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, traditional herbal medicinal products and medicinal products pursuant to Article 17 of the Medicinal Products Act No 100/2020.

The applicant for a marketing authorisation for a proprietary medicinal product, parallel-imported medicinal product, traditional herbal medicinal product, homeopathic medicinal product and a medicinal product pursuant to Article 17 of the Medicinal Products Act No 100/2020 shall pay a fee to the Icelandic Medicines Agency in accordance with Article 89, para.1.1 of the Act, covering the cost of its evaluation in accordance with Article 6, para.1.1 of the Act. The fee shall also cover the cost of issuance of the marketing authorisation.

Each application is only valid for one medicinal product in one pharmaceutical form and strength. For parallel-imported medicinal products and medicinal products pursuant to Article 17 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medicinal products in accordance with para.1 or their renewal are non-refundable even though an application has been withdrawn or rejected.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to the work undertaken in evaluating an authorisation application, in accordance with para.1, which is subsequently withdrawn. This fee is never lower than ISK 15,000, however.

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 17, para.1 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 89, para.1.2 of the Medicinal Products Act No 100/2020, covering the cost of evaluating the variation, in accordance with Article 6, 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. This fee is never lower than ISK 15,000, however.

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 (VIII), cf. also Regulation No. 1150/2013 implementing European Union Regulations regarding pharmaceutical issues (XII), 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, cf. also Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008, 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 545/2018 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.

The fee for worksharing of variations where Iceland acts as RMS shall be the same as for a variation application where Iceland is a CMS, regardless of the registration processes of the medicinal products concerned. If Iceland is an RMS, the same fee is collected as when Iceland is a Reference National Competent Authority (Ref-NCA).

The fee for the notification of a change in 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 fee is paid for each marketing authorisation number.

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 89, para.1.7 of the Medicinal Products Act No 100/2020, 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. Article 6, para. 1.3 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 220,000.

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 17 of the Medicinal Products Act No 100/2020, 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 89, para.1.3 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

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 89, para.1.1 of the Medicinal Products Act No 100/2020, and bear the cost of their evaluation, pursuant to Article 6, 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 7

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 Icelandic Medicines Agency grants, cf. Article 22 of the Medicinal Products Act No 100/2020, shall pay a fee in accordance with Article 89, para.1.8 of the said Act, 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 part of the fee and/or provide a discount in connection with an application for authorisation to conduct a clinical trial of a medicinal product. Special applications must be made for such a waiver and/or discount.

Chapter III.

Fees for surveillance.

Article 8

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 6, para.1.3 of the Medicinal Products Act No 100/2020, 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 9

Fees for granting an authorisation to sell veterinary medicinal products.

The Icelandic Medicines Agency collects a fee for granting an authorisation to sell veterinary medicinal products in accordance with Article 6, para.1.8 of the Medicinal Products Act No. 100/2020. 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 licence to sell medicinal products, shall pay a fee in accordance with Article 6, para.1.3 of the Medicinal Products Act No 100/2020, 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 89, para.1.6 of the Medicinal Products Act No 100/2020, 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 licences and exceptions in accordance with the Narcotics Act.

The Icelandic Medicines Agency collects a fee for the granting of licences and exceptions in accordance with the Narcotics Act, cf. Article 89, para.1.9 of the Medicinal Products Act No 100/2020. The fees according to this article shall be in accordance with Annex I to this Tariff.

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

Article 12a

Fee for quality audits and/or certifications of the activities of a blood centre (blood bank) or tissue establishment.

The Icelandic Medicines Agency collects fees in accordance with Article 89, para.1.14 of the Medicinal Products Act No 100/2020 for surveying the collection, handling, storing and distribution of blood, and quality and safety in the handling of human cells and tissue.

Before the necessary quality audit and/or certification of the activity of a blood centre (blood bank) or tissue establishment according to para.1 is carried out, the Icelandic Medicines Agency shall account for the work that it expects to be required for the necessary quality audit and/or certification. 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.

For the carrying out of quality audits and certification of the activities of a blood centre (blood bank) or tissue establishment, 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.

Chapter IV

Fees for services.

Article 13

Certificates etc.

The Icelandic Medicines Agency shall receive a fee, cf. Article 89, para.1.10 of the Medicinal Products Act no. 100/2020, 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

Expert advice.

The Icelandic Medicines Agency collects fees, cf. Article 89, para.1.6 of the Medicinal Products Act no. 100/2020 for scientific advice and other expert advice. These fees are 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 2, para.3 of the Medicinal Products Act No 100/2020, in connection with proposed distribution and resale shall, in accordance with Article 89, para.1.4 of the Medicinal Products Act, pay to the Icelandic Medicines Agency a fee that covers 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 effect.

This Tariff, which is laid down pursuant to an authorisation in Article 89, para.2 of the Medicinal Products Act No 100/2020, in line with proposals from the Icelandic Medicines Agency, shall enter into force forthwith. Concurrently, Tariff No 1142/2019 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 2020.

Annex 1

		RMS in DCP/MRP	
		Human	**Veterinary**
1.1	Reference medicinal product/medicinal product with well-established use/combinations, Art. 8(3)/10a/10b/12,3/13a/13b [3)]	6,064,000	4,845,000
1.1.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	432,500	428,000
1.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) [3)]	4,876,000	4,274,000
1.2.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	432,500	428,000
1.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c [3)]	3,746,500	3,532,500
1.3.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	432,500	428,000
1.4	Additional application (duplicate) [3)]	1,581,000	1,550,500
1.4.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	437,000	428,500
1.5	Repeat Use [3)]	1,391,000	
1.5.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	426,000	
1.6	Annex I[1)] -New pharmaceutical forms/strengths (line extensions) [3)]	1,530,000	1,530,000
1.6.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	426,000	426,000
1.7	Other annex I applications [1)]	1271500	1271500
1.7.1	Additional pharmaceutical form and strengths applied at the same time	361,000	361,000
1.8	Annex I for products previously approved for food producing animals [1)]		597,000
1.8.1	Additional pharmaceutical form and strengths applied at the same time		167,500
1.9	Variation Type IA_{IN} and IA	54,000	54,000
1.10	Variation Type IB	85,000	85,000
1.11	Variation Type II; change in therapeutic indication	666,000	666,000
1.12	Variation Type II; change in posology	374,000	374,000
1.13	Other variation Type II	322,000	322,000
1.14	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	98,000	
1.15	Renewals	776,500	765,500
1.15.1	Additional pharmaceutical forms and strengths	207,000	205,000
1.16	PSUR assessment - one fee per PSUR	454,000	454,000
		CMS to DCP/MRP	
2		**Human**	**Veterinary**
2.1	Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	391,500	111,000
2.1.1	Additional pharmaceutical form and strengths applied at the same time	56,000	28,000

2.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	338,000	67,000
2.1.1	Additional pharmaceutical form and strengths applied at the same time	56,000	28,000
2.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	339,500	67,000
2.3.1	Additional pharmaceutical form and strengths applied at the same time	56,000	28,000
2.4	Additional application (duplicate)	143,500	33,500
2.4.1	Additional pharmaceutical form and strengths applied at the same time	33,500	17,000
2.5	Annex I[1)] New pharmaceutical forms/strengths (line extensions)	110,500	44,000
2.5.1	Additional pharmaceutical form and strengths applied at the same time	22,500	11,500
2.6	Other annex I applications [1)]	66,000	27,000
2.6.1	Additional pharmaceutical form and strengths applied at the same time	22,000	11,500
2.7	Annex I for products previously approved for food producing animals [1)]		27,000
2.7.1	Additional pharmaceutical form and strengths applied at the same time		11,500
2.8	Variation Type IA_{IN} and IA	16.000	10,500
2.9	Variation Type IB	31,000	15,500
2.10	Variation Type II; change in therapeutic indication	58,000	19,000
2.11	Variation Type II; change in posology	58,000	19,000
2.12	Other variation Type II	49,000	15,000
2.13	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	45,500	
2.14	Renewals	145,500	55,500
2.14.1	Additional pharmaceutical forms and strengths	34,000	22,500
2.15	PSUR assessment - one fee per PSUR	18,000	13,000
		National	
3		**Human**	**Veterinary**
3.1	Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	4,348,500	3,287,000
3.1.1	Additional pharmaceutical form and strengths applied at the same time	217,500	217,500
3.2	Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	3271500	2712000
3.2.1	Additional pharmaceutical form and strengths applied at the same time	217,500	217,500
3.3	Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	2195500	1967500
3.3.1	Additional pharmaceutical form and strengths applied at the same time	217,500	217,500
3.4	Additional application (duplicate)	983,500	983,500
3.4.1	Additional pharmaceutical form and strengths applied at the same time	217,500	217,500
3.5	Annex I[1)] New pharmaceutical forms/strengths (line extensions)	983,500	983,500
3.5.1	Additional pharmaceutical form and strengths applied at the	217,500	217,500

	same time		
3.6	Other annex I applications [1)]	652,500	652,500
3.6.1	Additional pharmaceutical form and strengths applied at the same time	54,500	54,000
3.7	Annex I for products previously approved for food producing animals [1)]		433,500
3.7.1	Additional pharmaceutical form and strengths applied at the same time		43,500
3.8	Variation Type IA_{IN} and IA [4)]	30,000	14,500
3.9	Variation Type IB [4)]	39,000	19,000
3.10	Variation Type II; change in therapeutic indication [4)]	373,000	138,500
3.11	Variation Type II; change in posology [4)]	218,000	93,000
3.12	Other variation Type II [4)]	141,000	70,000
3.13	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	44,500	
3.14	Renewals [4)]	326,000	326,000
3.14.1	Additional pharmaceutical forms and strengths [4)]	81,500	81,000
3.15	PSUR assessment - one fee per PSUR [4) 7)]	424,500	298,000
4	**Other changes**		
4.1	Variation Type II, Change in legal status (prescription/non-prescription) [5)]	242,000	242,000
4.2	Transfer to CTD format, without any substantial changes [5)]	12,500	
4.3	Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number [5)]	31,500	31,500
4.4	Request for a temporary exemption from approved Labelling/PIL requirements, with or without repackaging/over stickering - not a part of an ongoing application [5)]	14,500	12,500
4.5	Withdrawal of a marketing authorisation - one fee per product [5)]	14,500	12,500
4.6	Deletion from the Icelandic Drug Catalogue and the Price List - one fee per request and product name [5)]	15,000	13,000
4.7	RMS transfer to IMA[6)] One fee for each marketing authorisation number.	196,000	
4.8	Corrections/improvements of texts. One fee per request.	15,000	15,000
4.9	The Icelandic Medicines Agency as Lead RMS in an IA Supergroup - change, type IA (medicinal product that does not have marketing authorisation in Iceland)	18,500	
5	**Authorisation to place a product on the market cf. Directive 2001/83/EC Article 126(a)**		
5.1	Application to place a product on the market cf. article 6 in Regulation No 545/2018, cf. article 126(a) in Directive 2001/83	356,000	
5.1.1	Additional pharmaceutical forms and strengths	59,500	
5.2	Variation Type IA_{IN} and IA	18,500	
5.3	Variation Type IB	36,500	

5.4	Variation Type II; change in therapeutic indication	71,000	
5.5	Variation Type II; change in posology	71,000	
5.6	Other variation Type II	59,500	
5.7	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	47,500	
5.8	Renewal	154,500	
5.8.1	Additional pharmaceutical forms and strengths	36,500	
6	**Parallel import**		
6.1	Parallel import (one country of origin)	189,000	166,000
6.1.1	Additional pharmaceutical forms and strengths applied at the same time	33,500	30,000
6.2	Changes to the criteria for authorisation	39,500	36,500
6.3	Renewal	186,500	164,000
6.3.1	Additional pharmaceutical forms and strengths	34,000	30,000
7	**Traditional herbal medicines**		
7.1	With monograph	1,600,000	
7.2	Without monograph	2,020,000	
7.3	Additional application (duplicate) applied at the same time.	574,000	
7.4	Application for MRP, with or without monograph – all forms, strengths and routes of administration applied at the same time – (CMS)	225,500	
7.5	Renewal – all pharmaceutical forms, strengths and routes of administration – national and RMS	471,500	
7.6	Renewal – one fee for all pharmaceutical forms and strengths– CMS	59,500	
7.8	Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number	33500	
8	**Homeopathic preparations**		
8.1	Application for registration for Homeopathic preparations when Iceland is RMS and National	296,000	295,000
8.2	Application for registration for Homeopathic preparations when Iceland is CMS	24,000	18,500
8.3	Application for a homeopathic product which has been granted a marketing authorisation within the European Economic Area	15,000	14,000
8.4	Annual fee (all variations IA/IB and II) for RMS/national registration and CMS	12,500	12,500
8.5	Annual fee (DCP and MRP)	2,500	2,500
9	**Classification to decide if a product is covered by the Pharmaceutical Act**		
9.1	Classification to decide if a product is covered by the Pharmaceutical Act	90,500	90,500

10	**Clinical trial applications**		
10.1	Application for authorisation for clinical trial	500,000	500,000
10.2	Substantial amendments	116,000	116,000
10.3	Bioavailability study	83,500	83,500
11	**Certificates**		
11.1	Certificate of a Pharmaceutical Product (CPP)	22,000	22,000
11.2	GXP certificate	14,500	14,500
11.3	Statement of Licensing Status of Pharmaceutical Products (FSC)	13,500	13,500
11.4	Expedite issue	7,500	7,500
11.5	Accelerated delivery fee	10,000	10,000
12	**Issuing of certicficates for operations that require licencing in accordance with the Medicinal Products Act No 93/1994**		
12.1	One licence	12,500	12,500
13	**Licences and exemptions according to Act No 65/1974 on narcotic and psychotropic substances**		
13.1	One licence	12,500	12,500
13.2	Expedite issue	4,500	4,500
14	**Scientific advice - hourly based fee**		
14.1	Scientific advice. Fee per hour	18,500	18,500
15	**Inspection Unit – hourly fee**		
15.1	Specialist.	16,500	16,500
15.2	Service agent.	13,000	13,000
16	**Annual fees**		
16.1	Annual fee for each marketing authorisation number - all processes	36,500	24,000

[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 (cf. the part of Annex 1 pertaining to pure national marketing authorisations), 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.

[7)] 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