The unofficial revised version of the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices comprises:

- the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 209/21, of 31 December 2021),
- the Amendments to the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 165/22, of 29 December 2022),
- the Amendments to the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 135/23, of 29 December 2023).

T A R I F F
of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices

(Unofficial consolidated version No. 2)

I. GENERAL PROVISIONS

Article 1
(Type of services)

(1) This Tariff lays down the fees for services provided by the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: JAZMP) for private individuals and legal entities, for the costs of performing administrative tasks that are part of public powers and are carried out by the JAZMP, and for the costs of performing professional tasks and services within the JAZMP's powers.

(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 the JAZMP shall also pay an annual fee for the costs of monitoring the medicinal product on the market, which relate to an individual medicinal product in terms of the number of its pharmaceutical forms or strengths.

(3) Fees to be charged by the JAZMP shall 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, variation 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 among medicinal product manufacturers;
4. fees for the issue, variation and termination of wholesale distribution authorisation and notification of a wholesaler established in the European Union;
5. the fee for the issue of a certificate on good distribution practice of medicinal products and active substances;
6. fees for the issue, variation and termination of retail sale authorisation for medicinal products in specialised shops for the issue of OTC medicinal products;
7. fees for entry in, change in the register entry and removal from the register of manufacturers, wholesalers and importers of active substances;
8. fees for entry in, change in the register entry or removal from the register of agents selling medicinal products and active substances;
9. fees for entry in, change in the register entry and removal from the register of medical sales representatives for the advertising of medicinal products;
10. fees for the authorisation procedure for a clinical trial of a medicinal product and an assessment of the conduct of a clinical trial;
11. fees for the procedure of notifying a non-interventional clinical trial or non-interventional study or the issue of a prior endorsement for a non-interventional clinical trial or non-interventional study;
12. fees for the issue of authorisation for the compassionate use of medicinal products;
13. fees for the issue, extension, renewal, variation, transfer and termination of marketing authorisation for a medicinal product for human use and marketing authorisation for a veterinary medicinal product;
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 training materials for safe and effective use of medicinal products and for other changes in information on a medicinal 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, variation, transfer and termination of marketing authorisation for herbal medicinal products;
18. fees for the issue, renewal, variation, transfer and termination of marketing authorisation for homeopathic medicinal products;
19. fees for the issue of temporary marketing authorisation and the entry or import of medicinal products with no marketing authorisation;
20. fees for the issue of authorisation for the entry or import and exit or export of illicit drugs in groups II and III – and for placing a seal on the register of medicinal products – which are illicit drugs in groups II, III a and III c;
21. fees for marketing authorisation for a parallel-imported medicinal product and a certificate on the parallel distribution of medicinal products;
22. fees for the issue, renewal, variation and revocation of marketing authorisation for a parallel imported medicinal product;
23. fees for the approval of individual derogations from the terms of a marketing authorisation (OOS) and for maintaining a medicinal product’s marketing authorisation;
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 blue box and the national identifier of medicinal products, for which marketing authorisation was obtained in accordance with the centralised procedure;
26. fees for the deferment of cancellation of marketing authorisation;
27. the 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 exceptional higher allowed price of a medicinal product;
30. fees for the determination of the maximum allowed price of a medicinal product;

31. fees for notifying corporate donations of medicinal products;
32. fees for the issue, variation and revocation of human tissue and cell supply authorisation;
33. fees for the issue, variation and revocation of blood supply authorisation;
34. fees for the issue, variation and revocation of authorisation for non-routinely prepared advanced therapy medicinal products;
35. fees for entry in, change in the register entry and removal from the register of doctors and veterinarians who use non-routinely prepared advanced therapy medicinal products in their practice;
36. fees for the notification of officinal medicinal products and the approval of risk assessments for the manufacture of officinal medicinal products, as well as for the preparation of high risk extemporaneous medicinal products.

(4) The JAZMP shall charge for the performance of the following professional tasks and services:
1. expert training, lecture, workshop and consultation;
2. consulting;
3. specialisation and mentoring;
4. travel and other expenses of experts and pharmaceutical inspectors when performing 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
(Tariff rates)

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

(2) The value of one point shall be EUR 5.8 excluding value added tax. The value of one point may be verified annually, i.e. based on actual costs relating to the performance of tasks and services herein. Any change in the value of one point shall be adopted by the JAZMP board with the founder's consent. 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 upon submission of an application or upon receipt of a call for payment or notification on how to pay the fee from the JAZMP.

(2) The JAZMP shall send a notification on such payment method to the applicant's email address that has been included in the application form. The notification on the fee's payment method shall include at least the information on the applicant, the received application, the object of the charged fee (products), the fee amount, the reference number and other information required for 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 upon receiving the notification on how to pay the fee to the JAZMP sub-account.

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

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

(5) In the case of non-payment of the fee, the JAZMP may charge statutory late payment 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. for marketing authorisation for a medicinal product or a parallel imported medicinal product in any pharmaceutical form: 60 points but not less than 180 points and not more than 9,600 points;
2. for individual marketing authorisation for a veterinary medicinal product or a parallel imported veterinary medicinal product in any pharmaceutical form: 60 points;
3. for individual marketing authorisation for a herbal medicinal product in any pharmaceutical form: 60 points;
4. for individual marketing authorisation for a homeopathic medicinal product in any pharmaceutical form: 14 points but not less than 42 points and not more than 1,050 points;
5. for individual manufacturing authorisation for a medicinal product: 240 points;
6. for individual wholesale distribution authorisation for a medicinal product: 240 points;
7. for individual retail sale authorisation for a medicinal product in specialised shops: 120 points;
8. for an individual certificate of entry in the register of manufacturers, wholesalers and importers of active substances: 240 points;
9. for an individual certificate of entry in the official register of a notified wholesaler of medicinal products, who obtained marketing authorisation for a medicinal product in another European Union Member State: 120 points;
10. for an individual certificate of the entry in the register of agents selling medicinal products and active substances: 120 points;
11. for authorisation to perform activities of blood supply: 120 points;
12. for individual authorisation to pursue activities of supplying human tissues and cells: 200 points;
13. for authorisation for an advanced therapy medicinal product prepared on a non-routine basis: 200 points.

Article 5
(Fees relating to medicinal product manufacturing)

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

1. for the issue of manufacturing authorisation for medicinal products based on verification of compliance with good manufacturing practice, per day of an expert committee's inspection at the applicant's premises: 380 points;
2. for processing a variation when reassessment of compliance with good manufacturing practice is not necessary and the variation requires a variation of the medicinal product manufacturing authorisation: 75 points;
3. for processing of a variation when reassessment of compliance with good manufacturing practice is necessary and the variation requires a variation of the medicinal product manufacturing authorisation, per day of an expert committee's inspection at the applicant's individual manufacturing locations: 305 points;
4. for the 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 a variation of the medicinal product manufacturing authorisation, per day of an expert committee's inspection at the applicant's premises: 305 points;
5. for the termination of the medicinal product manufacturing authorisation at the request of the authorisation holder: 40 points;
6. for the issue of a compliance assessment for the manufacturing of medicinal products, when reassessment of compliance with good manufacturing practice is not necessary and the variation does not require a variation of a medicinal product manufacturing authorisation: 75 points;
7. for entry in the register of persons responsible for the release of individual medicinal product series: 20 points;
8. for a change in the entry in the register of persons responsible for the release of individual medicinal product series: 20 points;
9. for 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 the manufacturer's good manufacturing practice shall be as follows:

- for the assessment of compliance with good manufacturing practice in a procedure for obtaining marketing authorisation at the applicant's premises, per pharmaceutical supervisor/day: 400 points;
- for the assessment of compliance with good manufacturing practice abroad on the proposal of a legal or natural entity, per pharmaceutical supervisor/day: 400 points;
- for the 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 sale 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 indents one and two of paragraph one of this Article, the applicant shall also cover other costs of pharmaceutical supervisors in accordance with Article 52 hereof.

Article 7

(Fees relating to wholesale distribution authorisation for medicinal products)

(1) Fees for the issue, variation and termination of wholesale distribution authorisation shall be as follows:

1. for the 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's premises: 210 points;
2. for processing a variation when reassessment of compliance with good distribution practice is not necessary and the variation requires a variation of the wholesale distribution authorisation for medicinal products: 55 points;
3. for processing a variation when reassessment of compliance with good distribution practice is necessary and when the variation requires a variation of the wholesale distribution authorisation for medicinal products, per day of expert committee inspection at the applicant's premises: 155 points;
4. for the issue of an assessment of compliance with the requirements for the wholesale distribution of medicinal products including an inspection, when reassessment of compliance with good distribution practice is necessary and the variation does not require a variation of the wholesale distribution authorisation for medicinal products, per day of expert committee inspection at the applicant's premises: 155 points;
5. for the issue of a certificate of good distribution practice: 100 points;
6. for the termination of wholesale distribution authorisation for medicinal products at the request of the authorisation holder: 40 points;
7. for entry in the register of persons responsible for the adoption of medicinal products: 20 points;
8. for a change in the entry in the register of persons responsible for receipt of medicinal products: 20 points;
9. for removal from the register of persons responsible for the adoption of medicinal products: 20 points;
10. for entry in the official register of a notified wholesaler of medicinal products who obtained marketing authorisation for a medicinal product in another European Union Member State: 150 points;
11. for a change in the entry in the official register of a notified wholesaler of medicinal products who obtained marketing authorisation for a medicinal product in another European Union Member State: 150 points;
12. for removal from the official register at the request of a notified wholesaler of medicinal products who obtained marketing authorisation for a medicinal product in another European Union Member State: 20 points.

Article 8
(Fees for retail sale authorisation for medicinal products in specialised shops)

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

- issue of retail sale authorisation for medicinal products in specialised shops based on verification of compliance with requirements, per day of expert committee inspection: 305 points;
- processing a variation when reassessment of compliance with requirements is not necessary and the variation requires a variation of the retail sale authorisation for medicinal products in a specialised shop: 75 points;
- 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 a variation of the retail sale authorisation for medicinal products in specialised shops, per day of expert committee inspection: 230 points;

- for processing a variation when a reassessment of compliance with the requirements is necessary and the variation requires a variation of the retail sale authorisation for medicinal products in specialised shops, per day of expert committee inspection: 230 points;
- for termination 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. for entry in the register of manufacturers, wholesalers and importers of active substances: 150 points;
2. for entry in the register of manufacturers, wholesalers and importers of active substances, per day of expert committee inspection: 225 points;
3. for a change in the entry in the register of manufacturers, wholesalers and importers of active substances: 75 points;
4. for a change in the entry in the register of manufacturers, wholesalers and importers of active substances, per day of expert committee inspection: 125 points;
5. for removal from the register of manufacturers, wholesalers and importers of active substances: 20 points;
6. for the consideration of annual reports of a manufacturer, wholesaler and importer of active substances: 40 points;
7. for the issue of an assessment of compliance with the requirements for entry in the register of manufacturers, wholesalers and importers of active substances where the modification does not require a change in the entry in the register, per day of expert committee inspection at the applicant’s premises: 125 points.

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

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

- for entry in the register of agents selling medicinal products and active substances: 40 points;
- for a change in the entry in the register of agents selling medicinal products and active substances: 40 points;
- for removal from the register of agents selling medicinal products and active substances: 20 points.

Article 11
(Fees for entry in, change in the register entry and removal from the register of medical sales representatives for the advertising of medicinal products)

Fees for the entry in, change in the register entry and removal from the register of medical sales representatives for the advertising of medicinal products shall be as follows:

- for the entry of a medical sales representative in the register: 20 points;
- for a change in the register entry of a medical sales representative in the register: 20 points;
- for the removal of a medical sales representative from the register: 20 points.

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

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

1. for notification or authorisation of clinical trials for a medicinal product based on an assessment from another European Union Member State: 190 points;
2. for notification or authorisation of clinical trials for a medicinal product based on an assessment of protocol: 1,210 points;
3. for notifying a modification of a clinical trial of a medicinal product: 40 points;
4. for an issue of consent to the protocol of non-interventional trial of a medicinal product or non-interventional study carried out at the request of the JAZMP and taking place only in the Republic of Slovenia: 305 points;
5. for notifying a non-interventional trial of a medicinal product or a non-interventional study: 75 points;
6. for notifying a major change in the protocol of a non-interventional trial of a medicinal product or a non-interventional study carried out at the request of the JAZMP and taking place only in the Republic of Slovenia: 35 points;
7. for the assessment of the conduct of a clinical trial for compliance with good clinical practice on the proposal of a legal or natural entity, per pharmaceutical supervisor/day: 305 points;
8. for the assessment of the conduct of a clinical trial for compliance with good clinical practice in the procedure for obtaining marketing authorisation, 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 in accordance with Article 52 hereof.

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

- for the authorisation of a clinical trial for a medicinal product based on protocol assessment: 150 points;
- for the authorisation of a modification of a clinical trial for a medicinal product: 40 points;
- for notifying a non-interventional clinical trial: 75 points;
- for notifying a modification of a non-interventional clinical trial: 35 points;

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

(5) Fees relating to the procedure of notification or authorisation of a clinical trial for a medicinal product and notification of a significant modification of a clinical trial for a medicinal product for human use, with sponsors being non-profit business entities and private individuals (non-commercial clinical trial) shall amount to half of the value of the individual fees referred to in paragraph one of this Article.

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

Article 12a

(Fees for clinical trials of medicinal products for human use in accordance with Regulation 536/2014/EU)

(1) Fees for procedures for clinical trials of medicinal products for human use in accordance with Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1), last amended by Commission Delegated Regulation (EU) 2022/2239 of 6 September 2022 amending Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use (OJ L 294, 15.11.2022, p. 5), (hereinafter: Regulation 536/2014/EU), and the distribution of fees between the JAZMP and the Medical Ethics Committee are set out in Annex 1, which forms an integral part of this Tariff.

(2) After the expiry of the first year following the commencement of the clinical trial in the Republic of Slovenia, the applicant referred to in the preceding paragraph shall pay for clinical trial monitoring procedures, such as the evaluation of sponsor notifications and safety reports, an annual fee of 180 points.

(3) For non-commercial clinical trials and for clinical trials of orphan medicinal products, the fees relating to the procedure for the authorisation of a clinical trial and the authorisation of a substantial modification of a clinical trial among a paediatric population shall be half the value of the individual fee referred to in paragraph one of this Article.

(4) Fees related to the supervision of the conduct of clinical trials in accordance with good clinical practice shall be as follows:
- for the assessment of the conduct of a clinical trial for compliance with good clinical practice on the proposal of a legal or natural entity, per pharmaceutical supervisor/day: 305 points;
- for the assessment of the conduct of a clinical trial for compliance with good clinical practice in the procedure for obtaining marketing authorisation, per pharmaceutical supervisor/day: 305 points.

(5) In addition to the fees referred to in the preceding paragraph of this Article, the applicant shall also cover other costs of pharmaceutical supervisors in accordance with Article 52 hereof.

6) No fees shall be charged in connection with the procedure for the transition of clinical trials to Regulation 536/2014/EU already authorised pursuant to the Act.

Article 13
(Fees for obtaining marketing authorisation for a medicinal product for human use)

(1) The JAZMP shall issue marketing authorisations or carry out the following procedures:
1. national procedures (hereinafter: NP);
2. mutual recognition procedures in which the Republic of Slovenia is the reference member state (hereinafter: MRP-RMS);
3. mutual recognition procedures in which the Republic of Slovenia is the concerned member state (hereinafter: MRP-CMS);
4. decentralised procedures in which the Republic of Slovenia is the reference member state (hereinafter: DCP-RMS);
5. decentralised procedures in which the Republic of Slovenia is the concerned member state (hereinafter: DCP-CMS);

6. repeat use procedure after a completed MRP or DCP in which the Republic of Slovenia is the reference member state (hereinafter: RUP-RMS).

(2) Fees for obtaining marketing authorisation for a medicinal product for human use shall be as follows:

1. for obtaining marketing authorisations pursuant to Articles 44 or 49 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos. 17/14 and 66/19; hereinafter: Act) in:
   - NP: 2,055 points;
   - MRP-CMS: 735 points;
   - MRP-RMS: 5,675 points;
   - RUP-RMS: 3,795 points;
   - DCP-CMS: 735 points;
   - DCP-RMS: 6,630 points;
2. for obtaining marketing authorisations pursuant to Article 47 of the Act in:
   - NP: 2,000 points;
   - MRP-CMS: 735 points;
   - MRP-RMS: 5,400 points;
   - RUP-RMS: 3,510 points;
   - DCP-CMS: 735 points;
   - DCP-RMS: 6,090 points;
3. for obtaining marketing authorisations pursuant to paragraphs one or six of Article 45 of the Act in:
   - NP: 1,775 points;
   - MRP-CMS: 615 points;
   - MRP-RMS: 4,740 points;
   - RUP-RMS: 3,225 points;
   - DCP-CMS: 615 points;
   - DCP-RMS: 5,490 points;
4. for obtaining marketing authorisations pursuant to Article 50 of the Act in:
   - NP: 650 points;
   - MRP-CMS: 510 points;
   - MRP-RMS: 2,450 points;
   - RUP-RMS: 1,615 points;
   - DCP-CMS: 735 points;
   - DCP-RMS: 3,975 points.

(3) Notwithstanding the preceding paragraph, the fee for obtaining marketing authorisation for a medicinal product shall be reduced by 50% if:

- the medicinal product, with its active substance, pharmaceutical form and strength, is included in the list of essential or indispensable medicinal products;
- the medicinal product has been brought in or imported in accordance with paragraph three of Article 20 of the Act during the 18 months preceding the submission of the application in question;
- there is no medicinal product with the same active substance in the same strength and pharmaceutical form with marketing authorisation in circulation at the time of submission of the application;
- the marketing authorisation holder declares in the application that it will place the medicinal product on the market within 18 months of the marketing authorisation being granted.

(4) If the applicant fails to place the medicinal product concerned on the market within 18 months of the granting of the marketing authorisation, it shall be liable to pay the difference up to the full fee referred to in paragraph one of this Article.

Article 14
(Fees for obtaining marketing authorisation for a veterinary medicinal product)

(1) Fees for obtaining marketing authorisation for a veterinary medicinal product shall be as follows:

1. for obtaining marketing authorisations pursuant to Articles 8, 20, 23 or 25 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43) last amended by Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans (OJ L 353, 6.10.2021, p. 1), (hereinafter: Regulation 2019/6/EU), in:
   - NP: 1,000 points;
   - MRP-CMS: 420 points;
   - MRP-RMS: 5,690 points;
   - DCP-CMS: 450 points;
   - DCP-RMS: 6,640 points;
   - SRP-RMS: 3,180 points;
2. for obtaining marketing authorisations pursuant to Article 22 of Regulation 2019/6/EU in:
   - NP: 800 points;
   - MRP-CMS: 380 points;
   - MRP-RMS: 4,745 points;
   - DCP-CMS: 420 points;
   - DCP-RMS: 5,215 points;
   - SRP-RMS: 2,655 points;
3. for obtaining marketing authorisations pursuant to Article 18 or Article 19 of Regulation 2019/6/EU in:
   - NP: 700 points;
   - MRP-CMS: 360 points;
   - MRP-RMS: 3,000 points;
   - SRP-RMS: 1,600 points;
   - DCP-CMS: 380 points;
   - DCP-RMS: 3,500 points;
4. for obtaining marketing authorisations pursuant to Article 21 of Regulation 2019/6/EU in:
   - NP: 200 points;
   - MRP-CMS: 200 points;
   - MRP-RMS: 2,100 points;
   - SRP-RMS: 1,600 points;
   - DCP-CMS: 200 points;
   - DCP-RMS: 2,800 points.

(2) Fees for obtaining marketing authorisations shall be reduced by 50% relative to the fees referred to in the preceding paragraph, if:

- the medicinal product, with its active substance, pharmaceutical form and strength, is included in the list of essential or indispensable medicinal products; and
- the medicinal product referred to in the preceding indent was placed on the market 12 months prior to the submission of the application in question pursuant to an entry or import authorisation.

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

Fees for processing applications for an extension of marketing authorisation for a medicinal product for human use shall be in:
- NP: 1,320 points;
- MRP-CMS: 615 points;
- DCP-CMS: 615 points;
- MRP-RMS: 2,985 points;
- DCP-RMS: 3,675 points.

(2) Notwithstanding the preceding paragraph, the fee for the extension of a marketing authorisation for a medicinal product shall be reduced by 50% if:
- the medicinal product, with its active substance, pharmaceutical form and strength, is included in the list of essential or indispensable medicinal products;
- the medicinal product was brought in or imported in accordance with paragraph three of Article 20 of the Act during the 18 months preceding the submission of the application in question;
- there is no medicinal product with the same active substance in the same strength and pharmaceutical form with marketing authorisation in circulation at the time of submission of the application;
- the marketing authorisation holder declares in the application that it will place the medicinal product on the market within 18 months of the marketing authorisation being granted.

(3) If the applicant fails to place the medicinal product concerned on the market within 18 months of the granting of the marketing authorisation, it shall be liable to pay the difference up to the full fee referred to in paragraph one of this Article.

Article 16
(Fees for renewal of marketing authorisation for medicinal products for human use)

Fees for renewal of marketing authorisation for a medicinal product for human use shall be in:
- NP: 400 points;
- MRP/DCP-CMS: 255 points;
- MRP/DCP-RMS: 1,995 points.

Article 17
(Fees for renewal of marketing authorisation for veterinary medicinal products for a limited market and in exceptional cases)

Fees for renewal of marketing authorisation for veterinary medicinal products for a limited market and in exceptional cases shall be in:
- NP: 300 points;
- MRP/DCP-CMS: 250 points;
- MRP/DCP-RMS: 2,230 points.

Article 18
(Fees for type I and II variations of medicinal products for human use)

Fees processing of type I and type II variations for medicinal products shall refer only to medicinal products for which marketing authorisations were obtained 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 shall include 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 notifying a type IA variation in:
   - NP: 50 points;
   - MRP/DCP-CMS: 30 points;
   - MRP/DCP-RMS: 295 points ;
2. for notifying a type IB variation in:
   - NP: 110 points;
   - MRP/DCP-CMS: 110 points;
   - MRP/DCP-RMS: 650 points;
3. for the approval of a type II variation in:
   - NP: 260 points;
   - MRP/DCP-CMS: 140 points;
   - MRP/DCP-RMS: 1,235 points;
4. in grouping of variations in accordance with Articles 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 Delegated Regulation (EU) No 2021/756 of 24 March 2021 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 162, 10.5.2021, p. 1), (hereinafter: Regulation 1234/2008/EC):
   a) in point a) of paragraph two of Article 7 of Regulation 1234/2008/EC and relating to point a) of paragraph two of Article 13d of Regulation 1234/2008/EC (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% of the total fee referred to in point 1 of this Article for each additional variation to the same marketing authorisation, but not more than:
      - in NP: 400 points;
      - in MRP/DCP-CMS: 250 points;
      - in MRP/DCP-RMS: 1,500 points;
   b) in point a) of paragraph two of Article 7 of Regulation 1234/2008/EC and relating to point a) of paragraph two of Article 13d of Regulation 1234/2008/EC (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 referred to in point 1 of this Article for further variations of the first marketing authorisation, and for the same variations to each additional marketing authorisation 75% of the total fee calculated for the variations of the first marketing authorisation, but not more than:
      - in NP: 400 points;
      - in MRP/DCP-CMS: 250 points;
      - in MRP/DCP-RMS: 1,500 points;
   c) in point b) of paragraph two of Article 7 of Regulation 1234/2008/EC and relating to point b) of paragraph two of Article 13d of Regulation 1234/2008/EC (extension of marketing authorisation and consequential variations): a full fee in accordance with Article 15 of this Tariff shall apply for a major variation and 75% of the total fee for each additional variation referred to in points 1, 2 or 3 of this Article, but not more than:
      - in NP: 2,000 points;
      - in MRP/DCP-CMS: 1,200 points;
      - in MRP/DCP-RMS: 4,200 points;
   č) in point b) of paragraph two of Article 7 of Regulation 1234/2008/EC and relating to point b) of paragraph two of Article 13d of Regulation 1234/2008/EC (type IB or type II variation and consequential or related variations): a full fee referred to in points 2 or

3 of this Article shall apply for a major variation and 75% of the total fee for each additional variation referred to in points 1, 2 or 3 of this Article, but not more than:
- in NP: 800 points;
- in MRP/DCP-CMS: 450 points;
- in MRP/DCP-RMS: 3,500 points;

d) in point c) of paragraph two of Article 13d of Regulation 1234/2008/EC (grouping type IB or type II variations and consequential or related variations for several purely 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% of the total fee referred to in points 1, 2 or 3 of this Article for consequential variations of the first marketing authorisation, and for the same variations of each additional marketing authorisation 75% of the total fee calculated for the variations of the first marketing authorisation;

5. notwithstanding the preceding point:
   a) regardless of the type of procedure, for a grouped single variation of the 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 several medicinal products (several marketing authorisations), even if it concerns only one medicinal product (single marketing authorisation) in the Republic of Slovenia, the fee shall be as follows:
      - from 1 to 20 medicinal products: 100 points;
      - from 21 to 50 medicinal products: 200 points;
      - more than 50 medicinal products: 400 points;
   b) for grouped variations concerning a change in the name of a medicinal product for human use in several European Union Member States for one marketing authorisation, 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 a change in the name or address of the marketing authorisation holder in several European Union Member States for a single medicinal product (single marketing authorisation), 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 1234/2008/EC, a full fee in accordance with points 2 or 3 or point č) of point 4 of this Article shall apply to a variation or variations of the first marketing authorisation in the Republic of Slovenia and 75% of the total fee for every additional marketing authorisation, calculated as per the variation or variations of the first marketing authorisation while taking into account whether the Republic of Slovenia is an RMS or a CMS in the relevant work-sharing procedure, but not more than:
   - in MRP/DCP-CMS: 780 points;
   - in MRP/DCP-RMS: 3,500 points.

Article 19
(Fees for the variation of marketing authorisation for veterinary medicinal products)

Fees for processing variations of a marketing authorisation for veterinary medicinal products shall refer only to medicinal products for which marketing authorisations were obtained 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. A single marketing authorisation pursuant to this Article shall include 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 for a veterinary medicinal product. Fees shall be as follows:

1. for the approval of variations not requiring assessment (VRNA) in:
   - NP: 29 points;
   - MRP/DCP-CMS: 29 points;
   - MRP/DCP-RMS: 200 points;
2. notwithstanding the preceding point, for a variation concerning a change in the name or address or contact details of a marketing authorisation holder, or for a variation concerning a change in the name or address or contact details of the qualified person responsible for pharmacovigilance, or for an introduction or a variation concerning the main dossier on a pharmacovigilance system or a notification of a change in the location of the main dossier on a pharmacovigilance system applicable to several medicinal products, the maximum fee shall be as follows:
   - from 4 to 20 medicinal products: 100 points;
   - from 21 to 50 medicinal products: 200 points;
   - more than 50 medicinal products: 400 points;
   - MRP/DCP-RMS: 1,250 points;
3. for the approval of variations requiring assessment (VRA) in:
   - NP: 157 points;
   - MRP/DCP-CMS: 157 points;
   - MRP/DCP-RMS: 1,235 points;
4. for the grouping of variations requiring assessment in accordance with Article 64 of Regulation 2019/6/EU a full fee referred to in the preceding point shall apply for the first variation and 75% of the total fee for each additional variation referred to in the preceding point, but not more than:
   - in NP: 570 points;
   - in MRP/DCP-CMS: 522 points;
   - in MRP/DCP-RMS: 2,845 points;
5. in work-sharing procedures pursuant to Article 65 of Regulation 2019/6/EU, a full fee in accordance with points 3 or 4 of this Article shall apply to a variation to the first marketing authorisation and 75% of the total fee for every additional marketing authorisation, calculated as per the variation or variations of the first marketing authorisation while taking into account whether the Republic of Slovenia is an RMS or a CMS in the relevant work-sharing procedure, but not more than:
   - in MRP/DCP-CMS: 740 points;
   - in MRP/DCP-RMS: 3,320 points;
6. for processing variations requiring assessment and requiring new marketing authorisation (addition of strength or pharmaceutical form):
   - in NP: 570 points;
   - in MRP-CMS: 240 points;
   - in DCP-CMS: 266 points;
   - in MRP/DCP-RMS: 2,370 points.

Article 20
(Fees for the transfer or termination of marketing authorisation for medicinal products for human use)

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

- for the transfer of marketing authorisation to another legal or natural entity: 70 points;
- maximum fees for a simultaneous transfer of several marketing authorisations to another legal or natural entity: 280 points;
- for the termination of marketing authorisation at the request of the marketing authorisation holder for an individual pharmaceutical form or strength: 20 points.

Article 21
(Fees for the transfer or termination of marketing authorisation for a veterinary medicinal product)

Fees for the transfer and termination of marketing authorisation at the request of the holder of marketing authorisation for a veterinary medicinal product shall be as follows:
- for the transfer of marketing authorisation to another legal or natural entity: 50 points;
- maximum fees for a simultaneous transfer of several marketing authorisations to another legal or natural entity: 200 points;
- for the termination of marketing authorisation at the request of the marketing authorisation holder for an individual pharmaceutical form or strength: 20 points.

Article 22
(Fees for PSUR assessment)

(1) The fee for the assessment of the regular Periodic Safety Update Report (PSUR) for a medicinal product for human use – national procedure (NP) – shall be 755 points.

(2) The fee for the assessment of the Periodic Safety Update Report (PSUR) for a medicinal product for human use that is included in the PSUR single assessment (PSUSA) shall not be charged.

Article 23
(Fees for a review of training materials for safe and effective use of medicinal products and for other changes to information on a medicinal product)

(1) Fees for a review of training materials for safe and effective use of medicinal products shall be as follows:
- for new training materials: 305 points;
- for updating training materials: 225 points.

(2) The fee for notifying changes to package leaflets and labelling that 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 the place or manner of dispensing a medicinal product for human use shall be as follows:
- for the variation of medicinal product classification in terms of the place of dispensing it: 110 points;
- for the variation of medicinal product classification in terms of the manner of its dispensing: 260 points.

(4) The fee for approving advertising, if this was not decided as part of an application for the obtaining or maintenance of marketing authorisation, shall be 15 points.

(5) Fees for reviewing the video content of package leaflets in conjunction with summaries of product characteristics and package leaflets shall be 110 points.

Article 24
(Fees for mutually interchangeable medicinal products)

The fee for processing an application for establishing the interchangeability of medicinal products under an independent procedure for establishing mutual interchangeability shall be 100 points.

Article 25
(Fees for herbal medicinal products with efficacy proven in clinical trials)

Fees for the obtaining, extension, renewal, variation, transfer and termination of marketing authorisation for a herbal medicinal product with efficacy proven in clinical trials shall be as follows:

1. for obtaining marketing authorisations pursuant to Articles 44 or 49 of the Act in:
   - NP: 1,030 points;
   - MRP-CMS: 510 points;
   - MRP-RMS: 5,675 points;
   - RUP-RMS: 3,795 points;
   - DCP-CMS: 510 points;
   - DCP-RMS: 6,630 points;
2. for obtaining 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: 5,400 points;
   - RUP-RMS: 3,510 points;
   - DCP-CMS: 510 points;
   - DCP-RMS: 6,090 points;
3. for obtaining marketing authorisations pursuant to Article 50 of the Act in:
   - NP: 325 points;
   - MRP-CMS: 310 points;
   - MRP-RMS: 2,450 points;
   - RUP-RMS: 1,615 points;
   - DCP-CMS: 310 points;
   - DCP-RMS: 3,975 points.
4. for an extension of marketing authorisation for a medicinal product in:
   - NP: 660 points;
   - MRP/DCP-CMS: 370 points;
   - MRP-RMS: 2,985 points;
   - DCP-RMS: 3,675 points;
5. for the renewal of marketing authorisation for a medicinal product in:
   - NP: 400 points;
   - MRP/DCP-CMS: 255 points;
   - MRP/DCP-RMS: 1,995 points.
6. fees for processing type I and II variations of marketing authorisation shall be equal to the fees referred to in Article 18 hereof;
7. for other variations of the medicinal product information the fees shall be the same as the fees referred to in paragraphs two, three, four and five of Article 23 hereof;
8. fees for the transfer or termination of marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 20 hereof.

Article 26
(Fees for traditional herbal medicinal products)

Fees for the approval, extension, renewal, variation, transfer and termination of marketing authorisation for a traditional herbal medicinal product in a simplified procedure shall be as follows:

1. for obtaining marketing authorisation for a medicinal product in:
   - NP pursuant to paragraph two of Article 52 of the Act if there is no EU monograph or if additional data is submitted: 600 points;
   - NP pursuant to paragraph two of Article 52 of the Act in accordance with the EU monograph: 500 points;
   - MRP and DCP-CMS: 300 points;
   - MRP-RMS: 3,795 points;
   - RUP-RMS: 2,560 points;
   - DCP-RMS: 4,265 points;
2. for an extension of marketing authorisation for a medicinal product in:
   - NP: 500 points;
   - MRP/DCP-CMS: 250 points;
   - RUP-RMS: 1,330 points;
   - MRP/DCP-RMS: 1,900 points;
3. for the renewal of marketing authorisation for a medicinal product in:
   - NP: 300 points;
   - MRP/DCP-CMS: 160 points;
   - MRP/DCP-RMS: 1,140 points.
4. for processing type I and II variations of a marketing authorisation: 70% of the fees stated in Article 18 hereof;
5. for other variations of the medicinal product information the fees shall be the same as the fees referred to in paragraphs two, three, four and five of Article 23 hereof;
6. fees for the transfer or termination of marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 20 hereof.

Article 27
(Fees for homeopathic medicinal products for human use)

Fees for the obtaining, renewal, variation, transfer and termination of marketing authorisation for a homeopathic medicinal product shall be as follows:

1. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock associated with one pharmaceutical form – NP: 200 points;

1a. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock where 5 applications are simultaneously submitted by the same manufacturer, in the same pharmaceutical form – NP 120 points/per application;

2. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock associated with one pharmaceutical form – MRP/DCP-CMS: 100 points;
3. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock associated with one pharmaceutical form – MRP/DCP-RMS: 3,500 points;
4. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains two to three homeopathic stocks associated with one pharmaceutical form – NP: 500 points;
5. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains two to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 300 points;

6. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains two to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,240 points;
7. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains more than three homeopathic stocks associated with one pharmaceutical form – NP: 900 points;
8. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains more than three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 700 points;
9. for obtaining marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains more than three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,655 points;
10. for the renewal of marketing authorisation for a homeopathic medicinal product referred to in points 4, 5, 7 and 8 of this Article: 140 points;
11. for the renewal of marketing authorisation for a homeopathic medicinal product referred to in point 1 of this Article: 80 points;
12. for the renewal of marketing authorisation for a homeopathic medicinal product referred to in points 3, 6 and 9 of this Article: 1,000 points;
13. for a variation of marketing authorisation for a homeopathic medicinal product referred to in points 4, 5, 7 and 8 of this Article: 90 points;
14. for a variation of marketing authorisation for a homeopathic medicinal product referred to in points 1, 1a and 2 of this Article: 70 points;
15. for a variation of marketing authorisation for a homeopathic medicinal product referred to in points 3, 6 and 9 of this Article: 1,000 points;
16. for the transfer or termination of marketing authorisation at the request of the marketing authorisation holder: equal to the fees referred to in Article 20 hereof;
17. for notifying an additional degree of dilution in the context of granted marketing authorisation for a homeopathic medicinal product: 5 points;
18. for the issue of marketing authorisation for a homeopathic medicinal product in accordance with paragraph one of Article 53 of the Act: equal to the fees referred to in Article 13 hereof.

Article 28
(Fees for homeopathic veterinary medicinal products)

(1) Fees for the registration and variation of registration of a homeopathic veterinary medicinal product shall equal the fees referred to in the preceding Article.

(2) Fees for terminating the registration of a homeopathic medicinal product at the request of the medicinal product registration holder shall equal the fees referred to in Article 21 hereof.

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

(1) Fees for the issue of temporary marketing authorisation for the entry or import of medicinal products with no marketing authorisation shall be as follows:
1. for the issue of authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) in urgent cases of individual treatment: 10 points;
2. for the issue of authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) from the list of essential or indispensable medicinal products: 30 points;

2a. for the issue of authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) from the list of essential or indispensable veterinary medicinal products: 10 points;
3. for the issue of authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) in exceptional circumstances in the interest of public health protection: 10 points;
4. for the issue of authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) for medicinal products financed from budgetary resources: 10 points;
5. for the issue of authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) for veterinary medicinal products upon the occurrence of epizootic diseases: 10 points;
6. for the issue of authorisation for import or entry of a medicinal product based on an annual tender of necessary quantities of medicinal products: 25 points.

(2) Notwithstanding points 1, 2, 3 and 4 of the preceding paragraph, the fee shall be 30 points for:
- the issue of temporary marketing authorisation and authorisation for the entry or import of a particular group of allergy tests or allergenic extracts,
- the issue of temporary marketing authorisation and authorisation for the entry or import of radiopharmaceuticals at the level of a particular medicinal product in all strengths, pharmaceutical forms and packaging.

Article 30
(Fees for the issue of authorisation for the entry or import and exit or export of illicit drugs in groups II and III and for sealing record books on medicinal products that are illicit drugs in groups II, III a and III c)

(1) The fee for the issue of authorisation for the entry or import and exit or export of medicinal products or active substances that are illicit drugs in groups II and III shall be 10 points for an individual medicinal product (pharmaceutical form, strength, packaging) or active substance.

(2) The fee for sealing each record book on medicinal products that are illicit drugs in groups II, III a and III c shall be 5 points.

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

Fees for the issue, renewal, variation and termination of marketing authorisation for a parallel imported medicinal product shall be as follows:
1. for the issue, renewal, variation and termination of marketing authorisation for a parallel-imported medicinal product for human use:
   - issue: 530 points;
   - renewal: 305 points;
   - variation: 150 points;
   - termination on the applicant’s proposal: 25 points;
2. for the issue, renewal, variation and termination of marketing authorisation for a parallel imported veterinary medicinal product:
   - issue: 300 points;
   - renewal: 150 points;
   - variation: 80 points;

- termination on the applicant’s proposal: 20 points;

3. maximum fees for the issue, renewal, variation and termination of marketing authorisation for parallel imported medicinal products, for additional pharmaceutical forms, strengths or packaging within a single application shall be as follows:
   - issue: 1,100 points;
   - renewal: 610 points;
   - variation: 300 points;
   - termination on the applicant’s proposal: 50 points;
4. for the issue of a confirmation of receipt of notification of the parallel distribution of an individual medicinal product (any pharmaceutical form, strength or packaging): 25 points.

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

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

(2) The fee for the issue of approval of an individual deviation from the marketing authorisation for veterinary medicinal products shall be reduced by 50% if the authority responsible for veterinary medicine issues a written opinion on such medicinal product being indispensable for the protection of public health.

Article 33
(Fees for different labelling of medicinal products)

(1) The fee for the issue of approval for the use of foreign-language-labelled packaging or for the use of foreign-language-labelled packaging with a label in Slovenian in accordance with paragraph five of Article 87 of the Act shall be 15 points for each pharmaceutical form and strength of a medicinal product.

(2) The fee for the issue of approval for the use of foreign-language-labelled packaging or for the use of foreign-language-labelled packaging with a label in Slovenian in accordance with the regulation governing the implementation of Regulation 2019/6/EU shall be 15 points for each pharmaceutical form and strength of a medicinal product.

Article 34
(Fees for determination of the elements in the blue box and the national identifier of medicinal products for which marketing authorisation was obtained under the centralised procedure)

Fees for determination of the elements in the blue box and the national identifier of medicinal products shall be as follows:

- 120 points per one marketing authorisation, taking into account that one marketing authorisation in accordance with this Article shall include 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 for a medicinal product for human use;
- for the determination of the national identifier of medicinal products: 10 points per packaging.

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

The fee for processing a proposal to defer the cancellation of marketing authorisation for a medicinal product that has not been on the market for three consecutive years since the exercise of the authorisation shall be 20 points.

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

The fee for the approval of a campaign with necessary data on vaccines included in the vaccination and protection products programme shall be 300 points.

Article 37
(Fees for product classification)

(1) The fee for the classification of a product and the issue of a decision on classification of the product in accordance with Article 7 of the Act shall be 190 points.

(2) The fee for the classification of a product and the issue of a decision on classification of the product in accordance with the regulation governing the implementation of Regulation 2019/6/EU shall be 190 points.

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

(1) Fees for the determination of an exceptional higher allowed price of a medicinal product 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:
- for the determination of an exceptional higher allowed price of a medicinal product – at the level of a particular active substance or particular combinations of active substances (ATC5): 140 points;
- for the determination of an exceptional higher allowed price of a medicinal product – additional pharmaceutical form or strength: 25 points;
- for the determination of an exceptional higher allowed price of a medicinal product – additional packaging: 10 points;
- for the reduction of an exceptional higher allowed price of a medicinal product before the expiry of the validity of the price, on the proposal of the person liable: 5 points.

(2) Fees for the determination of an exceptional higher allowed price for other medicinal products for human use shall be as follows:
- for the determination of an exceptional higher allowed price of a medicinal product – at the level of a particular active substance or particular combinations of active substances (ATC5): 70 points;
- for the determination of an exceptional higher allowed price of a medicinal product – additional pharmaceutical form or strength: 15 points;
- for the determination of an exceptional higher allowed price of a medicinal product – additional packaging: 5 points;
- for the reduction of an exceptional higher allowed price of a medicinal product before the expiry of the validity of the price, on the proposal of the person liable: 5 points.

(3) Notwithstanding paragraphs one and two of this Article, the fee for the determination of an exceptional higher allowed price for each group of allergy tests or allergen extracts shall be 140 points.

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

(1) Fees for the determination of the maximum allowed price of a medicinal product for human use shall be as follows:

- for the determination of the maximum allowed price of a medicinal product at the level of an active substance or combinations of active substances (ATC5), strengths, pharmaceutical forms or packaging: 10 points;
- for periodic reconciliation and reduction of the maximum allowed price of a medicinal product at the level of an active substance or combinations of active substances (ATC5), strengths, pharmaceutical forms or packaging: 6 points.

(2) Notwithstanding the preceding paragraph, the fee for the initial determination of the maximum allowed price and for the periodic reconciliation or reduction of the maximum allowed price for a particular group of allergy tests or allergen extracts shall be: 50 points.

Article 40
(Fee for notification of a corporate donation of a medicinal product)

The fee for notifying a corporate donation of a medicinal product (any pharmaceutical form, strength or packaging) shall be 40 points.

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

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

1. for the issue of authorisation for human tissue and cell supply, per day of verification at the applicant’s premises by the committee: 245 points;
2. for processing a variation, when a repeated verification at the applicant’s premises is required and the variation requires a variation of the authorisation for human tissue and cell supply, per day of verification by the committee: 225 points;
3. for processing a variation when a repeated verification at the applicant’s premises is not necessary and the variation requires a variation of the authorisation for human tissue and cell supply: 75 points;
4. for the assessment of compliance with the requirements for supplying human tissues and cells when a repeated verification at the applicant’s premises is necessary and the variation does not require a variation of the authorisation for human tissue and cell supply, per day of inspection by the committee: 225 points;
5. for the assessment of compliance with the requirements for supplying human tissues and cells when a repeated verification at the applicant’s premises is not necessary and the variation does not require a variation of the authorisation for human tissue and cell supply per committee member drawing up the compliance assessment based on submitted documentation: 75 points;
6. for the revocation of authorisation for human tissue and cell supply on the proposal of the authorisation holder: 20 points.

(2) Fees for the issue of authorisation for single entry or import and exit or export of human tissue and entry or import and exit or export of human tissue and cells in urgent cases shall be as follows:

- for the issue of authorisation for single entry or import and exit or export of human tissue and cells: 165 points;
- for the issue of authorisation for the entry or import and exit or export of human tissue and cells in urgent cases: 115 points.

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

Fees for the issue, variation and revocation of blood supply authorisation shall be as follows:

- for the issue of authorisation for blood supply, per day of verification by the committee: 245 points;
- for processing a variation when a repeated verification at the applicant's premises is necessary and the variation requires a variation of the authorisation for blood supply, per day of verification by the committee: 225 points;
- for processing a variation when a repeated inspection at the applicant's premises is not necessary and the variation requires a variation of the authorisation for blood supply: 75 points;
- for the assessment of compliance with the requirements for supplying blood when a repeated verification at the applicant's premises is necessary and the variation does not require a variation to the authorisation for blood supply, per day of verification by the committee: 225 points;
- for the revocation 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, variation and revocation of authorisation for non-routinely prepared advanced therapy medicinal products shall be as follows:

- for the issue of authorisation for non-routinely prepared medicinal products for advanced therapy, per day of expert committee inspection at the applicant's premises: 480 points;
- for processing a variation when a repeated inspection at the applicant's premises is necessary and the variation requires a variation of the authorisation for non-routinely prepared medicinal products for advanced therapy, per day of expert committee inspection at the applicant's premises: 300 points;
- for processing a variation when a repeated inspection at the applicant's premises is not necessary and the variation requires a variation of the authorisation for non-routinely prepared medicinal products for advanced therapy at the applicant's premises: 120 points;
- for the assessment of compliance with the requirements for non-routinely prepared medicinal products for advanced therapy when a repeated verification at the applicant's premises is necessary and the variation does not require a variation of the authorisation for non-routinely prepared medicinal products for advanced therapy, per day of expert committee inspection at the applicant's premises: 300 points;
- for the revocation of authorisation for non-routinely prepared medicinal products for advanced therapy: 40 points.

Article 44

(Fees for the register of doctors or veterinarians)

Fees for entry in, change in the register 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:

- for the entry of a doctor or veterinarian in the register: 20 points;
- for a change in the register entry of a doctor or veterinarian: 20 points;
- for the removal of a doctor or veterinarian from the register: 20 points.

Article 45
(Fee for notification of officinal medicinal products and the approval of risk assessments for the manufacture of officinal medicinal products and for the preparation of high risk extemporaneous medicinal products)

(1) The fee for notifying a particular pharmaceutical form, strength and packaging of an officinal medicinal product shall be 50 points.

(2) The fee for the approval of a risk assessment for the manufacture of officinal medicinal products and for the preparation of high risk extemporaneous medicinal products shall be 50 points.

Article 46
(Fees for minor administrative procedures)

(1) The fee for minor administrative procedures not specifically provided for herein shall be 180 points.

(2) The processing of a variation or the assessment of compliance with the requirements for the manufacture of medicinal products, the wholesale distribution or retail sale of medicinal products, the supply of blood, tissues and cells when an inspection at the applicant's premises is not necessary, the assessment of compliance with the requirements for entry in the register of manufacturers, wholesalers and importers of active substances, and other similar procedures shall be considered minor procedures.

Article 47
(Costs of procedure)

(1) If an applicant withdraws their application before the completion of the procedure or if the JAZMP rejects the application, the JAZMP shall charge:

- 15% of the amount of the fee if the application has not yet been processed (i.e. the review of formal completion of the application or until the submitted notification on the fee payment method);
- up to 100% 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 the JAZMP.

(2) The JAZMP shall determine the costs of the administrative procedure in decisions on the termination of the administrative procedure or in the decision rejecting the application.

III. PROFESSIONAL TASKS AND SERVICES

Article 48
(Payment obligations, methods and deadline)

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

(2) In the event of non-payment, the JAZMP may charge the applicant statutory late payment interest.

Article 49
(Expert training, lectures and consultations)

(1) The JAZMP shall charge the user for the participation of its staff in expert training, lectures, workshops and consultations 30 points per hour and 20 points per hour for each hour of preparation for participation.

(2) Based on a proposal for expert training, lecture or consultation, the JAZMP shall issue a pro forma invoice.

(3) In addition to the tariff rate referred to in paragraph one of this Article, the user shall be required to settle any costs arising from expert training, lectures and consultations, which shall include expenses pursuant to the regulations governing the reimbursement of expenses for staff business travel.

(4) The costs of training, seminars and workshops organised by the 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 producing training materials and other costs incurred during the implementation of training, seminars or consultations. The JAZMP shall publish information on the amount of the participation fee on its website or in the application for training, seminar or consultation.

Article 50
(Consulting)

(1) The JAZMP shall charge for its consultation 30 points per hour.

(2) Based on a proposal for consultation relating to drafting documentation within the powers of the JAZMP referred to in the preceding paragraph, the JAZMP shall issue a pro forma invoice including an estimated value. The user shall settle 50% of the amount on the pro forma invoice before the consultation starts.

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

Article 51
(Specialisation and mentoring of external users)

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

(2) Based on a proposal for specialisation or mentoring, the JAZMP shall issue a pro forma invoice for external users. Participation in the specialisation or mentoring of external users shall not take place until the user confirms the pro forma invoice for specialisation or mentoring.

Article 52
(Travel and other expenses of the members of expert and verification committees when performing their tasks)

In addition to the fees under this Tariff, the applicant shall pay for the expenses of expert and verification committee members referred to in Articles 6 and 12 hereof, which shall be charged as prescribed in the regulation governing the reimbursement of expenses for business travel.

Article 53
(Publishing)

The JAZMP shall charge users for delivering editions of Formularum Slovenicum as follows:
- Formularum Slovenicum – printed edition: 60 points per copy;
- Formularium Slovenicum – printed supplement to an edition: 60 points per copy;
- Formularum Slovenicum – 1 to 5 passwords for an online edition: 17 points per copy;
- Formularum Slovenicum – 6 to 25 passwords for an online edition: 15 points per copy;
- Formularum Slovenicum – more than 25 passwords for an online edition: 13 points per copy;
- The brochure accompanying a presentation of Formularum Slovenicum: 12 points per copy.

Article 54
(Photocopying)

(1) Photocopying, printing and scanning shall be charged by the JAZMP to the user as follows:
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. scanning – A4, single-sided: 0.024 points per copy;
6. scanning – A4, double-sided: 0.036 points per copy.

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

Article 55
(Issue of additional copies and duplicates, and confirmation of the finality of individual administrative acts)

The issuing of additional copies and duplicates and confirmation of the finality of individual administrative acts shall be charged by the JAZMP to the user as follows:
- each additional copy of an individual administrative act (decision, resolution, notification, certificate etc.): 6 points;

- the issue of duplicates of individual administrative acts (decision, resolution, notification, certificate etc.): 15 points;
- confirmation of the finality of individual administrative acts (decision, resolution, notification, certificate etc.): 6 points.

Article 56
(Other professional tasks)

The JAZMP may charge for the implementation of other professional tasks which are not governed by this Tariff, specifically based on calculations using as relevant the tariffs for consultations and photocopying and other direct costs.

Article 57
(Issue of reminders for outstanding liabilities)

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

Annex: Fees and distribution of fees between the JAZMP and the Medical Ethics Committee

Annex to the Draft Amendments to the Tariff

The Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 209/21**) includes the following transitional and final provision:**

"IV. TRANSITIONAL AND FINAL PROVISION

Article 58
(End of validity)

(1) On the day this Tariff enters into force, the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 9/18) shall cease to apply.

(2) The Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 9/18) shall still apply to the procedures which were initiated prior to the entry into force of this Tariff or in respect of which a legal remedy was filed prior to the entry into force of this Tariff.

Article 59
(Date of application)

(1) The provisions of Article 12 of this Tariff shall apply as of the date of applicability of the regulation governing the implementation of Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1), last amended by Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 amending Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use (OJ L 238, 16.9.2017, p. 12), (hereinafter: Regulation 536/2014/EU).

(2) The provisions of Articles 14, 17 and 19 of this Tariff shall apply from 28 January 2022.

(3) Paragraph two of Article 33 and paragraph two of Article 37 of this Tariff shall apply from the date of application of the regulation governing the implementation of Regulation 2019/6/EU.

Article 60
(Entry into force)

This Tariff shall enter into force on 1 January 2022."

The Amendments to the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 165/22**) include the following transitional and final provision:**

"TRANSITIONAL AND FINAL PROVISION

Article 11
(Completion of procedures)

The Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 209/21) shall apply to the procedures which were initiated prior to the entry into force of these Amendments to the Tariff or in respect of which a legal remedy was filed prior to the entry into force of these Amendments to the Tariff.

Article 12
(Entry into force)

These amendments shall enter into force on 1 January 2023."

The Amendments to the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 135/23**) include the following transitional and final provision:**

"TRANSITIONAL AND FINAL PROVISION

Article 15
(Completion of procedures)

The Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia *[Uradni list RS]*, Nos. 209/21 and 165/22) shall apply to the procedures which were initiated prior to the entry into force of this Tariff or in respect of which a legal remedy was filed prior to the entry into force of this Tariff.

Article 16
(Entry into force)

This Tariff shall enter into force on 1 January 2024."