Bill

on the amendment of the Medicinal Products Act, No. 93/1994, and the Medical Devices Act, No. 16/2001, with subsequent amendments. (Fees).

(Presented to the Althingi during its 145th legislative session, 2015–16.)

CHAPTER I

Amendments to the Medicinal Products Act, No. 93/1994, with subsequent amendments.

Article 1

The following amendments shall be made to Article 3.

a. A new indent, 8th indent is added, changing the order of other indents subsequently, reading as follows:

To carry out in Iceland and abroad quality audits and certification of undertakings' manufacturing processes at their request and in accordance with this Act and the rules applying in the European Economic Area and under the EFTA Convention.

b. A new paragraph, which will be the third paragraph, shall be added to the Article, reading as follows:

An applicant for a licence for the sale of medicinal products, for a licence for the import of fully-processed medicinal products and/or medicinal substances for wholesale distribution, for a licence for the production of medicinal products and for a licence for the importing and/or manufacture of medicated animal feeds shall pay the Icelandic Medicines Agency (Lyfjastofnun) a fee to meet the cost of processing the application. In addition, the applicant shall pay the Icelandic Medical Agency a fee that shall meet the cost of the necessary examination of the proposed activity.

c. A new sentence shall be added to the seventh paragraph, reading as follows:

The Icelandic Medicines Agency may furthermore collect special fees in connection with quality audits and the certification of undertakings' manufacturing processes, in Iceland or abroad, at their request and in accordance with this Act and the rules applying in the European Economic Area and under the EFTA Convention.

d. The words "paragraphs 3-8" in the ninth paragraph shall be replaced by "paragraphs 3-9".

Article 2

The seventh paragraph of Article 20 shall be deleted.

The second paragraph of Article 32 shall be deleted.

The second paragraph of Article 34 shall be deleted.

CHAPTER II

Amendments to the Medical Devices Act, No. 16/2001, with subsequent amendments.

Article 3

The following amendments shall be made to Article 3.

a. Indent 1 shall read as follows: *Medical device*: Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software which the manufacturer intends specifically for its use in diagnosis or treatment and is necessary for its proper application, intended by the manufacturer to be used to:

a. diagnose, prevent, monitor, treat or alleviate diseases,
b. diagnose, monitor, treat, reduce or compensate for an injury, disability or impaired capacity,
c. investigate, change or replace an organ or a physiological function,
d. control conception,

but which does not have its primary effect in or on the human body by pharmacological, immunological or metabolic means, though its efficacy may be supported by such means.

In the event of doubt as to whether a device or item constitutes a medical device, the Icelandic Medical Agency shall resolve the question.

b. The word “devices” in indent 3 shall be replaced by “medical devices”.

Article 4

A new article, Article 8 *a*, shall stand after Article 8, with a heading, reading as follows:

Issue of certificates.

The Icelandic Medicines Agency shall see to the issue of certificates requested by manufacturers of medical devices.

Article 5

The following amendments shall be made to Article 10:

a. A new sentence shall stand after the second sentence of the first paragraph, reading as follows: Surveillance here also refers to monitoring to ensure compliance by the manufacturer with the provisions of this Act and of regulations issued hereunder covering the manufacture of medical devices.

b. Two new sentences shall stand after the first sentence of the second paragraph, reading as follows: In addition, surveillance bodies may visit any location where medical devices are to be found, whether this is a place of manufacture, a place of sale (whether in retailing or in wholesaling) or a place where they are used. Private residences or other similar places may not be entered for this purpose without the permission of the owner or person in charge of the property except by order of a court.

Article 6

Article 12 shall read as follows:

The Icelandic Medicines Agency may charge a fee for:

1. the registrations of parties who operate undertakings based in Iceland and manufacture medical devices or are responsible for the marketing of medical devices (*cf.* Article 8),
2. the issue of certificates (*cf.* Article 8*a*),
3. the assessment of applications for clinical trials of medical devices (*cf.* Article 9),
4. market surveillance (*cf.* the first paragraph of Article 10),
5. audits of manufacturers and importers of medical devices (*cf.* the first paragraph of Article 10).

After receiving proposals from the Icelandic Medicines Agency, the minister shall issue a tariff of fees for services rendered, surveillance and tasks entrusted to the agency under this Act. The amount of each fee shall take account of the cost of the service and the execution of individual tasks, and shall be based on an operating budget in which reasons are given for the factors on which the fees are based. Fees may not exceed actual costs. The tariff of fees shall be published in Section B of the Government Gazette. Fees may be recovered by attachment.

Article 7

This Act takes immediate effect.