Pursuant to paragraph three of Article 62 of the Medical Devices Act (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 98/09), the Minister of Health hereby issues

R U L E S

relating to fees in the field of medical devices

I. GENERAL PROVISIONS

Article 1
(Subject)

The Rules shall determine the level of fees to be paid by the applicant for the relevant procedure, in accordance with the act regulating medical devices, to the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter: JAZMP).

Article 2
(Fee levels)

(1) The fees referred to in these Rules shall be specified in points. The level of fee shall be the point value multiplied by the number of points.

(2) The value of one point shall be 5 EUR excluding VAT. The point value may be evaluated annually, i.e. on the basis of actual costs relating to the implementation of tasks and services under the present Rules.

Article 3
(Payment mode)

(1) The applicant shall pay the fee after receiving the notification of due fee and payment method by the JAZMP.

(2) The JAZMP shall send a notification on the payment method to the email address of the applicant indicated in the application form. The notification on the payment method of the fee shall include at least information on the applicant, the received application, the object of the charged fee, the amount of the fee, the reference number and other information required for the payment. The notification on the payment method shall be drawn up by the person responsible for the procedure on the basis of data from the information system intended for managing procedures and keeping records. The applicant shall pay the fee within 15 days to the JAZMP sub-account.

(3) Annual fees shall be settled within 15 days of receipt of notification of the due fee and the payment method. The JAZMP shall submit notifications for the payment of annual fees to the authorisation holder no later than by 31 March of the current year.

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

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

II. FEES

Article 4
(Fees for expert advice)

Fees for expert advice shall amount to as follows:

- for expert advice relating to the translation of instructions for use and labelling of a medical device (1,500 characters per page, without spaces) – 50 points;
- for expert advice relating to the distinction between medical devices and other products – 200 points;
- for expert advice relating to placing medical devices in the appropriate class – 250 points.

Article 5
(Fees for the classification of products as medical devices)

The fee for the procedure of classifying products as medical devices shall be 190 points.

Article 6
(Fees for the appointment of a notified body)

The fee for the appointment of a notified body in the field of medical devices for the applicant on the day of the Commission inspection shall be 910 points.

Article 7
(Fees for the notification of a clinical investigation of medical devices or a change of clinical investigation)

(1) Fees for the procedure of notification of a clinical investigation of medical devices shall be as follows:

- for notification of a clinical investigation of class I and IIa medical devices – 760 points;
- for notification of a clinical investigation of class IIb and III medical devices and active implantable medical devices – 835 points.

(2) The fee for the procedure of notification of a change of clinical investigation of class I, IIa, IIb, III medical devices and active implantable medical devices shall be 380 points.

(3) The fee for the notification of a study for the evaluation of in vitro diagnostic medical device performance shall be 530 points.

(4) The fee for the notification of a change of study for the evaluation of in vitro diagnostic medical device performance shall be 230 points.

Article 8
(Fees for the procedure relating to the entry into the register of medical devices)

Fees for the procedure relating to entry into the register of medical devices:

1. for initial registration:
   - 40 points per request (1 to 10 requests per application);
   - 35 points per request (11 to 20 requests per application);
   - 30 points per request (21 to 30 requests per application);
   - 25 points per request (over 31 requests per application to a maximum of 2,000 points);
2. for a change of data not affecting the entry in the register:
   - 20 points per request (1 to 10 requests per application);
   - 16 points per request (11 to 20 requests per application);
   - 12 points per request (21 to 30 requests per application);
   - 10 points per request (over 31 requests per application to a maximum of 800 points);
3. for a change of data affecting the entry in the register:
   - 30 points per request (1 to 10 requests per application);
   - 25 points per request (11 to 20 requests per application);
   - 20 points per request (21 to 30 requests per application);
   - 15 points per request (over 31 requests per application to a maximum of 1,200 points).

Article 9
(Fees for issuing a certificate on free sale of a medical device)

Fee for issuing a certificate on free sale of medical devices shall be 30 points.

Article 10
(Annual fee)

The annual fee for monitoring the implementation of conformity assessment procedures and compliance with the conditions of notified bodies shall be 4,000 points.

III. FINAL PROVISIONS

Article 11
(End of validity)

On the day these Rules enter into force, the Rules on fees in the field of medical devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 37/10), shall cease to be in force.

Article 12
(Entry into force)

These rules shall enter into force fifteen days after their publication in the Official Gazette of the Republic of Slovenia.

No. 0070-117/2017
Ljubljana, 28 March 2019
EVA 2017-2711-0072

Aleš Šabeder, m.p.
Minister of Health