DISCLAIMER: This text is an informal translation of Tariff No 1141/2019.

TARIFF

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

Article 1

Registration of parties who operate companies where the country of residence is Iceland, and manufacture medical equipment or are responsible for the marketing of such equipment.

The Icelandic Medicines Agency collects a fee for the registration of parties who operate companies where the country of residence is Iceland, and manufacture medical equipment or are responsible for the marketing of such equipment in accordance with Article 8 of the Act on Medical Devices No 16/2001. The fee for registration in this registry at the Icelandic Medicines Agency is as follows:

	Type of registration	ISK
1.1	Fee for the registration of a company that manufactures medical equipment	52,500
1.2	Fee for the registration of a company that is responsible for the marketing of a medical device	52,500

Article 2

Issue of certificates requested by manufacturers of medical equipment.

The Icelandic Medicines Agency collects a fee for the issue of certificates that are requested by manufacturers of medical equipment in accordance with of Article 8, item a, of the Act on Medical Devices No 16/2001. The fee for certificates is as follows:

	Type of certificate	ISK
2.1	Free Sales Certificate (FSC) – five copies	16,000
2.2	Free Sales Certificate (FSC) – fee per copy if a number of copies is requested that exceeds five copies	1,600
2.3	Other certificates – fee per copy	8,500

If the issue of certificates other than Free Sales 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 6. This hourly rate shall be charged in addition to the fee for the issue of other certificates.

Article 3

Clinical trials of medical equipment.

An applicant for a certificate issued by the Icelandic Medicines Agency for a clinical trial of a medical device, cf. Article 9, para.1, of the Act on Medical Devices no. 16/2001, shall pay a fee to the Icelandic Medicines Agency in accordance with Article 12 of the Act on Medical Devices, to cover the costs of assessing the application.

These fees are as follows:

	Type of fee	ISK
3.1	Preliminary assessment of the subject of an application for clinical trial of a medical device – devices in category I	31,500

3.2	Preliminary assessment of the subject of an application for 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.	63,000
3.3	Assessment of an application for clinical trial of a medical device – all device categories	696,500
3.4	Major alterations to clinical trial of medical devices	158,500
3.5	Minor alterations to clinical trial of medical devices	26,500

At present, the fee according to para.2 does not cover the cost of assessing an application for clinical trial of a medical device, and the applicant shall pay an hourly rate to cover the additional cost, cf. Article 6. 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.

Article 4

Market surveillance.

The Icelandic Medicines Agency collects a fee for market surveillance of medical devices pursuant to Paragraph 1 of Article 10 of the Act on Medical Devices. Market surveillance refers to surveillance to ensure that medical devices marketed in Iceland comply with safety requirements and requirements on labelling.

Fees for market surveillance shall be as follows:

	Type of market surveillance	ISK
4.1	Wholesale/retail - questionnaire	91,500
4.2	Wholesale/retail - market inspection	137,500

If market surveillance pursuant to Paragraph 1 proves to be unusually extensive, the Icelandic Medicines Agency may collect a fee pursuant to Article 6. Such a fee is added to the market surveillance fee pursuant to Paragraph 2.

An invoice shall be issued when Icelandic Medicines Agency’s market surveillance report has been completed.

Article 5

Surveillance of use and maintenance

The Icelandic Medicines Agency collects a fee for surveillance of the use and maintenance of medical devices pursuant to Paragraph 1 of Article 10 of the Act on Medical Devices. Surveillance of use and maintenance refers to surveillance to ensure the proper maintenance of medical devices, and surveillance of the use of medical devices where they are located and used within the health system.

Fees for surveillance of use and maintenance shall be as follows:

	Type of surveillance	ISK

4.3	Surveillance of use and maintenance – questionnaire	92,000
4.4	Surveillance of use and maintenance – audit	137,500

If market surveillance pursuant to Paragraph 1 proves to be unusually extensive, the Icelandic Medicines Agency may collect a fee pursuant to Article 6. Such a fee is added to the market surveillance fee pursuant to Paragraph 2.

An invoice shall be issued when Icelandic Medicines Agency's market surveillance report has been completed.

Article 6

Audits of manufacturers.

The Icelandic Medicines Agency collects a fee for audits of the activities of manufacturers of medical devices who operate in Iceland cf. Article 10 of the Act on Medical Devices no. 16/2001. Such audits are carried out when deemed necessary.

The fee for auditing is calculated in accordance with Article 6 and travelling expenses and per diem according to Article 7 is added. Before an audit is carried out, the Icelandic Medicines Agency shall inform the relevant manufacturer about the estimated fee for auditing. When necessary, the Icelandic Medicines Agency can carry out an audit in accordance with para.1 without informing the manufacturer beforehand. An invoice for the audit shall be issued when the audit report has been completed.

Article 7

Hourly rates of the Icelandic Medicines Agency.

The Icelandic Medicines Agency collects a fee according to this Tariff which amounts to ISK 14,500 for a specialist and ISK 11,000 for a service agent per hour for surveillance and services which the Agency is required to do in accordance with the Act on Medical Devices no. 16/2001, and for which it is entitled to charge a fee.

Article 8

Travel expenses.

For the carrying out of surveillance according to the provisions of the Act on Medical Devices no. 16/2001, 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.

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 Article 13 of Act No 16/2001 on Medical Devices, cf. Chapters IV and V of Act No 134/1995 on Product Safety and Official Market Control, 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 taking samples from medical devices taken for testing, shall be paid by the manufacturer of the medical device or their representative, 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.

This Tariff, which is laid down pursuant to an authorisation in Article 12 of the Act on Medical Devices No 16/2001, in line with proposals from the Icelandic Medicines Agency, enters into force forthwith. From that time on, Tariff no. 1295/2013, for assessment of applications for clinical trials of medical equipment, shall cease to apply.