,00
b) Over 25 products	9.120,00
7) Other "In vitro" medical devices	
a) Up to 25 products	11.400,00
b) From 26 to 100 products	10.000,00
c) From 101 to 200 products	9.200,00
d) Over 200 products	7.000,00
8) Active implantable medical devices and appliances referred to in clauses 1-7. of this Article	
a) Up to 10 products	57.000,00
b) From 11 to 25 products	45.600,00
c) Over 25 products	34.200,00

Article 13

Amounts of fees for issuance of the decision on entry into the Registry for medical devices which are not in compliance with EU Directives and which are not "CE" marked:

1) Medical devices of the Class I	11.400,00
2) Medical devices of the Class IIa	28.500,00
3) Medical devices of the Class IIb	34.200,00
4) Medical devices of the Class III	57.000,00
5) Medical devices from the A i B lists ("In vitro" diagnostic medical devices)	13.680,00
6) Medical devices for self-testing ("In vitro" diagnostic medical devices)	11.400,00
7) Other "In vitro" medical devices	11.400,00
8) Active implantable medical devices and appliances referred to in clauses 1-7. of this Article	57.000,00
9) Medical devices for use in veterinary medicine	11.400,00

Fees for renewal of the registration of medical device in the Registry of medical devices amount 50% of the fees set out in Article 12 and Article 13, Paragraph 1, clauses 1) -8) of this Decision.

Fees for renewal of the registration of medical device intended for use in veterinary medicine in the Registry of medical devices amount 50% of the fees set out in Article 13. Paragraph 1. clause 9. of this Decision.

10. Amounts of fees for amendments related to entry of medical device into the Registry

Article 14

Fees for amendments related to entry of medical device into the Registry:

1) Amendments related to the entry of the medical device into the Registry which	10.000,00

require modifications of the decision	
2 Amendments related to the entry of the medical device into the Registry which do not require modifications of the decision	1.000,00

11. Amount of fee for issuance of the Decision on removal of the medical device from the Registry

Article 15

Fee for issuance of the Decision on removal of the medical device from the Registry	10.000,00

12. Amounts of fees for vigilance of medical devices

Article 16

Amounts of fees for vigilance of medical devices:

1) Annual fee for vigilance of medical devices, for each medical device:

a) Class I; Other "In vitro" diagnostic medical devices	1.000,00
b) "In vitro" diagnostic medical devices from the List A; "In vitro" diagnostic medical devices from the List B; "In vitro" diagnostic medical devices for self-testing.	1.500,00
v) Class IIa	2.000,00
g) Class IIb	3.000,00
d) Class III; Active implantable medical devices	5.000,00
2) administrative processing of the Periodic summary report on adverse events	10.000,00
3) half-day education for registration holders in the field of vigilance	20.000,00
4) one-day education for registration holders in the field of vigilance	30.000,00

Annual fee for the vigilance of medical devices shall be paid, for current year, no later than 31 March of the current year, for each medical device that has a valid Decision on entry into the Registry of Medical Devices on a 1 January of the current year.

13. Amounts of fees for issuing a Certificate of analysis of medicinal product and medical device

Article 17

Fees for issuing a Certificate of analysis on performed quality control of the medicine and medical devices:

1) document control of the imported medicine, which has a certificate of quality of the medicine, issued by the manufacturer or professional authority for quality control of the EU country, or other country which has the same or similar requirements for authorization	35.000,00
2) document control of vaccines, serums, blood-derived and plasma-derived medicines, ie of imported medicinal product which has a certificate of quality of	50.000,00

the medicine, issued by the manufacturer, the summary protocol and marketing authorization certificate issued by professional authority for quality control of the EU country, or other country which has the same or similar requirements for authorization, ie member of the OMCL Network	
3) document control of each batch of medical device which is not entered into the registry, but for which the Agency has issued an import approval	35.000,00
4) administrative tasks related to services of laboratory quality control of a: - medicine in a procedure of issuing a marketing authorization, amendments (variations) or renewal of marketing authorization for the medicine - first batch of medicine, - systematic control, - for-cause regulatory audit, - special controls for vaccines, serums and blood-derived and plasma-derived medicines of a domestic producers, as well as imported from countries that do not have the same or similar requirements for issuing a marketing authorization, - each batch of medicine imported from non-EU countries, ie countries that do not have the same or similar requirements for issuing a marketing authorization, - magistral and galenic medicines, - medical devices which are not compliant with EU regulations or regulations of the countries that have the same or similar requirements for market placement of medical devices	35.000,00
5) laboratory control on the basis of international agreements	350.000,00

Article 18

Amounts of fees for performed laboratory quality control of pharmaceutical form of medicines and medical devices, under Article 17, clause 4 of this Decision:

1) liquid and semi-solid medicines for oral administration	45.000,00
2) solid medicines for oral administration	55.000,00
3) medicines for use in the oral cavity	40.000,00
4) medicines for dental administration	40.000,00
5) medicines for cutaneous and transdermal administration	45.000,00
6) medicines for eyes	35.000,00
7) medicines for ears	35.000,00
8) medicines for nose	35.000,00
9) medicines for vaginal administration	45.000,00
10) medicines for rectal administration	40.000,00
11) medicines for inhalation	45.000,00
12) medicines for parental administration, implants, medicines for intramammal administration	50.000,00
13) vaccines, serums and blood-derived products	150.000,00
14) medicines for dialysis	50.000,00
15) medicines for intravesicular administration and urethral administration	40.000,00
16) medicines for tracheo-pulmonal administration	45.000,00
17) medicines for intrauterine administration	40.000,00
18) partial controls	30.000,00

19) medical devices	45.000,00
20) other	45.000,00

Article 19

Amount of fee for performed laboratory quality control of pharmaceutical form of medicines and medical devices, under the Article 18 of this Decision, shall be added to amount of fee for issuing the Certificate of analysis, under the Article 17 clause 4 of this Decision.

14. Amounts of fees for clinical trials of medicines or medical devices

Article 20

Amounts of fees for issuance of permit for conducting a clinical trial:

1) Issuance of permit for conducting a clinical trial of medicine	265.000,00
2) Issuance of permit for conducting a clinical trial of bioavailability or bioequivalence	178.000,00
3) Issuance of permit for conducting a non-commercial clinical trial of medicine (academic clinical trial of medicine)	50.000,00
4) Issuance of permit for conducting a clinical trial of medical device	185.000,00
5) Issuance of essential protocol amendments or amendments to a permit for clinical trial of medicine	60.000,00
6) Issuance of essential protocol amendments or amendments to a permit for conducting a non-commercial clinical trials	10.000,00
7) Issuance of essential protocol amendments or amendments to a permit for clinical trial of medical device	23.000,00
8) Issuance of permit for conducting a non-commercial clinical trial of medical device (academic clinical trial of medical device)	20.000,00
9) Issuing a permit for registration of post-marketing non-interventional clinical trial of a medicine and medical device	22.000,00
10) Issuing a permit for registration of clinical trial of medical device	22.000,00
11) Providing an opinion on import and export of the cell samples or tissue samples for procedures of clinical trials of medicines	5.600,00

For registration of administrative amendments to the protocol for conducting the clinical trials fees shall not be charged.

15. Amounts of fees for pharmacovigilance

Article 21

Amounts of fees for pharmacovigilance:

1) annual fee for pharmacovigilance of the medicine for each valid Decision on the marketing authorization of medicinal product	20.000,00
2) assessment of risk minimization measures and educational material	60.000,00
3) assessment of amendments to a risk minimization measures and educational	20.000,00

material	
4) administrative processing of the Periodical safety report	10.000,00
5) half-day education for authorization holders in the field of pharmacovigilance	20.000,00
6) one-day education for authorization holders in the field of pharmacovigilance	30.000,00

Annual fee for pharmacovigilance of the medicine, for the current year, shall be paid no later than 31 March of the current year, for marketing authorization for medicinal product to be valid on 1 January of the current year.

16. Amounts of fees for issuance of reports, decisions and opinions for medicines and medical devices

Article 22

Amount of fee for issuance of reports on the assessment of the documentation for medicine and medical device	9.500,00
Amount of fee for issuance of a decision on categorization of medicines and medical devices	20.000,00
Amount of fee for providing an opinion on import of the samples of a medicine, or substances and other materials, required in the process of issuing the authorization for the medicine	8.000,00
Amount of fee for providing an opinion on the approval of additional content labels on the outer package of the medicine	8.000,00
Amount of fee for providing an opinion on matters within the competence of the Medicines and Medical Devices Agency of Serbia	12.000,00

17. Amount of fee for issuance and monitoring of control labels

Article 23

Amount of fee for issuance and monitoring of control labels	1.000,00

18. Amount of fee for issuance of a transcription of the Agency files and decision on amendments

Article 24

Amount of fee for issuance of a transcription of the Agency files	1.500,00

19. Amount of fee for issuance of the decision on approval of promotional materials and other documentation for advertising and promotion of medicines and medical devices

Article 25

Amount of fee for issuance of the decision on approval of promotional materials and other documentation for advertising and promotion of medicines and medical devices:

1) advertising intended for general public	
a) print media	30.000,00

b) internet media	35.000,00
c) TV / radio media	40.000,00
2) advertising intended for professional public	
a) print media	35.000,00
b) internet media	40.000,00

20. Amounts of fees for issuing permits for import of medicines which do not have a marketing authorization for medicinal product or medical devices not entered into the Registry

Article 26

Amount of fee for issuing permits for import of medicines which do not have a marketing authorization for medicinal product or medical devices not entered into the Registry	15.000,00
Amount of fee for issuing permit for import of medicines and medical devices intended for clinical trials	10.000,00

21. Payment of fees

Article 27

Amounts of fees, set out in Articles 2 to 26 of this Decision, applicant shall pay to the business account of the Agency.

22. Refund of a certain amount of fee

Article 28

If applicant withdraws from the services stated in Articles 2-26 of this decision, in written form, before initiating the process of determining a completeness of the request, the entire amount of prescribed fee shall be refunded to applicant.

If applicant withdraws from the services stated in Articles 2-26 of this decision, in written form, within the seven days upon the receipt of a confirmation on the completeness or incompleteness of the documentation from the Agency, applicant shall be refunded with the amount of prescribed fees reduced by 40%.

If applicant withdraws from the services stated in Articles 17-19 of this decision, in written form, in the course of laboratory or document quality control of a medicine or medical device, applicant shall be refunded with the amount of prescribed fees reduced by 80%.

If applicant withdraws from the services stated in Articles 2-26 of this decision, in written form, in the course of expert assessment of documentation on medicine or medical device, within seven days upon the receipt of the first clock-stop letter or the letter of essential incompleteness, applicant shall be refunded with the amount of prescribed fees reduced by 80%.

Agency will refuse requests for refund of a certain amount of prescribed fees if applicant submits requirements beyond the prescribed conditions stated in paragraphs 1-4 of this Article.

In a case that applicant has not submitted a request from paragraphs 1-4 of this Article, and the Agency has made a decision on refusal of the request, paid amount of the fee shall not be refunded.

23. Exceptions when Agency does not charge fees for services within its competence

Article 29

Agency does not charge fees for services within its competence related to medicines used for the treatment of rare human diseases ("Orphan" medicines), for the treatment of rare diseases in minor animal species ("MUMS"), medicines and medical devices from the donation or humanitarian aid, as well as for performing the tasks at the request of the competent ministries.

Article 30

On a day when this decision takes effect, Decision on the amount and method of payment of the fees for the services of the Medicines and Medical Devices Agency of Serbia ("Official Gazette of the Republic of Serbia" No. 52/05 and 75/06) will cease to have effect.

Article 31

This decision, after obtaining the consent of the Government of the Republic of Serbia, shall be published in "Official Gazette of the Republic of Serbia" and shall enter into force on an eighth day after its publication and shall apply from the 1 January, 2018.