TARIFF

for marketing authorisations, annual fees and other licence fees for medicinal products and other related products, collected by the Icelandic Medicines Agency.

Chapter I

Fees for the registration of medicinal products.

Article 1

Proprietary medicinal products, parallel-imported medicinal products, herbal medicinal products and medicinal products pursuant to Article 8, para.2 of the Medicinal Products Act No 93/1994.

The applicant for a marketing authorisation for a proprietary medicinal product, parallel-imported medicinal product, herbal medicinal product and a medicinal product pursuant to Article 8, para.2 of the Medicinal Products Act No 93/1994 shall pay a fee to the Icelandic Medicines Agency in accordance with Article 3, para.3 of the Act, covering the cost of its evaluation in accordance with Article 3, para.3.1 of the Act. The fee shall also cover the cost of issuance of the marketing authorisation.

Each application is only valid for one proprietary medicinal product in one pharmaceutical form and strength. For parallel-imported products and medicinal products pursuant to Article 8, para.2 of the Medicinal Products Act, an application is only valid for one country of origin.

A new application form shall be completed when submitting an application for a renewal of the marketing authorisation and each application is only valid for one medicinal product in one pharmaceutical form and strength.

Application fees for authorisation applications for medicinal products in accordance with para.1 or their renewal are non-refundable even though an application has been withdrawn or rejected.

The Icelandic Medicines Agency is authorised to collect fees in proportion to the work undertaken in evaluating an authorisation application, in accordance with para.1, which is subsequently withdrawn.

The Icelandic Medicines Agency collects a fee for external experts' review of a translation of product information, from languages other than Danish, English, Norwegian or Swedish, pursuant to Article 8, para.2 of the Medicinal Products Act.

The fees according to this article shall be in accordance with Annex I to this Tariff.

Article 2

Changes in terms of the marketing authorisations.

The applicant requesting a variation in terms of the marketing authorisation shall pay the Icelandic

Medicines Agency a fee in accordance with Article 3, para.3 of the Medicinal Products Act No 93/1994, covering the cost of evaluating the variation, in accordance with Article 3, para.1.2 of the Act. Fees in respect of applications for variations in the marketing authorisation for medicinal products are non-refundable even though an application is withdrawn or has been rejected. The Icelandic Medicines Agency is authorised to collect a fee in proportion to the work undertaken in evaluating an application for a variation in the marketing authorisation which is withdrawn.

A fee shall be paid in accordance with Annex I to this Tariff for Type IA_{IN}, IA, IB and type II variations cf. Regulation No 418/2010 implementing European Union Regulations regarding pharmaceutical issues, cf. Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variation to terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, and for changes according to Annex I to Regulation No 1234/2008 (EC).

Each application is valid for only one variation unless it concerns a variation that results in consequential variations.

A special fee shall be paid in accordance with Annex I to this Tariff when transferring the marketing authorisation to a third party.

The applicant requesting a variation to the terms of a marketing authorisation which is the basis for Mutual Recognition in another Member State of the European Economic Area pursuant to Section IV of Regulation No 462/2000 concerning marketing authorisations for proprietary medicinal products, their labelling and package leaflets, shall bear the cost of the experts' work, including external experts, in connection with changes to the product's Assessment Report.

If an application covers more than one pharmaceutical form/strength of the same product belonging to the same marketing authorisation holder, a full fee is collected for the first marketing authorisation number and a half fee for the remaining marketing authorisation numbers.

The fee for the notification of a new representative for a medicinal product shall be the same as for a Type IB application when Iceland is a CMS.

The fee for a notification of a change in the name and/or address of a representative shall be the same as for a Type IA application when Iceland is a CMS.

If a marketing authorisation holder requires corrections/amendments of the summary of product characteristics, labelling or leaflet, following the issuance of approved texts, this can be requested with a formal letter, although an application form is not needed. Proposed corrected texts shall be submitted to the Icelandic Medicines Agency in line with relevant guidelines. The Icelandic Medicines Agency is authorised to collect a fee for such requests.

A special fee shall be paid in accordance with Annex I to this Tariff when transferring the role of RMS to Iceland.

A special fee shall be paid in accordance with Annex I to this Tariff when it is requested that Iceland

shall have the role of Lead RMS in the IA Supergroup. One fee shall be paid for each change in type, irrespective of the number of medicinal products/strengths.

The fees according to this article shall be in accordance with Annex I to this Tariff.

If needed and requested that an application variation in the terms of the marketing authorisation for a product which has been granted a pure national marketing authorisation is to be given a priority, the applicant shall pay an additional fee, which shall be the same as the original fee for the application.

Article 3

Medicinal products which have not been granted an authorisation.

The Icelandic Medicines Agency shall collect a fee in accordance with Article 3, para. 9 of the Medicinal Products Act No 93/1994, to meet the cost of handling applications for authorisation to import and sell by prescription, products that do not have a marketing authorisation in Iceland, cf. item 3 of para.3 of the Act. The Icelandic Medicines Agency collects 2% of the medicinal product's total annual wholesale purchase price if it exceeds ISK 16,000, and the fee is collected annually for the previous year. These fees will, however, never exceed the amount of ISK 200,000.

Article 4

Special marketing authorisations.

In instances when the Icelandic Medicines Agency specifically requests that applications are made for a marketing authorisation for a medicinal product in Iceland, in order to ensure to every extent possible the availability of the medicinal product, the Agency can collect a minimum fee for the application, which shall not be higher than the fee for an application for a change in labelling/leaflet of medicinal products for human use, and which is not part of another application, when Iceland is a CMS.

Article 5

Annual fees

For each pharmaceutical form and strength of a proprietary medicinal product, along with an imported medicinal product, natural medicinal product and medicinal product according to Article 8, para. 2 of the Medicinal Products Act No 93/1994, for which there is marketing authorisation or authorisation to put the medicinal product on the market on 1 January each year, the authorisation holder shall pay an annual fee in accordance with Article 3, para. 5 of the Medicinal Products Act according to Annex I to this Tariff, in accordance with an invoice from the Icelandic Medicines Agency. No annual fee is collected for products which have been granted a marketing authorisation based on a centralised marketing authorisation.

The annual fees are *inter alia* intended to cover the maintenance of the drug catalogues, the registration of adverse reactions and the information service in respect of medicinal products which have a marketing authorisation in Iceland, as well as expenses resulting from necessary co-operation with foreign agencies in respect of medicinal products that have already been granted marketing authorisations in Iceland.

If the marketing authorisation holder does not reside in Iceland, their national representative is responsible for paying the annual fee.

Article 6

Officinal formulae

The Icelandic Medicines Agency shall be paid a fee in accordance with Article 3, para.8 of the Medicinal Products Act No 93/1994 when evaluating officinal formulae in accordance with Article 5 of the Act.

Application fee for the evaluation according to para.1 is non-refundable even though an application has been rejected.

The Icelandic Medicines Agency is authorised to collect fees in proportion to the work undertaken in evaluating an authorisation application, in accordance with para.1, which is subsequently withdrawn.

The fee according to this article shall be in accordance with Annex 1 of this Tariff.

Article 7

Homeopathic medicinal products.

The applicant requesting permission to import, sell and distribute homeopathic medicinal products which have a valid marketing authorisation in another member state of the European Economic Area and which are exempt from the requirement for a special marketing authorisation in Iceland, shall pay the Icelandic Medicines Agency a fee in accordance with Article 3, para.3 of the Medicinal Products Act No 93/1994, and bear the cost of their evaluation, pursuant to Article 3, para.1.1 of the Act. This fee shall be in accordance with Annex I to this Tariff.

Each application is valid for a stock solution and its dilutions.

The fee for an application pursuant to para.1 is non-refundable even though the application is rejected.

Chapter II.

Fees for clinical trials.

Article 8

Clinical trials of medicinal products and bioavailability studies

The applicant requesting permission to conduct a clinical trial of a medicinal product and a bioavailability study, which the IMCA grants, cf. Article 3, para.1.4 of the Medicinal Products Act No 93/1994, shall pay a fee in accordance with Article 3, para.8 and Article 9 of the said Act, and covering the cost of the evaluation of the application, granting the authorisation and surveillance. The fees shall be in accordance with Annex I to this Tariff. Additionally, the applicant shall bear all the costs of the work undertaken by external experts hired by the Icelandic Medicines Agency, in those instances where there is need for such expert evaluation.

These fees are non-refundable even though the application for authorisation to conduct a clinical trial of a medicinal product or a bioavailability study is rejected.

The Icelandic Medicines Agency can in exceptional circumstances waive the fee for clinical trials if there is a valid rationale for doing so.

Chapter III.

Fees for surveillance.

Article 9

A fee for the processing of an application for authorisation for activities that require licensing.

The Icelandic Medicines Agency collects a fee in accordance with Article 3, para.3 of the Medicinal Products Act No 93/1994, for the granting of authorisation in connection with activities that require licensing in accordance with the provisions of the Medicinal Products Act. The fees according to this article shall be in accordance with Annex I to this Tariff.

Article 10

Fee for necessary audits of intended activities that require licensing.

An applicant for authorisation for the manufacture of medicinal products, authorisation for importation and wholesale distribution of medicinal products, authorisation for importation and/or manufacture of medicated feedingstuffs or a license to sell medicinal products, shall pay a fee in accordance with Article 3, para.3 of the Medicinal Products Act No 93/1994, for the necessary auditing of the proposed activities.

Before the necessary auditing of the proposed activities takes place in accordance with para.1, the applicant shall be made aware of the extent of the work which the Icelandic Medicines Agency estimates will be devoted to the necessary auditing. Following the 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 and/or hourly rates in accordance with para.2 shall be in accordance with Annex I to this Tariff.

Article 11

Fee for quality audits and certification of the manufacturing procedures of pharmaceutical companies, in Iceland or abroad.

The Icelandic Medicines Agency collects fees in accordance with Article 3, para.8 of the Medicinal Products Act No 93/1994, for quality audits and certification of the manufacturing procedures of pharmaceutical companies, in Iceland or abroad, at their request and/or in accordance with this Act and the rules applying in the European Economic Area and in accordance with the Convention Establishing the European Free Trade Association.

Before a quality audit and/or certification of a pharmaceutical company is carried out, in Iceland or abroad, in accordance with para.1, the pharmaceutical company shall be made aware of the extent of the work which the Icelandic Medicines Agency estimates will be devoted to the necessary quality audit and/or certification. If the applicant approves the estimate of the Icelandic Medicines Agency, the quality audit and/or certification is carried out. Once this work has been carried out, the Icelandic Medicines Agency will send to the applicant an invoice for the work, 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 quality audit and/or certification as well as out-of-pocket costs incurred for the Medicines Agency, such as travel expenses.

The hourly rate and/or hourly rates in accordance with para.2 shall be in accordance with Annex I to

this Tariff.

For the carrying out of quality audits and certification of the manufacturing procedures of pharmaceutical companies, the Icelandic Medicines Agency also collects, if applicable, travel expenses and per diem allowance in accordance with the rules of the Travelling Expenses Committee of the Ministry of Finance and Economic Affairs.

Article 12

Fees for the granting of licenses and exceptions in accordance with the Narcotics Act.

The Icelandic Medicines Agency collects a fee for the granting of licenses and exceptions in accordance with the Narcotics Act, cf. sentence 2 of item 10 of Article 3, para.1, of the Medicinal Products Act no. 93/1994. The fees according to this article shall be in accordance with Annex I to this Tariff.

An applicant for a license in accordance with para.1 can request an accelerated procedure and accordingly pay a fee in accordance with Annex I of this Tariff.

Chapter IV.

Fees for services.

Article 13

Certificates etc.

The Icelandic Medicines Agency shall receive a fee, cf. Article 3, para.7 of the Medicinal Products Act no. 93/1994, for the issuing of certificates for marketing authorisations for medicinal products for which pharmaceutical companies intend to apply for marketing authorisation in other countries (Certificate of a Pharmaceutical Product), as well as the issuing of Certificates of GMP Compliance of a Manufacturer and the issuing of Statements of Licensing Status of Pharmaceutical Products.

The fees according to this Article shall be based on the cost of specialist work that is provided in the issuing of certificates and shall be in accordance with Annex I to this Tariff. Anyone who desires the issue of a certificate in accordance with para.1 can request an accelerated procedure and accordingly pay a fee in accordance with Annex I of this Tariff.

Article 14

Scientific advice.

The Icelandic Medicines Agency collects a fee, cf. Article 3, para.8, of the Medicinal Products Act no. 93/1994, for scientific advice requested by a pharmaceutical company or investigators. This fee is collected as an hourly rate and shall be in accordance with Annex I to this Tariff.

Article 15

Classification of product and/or material/materials.

An applicant requesting an assessment of whether a product comes under the definition of a medicinal product in accordance with Article 5, para.2 of the Medicinal Products Act No 93/1994, in connection with proposed distribution and resale shall, in accordance with Article 3, para.6 of the Medicinal Products Act shall pay to the Icelandic Medicines Agency a fee that shall cover the cost of the assessment. This fee shall be in accordance with Annex I to this Regulation and shall be irrevocable.

If the classification of a product or material requires much preparation, such as data collection, on the part of the Icelandic Medicines Agency, or if the work that goes into the classification of a product or material proves to be particularly extensive, an hourly rate for specialist work shall be charged in accordance with Annex I to this Tariff for the time involved. This cost shall be added to the fee according to para.1.

Once it becomes apparent that additional work in accordance with para.2 is necessary to complete the classification of a product and/or material/materials, the applicant shall be informed of such additional cost and given the opportunity to withdraw their application. The Icelandic Medicines Agency may in such cases collect the cost involved with the work provided, to a maximum amount equal to the fee according to para.1.

Chapter V.

Reduction of fees.

Article 16

Special reduction of annual fees.

The Icelandic Medicines Agency is authorised to lower the annual fee in exceptional circumstances. The Agency shall decide and publish on its website guidelines for its criteria and arrangements concerning this issue. Applications for such exemptions shall be submitted to the Agency at the beginning of each year, and no later than 20 January. The application shall be supported by information concerning the total wholesale price of the product for the two preceding years.

Article 17

Special reduction of fees

The Icelandic Medicines Agency can reduce all fees, including fees collected in accordance with this Tariff, based on special circumstances. The Agency shall decide and publish on its website guidelines for its criteria and arrangements concerning this issue.

Chapter VI.

Collection of fees and entry into effect.

Article 18

Collection of fees

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 19

Entry into force.

This Tariff, which is laid down pursuant to an authorisation in Article 3 of the Medicinal Products Act No 93/1994, as subsequently amended, in line with proposals from the Icelandic Medicines Agency, enters into force forthwith. Concurrently, Tariff No 404/2018 for marketing authorisations, annual fees and other licence fees relating to medicinal products and related products which the Icelandic Medicines Agency collects, is repealed.

The Ministry of Welfare, xx. xxxx 2018.

Annex I

		The Ministry of Welfare, 10 December 2018. **Svandís Svavarsdóttir.**	
1		**Human**	**Veterinary**
1.1	Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	5,800,000	4,640,000
1.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	4,640,000	4,070,000
1.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	3,480,000	3,363,000
1.3.1	Additional pharmaceutical form and strengths applied at the same time	407,000	407,000
1.4	Additional application (duplicate)	1,463,000	1,463,000
1.4.1	Additional pharmaceutical form and strengths applied at the same time	407,000	407,000
1.5	Annex I[1)] New pharmaceutical forms/strengths (line extensions)	1,216,000	1,216,000
1.5.1	Additional pharmaceutical forms and strengths applied at the same time	407,000	407,000
1.6	Other annex I applications [1)]	1,216,000	1,216,000
1.6.1	Additional pharmaceutical forms and strengths applied at the same time	345,000	345,000
1.7	Annex I for products previously approved for food producing animals [1)]		577,000
1.7.1	Additional pharmaceutical forms and strengths applied at the same time		162,000
1.8	Annual fee for each marketing authorisation number	35,000	23,000
1.9	Variation Type IA_{IN} and IA	58,000	56,500
1.10	Variation Type IB	93,000	89,000
1.11	Variation Type II; change in therapeutic indication	731,000	731,000
1.12	Variation Type II; change in posology	410,000	410,000

1.13	Other variation Type II	350,000	350,000
1.14	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	93,000	
1.15	Renewals	732,000	732,000
1.15.1	Additional pharmaceutical forms and strengths	196.00	196,000
1.16	PSUR assessment - one fee per PSUR	443.00	443,000
		RMS to MRP	
2		**Human**	**Veterinary**
2.1	Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b [3)]	5,800,000	4,635,000
2.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) [3)]	4,635,000	4,070,000
2.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c [3)]	3,480,000	3,363,000
2.3.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	407,000	407,000
2.4	Additional application (duplicate) [3)]	1,463,000	1,463,000
2.4.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	407,000	407,000
2.5	Repeat procedure	1,330,000	
2.5.1	Additional pharmaceutical forms and strengths applied at the same time	407,000	
2.6	Annex I[1)] New pharmaceutical forms/strengths (line extensions) [3)]	1,463,000	1,463,000
2.6.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	407,000	407,000
2.7	Other annex I applications [1)]	1,216,000	1,216,000
2.7.1	Additional pharmaceutical forms and strengths applied at the same time	345,000	345,000
2.8	Annex I for products previously approved for food producing animals [1)]		577,000
2.8.1	Additional pharmaceutical forms and strengths applied at the		162,000

	same time		
2.9	Annual fee for each marketing authorisation number	35,000	23,000
2.10	Variation Type IA_{IN} and IA	58,000	56,500
2.11	Variation Type IB	93,000	89,000
2.12	Variation Type II; change in therapeutic indication	731,000	731,000
2.13	Variation Type II; change in posology	410,000	410,000
2.14	Other variation Type II	350,000	350,000
2.15	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	93,000	
2.16	Renewals	732,000	732,000
2.16.1	Additional pharmaceutical forms and strengths	196.00	196,000
2.17	PSUR assessment - one fee per PSUR	443,000	443,000
		CMS to DCP/MRP	
3		**Human**	**Veterinary**
3.1	Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	371,000	105,000
3.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	316,000	63,000
3.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	316,000	63,000
3.3.1	Additional pharmaceutical forms and strengths applied at the same time	52,500	26,000
3.4	Additional application (duplicate)	137,000	31,500
3.4.1	Additional pharmaceutical forms and strengths applied at the same time	32,000	16,000
3.5	Annex I[1)] New pharmaceutical forms /strengths (line extensions)	105,000	42,000
3.5.1	Additional pharmaceutical forms and strengths applied at the same time	21,000	11,000
3.6	Other annex I applications [1)]	63,000	26,000

3.6.1	Additional pharmaceutical forms and strengths applied at the same time	21,000	11,000
3.7	Annex I for products previously approved for food producing animals [1)]		26,000
3.7.1	Additional pharmaceutical forms and strengths applied at the same time		11,000
3.8	Annual fee for each marketing authorisation number	35,000	22,000
3.9	Variation Type IA_{IN} and IA	16,500	11,000
3.10	Variation Type IB	32,500	17,000
3.11	Variation Type II; change in therapeutic indication	63,000	21,000
3.12	Variation Type II; change in posology	63,000	21,000
3.13	Other variation Type II	53,000	16,000
3.14	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	42,500	
3.15	Renewals	137,000	52,500
3.15.1	Additional pharmaceutical forms and strengths	32,000	21,000
3.16	PSUR - one fee per PSUR	17,000	12,000
		National	
4		**Human**	**Veterinary**
4.1	Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	4,200,000	3,160,000
4.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	3,160,000	2,620,000
4.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	2,120,000	1,900,000
4.3.1	Additional pharmaceutical forms and strengths applied at the same time	210,000	210,000
4.4	Additional application (duplicate)	950,000	950,000
4.4.1	Additional pharmaceutical forms and strengths applied at the same time	210,000	210,000

4.5	Annex I[1)] New pharmaceutical forms /strengths (line extensions)	950,000	950,000
4.5.1	Additional pharmaceutical forms and strengths applied at the same time	210,000	210,000
4.6	Other annex I applications [1)]	630,000	630,000
4.6.1	Additional pharmaceutical forms and strengths applied at the same time	52,500	52,500
4.7	Annex I for products previously approved for food producing animals [1)]		420,000
4.7.1	Additional pharmaceutical forms and strengths applied at the same time		42,000
4.8	Annual fee for each marketing authorisation number	35,000	21,000
4.9	Variation Type IA_{IN} and IA [4)]	32,500	16,000
4.10	Variation Type IB [4)]	42,500	21,000
4.11	Variation Type II; change in therapeutic indication [4)]	420,000	155,000
4.12	Variation Type II; change in posology [4)]	245,000	90,000
4.13	Other variation Type II [4)]	158,000	78,000
4.14	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	42,500	
4.15	Renewals [4)]	315,000	315,000
4.15.1	Additional pharmaceutical forms and strengths [4)]	78,500	78,500
4.16	PSUR assessment - one fee per PSUR [4) 6) (except PSUSA)]	410,000	285,000
5	**Other changes**		
5.1	Variation Type II, Change in legal status (prescription/non-prescription) [5)]	230,000	230,000
5.2	Transfer to CTD format, without any substantial changes [5)]	11,800	
5.3	Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number [5)]	29,500	29,500

5.4	Request for a temporary exemption from approved Labelling/PIL requirements, with or without repackaging/over stickering - not a part of an ongoing application [5)]	13,800	11,800
5.5	Withdrawal of a marketing authorisation - one fee per product [5)]	13,800	11,800
5.6	Deletion from the Icelandic Drug Catalogue and the Price List - one fee per request and product name [5)]	14,000	12,000
5.7	RMS transfer to IMA	185,000	
5.8	Corrections/improvements of texts	14,000	14,000
5.9	The Icelandic Medicines Agency as Lead RMS in an IA Supergroup - change, type IA (medicinal product that does not have marketing authorisation in Iceland)	17,500	
6	**Authorisation to place a product on the market cf. Directive 2001/83/EC Article 126(a)**		
6.1	Application to place a product on the market cf. article 3(a) in Regulation No 462/2000, cf. article 126(a) in Directive 2001/83	347,000	
6.1.1	Additional pharmaceutical forms and strengths	57,500	
6.2	Variation, Type IA_{IN} and IA	17,500	
6.3	Variation, Type IB	35,000	
6.4	Variation, Type II; change in therapeutic indication	69,000	
6.5	Variation, Type II; change in posology	69,000	
6.6	Other variation, Type II	57,500	
6.7	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	46,000	
6.8	Renewal	150,000	
6.8.1	Additional pharmaceutical forms and strengths [5)]	35,000	
6.9	Annual fee for each authorisation number	35,000	

7	**Parallel import**		
7.1	Parallel import (one country of origin)	182,000	160,000
7.1.1	Additional pharmaceutical forms and strengths applied at the same time	32,000	28,500
7.2	Changes to the criteria for authorisation	38,000	35,000
7.3	Renewals	182,000	160,000
7.3.1	Additional pharmaceutical forms and strengths	32,500	28,500
7.4	Annual fee for each marketing authorisation number	35,000	20,500
8	**Traditional herbal medicines**		
8.1	With monograph	1,560,000	
8.2	Without monograph	1,970,000	
8.3	Additional application (duplicate) applied at the same time	560,000	
8.4	Application for MRP, with or without monograph – all forms, strengths and routes of administration applied at the same time – (CMS)	220,000	
8.5	Renewal – all pharmaceutical forms, strengths and routes of administration – national and RMS	460,000	
8.6	Renewal – one fee for all pharmaceutical forms and strengths– CMS	57,500	
8.7	Annual fee	35,000	
8.8	Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number	32,000	
9	**Homeopathic preparations**		
9.1	Application for registration for Homeopathic preparations when Iceland is RMS and National	288,000	288,000
9.2	Application for registration for Homeopathic preparations when	23,000	17,500

	Iceland is CMS		
9.3	Application for a homeopathic product which has been granted a marketing authorisation within the European Economic Area	14,400	13,300
9.4	Annual fee (all variations IA/IB and II) for RMS/national registration and CMS	11,800	11,800
9.5	Annual fee (DCP and MRP)	2,300	2,300
10	**Classification to decide if a product is covered by the Pharmaceutical Act**		
10.1	Classification to decide if a product is covered by the Pharmaceutical Act.	87,500	87,500
11	**Clinical trial applications**		
11.1	Application for authorisation for clinical trial	245,000	245,000
11.2	Substantial amendments	111,000	111,000
11.3	Bioavailability study	80,000	80,000
12	**Officinal formula**		
12.1	Application for an assessment of an officinal formula	115,000	115,000
13	**Certificates**		
13.1	Certificate of a Pharmaceutical Product	20,500	20,500
13.2	GMP certificate	13,900	13,900
13.3	Statement of Licensing Status of Pharmaceutical Products	12,800	12,800
13.4	Expedite issue	7,100	7,100
14	**Issuing of certicficates for operations that require licencing in accordance with the Medicinal Products Act No 93/1994.**		

14.1	One license	11,800	11,800
15	**Licenses and exemptions according to Act No 65/1974 on narcotic and psychotropic substances**		
15.1	One license	11,800	11,800
15.2	Expedite issue	4,100	4,100
16	**Scientific advice - hourly based fee**		
16.1	Scientific advice. Fee per hour	17,500	17,500
17	**Inspection Unit – hourly fee**		
17.1	Specialist.	15,400	15,400
17.2	Service agent.	12,300	12,300

[1)] Annex I to Variation Regulation (EC) No 1234/2008

[2)] Article 61(3) of Directive 2001/83/EC

[3)] When Iceland is acting as RMS for products previously approved nationally, a fee corresponding to the difference between RMS fee and the fee originally paid for the national marketing authorisation will be invoiced. In all other cases a full MRP application fee shall be paid.

[4)] For nationally authorised medicinal products, for which the application dossier is fully compatible with a corresponding application dossier which has been accepted in another European Economic Area (EEA) state sharing the packaging with Iceland, the same fee is charged as when Iceland is a concerned member state in the MRP/DCP process.

[5)] This fee is valid for DCP and MRP products where Iceland is a RMS or a CMS, as well as for purely national products.

[6)] The fee also applies if the process is a split process.

[6)] For a PSUR which is handled via the PSUR harmonisation project, the fee will be the same as when Iceland is a CMS in DCP/MRP