Pursuant to Articles 189 and 190 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, no. 17/14), Articles 39 and 40 of the Public Agencies Act (Official Gazette of the Republic of Slovenia, Nos 25/02, 51/04 – EZ-A and 33/11 – ZEKom-C), Article 11 of the Decision on the establishment of the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (Official Gazette of the Republic of Slovenia, no. 115/06) and consent of the Government of the Republic of Slovenia of 11 January 2018, I hereby issue

THE LIST OF RATES
of the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices

I. GENERAL PROVISIONS

Article 1
(Type of service)

(1) This List of Rates lays down the fees for services implemented by the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: JAZMP) for private and legal persons, for the costs of implementing administrative tasks which are part of the public authorisation and which are implemented by JAZMP and for the costs of implementing professional tasks and services as per the competence of JAZMP.

(2) The holder of the marketing authorisation for a medicinal product or a marketing authorisation for a parallel-imported medicinal product and the holder of a licence to pursue the activity issued by JAZMP shall also pay an annual fee for the costs of monitoring the medicinal product on the market, which refer to an individual medicinal product as per the number of pharmaceutical forms or strengths.

(3) Fees to be charged by JAZMP include:

1. annual fees for monitoring a medicinal product with marketing authorisation on the market and for monitoring activities relating to medicinal products;
2. fees for the issue, amendment and termination of manufacturing authorisation for medicinal products;
3. fees for the issue of certificates relating to the verification of conformity with good manufacturing practice at medicinal product manufacturers;
4. fees for the issue, amendment and termination of a wholesale distribution authorisation and notification of a wholesaler established in the European Union;
5. fee for the issue of a certificate on good distribution practice of medicinal products and active substances;
6. fees for the issue, amendment and termination of a retail sale authorisation for medical products in specialised shops for the issue of OTC medical products;
7. fees for the entry in, amendment of and removal from, a register of manufacturers, wholesalers and importers of active substances;
8. fees for the entry in, amendment of or removal from, the register of agents selling medicinal products and substances;
9. fees for the entry in, amendment of and removal from, a register of professional associates when advertising medical products;
10. fees for the procedure of notification or approval of a clinical trial for a medicinal product and the evaluation of clinical trial performance;
11. fees for the procedure of notification of a non-interventional clinical trial or non-interventional study or the issue of a preliminary approval of a non-interventional clinical trial or non-interventional study;
12. fees for the issue of an authorisation for the compassionate use of medicinal products;

13. fees for the issue, line extension, renewal, amendment, transfer and withdrawal of a marketing authorisation for a medicinal product for human use and a marketing authorisation for a medicinal product used in veterinary medicine;
14. fees for the assessment of an updated Periodic Safety Update Report (PSUR) for a medicinal product with unlimited marketing authorisation;
15. fees for a review of educational materials for safe and effective use of medicinal products and for other amendments to information on a medical product;
16. fees for an application for listing a medicinal product among interchangeable medicinal products under an independent procedure;
17. fees for the issue, renewal, amendment, transfer and withdrawal of a marketing authorisation for medicinal products of herbal origin;
18. fees for the issue, renewal, amendment, transfer and withdrawal of a marketing authorisation for homeopathic medicinal products;
19. fees for the issue of a temporary marketing authorisation and the entry or import of medicinal products with no marketing authorisation;
20. fees for the issue of an authorisation for the entry or import and removal or export of illicit drugs in groups II and III and for sealing the register of medicinal products, which are illicit drugs in groups II, III a and III c;
21. fees for the marketing authorisation for a parallel-imported medicinal product and the certificate on the parallel distribution of medicinal products;
22. fees for the issue, renewal, variation and cessation of a marketing authorisation for a parallel-imported medicinal product;
23. fees for approval of individual deviations from the conditions of marketing authorisation (OOS) and for preservation of marketing authorisation for a medical product;
24. fees for approval of the use of foreign-language-labelled packaging with a label in Slovenian attached;
25. fees for determining the elements in the so-called blue box and the national identifier of medical products, for which the marketing authorisation was obtained in accordance with the centralised procedure;
26. fees for the deferment of cancellation of a marketing authorisation;
27. fee for the approval of conducting a campaign for vaccination with necessary data on vaccines;
28. fees for the definition of a product;
29. fees for the determination of an extraordinary higher allowed price of a medicinal product;
30. fees for the determination of the maximum allowed price of a medicinal product;
31. fees for the notification of business donations of medicinal products;
32. fees for the issue of, amendment to and withdrawal of, a human tissue and cell supply authorisation;
33. fees for the issue of, amendment to and withdrawal of, a blood supply authorisation;
34. fees for the issue of, amendment to and withdrawal of, an authorisation for the preparation of non-routinely prepared advanced therapy medicinal products;
35. fees for the entry into, amendment to and deletion from, the register of doctors and veterinarians who use non-routinely prepared advanced therapy medicinal products in their practice.

(4) JAZMP shall charge the implementation of the following professional tasks and services:

1. expert education, lecture, workshop and consultation;
2. consulting;
3. specialisation and mentoring;
4. travel and other costs of experts and pharmaceutical inspectors when implementing their tasks;
5. publishing;
6. photocopying, printing and scanning;
7. issuing additional copies and duplicates and confirmation of the finality of individual administrative acts;
8. other professional tasks;
9. issue of reminders for outstanding liabilities.

Article 2
(Rate levels)

(1) The rates are laid down in points. The amount for payment is the point value multiplied by the number of points.

(2) The value of one point is 5 euros excluding value added tax. The value of one point may be verified annually, i.e. on the basis of actual costs relating to the implementation of tasks and services in this List of Rates. Any change in the value of one point shall be adopted by the JAZMP council with the prior consent of the founder. The new value of the point shall be published in the Official Gazette of the Republic of Slovenia.

II. FEES

Article 3
(Payment obligations, methods and deadlines)

(1) The fee shall be subject to payment after the receipt of the payment notification or notification on the payment method of the fee from the JAZMP.

(2) JAZMP shall send a notification on the payment method of the fee to the e-mail address of the applicant, which is included in the application form. The notification on the payment method of the fee shall include at least the information on the applicant, the received application, the object of the charged fee (products), the amount of the fee, reference number and other information required for the payment. The notification on the payment method of the fee shall be produced by the person responsible for the procedure from the information system intended for managing procedures and keeping records. The applicant shall settle the fee for the procedures within 15 days to the sub-account of the JAZMP.

(3) An annual fee shall be settled within 15 days. JAZMP shall submit notifications for the payment of annual fees to the authorisation holders no later than by 31 March of the current year for all applicable authorisations as of 1 January of the current year.

(4) When settling the fee, the applicant shall provide the reference number stated in the notification on the payment method of the fee.

(5) In the case of non-payment of the fee, JAZMP may charge legal default interest to the applicant.

Article 4
(Annual fees)

Annual fees for monitoring a medicinal product on the market and for monitoring activities relating to medicinal products shall be as follows:

1. individual marketing authorisation for a homeopathic medicinal product in any pharmaceutical form: 7 points;
2. individual manufacturing authorisation for a medicinal product: 26 points;
3. individual wholesale distribution authorisation for medicinal products: 20 points,
4. individual retail sale authorisation for medicinal products in specialised shops: 13 points.

Article 5
(Fees relating to medicinal product manufacturing)

Fees for the issue, amendment and termination of manufacturing authorisation for medicinal products shall be as follows:

1. issue of an authorisation for medicinal product manufacturing based on verification of compliance with good manufacturing practice per day of an expert committee inspection at the applicant: 380 points;

2. consideration of a variation, when reassessment of compliance with good manufacturing practice is not necessary and the variation requires an amendment to the medicinal product manufacturing authorisation: 75 points;
3. consideration of a variation, when reassessment of compliance with good manufacturing practice is necessary and the variation requires an amendment to the medicinal product manufacturing authorisation per day of an expert committee inspection at the applicant at individual manufacturing locations: 305 points;
4. issue of a compliance assessment for the manufacturing of medicinal products, when reassessment of compliance with good manufacturing practice is necessary and the variation does not require an amendment to the medicinal product manufacturing authorisation on the day of an expert committee inspection at the applicant: 305 points;
5. revocation of medicinal product manufacturing authorisation at the request of the authorisation holder: 40 points;
6. entry in the register of persons responsible for the release of individual medicinal product series: 20 points;
7. amendment to the entry in the register of persons responsible for the release of individual medicinal product series: 20 points;
8. removal from the register of persons responsible for the release of individual medicinal product series: 20 points.

Article 6
(Fees relating to the inspection of good manufacturing practice and certificates of quality and status of medicinal products)

(1) Fees for the inspection of good manufacturing practice at a manufacturing site of a medicinal product and an active substance, and fees for the issue of certificates for good manufacturing practice compliance of the manufacturer thereof shall be as follows:

1. assessment of compliance with good manufacturing practice in a procedure for marketing authorisation acquisition at the applicant per pharmaceutical supervisor/day: 400 points;
2. assessment of compliance with good manufacturing practice abroad at the proposal of a legal entity or a natural person per pharmaceutical supervisor/day: 400 points;
3. issue of a certificate of good manufacturing practice compliance abroad for medicinal products and active substances: 100 points.

(2) Fee for the issue of certificates of quality and status of medicinal products entering international trade (CPP, certificate of the manufacture and sales of a medicinal product in compliance with GMP, certificate of the regulatory status of the medicinal product, statement that the medicinal product is manufactured in Slovenia): 50 points.

(3) In addition to the fees referred to in points 1 and 2 of the preceding paragraph, the applicant shall also cover other costs of pharmaceutical supervisors as per Article 50 of this List of Rates.

Article 7
(Fees relating to wholesale distribution authorisation for medicinal products)

(1) Fees for the issue, amendment and termination of a licence for medicinal products wholesale – full scope of activities, and for procedures proposed by the Institute of the Republic of Slovenia for Commodity Reserves shall be as follows:

1. issue of wholesale distribution authorisation for medicinal products based on verification of compliance with good distribution practice per day of expert committee inspection at the applicant: 210 points;
2. consideration of a variation, whereby reassessment of compliance with good distribution practice is not necessary and the variation requires an amendment to the wholesale distribution authorisation for medicinal products: 55 points;
3. consideration of a variation, whereby reassessment of compliance with good distribution practice is necessary and whereby the variation requires an amendment to the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant: 155 points;

4. issue of an assessment of compliance with the requirements for wholesale of medicinal products, when reassessment of compliance with good distribution practice is necessary and the variation does not require an amendment to the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant: 155 points.

(2) Fees for the issue, amendment and termination of a wholesale distribution authorisation – product-limited scope of activities shall be as follows:

1. issue of wholesale distribution authorisation for medicinal products based on verification of compliance with good distribution practice per day of expert committee inspection at the applicant: 480 points;
2. consideration of a variation, when reassessment of compliance with good distribution practice is not necessary and the variation requires an amendment to the wholesale distribution authorisation for medicinal products: 95 points;
3. consideration of a variation, whereby reassessment of compliance with good distribution practice is necessary and the variation requires an amendment to the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant: 385 points;
4. issue of an assessment of compliance with the requirements for product-limited scope of activities for wholesale marketing of medicinal product with an inspection, when reassessment of compliance with good distribution practice is necessary and the variation does not require an amendment to the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant: 385 points.

(3) Fees for the issue, amendment and termination of a wholesale distribution authorisation – contact-limited scope of activities be as follows:

1. issue of wholesale distribution authorisation for medicinal products based on verification of compliance with good distribution practice per day of expert committee inspection at the applicant: 305 points;
2. consideration of a variation, when reassessment of compliance with good distribution practice is not necessary and the variation requires an amendment to the wholesale distribution authorisation for medicinal products: 75 points;
3. consideration of a variation, whereby reassessment of compliance with good distribution practice is necessary and the variation requires an amendment to the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant: 230 points;
4. issue of an assessment of compliance with the requirements for contact-limited scope of activities for wholesale marketing of medicinal products, when reassessment of compliance with good distribution practice is necessary and the variation does not require an amendment to the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant: 230 points.

(4) Other fees relating to the issue, amendment and termination of wholesale distribution authorisations for medicinal products shall be as follows:

1. issue of a Certificate of Good Distribution Practice compliance: 100 points;
2. revocation of a wholesale distribution authorisation for medicinal products at the request of the authorisation holder: 40 points;
3. entry in the register of persons responsible for the adoption of medicinal products: 20 points;
4. amendment to the entry in the register of persons responsible for the adoption of medicinal products: 20 points;
5. removal from the register of persons responsible for the adoption of medicinal products: 20 points;
6. entry in the official register of a notified wholesaler of medicinal products, who obtained a marketing authorisation for medicinal products in another European Union Member State: 150 points;
7. amendment of entry in the official register of a notified wholesaler of medicinal products, who obtained a marketing authorisation for medicinal products in another European Union Member State: 150 points;
8. Deletion of a notified wholesaler of medicinal products, who obtained a marketing authorisation for medicinal products in another European Union Member State, from an official register: 20 points.

Article 8
(pristojbine za dovoljenje za opravljanje prometa z zdravili na drobno v specializiranih prodajalnah)

Fees for the issue, amendment and termination of a retail sale-+ authorisation for medicinal products in specialised shops shall be as follows:

1. issue of the retail sale authorisation for medicinal products in specialised shops based on verification of compliance with requirements per day of expert committee inspection: 305 points;
2. consideration of a variation, when reassessment of compliance with requirements is not necessary and the variation requires an amendment to the retail sale authorisation for medicinal products in a specialised shop: 75 points;
3. assessment of compliance with requirements with regard to retail sales of medicinal products in specialised shops, when reassessment of compliance with the requirements is necessary and the variation does not require an amendment to the retail sale authorisation for medicinal products in specialised shops per day of expert committee inspection: 230 points;
4. consideration of a variation, when reassessment of compliance with the requirements is necessary and the variation requires an amendment to the retail sale authorisation for medicinal products in specialised shops per day of expert committee inspection: 230 points;
5. revocation of the retail sale authorisation for medicinal products in a specialised shop at the request of the authorisation holder: 40 points.

Article 9
(Fees for registers of manufacturers, wholesalers and importers of active substances)

Fees for registers of manufacturers, wholesalers and importers of active substances shall be as follows:

1. entry in the register of manufacturers, wholesalers and importers of active substances: 150 points;
2. entry in the register of manufacturers, wholesalers and importers of active substances per day of expert committee inspection: 225 points;
3. amendment to the entry in the register of manufacturers, wholesalers and importers of active substances: 75 points;
4. amendment to the entry in the register of manufacturers, wholesalers and importers of active substances per day of expert committee inspection: 125 points;
5. removal from the register of manufacturers, wholesalers and importers of active substances: 20 points;
6. consideration of annual reports by a manufacturer, wholesaler and an importer of active substances: 40 point.

Article 10
(Fees for brokerage of medicinal products and active substances)

Fees for brokerage of medicinal products and active substances shall be as follows:

1. entry in the register of agents selling medicinal products and active substances: 40 points;
2. amendment to the entry in the register of agents selling medicinal products and active substances: 40 points;
3. entry in the register of agents selling medicinal products and active substances: 20 points

Article 11
(Fees for the entry, amendment and removal from the register of professional associates when advertising medicinal products)

Fees for the entry, amendment and removal from the register of professional associates when advertising medicinal products shall be as follows:

1. entry of a professional associate in the register: 20 points,
2. amendment to the entry of a professional associate in the register: 20 points,
3. removal of a professional associate from the register: 20 points.

Article 12
(Fees for clinical trial and non-interventional trial of medicinal products or for non-interventional study)

(1) Fees for the procedure of notification or approval of a clinical trial of a medicinal product and fees for the supervision of the implementation of clinical trials in compliance with good clinical practice shall be as follows:

1. notification or approval of clinical trials of a medicinal product based on an assessment from another European Union Member State: 190 points;
2. notification or approval of clinical trials of a medicinal product based on an assessment of protocol: 1,210 points;
3. notification of an amendment to a clinical trial of a medicinal product: 40 points;
4. issue of consent to the protocol of non-interventional trial of a medicinal product or non-interventional study carried out at the request of JAZMP and taking place only in the Republic of Slovenia: 305 points;
5. notification of a non-interventional trial of a medicinal product or non-interventional study: 75 points;
6. notification of a major change of the protocol of non-interventional trial of a medical product or non-interventional study carried out at the request of the JAZMP and taking place only in the Republic of Slovenia: 35 points;
7. assessment of a clinical trial for compliance with good clinical practice at the proposal of a legal entity or a natural person per pharmaceutical supervisor/day: 305 points;
8. assessment of a clinical trial for compliance with good clinical practice in the procedure for marketing authorisation acquisition per pharmaceutical supervisor/day: 305 points

(2) In addition to the fees referred to in points 7 and 8 of the preceding paragraph, the applicant shall also cover other costs of pharmaceutical supervisors as per Article 50 of this List of Rates.

(3) Fees for the procedure of notification of a clinical trial of a veterinary medicinal product shall be as follows:

1. notification of a clinical trials of a medicinal product based on an assessment of protocol: 150 points;
2. notification of an amendment to a clinical trial of a medicinal product: 40 points;
3. notification of a non-interventional clinical trial: 75 points,
4. notification of an amendment to a non-interventional clinical trial: 35 points.

(4) Fees relating to the procedure of notification or approval of a clinical trial of a medicinal product in a paediatric population and in orphan medicines shall amount to half the value of individual fees referred to in paragraph (1) of this Article.

(5) Fees relating to the procedure of notification or approval of a clinical trial of a medicinal product and notification of important amendment to clinical trials of a medicinal product for human use, and sponsors shall be non-profit businesses and private individuals (non-commercial clinical trial) shall amount to a half of the value of individual fees from paragraph (1) of this Article.

(6) Fees relating to the procedure of obtaining authorisation for compassionate use shall not be charged.

Article 13
(Fees for the issue of a marketing authorisation for medicinal products for human use)

(1) JAZMP shall issue marketing authorisations under the following procedures:

1. a national procedure (hereinafter: NP),
2. a mutual recognition procedure in which the Republic of Slovenia is the Reference Member State (hereinafter: MRP-RMS),
3. a mutual recognition procedure in which the Republic of Slovenia is the Concerned Member State (hereinafter: MRP-CMS),

4. a decentralised procedure in which the Republic of Slovenia is the Reference Member State (hereinafter: DCP-RMS),
5. a decentralised procedure in which the Republic of Slovenia is the Concerned Member State (hereinafter: DCP-CMS).
6. repeated application of the mutual recognition procedure after a completed MRP or DCP procedure in which the Republic of Slovenia is the Reference Member State (hereinafter: RUP-RMS)

(2) Fees for the issue of a marketing authorisation for medicinal products for human use shall be as follows:

1. for the issue of marketing authorisations pursuant to Articles 44 or 49 of the Act in:
1. NP 2.055 points,
2. MRP-CMS 735 points,
3. MRP-RMS 5,985 points,
4. RUP-RMS 4,000 points,
5. DCP-CMS 735 points,
6. DCP-RMS 6,990 points;

2. for the issue of marketing authorisations pursuant to Article 47 of the Act in:
1. NP 2.000 points,
2. MRP-CMS 735 points,
3. MRP-RMS 5,695 points,
4. RUP-RMS 3,700 points,
5. DCP-CMS 735 points,
6. DCP-RMS 6,420 points;

3. for the issue of marketing authorisations pursuant to paragraph (1) or (6) of Article 45 of the Act in:
1. NP 1.775 points,
2. MRP-CMS 615 points,
3. MRP-RMS 4,995 points,
4. RUP-RMS 3,400 points,
5. DCP-CMS 615 points,
6. DCP-RMS 5,790 points;

4. for the issue of marketing authorisations pursuant to Article 50 of the Act in:
1. NP 650 points,
2. MRP-CMS 510 points,
3. MRP-RMS 2,580 points,
4. RUP-RMS 1,700 points,
5. DCP-CMS 735 points,
6. DCP-RMS 4,190 points;

(3) Fees for the acquisition of a marketing authorisation for a medicinal product regardless of the type of procedure with all legal bases for medicinal products on the list of urgently needed or essential medicinal products and which before the submission of an application for the acquisition of a marketing authorisation entered and were imported in compliance with paragraph three of Article 20 of the Act, are 50 per cent lower than the fees referred to in the preceding paragraph v.

Article 14
(Fees for the issue of a marketing authorisation for a veterinary medicinal product)

(1) Fees for the issue of a marketing authorisation for a veterinary medicinal product shall be the following:

1. for the issue of marketing authorisations pursuant to Articles 44 or 49 of the Act in:
– NP 1,000 points,
– MRP-CMS 420 points,

– MRP-RMS 6,000 points,
– DCP-CMS 450 points,
– DCP-RMS 7,000 points;

2. for the issue of marketing authorisations pursuant to Article 48 of the Act in:
– NP 800 points,
– MRP-CMS 380 points,
– MRP-RMS 5,000 points,
– DCP-CMS 420 points
– DCP-RMS 5,500 points;

3. for the issue of marketing authorisations pursuant to paragraph (1) or (6) of Article 46 of the Act in:
– NP 700 points,
– MRP-CMS 360 points,
– MRP-RMS 5,000 points,
– RUP-RMS 2,700 points,
– DCP-CMS 380 points,
– DCP-RMS 5.,800 points;

4. for the issue of marketing authorisations pursuant to Article 50 of the Act in:
– NP 200 točk,
– MRP-CMS 200 points,
– MRP-RMS 3,500 points,
– RUP-RMS 2,700 points,
– DCP-CMS 200 points,
– DCP-RMS 4,600 points.

(2) Fees for the acquisition of a marketing authorisation for a medicinal product regardless of the type of procedure with all legal bases for medicinal products, which contain active substances and which are currently placed on the market for the needs of market supply as urgently needed and essential medicinal products without a marketing authorisation for a medicinal product and which in the previous year were marketed based on an authorisation for entry and import, are 50 per cent lower than the fees referred to in the preceding paragraph.

Article 15
(Fees for line extension of the marketing authorisation for a medicinal product for human use)

Fees for considering applications for the line extension of marketing authorisations for medicinal products for human use shall be as follows:
1. NP 1,320 points,
2. MRP-CMS 615 points,
3. DCP-CMS 615 points,
4. MRP-RMS 3,145 points,
5. DCP-RMS 3,875 points.

Article 16
(Fees for line extension of marketing authorisations for medicinal products used in veterinary medicine)

Fees for considering applications for the line extension of marketing authorisations for medicinal products used in veterinary medicine shall be as follows:
1. NP 600 points,
2. MRP-CMS 250 points,
3. DCP-CMS 280 points,
4. MRP-RMS 3,000 points,
5. DCP-RMS 3,000 points.

Article 17
(Fees for renewal of a marketing authorisation for medicinal products for human use)

Fees for renewal of a marketing authorisation for medicinal products for human use shall be as follows:
1. NP 400 points,
2. MRP/DCP-CMS 255 points,
3. MRP/DCP-RMS 2,100 points.

Article 18
(Fees for renewal of a marketing authorisation for medicinal products used in veterinary medicine)

Fees for renewal of a marketing authorisation for medicinal products used in veterinary medicine shall be as follows:
1. NP 300 points,
2. MRP/DCP-CMS 250 points,
3. MRP/DCP-RMS 2,350 points.

Article 19
(Fees for type I and II variations of medicinal products for human use)

Fees for consideration of type I and type II variations for medicinal products shall refer only to medicinal products which have obtained marketing authorisations in the Republic of Slovenia. If the application is filed as a grouped variation applicable to several marketing authorisations or work-sharing, the fee for the grouped variation or work-sharing shall be observed at all times. One marketing authorisation according to this Article includes a medicinal product of all strengths, pharmaceutical forms or packaging as determined by the root or the main part of the number of the marketing authorisation. Fees shall be as follows:

1. for notification of a type IA variation in:
- NP 50 points,
- MRP/DCP-CMS 25 points,
- MRP/DCP-RMS 310 points;

2. for notification of a type IB variation in:
- NP 110 points,
- MRP/DCP-CMS 110 points,
- MRP/DCP-RMS 685 points;

3. for approval of a type II variation in:
- NP 260 points,
- MRP/DCP-CMS 140 points,
- MRP/DCP-RMS 1,300 points;

4. in grouping of variations in accordance with Article 7 and 13d of Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7) last amended by Commission Regulation (EU) No. 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 209, 4.8.2012, p. 4) (hereinafter: Regulation (EC) No 1234/2008):
a) in point (a) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (a) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (notification of type IA variations for one marketing authorisation): a full fee referred to in point 1 of this Article shall apply for the first variation, and 75 per cent of the total fee referred to in point 1 of this Article for each additional variation to the relevant marketing authorisation, but not more than
- NP 400 points,
- MRP/DCP-CMS 250 points,

– MRP/DCP-RMS 1,500 points;

b) in point (a) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (a) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (notification of type IA variations for several marketing authorisations of the same holder): a full fee in accordance with point 1 of this Article shall apply for the first variation of the first marketing authorisation, 75 per cent of the total fee referred to in point 1 of this Article for further variations of the first marketing authorisation, and 75 per cent of the total fee for the same variations to each additional marketing authorisation calculated as per the variations of the first marketing authorisation, but not more than:

– NP 400 points,
– MRP/DCP-CMS 250 points,
– MRP/DCP-RMS 1,500 points;

c) in point (b) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (b) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (extension of marketing authorisation and subsequent variations): a full fee in accordance with Article 16 of this List of Rates shall apply for a major variation and 75 per cent of the total fee for each additional variation referred to in points 1, 2 or 3 of this Article, but not more than:

– NP 2,000 points,
– MRP/DCP-CMS 1,200 points,
– MRP/DCP-RMS 4,200 points;

č) in point (b) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (b) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (variation of type IB or II and subsequent or related variations): a full fee referred to in points 2 or 3 of this Article shall apply for a major variation and 75 per cent of the total fee for each additional variation referred to in points 1, 2 or 3 of this Article, but not more than:

– NP 800 points,
– MRP/DCP-CMS 450 points,
– MRP/DCP-RMS 3.500 points;

d) in point (c) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (combining variations of type IB or II and subsequent or related variations for several exclusively national marketing authorisations of the same holder): a full fee referred to in points 2 or 3 of this Article shall apply for the first variation of the first marketing authorisation, 75 per cent of the total fee referred to in points 1, 2 or 3 of this Article for subsequent variations of the first marketing authorisation, and 75 per cent of the total fee for the same variations to each additional marketing authorisation calculated as per the variations of the first marketing authorisation;

5. notwithstanding the preceding point:

a) for a change of name or address of a marketing authorisation holder or for a single notification of a summary of the main dossier on a pharmacovigilance system applicable to more medicinal products, the maximum fee may be as follows:

– up to 20 medicinal products: 100 points,
– more than 20 medicinal products: 200 points,
– more than 50 medicinal products: 400 points;

b) for grouped variations concerning the change of name of a medicinal product for human use in several EU Member States, the fee for a single variation shall be as specified in point 2 of this Article, which also applies in cases when the medicinal product's name in the Republic of Slovenia remains unchanged;

c) for grouped variations concerning the change of name or address of the marketing authorisation holder in several Member States for a single medicinal product (single marketing authorisation of a medical product), the fee for a single variation shall be as specified in point 1 of this Article, regardless of whether the name or address of the marketing authorisation holder changes in the Republic of Slovenia or not;

6. in work-sharing procedures pursuant to Article 20 of Regulation (EC) No 1234/2008, a full fee in accordance with points (b), (c) or (d) of point 4 of this Article shall apply for a variation of the first marketing authorisation and 75 per cent of the total fee for every additional marketing authorisation, calculated as per the variation or variations of the first marketing authorisation while taking account whether the Republic of Slovenia is an RMS or a CMS in the relevant work-sharing procedure.

Article 20
(Fees for type I and II variations of medicinal products for veterinary use)

Fees for consideration of type I and type II variations for medicinal products for veterinary use shall refer only to medicinal products which have obtained marketing authorisations in the Republic of Slovenia. If the application is filed as a grouped variation applicable to several marketing authorisations or work-sharing, the fee for the grouped variation or work-sharing shall be observed at all times. Fees shall be as follows:

1. for notification of a type IA variation in:
– NP 30 points,
– MRP/DCP-CMS 30 points,
– MRP/DCP-RMS 400 points;

2. for notification of a type IB variation in:
– NP 99 points,
– MRP/DCP-CMS 99 points,
– MRP/DCP-RMS 800 points;

3. for approval of a type II variation in:
– NP 165 points,
– MRP/DCP-CMS 165 points,
– MRP/DCP-RMS 1,300 points;

4 in grouping of variation in accordance with Articles 7 and 13d of Commission Regulation No. 1234/2008/EC:
a) in point (a) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to Article 8 of Regulation (EC) No 1234/2008 (annual notification of type IA variations): a full fee referred to in point 1 of this Article shall apply for the first variation, and 75 per cent of the total fee for each additional variation;
b) in point (a) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (a) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (notification of type IA variations for one marketing authorisation): a full fee referred to in point 1 of this Article shall apply for the first variation, and 75 per cent of the total fee referred to in point 1 of this Article for each additional variation to the relevant marketing authorisation, but not more than:
– NP 400 points,
– MRP/DCP-CMS 250 points,
– MRP/DCP-RMS 1,500 points;
c) in point (a) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (a) of paragraph (2) of Article 13d of Regulation (EC) No 1234/2008 (notification of type IA variations for several marketing authorisations of the same holder): a full fee referred to in point 1 of this Article shall apply for the first variation of the first marketing authorisation, 75 per cent of the fee referred to in point 1 of this Article for further variations of the first marketing authorisation, and 75 per cent of the total fee for the same variations to each additional marketing authorisation calculated as per the variations of the first marketing authorisation, but not more than:
– NP 400 points,
– MRP/DCP-CMS 250 points,
– MRP/DCP-RMS 5,000 points;
č) in point (b) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (b) of paragraph (2) of Article 13d of Regulation (EC) No 1234/2008 (extension of marketing authorisation and subsequent variations): a full fee referred to in Article 15 of this List of Rates shall apply for a major variation and 75 per cent of the total fee referred to in points 1, 2 or 3 of this Article for each additional variation, but not more than:
– NP 1.000 points,
– MRP/DCP-CMS 800 points,
– MRP/DCP-RMS 5,000 points;
d) in point (b) of paragraph (2) of Article 7 of Regulation (EC) No 1234/2008 and relating to point (b) of paragraph (2) of Article 13d of Regulation (EC) No 1234/2008 (variation of type IB or II and subsequent or related variations): a full fee referred to in points 2 or 3 of this Article shall apply for a major variation and 75 per cent of the total fee referred to in points 1, 2 or 3 of this Article for each additional variation, but not more than:

– NP 600 points,
– MRP/DCP-CMS 550 points,
– MRP/DCP-RMS 3,000 points;

e) in point (c) of paragraph (2) of Article 13d of Regulation (EC) No 1234/2008 (combining variations of type IB or II and subsequent or related variations for several exclusively national marketing authorisations of the same holder): a full fee referred to in points 2 or 3 of this Article shall apply for the first variation of the first marketing authorisation, 75 per cent of the total fee referred to in points 1, 2 or 3 of this Article for subsequent variations of the first marketing authorisation, and 75 per cent of the total fee for the same variations to each additional marketing authorisation calculated as per the variations of the first marketing authorisation;

5. notwithstanding the preceding point:
a) for a change of name or address of a marketing authorisation holder or a single change of an existing detailed description of a pharmacovigilance system applicable to more medicinal products, the maximum fee is as follows:
– up to 20 medicinal products: 100 points,
– more than 20 medicinal products: 200 points,
– more than 50 medicinal products: 400 points;

b) for grouped variations concerning the change of name of a medicinal product used in veterinary medicine in several EU Member States, the fee for a single variation shall be as specified in point 2 of this Article, which also applies in cases when the medicinal product's name is changed in the Republic of Slovenia;

6. in work-sharing procedures pursuant to Article 20 of Regulation (EC) No 1234/2008, a full fee in accordance with points (b), (c) or (d) of point 4 of this Article shall apply for a variation of the first marketing authorisation and 75 per cent of the total fee for every additional marketing authorisation, calculated as per the variation or variations of the first marketing authorisation while taking account whether the Republic of Slovenia is an RMS or a CMS in the relevant work-sharing procedure.

Article 21
(Fees for the transfer or cessation of a marketing authorisation for medicinal product for human use)

Fees for the transfer or cessation of a marketing authorisation at the request of the marketing authorisation holder shall be as follows:

1. transfer of marketing authorisation to another legal entity or natural person: 70 points,
2. maximum fees for a simultaneous transfer of several marketing authorisations to another legal entity or natural person: 280 points,
3. cessation of marketing authorisation at the request of the marketing authorisation holder for an individual pharmaceutical form or strength: 15 points.

Article 22
(Fees for the transfer or withdrawal of a marketing authorisation for a veterinary medicinal product)

Fees for the transfer and cessation of a marketing authorisation at the request of the marketing authorisation for a veterinary medicinal product holder shall be as follows:

1. transfer of marketing authorisation to another legal entity or natural person: 50 points,
2. maximum fees for a simultaneous transfer of several marketing authorisations to another legal entity or natural person: 200 points,
3. cessation of marketing authorisation at the request of the marketing authorisation holder for an individual pharmaceutical form or strength: 20 points.

Article 23
(Fees for the assessment of a Periodic Safety Update Report – PSUR)

(1) Fees for the assessment of the updated Periodic Safety Update Report (PSUR) for a medicinal product used in veterinary medicine with unlimited marketing authorisation according to the procedure by which the medicinal product has been authorised shall be as follows:

1. NP 300 points,
2. MRP/DCP-CMS 50 points,

3. MRP/DCP-RMS 1,995 points.

(2) Fees for the assessment of the updated Periodic Safety Update Report (PSUR) for a medicinal product for human use – national procedure (NP) shall be 755 points.

(3) Fees for the assessment of the Periodic Safety Update Report (PSUR) for a medicinal product for human use which is included in PSUR single assessment (PSUSA), shall not be charged.

Article 24
(Fees for a review of educational materials for safe and effective use of medicinal products and for other amendments to information on a medical product)

(1) Fees for a review of educational materials for safe and effective use of medicinal products shall be as follows:

1. for new educational materials: 305 points,
2. for updating educational materials: 225 points.

(2) The fee for the notification of changes to package leaflet and labelling which are not associated with changes to the summary of product characteristics for an individual pharmaceutical form or strength shall be 15 points.

(3) Fees for variations in place or manner of dispensing medicinal product for human use shall be as follows:

1. for variation to the medicinal product classification in terms of the place of dispensing it: 110 points,
2. for variation to the medicinal product classification in terms of the manner of dispensing it: 260 points.

(4) The fee for approving advertising, if this was not decided in the framework of an application for the acquisition or maintenance of a marketing authorisation, shall be 15 points.

Article 25
(Fees for putting a medicinal product on the list of interchangeable medicinal products)

Fees for an application for listing a medicinal product among interchangeable medicinal products under an independent procedure for determining interchangeability shall be 100 points.

Article 26
(Fees for medicinal products of herbal origin with effectiveness proven in clinical trials)

Fees for the issue, line extension, renewal, variation, transfer and withdrawal of a marketing authorisation for a medicinal product of herbal origin with effectiveness proven in clinical trials shall be as follows:

1. for the issue of marketing authorisations pursuant to Articles 44 or 49 of the Act in:
– NP 1,030 points,
– MRP-CMS 510 points,
– MRP-RMS 5,985 points,
– RUP-RMS 4,000 points,
– DCP-CMS 510 points,
– DCP-RMS 6,990 points;

2. for the issue of marketing authorisations pursuant to Article 47 of the Act in:
– NP 1,000 points,
– NP – if there is an EC Monograph, 750 points,
– MRP-CMS 510 points,
– MRP-RMS 5,695 points,
– RUP-RMS 3,700 points,
– DCP-CMS 510 points,
– DCP-RMS 6,420 points;

3. for the issue of marketing authorisations pursuant to Article 50 of the Act in:
– NP 325 points,
– MRP-CMS 310 points,

– MRP-RMS 2,580 points,
– RUP-RMS 1,700 points,
– DCP-CMS 310 points,
– DCP-RMS 4,190 points;

4. extension of a marketing authorisation for a medicinal product in:
– NP 660 points,
– MRP/DCP-CMS 370 points,
– MRP-RMS 3,145 points,
– DCP-RMS 3,875 points;

3. renewal of a marketing authorisation for a medicinal product in:
– NP 400 points,
– MRP/DCP-CMS 255 points,
– MRP/DCP-RMS 2,100 points;

4. fees for consideration of type I and II variations of a marketing authorisation shall be equal to the fees from Article 19 of this List of Rates;

5. notification of changes to package leaflet and labelling which are not associated with changes to the summary of product characteristics for an individual pharmaceutical form or strength: 15 points;

6. the fees for the transfer or cessation of a marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 21 of this List of Rates.

Article 27
(Fees for traditional medicinal products)

Fees for the issue, line extension, renewal, variation, transfer and withdrawal of a marketing authorisation for a medicinal product of herbal origin in a simplified procedure shall be as follows:

1. issue of a marketing authorisation for a medicinal product in:
– NP pursuant to paragraph (2) of Article 52 of the Act if there is no EC monograph or if additional data are submitted: 600 points,
– NP pursuant to paragraph (2) of Article 52 of the Act as per EC monograph: 500 points,
– MRP in DCP-CMS 300 points,
– MRP-RMS 4,000 points,
– RUP-RMS 2,700 points,
– DCP-RMS 4,500 points;

2. extension of a marketing authorisation for a medicinal product in:
– NP 500 points,
– MRP/DCP-CMS 250 points,
– RUP-RMS 1,400 points,
– MRP/DCP-RMS 2,000 points;

3. renewal of a marketing authorisation for a medicinal product in:
– NP 300 points,
– MRP/DCP-CMS 160 points,
– MRP/DCP-RMS 1,200 points;

4. fees for consideration of type I and II variations of a marketing authorisation shall amount to 70 per cent of the fees from Article 19 of this List of Rates

5. notification of changes to package leaflet and labelling which are not associated with changes to the summary of product characteristics for an individual pharmaceutical form or strength: 15 points;

6. the fees for the transfer or cessation of a marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 21 of this List of Rates.

Article 28

(Fees for homeopathic medicinal products)

Fees for the issue, renewal, amendment, transfer and withdrawal of a marketing authorisation for a homeopathic medicinal product shall be as follows:

1. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains a single homeopathic stock associated with one pharmaceutical form – NP: 300 points;
2. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains a single homeopathic stock associated with one pharmaceutical form – MRP/DCP-CMS: 100 points;
3. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains a single homeopathic stock associated with one pharmaceutical form – MRP/DCP-RMS: 3,500 points;
4. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains two to three homeopathic stocks associated with one pharmaceutical form – NP: 750 points;
5. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains two to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 300 points;
6. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains two to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,240 points;
7. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains more than three homeopathic stocks associated with one pharmaceutical form – NP: 1,200 points;
8. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains more than three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 700 points;
9. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains more than three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,655 points;
10. renewal or variation of a marketing authorisation for a homeopathic medicinal product referred to in points 1, 4, 5, 7 and 8 of this Article: 170 points;
11. renewal of a marketing authorisation for a homeopathic medicinal product referred to in point 2 of this Article: 80 points;
12. renewal of a marketing authorisation for a homeopathic medicinal product referred to in points 3, 6 and 9 of this Article: 1,000 points;
13. variation of a marketing authorisation for a homeopathic medicinal product referred to in points 1, 4, 5, 7 and 8 of this Article: 120 points;
14. variation of a marketing authorisation for a homeopathic medicinal product referred to in point 2 of this Article: 70 points;
15. variation of a marketing authorisation for a homeopathic medicinal product referred to in points 3, 6 and 9 of this Article: 1,000 points;
16. fees for the transfer or cessation of a marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 21 of this List of Rates;
17. fees for the issue of a marketing authorisation for a homeopathic medicinal product in accordance with paragraph (1) of Article 53 of the Act shall equal the fees referred to in Article 13 of this List of Rates.

Article 29
(Fees for a temporary marketing authorisation or the entry or import of medicinal products with no marketing authorisation for a medical product)

Fees relating to the issue of a temporary marketing authorisation for the entry or import of medicinal products with no marketing authorisations shall be as follows:

1. issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) in urgent cases of individual treatment: 10 points;
2. issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) from the list of essential or urgently needed medicinal products: 10 points;

3. issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) in exceptional cases in the interest of public health protection: 10 points;
4. issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) for medicinal products financed from budgetary resources: 10 points;
5. issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) for medicinal products used in veterinary medicine upon the occurrence of epizootic diseases: 10 points;
6. issue of an authorisation for import or entry of a medicinal product on the basis of an annual tender of necessary quantities of medicinal products: 25 points.

Article 30
(Fees for the issue of an authorisation for the entry or import and removal or export of illicit drugs in groups II and III and for sealing the register of medicinal products, which are illicit drugs in groups II, III a and III c)

(1) Fees relating to the issue of an authorisation for the entry or import and removal or export of medicinal products or active substances which are illicit drugs in groups II and III shall amount to 5 points for an individual medicinal product (pharmaceutical form, strength, packaging) or active substance.

(2) Fee for sealing any record books on medicinal products which are illicit drugs in groups II, III a and III c, shall amount to 1 point.

Article 31
(Fees for the marketing authorisation for a parallel-imported medicinal product and the certificate on the parallel distribution of medicinal products)

Fees for the issue, renewal, variation and cessation of a marketing authorisation for a parallel-imported medicinal product, shall be as follows:

1. for the issue, renewal, variation and cessation of a marketing authorisation for a parallel-imported medicinal product for human use:
- issue: 530 points,
- renewal: 305 points,
- variation: 150 points,
- cessation at the proposal of the applicant: 25 points;

2. for the issue, renewal, variation and cessation of a marketing authorisation for a parallel-imported veterinary medicinal product:
- issue: 300 points,
- renewal: 150 points,
- variation: 80 points,
- cessation at the proposal of the applicant: 20 points;

3. maximum fees for the issue, renewal, variation and cessation of marketing authorisation for parallel-imported medicinal products, for additional pharmaceutical forms, strengths or packaging within an application shall be as follows:
- issue: 1,100 points,
- renewal: 610 points,
- variation: 300 points,
- cessation at the proposal of the applicant: 50 points;

4. for the issue of a confirmation on the receipt of a notification of the parallel distribution of an individual medicinal product (every pharmaceutical form, strength or packaging): 25 points.

Article 32
(Fees for the approval of individual exemptions from the marketing authorisation)

(1) Fees for the issue of an approval of individual deviation from the marketing authorisation for an individual medicinal product (pharmaceutical form, strength, packaging): 200 points.

(2) Fee for the issue of an approval of individual deviation from the marketing authorisation for medicinal products used in veterinary medicine, shall be reduced by 50 per cent if the authority responsible for veterinary medicine issues a written opinion on the necessity of the medicinal product in the interest of protecting public health.

Article 33
(Fees for the issue of an approval for the use of foreign-language-labelled packaging with a Slovene label attached)

Fees relating to the issue of an approval for the use of foreign-language-labelled packaging with a label in Slovenian attached as per paragraph (5) of Article 87 of the Act shall amount to 15 points for each pharmaceutical form and strength of a medicinal product.

Article 34
(Fees for determining the elements in the so-called blue box and the national identifier of medical products, for which the marketing authorisation was obtained in accordance with the centralised procedure)

Fees for determining the elements in the so-called blue box and the national identifier of medicinal products shall be as follows:

1. determination of the elements in the so-called blue box: 10 points per medicinal product,
2. determination of the national identifier of medicinal products: 1 point per packaging.

Article 35
(Fees for the deferment of cancellation of marketing authorisation)

Fee for the consideration of a proposal to defer the cancellation of marketing authorisation for a medicinal product which has not been on the market for three consecutive years since the exercise of the authorisation: 20 points.

Article 36
(Fee for the approval of conducting a campaign with necessary data on vaccines included in the vaccination and protection products programme)

Fee for the approval of conducting a campaign with necessary data on vaccines included in the vaccination and protection products programme: 300 points.

Article 37
(Fees for the classification of a product)

Fees for the classification of a product and the issue of a decision on classification of the product as per Article 7 of the Act: 190 points.

Article 38
(Fees for the determination of an extraordinary higher allowed price of a medicinal product)

(1) Fees for the determination of an extraordinary maximum price of medicinal products for human use, with evidenced total public expenditure above EUR 50,000 for all packagings marketed in the Republic of Slovenia by the applicant, or with an established target population for medicinal product therapeutic indications exceeding 1,000 patients in the Republic of Slovenia, shall be as follows:

1. determination of an extraordinary higher allowed price of a medicinal product – at ATC 5 level or particular fixed combinations: 125 points;
2. determination of an extraordinary higher allowed price of a medicinal product – additional pharmaceutical form or strength: 25 points;

3. determination of an extraordinary higher allowed price of a medicinal product – additional packaging: 5 points;
4. termination of an extraordinary higher allowed price of a medicinal product at the proposal of the applicant: 5 points.

(2) Fees for the determination of an extraordinary maximum price for other medicinal products for human use shall be as follows:

1. determination of an extraordinary higher allowed price of a medicinal product – at ATC 5 level or particular fixed combinations of active substances: 55 points;
2. determination of an extraordinary higher allowed price of a medicinal product – additional pharmaceutical form or strength: 11 points;
3. termination of an extraordinary higher allowed price of a medicinal product at the proposal of the applicant: 2 points.

(3) Notwithstanding the first and second paragraphs of this Article, there shall be no fee liability for medicinal products for human use marketed in the Republic of Slovenia by the applicant for which total annual turnover for all packagings does not exceed EUR 15,000 per million population with access to the medicinal product on the market of the Republic of Slovenia, or in cases when the medicinal product is not available on the market of the Republic of Slovenia or on the markets of the European Union or the European Economic Area.

Article 39
(Fees for the determination of the maximum allowed price of a medicinal product)

Fees for the determination of the maximum allowed price of a medicinal product for use in human medicine shall be as follows:

1. determination of the maximum allowed price of a medicinal product (for an individual form of the medicinal product of all strengths, pharmaceutical forms or packaging): 10 points,
2. periodic reconciliation and reduction of the maximum allowed price of a medicinal product (for an individual form of the medicinal product of all strengths, pharmaceutical forms or packaging) at the proposal of the applicant: 6 points.

Article 40
(Fees for a notification of a business donation of a medicinal product)

Fees for a notification of a business donation of a medicinal product (any pharmaceutical form, strength or packaging): 40 points.

Article 41
(Fees for the issue of an authorisation in relation to human tissue and cell supply)

(1) Fees for the issue, amendment and withdrawal of a human tissue and cell supply authorisation shall be as follows:

1. issue of an authorisation for human tissue and cell supply per commission member on the day of verification inspection at the applicant: 245 points;
2. consideration of a variation, when a repeated verification inspection at the applicant is necessary and the variation requires an amendment to the authorisation for human tissue and cell supply on the day of inspection by the committee: 225 points;
3. consideration of a variation, whereby a repeated verification inspection at the applicant is not necessary and the variation requires an amendment to the authorisation for human tissue and cell supply: 75 points;
4. assessment of compliance with the requirements for performing activity of supply with human tissues and cells, when a repeated verification inspection at the applicant is necessary and the variation does not require an amendment to the authorisation for human tissue and cell supply on the day of inspection by the committee: 225 points;
5. withdrawal of an authorisation for human tissue and cell supply upon the proposal of the holder of the authorisation: 20 points.

(2) Fees for the issue of an authorisation for single entry or import and removal or export of human issues and entry or import and removal or export of human tissues and cells in urgent cases, shall be as follows:

1. issue of an authorisation for single entry or import and removal or export of human tissues and cells: 165 points,
2. issue of an authorisation for the entry or import and removal or export of human tissues and cells in urgent cases: 115 points.

Article 42
(Fees for the issue of a blood supply authorisation)

Fees for the issue, amendment and withdrawal of a blood supply authorisation shall be as follows:

1. issue of an authorisation for blood supply on the day of verification inspection: 245 points;
2. consideration of a variation, whereby a repeated verification inspection at the applicant is necessary and the variation requires an amendment to the authorisation for blood supply on the day of verification inspection: 225 points;
3. consideration of a variation, whereby a repeated review at the applicant is not necessary and the variation requires an amendment to the authorisation for blood supply: 75 points;
4. . assessment of compliance with the requirements for performing the activity of blood supply, when a repeated verification inspection at the applicant is necessary and the variation does not require an amendment to the authorisation for blood supply on the day of verification inspection by the committee: 225 points;
5. withdrawal of authorisation for blood supply: 40 points.

Article 43
(Fees for the preparation of non-routinely prepared medicinal products for advanced therapy)

Fees for the issue, amendment and withdrawal of an authorisation for the preparation of non-routinely prepared advanced therapy medicinal products shall be as follows:

1. issue of the authorisation for preparation of non-routinely prepared medicinal products for advanced therapy per day of expert committee inspection at the applicant: 480 points;
2. consideration of a variation, whereby a repeated inspection at the applicant is necessary and the variation requires an amendment to the authorisation for the preparation of non-routinely prepared medicinal products for advanced therapy per day of expert committee inspection at the applicant: 300 points;
3. consideration of a variation, whereby a repeated inspection at the applicant is not necessary and the variation requires an amendment to the authorisation for the preparation of non-routinely prepared medicinal products for advanced therapy at the applicant: 120 points;
4. assessment of compliance with the requirements for non-routinely prepared medicinal products for advanced therapy, when a repeated verification inspection at the applicant is necessary and the variation does not require an amendment to the authorisation for non-routinely prepared medicinal products for advanced therapy on the day of expert committee inspection at the applicant: 300 points;
5. withdrawal of authorisation for the preparation of a non-routinely prepared medicinal products for advanced therapy: 40 points.

Article 44
(Fees for the register of doctors or veterinarians)

Fees for the entry, amendment of an entry and removal from the register of doctors or veterinarians who use non-routinely prepared advanced therapy medicinal products in their practice, shall be as follows:

1. entry of a doctor or veterinarian in the register: 20 points,
2. amendment to the entry of a doctor or veterinarian in the register: 20 points,
3. removal of a doctor or veterinarian from the register: 20 points.

Article 45
(Costs of proceedings)

(1) If an applicant withdraws their application before the completion of the procedure, JAZMP shall charge:
1. 15 per cent of the amount of the fee if the application has not yet been processed (i.e. until the establishment of formal completion of the application or until the submitted notification on the method of paying the fee);
2. to 90 per cent of the amount of the fee if the applicant withdraws the application before the completion of the procedure with regard to the scope of acts already performed within the proceedings, which shall be decided by JAZMP.

(2) JAZMP also determines the costs of the administrative procedure in the decision on the termination of the administrative procedure.

III. EXPERT TASKS AND SERVICES

Article 46
(Payment obligations, methods and deadline)

(1) Fees for services rendered to the user of professional tasks and services shall arise after the receipt of the invoice or the payment notification from JAZMP and they must be paid to the JAZMP sub-account within 15 days.

(2) In the case of the non-payment, JAZMP may charge default interest to the applicant.

Article 47
(Expert education, lectures and consultations)

(1) JAZMP shall charge the user for the participation of its staff in expert education, lectures, workshops and consultations with 10 points per hour.

(2) On the basis of a proposal for expert education, lecture or consultation, JAZMP shall prepare a pro forma invoice.

(3) In addition to the rate referred to in paragraph (1) of this Article, the user is also obliged to settle the costs arising from expert education, lectures and consultations, which include costs pursuant to the regulations governing refund of costs for staff business trips.

(4) The costs of education, seminars and workshops organised by JAZMP shall be determined by means of a participation fee.

(5) The aforementioned participation fee shall be determined according to labour costs, the costs of renting premises, costs of preparing expert material and other costs incurred during the implementation of education, seminars or consultations. JAZMP shall publish information on the amount of the participation fee on its website or on the application for education, seminar or consultation..

Article 48
(Consulting)

(1) JAZMP consultations shall amount to 10 points per hour.

(2) Based on a proposal for consultation relating to expert preparation of documentation in the area of competence of JAZMP from the preceding paragraph, JAZMP shall prepare a pro forma invoice including an estimated value. The user shall settle 50 per cent of the amount on the pro forma invoice before the consultation starts.

(3) JAZMP shall issue an invoice with actual hours of work performed.

Article 49
(Specialisation and mentoring of external users)

(1) JAZMP shall charge 5 points per hour for the implementation of specialisation or mentoring of external users.

(2) On the basis of a proposal for specialisation or mentoring, JAZMP shall draft a pro forma invoice for external users. Participation in specialisation or mentoring of external users shall not be implemented until the user confirms the pro forma invoice for the implementation of specialisation or mentoring.

Article 50
(Travel and other costs of the members of expert and verification committees when implementing their tasks)

Alongside the fees from this List of Rates, the applicant shall also pay for the costs of expert and verification committee members referred to in Articles 6 and 12 of this List of Rules, which shall be charged as prescribed in regulation governing refund of costs for business trips.

Article 51
(Publishing)

JAZMP shall charge for the delivery of the Formularum Slovenicum edition to users as follows:
1. Formularum Slovenicum – printed edition: 15 points per copy,
2. Formularum Slovenicum – 1 to 5 passwords in electronic form: 17 points per copy,
3. Formularum Slovenicum – 6 to 25 passwords in electronic form: 15 points per copy,
4. Formularum Slovenicum – more than 25 passwords in electronic form: 13 points per copy,
5. Brochure accompanying a presentation of Formularum Slovenicum: 12 points per copy.

Article 52
(Photocopying)

(1) Photocopying, printing and scanning shall be charged by JAZMP to the user:
1. photocopying, printing – A4, black and white, single-sided: 0.028 points per copy,
2. photocopying, printing – A4, black and white, double-sided: 0.04 points per copy,
3. photocopying, printing – A4, colour, single-sided: 0.12 points per copy,
4. photocopying, printing – A4, colour, double-sided: 0.22 points per copy,
5. skeniranje – A4, single-sided: 0.024 points per copy,
6. skeniranje – A4, double-sided: 0.036 points per copy.

(2) JAZMP shall charge scanning and printing to the user according to the rate for printing.

Article 53
(Issuing additional copies and duplicates and confirmation of the finality of individual administrative acts)

Issuing of additional copies and duplicates and confirmation of the finality of individual administrative acts shall be charged by JAZMP to the user:
1. every additional copy of individual administrative act (decision, notification, certificate etc.): 6 points,
2. issue of duplicates of individual administrative acts (decision, notification, certificate etc.): 15 points,
3. confirmation of the finality of individual administrative acts (decision, notification, certificate etc.): 6 points.

Article 54
(Other professional tasks)

JAZMP may charge for the implementation of other professional tasks, which are not governed by this List of Rates, namely based on calculations, mutatis mutandis use of rates for consultations and photocopying and other direct costs.

Article 55
(Issue of reminders for outstanding liabilities)

JAZMP may charge the debtor 0.4 point for the issue of a reminder for outstanding liabilities.

IV. TRANSITIONAL AND FINAL PROVISION

Article 56
(Termination of validity)

(1) As of the date of entry into force of this List of Rates, the Rules on the charges in the field of medicines (Official Gazette of the Republic of Slovenia, No. 65/11 and 17/14 – ZZdr-2), shall cease to apply.

(2) The Rules on charges in the field of medicines (Official Gazette of the Republic of Slovenia, no. 65/11) shall still apply to procedures which began before the day of the entry into force of this List of Rates or relating to which a legal remedy had already been filed upon the entry into force of this List of Rates (Official Gazette of the Republic of Slovenia [*Uradni list RS*] No. 65/11 and 17/14 – ZZdr-2).

Article 57
(Effective date)

This List of Rates shall enter into force on the fifteenth day following their publication in the Official Gazette of the Republic of Slovenia.

Št. 0070-25/2017
Ljubljana, 0070-25/2017
EVA 2017-2711-0025

Marko Rupret
President of the Council of the
Agency of the Republic of
Slovenia for Medicinal Products
and Medical Devices