No. 2022

TARIFF

for the Icelandic Medicines Agency's surveillance of medical equipment.

Article 1

The issue of certificates.

The Icelandic Medicines Agency issues certificates requested by manufacturers of medical equipment. The Icelandic Medicines Agency collects fees for the issue of certificates as follows:

	Type of certificate	ISK
1.1	Free Sales Certificate (FSC) – five copies	33,200
1.2	Free Sales Certificate (FSC) – fee per copy if more than five copies are requested	4,300
1.3	Other certificates – fee per copy	26,000

If the issue of certificates requires a great deal of preparation, or if the volume thereof is particularly high, an hourly rate shall be charged in accordance with Article 7. This hourly rate shall be charged in addition to the fee for the issue of other certificates.

Article 2

Registration of distributors

The Icelandic Medicines Agency collects a fee for registration of distributors, cf. Article 28, para. 3, of the Medical Devices Act No. 132/2020. Distributors are all persons or legal entities in the supply chain, other than the manufacturer or importer, who offer a device on the market until the time when it is taken into use, cf. Article 4, para. 1.6 of the Medical Devices Act No. 132/2020.

The fee for registration in this registry at the Icelandic Medicines Agency and maintenance of the registration is as follows:

	Type of registration	ISK
2.1	Registration fee	31,000
2.2	Maintenance registration	7,200

Article 3

Surveillance of the use of medical devices

The Icelandic Medicines Agency collects a fee for surveillance of use pursuant to Article 16, para. 1 of the Medical Devices Act No. 132/2020. Surveillance of use refers to ascertaining that the use of medical devices is consistent with their intended use and that users have received minimal level of training in the handling and use of these devices, so that their use is effective and safe for patients, users and others.

Fees for surveillance of use shall be as follows:

	Type of surveillance	ISK
3.1	Surveillance of use – surveillance of medical device	73,000
3.2	Surveillance of use – surveillance of control system	274,300

If surveillance according to para. 1 proves to be wide in scope, the Icelandic Medicines Agency may collect a fee according to Article 7. Such fee is added to the surveillance fee according to para. 2. An invoice shall be issued when the Icelandic Medicines Agency's surveillance report has been completed.

The Icelandic Medicines Agency collects a fee for the evaluation of an application for the use of a medical device that does not meet quality and safety requirements for public health or for the safety of the patient(s).

The fee for the assessment of an application according to Paragraph 4 is as follows:

	Type of surveillance	ISK
3.3	Surveillance fee for exemptions	73,000

Article 4

Surveillance of the maintenance of medical devices

The Icelandic Medicines Agency collects a fee for maintenance and reuse of medical devices pursuant to Article 17, para. 1 of the Medical Devices Act No. 132/2020. Surveillance of maintenance means monitoring that there is regular quality and safety monitoring and maintenance of medical devices in accordance with the requirements of the manufacturer's specifications and the best professional knowledge at any time, and that maintenance and surveillance is documented.

Fees for surveillance of maintenance shall be as follows:

	Type of surveillance	ISK
4.1	Surveillance of maintenance – surveillance of medical device	73,000
4.2	Surveillance of maintenance – surveillance of control system	274,300

If surveillance according to para. 1 proves to be wide in scope, the Icelandic Medicines Agency may collect a fee according to Article 7. Such fee is added to the surveillance fee according to para. 2. An invoice shall be issued when the Icelandic Medicines Agency's surveillance report has been completed.

Article 5

Surveillance of operators of medical devices

The Icelandic Medicines Agency collects a fee for surveillance of operators of medical devices pursuant to Article 34, para. 1 of the Medical Devices Act No. 132/2020. Operators of medical devices are defined as the manufacturer, authorised representative, importer, distributor or person referred to in Article 22, para. 1 and 3 of the Regulation on Medical Devices, cf. Article 4, item 24 of the Medical Devices Act No. 132/2020.

The Icelandic Medicines Agency shall, on its own initiative or following a recommendation, take under consideration matters regarding the safety of medical devices and the obligations of parties governed by the Medical Devices Act No. 132/2020 and its regulations, cf. Article 4, item 26 of the Medical Devices Act No. 132/2020.

Fees for surveillance of operators shall be as follows:

	Type of surveillance	ISK
5.1	Surveillance – retailers	91,800
5.2	Surveillance – distributors – surveillance of control system	274,300
5.3	Surveillance fee for inspection of product	31,000
5.4	Surveillance fee for registration in Eudamed (SRN)	9,400

If surveillance according to para. 1 proves to be wide in scope, the Icelandic Medicines Agency may collect a fee according to Article 7. Such fee is added to the surveillance fee according to para. 2. An invoice shall be issued when the Icelandic Medicines Agency's surveillance report has been completed.

Article 6

Clinical trial applications

An applicant for a certificate issued by the Icelandic Medicines Agency for a clinical trial of a medical device, cf. Article 20, para. 1, of the Medical Devices Act No. 132/2020, shall pay a fee to the Icelandic Medicines Agency in accordance with Article 39 of the Medical Devices Act No. 132/2020, to cover the costs of assessing the application.

The Icelandic Medicines Agency collects a fee for surveillance of clinical trials of medical devices pursuant to Article 6, para. 2 of the Medical Devices Act No. 132/2020.

These fees are as follows:

	Type of fee	ISK

6.1	Preliminary assessment of the subject of an application for clinical trial of a medical device – devices in category I, and non-invasive devices in categories IIa and IIb	73,000
6.2	Preliminary assessment of the subject of an application for a clinical trial of a medical device – devices in categories IIa, IIb, III, (includes implantable medical devices, invasive devices intended for long-term use and in vitro diagnostic medical devices)	146,000
6.3	Assessment of an application for clinical trials of a medical device – all device categories	788,700
6.4	Amendments to clinical trials of medical devices	27,650

In the event that the fee according to para. 2 does not cover the cost of assessing an application for clinical trial of a medical device, the applicant shall pay an hourly rate to cover the additional cost, cf. Article 7.

The applicant shall be informed about this additional cost and given the opportunity to withdraw their application within 14 days, should they wish to do so rather than pay the cost.

The fees according to para. 1 are non-refundable even though the application for authorisation to conduct a clinical trial of a medical device is rejected or withdrawn. The Icelandic Medicines Agency can, in exceptional circumstances, waive or lower the fee for assessment of an application for clinical trial of a medical device if there is a valid rationale for doing so.

An authorisation holder for a clinical trial of a medical device pays a fee for the Icelandic Medicines Agency's surveillance/audit at the trial site. Before the necessary quality audit and/or certification according to para. 6 is carried out, the Icelandic Medicines Agency shall account for the work that it expects to be required for the necessary surveillance/audit. Following the surveillance/audit, the Icelandic Medicines Agency will send to the applicant an invoice for the auditing, based on the number of hours of work executed by a specialist/specialists and/or service agent/agents from the Icelandic Medicines Agency in the course of the auditing. The hourly rate(s) shall be in accordance with Article 7.

Article 7

Hourly rates of the Icelandic Medicines Agency.

The Icelandic Medicines Agency collects a fee according to this Tariff which amounts to ISK 17,500 for a specialist and ISK 13,500 for a service agent per hour for surveillance and services which the Agency is required to do in accordance with the Medical Devices Act No. 132/2020, and for which it is entitled to charge a fee.

Article 8

Travel expenses, etc.

For the carrying out of surveillance according to the provisions of the Medical Devices Act No. 132/2020, and in accordance with this Tariff, the Icelandic Medicines Agency collects travelling expenses and per diem in accordance with the rules of the Travelling Expenses Committee of the Ministry of Finance and Economic Affairs.

The fee for surveillance according to Art. 2-3 and 6 is calculated plus travel expenses and per diem allowance. Prior to auditing, the Icelandic Medicines Agency shall inform the manufacturer of the estimated surveillance fee. When necessary, the Icelandic Medicines Agency can carry out surveillance without informing the manufacturer beforehand. An invoice for the audit shall be issued when the audit report has been completed.

Article 9

Use of coercive means.

For the work of the Icelandic Medicines Agency's specialists as regards follow-up to surveillance and the use of coercive means in accordance with Chapter VII of the Medical Devices Act No. 132/2020, an hourly rate shall be charged in accordance with Article 6 of this Tariff. An invoice shall be issued when the decision to use coercive means has been taken.

Other costs for surveillance, such as in connection with samples from medical devices taken for testing, shall be paid by the manufacturer of the medical device or their representative, cf. Chapter VII of the Medical Devices Act No. 132/2020 and cf. Chapters IV and V of Act No 134/1995, on Product Safety and Official Market Control.

Article 10
Collection

The Icelandic Medicines Agency collects fees in accordance with this Tariff. The final due date for payment is 30 days from the date of issuance of the invoice. In case the fee is not paid before the final due date, interest will be collected. Fees in accordance with this Regulation are enforceable.

Article 11
Entry into force and legal references

This Tariff, which is laid down pursuant to an authorisation in Article 39 of the Act on Medical Devices No. 132/2020, in line with proposals from the Icelandic Medicines Agency, enters into force on 1 January 2023. From that time on, Tariff no. 477/2022, for the Icelandic Medicines Agency's surveillance of medical devices, shall cease to apply.

The Ministry of Health, 20 December 2022.

Willum Þór Þórsson

Heiða Björg Pálmadóttir.