Pursuant to Articles 189 and 190 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, no. 17/14), Article 39 and 40 of the Public Agencies Act (Official Gazette of the Republic of Slovenia, no. 25/02), Article 11 of the Decision on the establishment of the Public agency for medical products and medical devices of the Republic of Slovenia (Official Gazette of the Republic of Slovenia, no. 115/06) and consent by the Government of the Republic of Slovenia of __ __ 2016, I hereby issue

RULES

on fees in the field of medicinal products, blood, tissues, cells and fees for the implementation of professional tasks and services of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices

I. GENERAL PROVISIONS

Article 1
(Fee types)

(1) These Rules lay down the fees for services ordered by natural persons and legal entities implemented by the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: the Agency). The costs of implementing administrative tasks which are part of the pubic authorisation and implemented by the Agency shall be covered by the applicant. 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 the Agency 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. The costs of implementing professional tasks and services as per the competence of the Agency shall be covered by the client according to the determined rate.

(2) These Rules lay down the types and amounts of fees to be paid as per Article 189 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, no. 17/14; hereinafter: the Act) by the applicant proposing the procedure concerned or the marketing authorisation holder, including the fee to cover the costs of implementing professional tasks and services as per the competence of the Agency, which in compliance with Article 190 of the Act shall be covered by the client of professional tasks and services of the Agency in the form of fee.

(3) Fees to be charged by the Agency 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 a decision on a conformity assessment of the amendment of conditions for manufacturing medicinal products;
4. fees for the issue of certificates relating to the verification of conformity with good manufacturing practice at medicinal product manufacturers;
5. fees relating to the assessment of risk management in the manufacture of medicinal products;
6. fees relating to the certification of galenic products and approval of the manufacture of large quantities of galenic products;
7. fees for the issue, amendment and termination of a wholesale distribution authorisation and notification of a wholesaler established in the European Union;
8. fees for the entry, amendment and removal from the register of manufacturers, wholesalers and importers of active substances;
9. fees for the entry, amendment and removal from the register of agents selling medicinal products and active substances;

10. fees for the issue, amendment and termination of a retail outlet authorisation;
11. fees for the issue and amendment to an authorisation for the preparation of non-routinely prepared advanced therapy medicinal products;
12. fees for the entry, amendment and removal from the register of doctors and veterinarians who use non-routinely prepared advanced therapy medicinal products in their practice;
13. fees relating to the procedure of notification or approval of a clinical trial for a medicinal product and the evaluation of clinical trial performance;
14. fees relating to the procedure of notification of an non-interventional clinical trial or the issue of a preliminary approval of a non-interventional clinical trial;
15. fees for the issue of an authorisation for the compassionate use of medicinal products;
16. fees for the issue, renewal, amendment, transfer and withdrawal of a marketing authorisation for a medicinal product used in human and veterinary medicine;
17. fees relating to the approval of individual exemptions from the conditions of the marketing authorisation;
18. fees relating to the consideration of proposals for the retention of the marketing authorisation;
19. fees relating to the assessment of a Periodic Safety Update Report (PSUR) for a medicinal product with unlimited marketing authorisation;
20. fees relating to other changes of product information on a medicinal product;
21. fees relating to an application for listing a medicinal product among interchangeable medicinal products under an independent procedure;
22. fees for the issue, renewal, amendment, transfer and withdrawal of a marketing authorisation for traditional medicinal products of herbal origin;
23. fees for the issue, renewal, amendment, transfer and withdrawal of a marketing authorisation for homeopathic medicinal products;
24. fees for the issue, renewal, amendment and withdrawal of a marketing authorisation for a parallel imported medicinal product;
25. fees for the issue of a certificate on the notification of a parallel distribution of a medicinal product;
26. fees for the issue of a temporary marketing authorisation and the entry or import of medicinal products with no marketing authorisation;
27. fees for the issue of an authorisation for the entry or import and removal or export of medicinal products classified as illicit drugs in groups II and III;
28. fees for approval of the use of foreign-language-labelled packaging with a label in Slovenian attached;
29. fees relating to the classification of a product among medicinal products and granting a certificate or an expert opinion thereof;
30. fees relating to a change in medicinal product classification;
31. fees for the approval of public advertising of medicinal products used in mass vaccination programmes;
32. fees for the entry, amendment and removal from the register of professional associates when advertising medicinal products;
33. fees for determining an element in the so-called blue box and the national identifier of medicinal products;
34. fees relating to the determination of prices of medicinal products;
35. fees relating to the notification of business donations of medicinal products;
36. fees for the issue and amendment of a blood supply authorisation;
37. fees for the issue and amendment of a tissue and cell supply authorisation;
38. fees for the issue of an authorisation for the entry or import and removal or export of tissues and cells.

(4) Fees charged by the Agency for implementing professional tasks and services include:

1. expert education, lectures, workshops and consultations;
2. specialisation and mentoring;

3. consulting;
4. travel and other costs of experts and pharmaceutical inspectors when implementing their tasks;
5. publishing;
6. photocopying, printing and scanning;
7. issue of reminders for outstanding liabilities.

Article 2
(Fee level)

(1) Fees are specified by points. The amount of the fee is the point value multiplied by the number of points.

(2) The value of one point is EUR 5 (in words: five euros) excluding VAT. 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 these Rules. Any change in the value of one point shall be approved by the Agency's 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 Agency.

(2) The Agency 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 applicant shall settle the fee for the procedures to the Agency's sub-account within fifteen days.

(3) The annual fee for monitoring a medicinal product on the market and for monitoring activities relating to medicinal products shall be settled by the authorisation holder within fifteen days. The Agency 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 31 December of the previous year.

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

(5) In the case of the non-payment of the fee, the Agency 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. marketing authorisation for a medicinal product or a parallel imported medicinal product in any pharmaceutical form: 20 points,
2. individual marketing authorisation for a homeopathic medicinal product in any pharmaceutical form: 5 points,

3. individual medicinal product manufacturing authorisation for an individual manufacturing site: 20 points,
4. individual wholesale distribution authorisation for medicinal products: 15 points,
5. individual retail sale authorisation for medicinal products in specialised shops: 10 points.

Article 5
(Fees relating to medicinal product manufacturing)

The fees relating to the issue, amendment and termination of medicinal product manufacturing authorisations shall be as follows:

1. issue of authorisation for medicinal product manufacturing based on verification of compliance with good manufacturing practice on the day of inspection at the applicant: 300 points,
2. consideration of a variation, whereby reassessment of compliance with good manufacturing practice is not necessary and the variation requires an amendment to the medicinal product manufacturing authorisation: 50 points,
3. consideration of a variation, whereby reassessment of compliance with good manufacturing practice is necessary and the variation requires an amendment to the medicinal product manufacturing authorisation on the day of inspection at the applicant: 300 points,
4. consideration of a variation, whereby 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 inspection at the applicant: 250 points,
5. revocation of medicinal product manufacturing authorisation at the request of the authorisation holder: 20 points,
6. issue of a decision on the assessment on the fulfilment of conditions for manufacturing medicinal products with verification at the applicant on the day of inspection: 300 points,
7. entry in the register of persons responsible for the release of a series: 10 points,
8. amendment to the entry in the register of persons responsible for the release of a series: 10 points,
9. removal from the register of persons responsible for the release of a series: 2 points.

Article 6
(Fees relating to registers of manufacturers, wholesalers and importers of active substances)

The fees relating to registers of manufacturers, wholesalers and importers of active substances shall be as follows:

- entry in the register of manufacturers, wholesalers and importers of active substances: 50 points,
- entry in the register of manufacturers, wholesalers and importers of active substances per commission member on the day of inspection: 300 points,
- amendment to the entry in the register of manufacturers, wholesalers and importers of active substances: 40 points,
- amendment to the entry in the register of manufacturers, wholesalers and importers of active substances per commission member on the day of inspection: 250 points,
- removal from the register of manufacturers, wholesalers and importers of active substances: 10 points,
- consideration of an annual report by a manufacturer of active substances: 50 points.

Article 7
(Fees relating to the inspection of good manufacturing practice)

(1) The fees relating to 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: 300 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: 300 points,
3. issue of a certificate of good manufacturing practice compliance abroad: 100 points,
4. issue of a certificate of good manufacturing practice for an individual medicinal product: 50 points.

(2) In addition to the fees under points 1 and 2 of the preceding paragraph, the applicant shall also cover other costs of pharmaceutical supervisors as per Article 43 of these Rules.

Article 8
(Fees relating to wholesale distribution authorisation for medicinal products)

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

1. issue of wholesale distribution authorisation for medicinal products based on verification of compliance with good distribution practice per the day of inspection at the applicant: 250 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: 50 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 inspection at the applicant: 250 points,
4. consideration of a variation, whereby 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 inspection at the applicant: 200 points,
5. notification of a wholesaler established in an EU Member State pursuant to paragraph (3) of Article 105 of the Act: 100 points,
6. revocation of a wholesale distribution authorisation for medicinal products at the request of the authorisation holder: 15 points,
7. entry in the register of persons responsible for the receipt of medicinal products: 20 points,
8. amendment to the entry in the register of persons responsible for the receipt of medicinal products: 6 points,
9. removal from the register of persons responsible for the receipt of medicinal products: 4 points,
10. amendment to the notification of a wholesaler established in an EU Member State: 50 points,
11. removal from the register of notified wholesalers established in an EU Member State: 15 points.

Article 9
(Fees relating to brokerage of medicinal products and active substances)

The fees relating to brokerage of medicinal products and active substances shall be as follows:

- entry in the register of agents selling medicinal products and active substances: 100 points,
- amendment to the entry in the register of agents selling medicinal products and active substances: 50 points,
- removal from the register of agents selling medicinal products and active substances: 10 points.

Article 10
(Fees relating to the preparation of non-routinely prepared medicinal products for advanced therapy)

The fees relating to the issue and amendment to the authorisation for the preparation of non-routinely prepared medicinal products for advanced therapy shall be as follows:

- issue of the authorisation for preparation of non-routinely prepared medicinal products for advanced therapy per commission member on the day of inspection at the applicant: 300 points,
- 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 commission member on the day of inspection at the applicant: 250 points,
- consideration of an amendment to the authorisation for preparation of non-routinely prepared medicinal products for advanced therapy at the applicant: 50 points,
- issue of a decision on the assessment of the fulfilment of conditions for the preparation of non-routinely prepared medicinal products for advanced therapy per commission member on the day of inspection at the applicant: 300 points.

Article 11
(Fees relating to the register of doctors or veterinarians)

The fees relating to the entry, amendment and removal from the register of doctors or veterinarians who use non-routinely prepared medicinal products for advanced therapy shall be as follows:

- entry of a doctor or veterinarian in the register: 10 points,
- amendment to the entry of a doctor or veterinarian in the register: 10 points,
- removal of a doctor or veterinarian from the register: 2 points.

Article 12
(Fees relating to the retail sale authorisation for medicinal products in specialised shops)

The fees relating to the issue, amendment and termination of retail sale authorisations 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 on the day of the inspection: 150 points,
2. consideration of a variation, whereby reassessment of compliance with requirements is not necessary and the variation requires an amendment to the retail sale authorisation for medicinal products in specialised shops: 50 points,
3. consideration of a variation, whereby 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 on the day of the inspection: 150 points,
4. consideration of a variation, whereby 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 on the day of the inspection: 100 points,
5. revocation of the retail sale authorisation for medicinal products in specialised shops at the request of the authorisation holder: 10 points.

Article 13
(Fees relating to clinical trials of medicinal products)

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

1. approval of a clinical trial of a medicinal product: 250 points,
2. notification of a clinical trial of a medicinal product: 150 points,

3. notification of an amendment to a clinical trial of a medicinal product: 50 points,
4. approval of a clinical trial by non-profit business entities and individuals in the role of a sponsor: 120 points,
5. notification of a clinical trial by non-profit business entities and individuals in the role of a sponsor: 80 points,
6. notification of an amendment to a clinical trial by non-profit business entities and individuals in the role of a sponsor: 40 points,
7. notification of a non-interventional clinical trial: 100 points,
8. notification of an amendment to a protocol of a non-interventional clinical trial: 35 points,
9. obtaining a consent for a non-interventional clinical trial as per point 1 of Article 138 of the Act: 150 points,
10. obtaining consent for the compassionate use of a medicinal product: 6 points,
11. 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: 300 points,
12. assessment of a clinical trial for compliance with good clinical practice in the procedure for marketing authorisation acquisition per pharmaceutical supervisor/day: 300 points.

(2) In addition to the fees under points 11 and 12 of the preceding paragraph, the applicant shall also cover other costs of pharmaceutical supervisors as per Article 43 of these Rules.

(3) The 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.

(4) There are no fees in connection with the notification or an approval of a clinical trial of a medicinal product within the compassionate use programme.

Article 14
(Fees relating to the marketing authorisation of a medicinal product)

(1) The Agency shall issue marketing authorisations under the following procedures:
- national procedure (hereinafter: NP),
- mutual recognition procedure in which the Republic of Slovenia is the Reference Member State (hereinafter: MRP-RMS),
- mutual recognition procedure in which the Republic of Slovenia is the Concerned Member State (hereinafter: MRP-CMS),
- decentralised procedure in which the Republic of Slovenia is the Reference Member State (hereinafter: DCP-RMS),
- decentralised procedure in which the Republic of Slovenia is the Concerned Member State (hereinafter: DCP-CMS),
- 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) The fees relating to the issue of marketing authorisations for medicinal products shall be as follows:

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,
- RUP-RMS: 2,000 points,

- DCP-CMS: 450 points,
- DCP-RMS: 7,000 points;

2. for the issue of marketing authorisations pursuant to Article 47 of the Act in:
- NP: 800 points,
- MRP-CMS: 380 points,
- MRP-RMS: 5,000 points,
- RUP-RMS: 2,000 points,
- DCP-CMS: 420 points,
- DCP-RMS: 5,500 points,
- NP for medicinal products of herbal origin in accordance with an EC Monograph: 500 points;

3. for the issue of marketing authorisations pursuant to paragraph (1) or (6) of Article 45 of the Act in:
- NP: 700 points,
- MRP-CMS: 360 points,
- DCP-CMS: 380 points,
- MRP-RMS: 5,000 points,
- RUP-RMS: 2,000 points,
- DCP-RMS: 5,800 points;

4. for the issue of marketing authorisations pursuant to Article 50 of the Act in:
- NP, MRP-CMS and DCP-CMS: 200 points,
- MRP-RMS: 3,500 points,
- RUP-RMS: 2,000 points,
- DCP-RMS: 4,600 points;

5. for the issue of marketing authorisations for additional pharmaceutical forms or strengths in grouped applications for marketing authorisations in:
- NP: 200 points,
- MRP/DCP-CMS: 100 points,
- MRP/DCP-RMS: 1,750 points.

Article 15
(Fees relating to the line extension of a marketing authorisation)

The fees for considering applications for the line extension of marketing authorisations for medicinal products shall be as follows:

1. for consideration of applications for an extension of marketing authorisation for medicinal products in:
- NP: 600 points,
- MRP-CMS: 250 points,
- DCP-CMS: 280 points,
- MRP/DCP-RMS: 3,000 points,
- RUP-RMS: 1,800 points;

2. for the issue of marketing authorisations for additional pharmaceutical forms or strengths in grouped applications for extension of marketing authorisations in:
- NP: 200 points,

- MRP/DCP-CMS: 100 points,
- MRP/DCP-RMS: 1,750 points.

Article 16
(Fees relating to renewal of marketing authorisation)

The fees relating to the renewal of marketing authorisations for a medicinal product shall be as follows:

1. for the renewal of marketing authorisations for medicinal products in:
- NP: 300 points,
- MRP/DCP-CMS: 250 points,
- MRP/DCP-RMS: 2,350 points;

2. for the renewal of marketing authorisations for additional pharmaceutical forms or strengths in grouped applications for renewal of marketing authorisations in:
- NP: 50 points,
- MRP/DCP-CMS: 50 points,
- MRP/DCP-RMS: 500 points.

Article 17
(Fees relating to the assessment of PSUR)

The fees relating to the assessment of the Periodic Safety Update Report (PSUR) for a medicinal product with unlimited marketing authorisation according to the procedure by which the medicinal product has been authorised shall be as follows:
- NP: 300 points,
- MRP/DCP-CMS: 50 points,
- MRP/DCP-RMS: 2,350 points.

Article 18
(Fees relating to type I and type II variations)

Fees relating to type I and type II variations for medicinal products used in human medicine 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 includes a medicinal product of all strengths, pharmaceutical forms and/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: 50 points,
- MRP/DCP-RMS: 400 points;

2. for notification of a type IB variation in:
- NP: 110 points,
- MRP/DCP-CMS: 110 points,
- MRP/DCP-RMS: 800 points;

3. for approval of a type II variation in:
- NP: 180 points,
- MRP/DCP-CMS: 140 points,
- MRP/DCP-RMS: 1,300 points;

4. in grouping of variations in accordance with Article 7 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):

- 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 in accordance with point 1 of this Article shall apply for the first variation, and 75% of the total fee for each additional variation;
- 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 in accordance with point 1 of this Article shall apply for the first variation, and 75% of the total fee in accordance with point 1 of this Article for each additional variation to the relevant marketing authorisation, but not more than:
  - NP: 400 points,
  - MRP/DCP-CMS: 400 points,
  - MRP/DCP-RMS: 2,000 points;
- 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% of the total fee in accordance with point 1 of this Article for further variations of the first marketing authorisation, and 75% 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: 800 points,
  - MRP/DCP-RMS: 2,000 points;
- 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 15 of these Rules shall apply for a major variation and 75% of the total fee in accordance with 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;
- 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 variations): a full fee in accordance with points 2 or 3 of this Article shall apply for a major variation and 75% of the total fee in accordance with 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;
- in point (c) of paragraph (2) of Article 13d. of Regulation (EC) No 1234/2008 (combining variations of type IB or II and subsequent variations for several exclusively national marketing authorisations of the same holder): a full fee in accordance with points 2 or 3 of this Article shall apply for the first variation of the first marketing authorisation, 75% of the total fee in accordance with points 1, 2 or 3 of this Article for subsequent variations of the first marketing authorisation, and 75% 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) in the case of a change of name or address of a marketing authorisation holder or a single variation in the existing detailed description of 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) in grouped variations concerning the change of name of a medicinal product in several EU Member States, the fee for a single variation shall be as specified in point 1 of this Article, which also applies in cases when the medicinal product's name in the Republic of Slovenia remains unchanged.

6. in work-sharing procedures pursuant to Article 20 of Regulation (EC) No 1234/2008, a full fee in accordance with points 2, 3 or intent (5) of point 4 of this Article shall apply for a variation of the first marketing authorisation and 75% of the total fee for every additional marketing authorisation, calculated as per the variation(s) 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 19
(Fees relating to other changes of product information on a medicinal product)

The fees relating to other changes of product information on a medicinal product shall be as follows:
1. regarding a review of educational materials for safe and effective use of a medicinal product: 70 points,
2. for a notification of changes to package leaflets and labelling which are not associated with changes to the summary of product characteristics for each pharmaceutical form or strength: 20 points.

Article 20
(Fees relating to temporary marketing authorisation or entry/import of medicinal products with no marketing authorisations)

The fees relating to the issue of an authorisation for the entry or import of medicinal products with no marketing authorisations shall be as follows:
- issue of an authorisation for an individual medicinal product (form, strength, packaging) in urgent cases of individual treatment: 6 points,
- issue of an authorisation for an individual medicinal product (form, strength, packaging) from the list of essential or urgently needed medicinal products: 6 points;
- issue of an authorisation for an individual medicinal product (form, strength, packaging) in exceptional cases in the interest of public health protection: 6 points,
- issue of an authorisation for an individual medicinal product (form, strength, packaging) for medicinal products financed from budgetary resources: 6 points,
- issue of an authorisation for an individual medicinal product (form, strength, packaging) for medicinal products used in veterinary medicine upon the occurrence of epizootic diseases: 6 points,
- issue of an authorisation for import/entry of a medicinal product on the basis of an annual tender of necessary quantities of medicinal products:
  - up to 50 medicinal products: 20 points,
  - between 50 and 100 medicinal products: 40 points, and

- more than 100 medicinal products: 50 points.

Article 21
(Fees relating to the transfer or cessation of a marketing authorisation)

The fees relating to 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: 50 points,
2. maximum fees for the 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 22
(Fees relating to the approval of individual deviations from the marketing authorisation and retention of the marketing authorisation)

The fees relating to the issue of an approval of an individual deviation from the marketing authorisation and the consideration of proposals to retain the marketing authorisation for a medicinal product which has not been on the market for three consecutive years since the exercise of the authorisation shall be as follows:

- approval of an individual deviation from the marketing authorisation for an individual medicinal product (form, strength, packaging): 40 points,
- consideration of proposals to retain the marketing authorisation for a medicinal product which has not been on the market for three consecutive years since the exercise of the authorisation for an individual medicinal product (form, strength, packaging): 40 points.

Article 23
(Fees relating to the placement of a medicinal product on the list of interchangeable medicinal products)

The fees relating to an application for listing a medicinal product among interchangeable medicinal products under an independent procedure for determining interchangeability shall amount to 100 points.

Article 24
(Fees relating to traditional medicinal products of herbal origin)

The fees relating to the issue, renewal, variation, transfer and cessation of a marketing authorisation for traditional medicinal products of herbal origin under the 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: 400 points,
- NP pursuant to paragraph (2) of Article 52 of the Act as per EC monograph: 300 points,
- MRP and DCP-CMS: 250 points,
- MRP-RMS: 4,000 points,
- DCP-RMS: 4,500 points;

2. issue of a marketing authorisation for an additional pharmaceutical form or strength in a grouped application for marketing authorisation in:
- NP: 200 points,
- MRP/DCP-CMS: 100 points,

- MRP/DCP-RMS: 1,750 points;

3. extension of a marketing authorisation for a medicinal product in:
- NP: 200 points,
- MRP/DCP-CMS: 160 points,
- MRP/DCP-RMS: 2,000 points;

4. issue of a marketing authorisation for an additional pharmaceutical form or strength in a grouped application for the extension of a marketing authorisation in:
- NP: 200 points,
- MRP/DCP-CMS: 100 points,
- MRP/DCP-RMS: 1,750 points;

5. renewal of a marketing authorisation for a medicinal product in:
- NP: 200 points,
- MRP/DCP-CMS: 160 points,
- MRP/DCP-RMS: 2,000 points;

6. renewal of a marketing authorisation for an additional pharmaceutical form or strength in a grouped application for the renewal of a marketing authorisation in:
- NP: 50 points,
- MRP/DCP-CMS: 50 points,
- MRP/DCP-RMS: 500 points;

7. the fees for consideration of type I and II variations of a marketing authorisation shall amount to 70% of the fees referred to in Article 18 of these Rules.

8. 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: 20 points;

9. 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 these Rules.

Article 25
(Fees relating to homeopathic medicinal products)

The fees relating to the issue, renewal, variation, transfer and cessation of marketing authorisations for homeopathic medicinal products 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: 100 points;
2. 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: 300 points;
3. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains up to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 50 points;
4. issue of a marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains up to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,000 points;

5. 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: 400 points;
6. 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: 60 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 – MRP/DCP-RMS: 4,400 points;
8. additional fees for the issue of a marketing authorisation for a homeopathic medicinal product referred to in points 1, 2 and 5 of this Article for each additional pharmaceutical form in the grouped application: 60 points;
9. additional fees for the issue of a marketing authorisation for a homeopathic medicinal product referred to in points 3 and 6 of this Article for each additional pharmaceutical form in the grouped application: 20 points;
10. additional fees for the issue of a marketing authorisation for a homeopathic medicinal product referred to in points 4 and 7 of this Article for each additional pharmaceutical form in the grouped application: 1,750 points;
11. renewal or variation of a marketing authorisation for a homeopathic medicinal product referred to in points 1, 2, 3, 5 and 6 of this Article: 30 points;
12. renewal or variation of a marketing authorisation for a homeopathic medicinal product referred to in points 4 and 7 of this Article: 1,000 points;
13. 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 these Rules;
14. 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 14 of these Rules.

Article 26
(Fees relating to the marketing authorisation for a parallel imported medicinal product and the certificate on the distribution of medicinal products)

The fees relating to the issue, renewal, variation and cessation of a marketing authorisation for a parallel imported medicinal product shall be as follows:

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

2. relating to the issue, renewal, variation and cessation of a marketing authorisation for a parallel imported medicinal product for each additional pharmaceutical form, strength or packaging in a grouped application:
   - issue: 100 points,
   - renewal: 50 points,
   - variation: 25 points,
   - cessation at the proposal of the applicant: 10 points;

3. maximum fees relating to the issue, renewal, variation and cessation of a marketing authorisation for a parallel imported medicinal product for additional pharmaceutical forms, strengths and/or packaging in one grouped application:
   - issue: 500 points,
   - renewal: 250 points,
   - variation: 125 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 form, strength or packaging), a fee in the amount of 150 points shall be paid.

Article 27
(Fee relating to an approval for the use of foreign-language-labelled packaging with a label in Slovenian attached)

The 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 30 points for each pharmaceutical form and strength of a medicinal product.

Article 28
(Fee relating to the classification of products as medicines)

The fee relating to the classification of a product and the issue of a decision on classification of the product as per Article 7 of the Act shall amount to 60 points.

Article 29
(Fee relating to a change in medicinal product classification)

The fee relating to a change in medicinal product classification in terms of the place of dispensing shall amount to 100 points.

Article 30
(Fees relating to an approval of advertising vaccine)

(1) The fee for verifying and approving the contents of public advertising of medicinal products used in mass vaccination programmes shall amount to 200 points.

(2) The fee for verifying variations of the approved contents of public advertising and the extension of approval of advertising medicinal products used in mass vaccination programmes shall amount to 100 points.

Article 31
(Fees relating to the determination of an extraordinary higher allowed price of a medicinal product)

(1) The fees relating to the determination of an extraordinary higher allowed price of medicinal products for human use with proven total public expenditure above EUR 50,000 for all types of packaging 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:
- determination of an extraordinary higher allowed price of a medicinal product – at ATC 5 level or particular fixed combinations: 120 points,

- determination of an extraordinary higher allowed price of a medicinal product – additional pharmaceutical form: 20 points,
- determination of an extraordinary higher allowed price of a medicinal product – additional strength: 15 points,
- determination of an extraordinary higher allowed price of a medicinal product – additional packaging: 5 points,
- termination of an extraordinary higher allowed price of a medicinal product at the proposal of the applicant: 15 points.

(2) The fees relating to the determination of an extraordinary higher allowed price for other medicinal products for human use shall be as follows:
- determination of an extraordinary higher allowed price of a medicinal product – at ATC 5 level or particular fixed combinations of active substances: 40 points,
- determination of an extraordinary higher allowed price of a medicinal product – additional pharmaceutical form: 5 points,
- determination of an extraordinary higher allowed price of a medicinal product – additional strength: 5 points,
- termination of an extraordinary higher allowed price of a medicinal product at the proposal of the applicant: 5 points.

(3) Notwithstanding the provisions of paragraph (1) and (2) of this Article, the fee relating to an extraordinary higher allowed price of a medicinal product for medicinal products for human use marketed in the Republic of Slovenia by the applicant for which a total annual turnover for all types of packaging fails to 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 shall amount to 4 points.

Article 32
(Fees relating to the determination of the maximum allowed price of a medicinal product)

The fees relating to the determination of the maximum allowed price of a medicinal product for use in human medicine shall be as follows:
- determination of the maximum allowed price of a medicinal product (for an individual form of the medicinal product of all strengths, pharmaceutical forms and/or packaging): 5 points,
- reduction of the maximum allowed price of a medicinal product (for an individual form of the medicinal product of all strengths, pharmaceutical forms and/or packaging) at the proposal of the applicant: 5 points.

Article 33
(Notification relating to a business donation of medicinal products)

The fee for a notification of a business donation of a medicinal product (any form, strength or packaging) shall amount to 20 points.

Article 34
(Fees relating to the entry, amendment and removal from the register of professional associates when advertising medicinal products)

The fees relating to the entry, amendment and removal from the register of professional associates when advertising medicinal products shall be as follows:
- entry of a professional associate in the register: 10 points,
- amendment to the entry of a professional associate in the register: 10 points,
- removal of a professional associate from the register: 2 points.

Article 35
(Fees relating to the issue of an authorisation for entry/import and removal/export of medicinal products which are illicit drugs in groups II and III)

The fees relating to the issue of an authorisation for the entry/import and removal/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 (form, strength, packaging) or active substance.

Article 36
(Fees relating to the authorisation for tissue and cell supply)

The fees relating to the issue and variation of an authorisation for tissue and cell supply shall be as follows:
- issue of an authorisation for tissue and cell supply per commission member on the day of inspection at the applicant: 80 points,
- consideration of a variation, whereby a repeated review at the applicant is necessary and the variation requires an amendment to the authorisation for tissue and cell supply per commission member on the day of inspection: 80 points,
- issue of an authorisation for the entry or import and removal or export of tissues and cells: 100 points.

Article 37
(Fees relating to the authorisation for blood supply)

The fees relating to the issue and variation of an authorisation for blood supply shall be as follows:
- issue of an authorisation for blood supply per commission member on the day of inspection: 80 points,
- consideration of a variation, whereby a repeated review at the applicant is necessary and the variation requires an amendment to the authorisation for blood supply per commission member on the day of inspection: 80 points.

Article 38
(Operative part of costs of the procedure)

(1) The Agency shall issue administrative decisions as per the regulations on administrative procedures. The Agency shall also determine the costs of procedures or fees in its decisions.

(2) If an applicant withdraws their application before the completion of the procedure, the Agency shall charge:
- 15% 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);
- 90% of the amount of the fee if the applicant withdraws the application before the procedure is completed.

(3) The Agency also determines the costs of the procedure in the decision on the termination of the procedure.

III. OTHER FEES

Article 39
(Payment obligations, methods and deadlines)

(1) Fees for services rendered to the client of professional tasks and services shall be subject to payment after the receipt of the invoice or payment notification from the Agency.

(2) The client shall pay fees into the Agency's sub-account within fifteen days.

(3) In the case of non-payment, the Agency may charge legal default interest to the client.

Article 40
(Expert education, lectures and consultations)

(1) The participation of the Agency's staff in expert education, lectures, workshops and consultations shall amount to 10 points per hour, charged by the Agency to the client.

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

(3) In addition to the fees referred to in paragraph (1), the client is also obliged to settle the costs arising from expert education, lectures and consultations, which include costs as per the regulation on the refund of costs for staff business trips.

(4) The costs of education, seminars and workshops organised by the Agency 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. The Agency shall publish information on the amount of the participation fee on its website or on the application for education, seminar or consultation.

Article 41
(Consulting)

(1) Consultations with Agency staff shall amount to 10 points per hour.

(2) On the basis of a proposal for consulting in the field of the JAZMP's competence from paragraph (1) of this Article, the Agency shall draft a pro forma invoice. The client shall be obliged to settle 50% of the value of the pro forma invoice before the start of consultations.

Article 42

(Specialisation and mentoring of external clients)

(1) Specialisation or mentoring of external clients by the Agency's staff shall amount to 5 points per hour.

(2) On the basis of a proposal for specialisation or mentoring, the Agency shall draft a pro forma invoice for external clients. The Agency shall not implement specialisation or mentoring of external clients without prior confirmation of the pro forma invoice by the client requesting specialisation or mentoring.

Article 43
(Travel and other costs of experts and pharmaceutical inspectors when implementing their tasks)

In addition to the fees stated in these Rules, an applicant for a procedure shall also cover the costs of experts or pharmaceutical inspectors, which include costs in accordance with the regulation on the refund of costs for business trips.

Article 44
(Publishing)

The Agency shall charge for the delivery of, or access to, the Formularum Slovenicum edition to clients as follows:

- Formularum Slovenicum – printed edition: 15 points per copy,
- Formularum Slovenicum – 1 to 5 passwords in electronic form: 17 points per copy,
- Formularum Slovenicum – 6 to 25 passwords in electronic form: 15 points per copy,
- Formularum Slovenicum – more than 25 passwords: 13 points per copy,
- Brochure accompanying a presentation of Formularum Slovenicum: 12 points per copy.

Article 45
(Photocopying)

(1) The Agency shall charge for photocopying, printing and scanning for clients as follows:

- photocopying, printing – A4, black and white, single-sided: 0.028 points per copy,
- photocopying, printing – A4, black and white, double-sided: 0.04 points per copy,
- photocopying, printing – A4, colour, single-sided: 0.12 points per copy,
- photocopying, printing – A4, colour, double-sided: 0.22 points per copy,
- scanning – A4, single-sided: 0.024 points per copy,
- scanning – A4, double-sided: 0.036 points per copy.

(2) In the case of scanning and printing, the Agency shall charge the service according to the rate for printing.

Article 46
(Issue of reminders for outstanding liabilities)

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

IV. TRANSITIONAL AND FINAL PROVISIONS

Article 47
(Cessation of application)

(1) As of the date of entry into force of these Rules, the Rules on charges in the field of medicines (Official Gazette of the Republic of Slovenia, no. 65/11) 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 these Rules or relating to which a legal remedy had already been filed upon the entry into force of these Rules.

Article 48
(Entry into force)

These Rules shall enter into force on the fifteenth day following publication in the Official Gazette of the Republic of Slovenia.

No.

Ljubljana,

EVA

President of the Council of the Public Agency
of the Republic of Slovenia for
Medicinal Products
and Medicinal Devices
Igor Velušček