TARIFF

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

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medicinal products in accordance with para.1 or their renewal are non-refundable even though an application has been withdrawn or rejected.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to the work undertaken in evaluating an authorisation application in accordance with para.1 which is subsequently withdrawn.

If the application fee, as set out in Annex I, does not cover the cost of assessing a marketing authorisation application, the applicant shall pay additional cost due to the assessment. The applicant shall be informed on such an additional cost and offered to withdraw the application within fourteen days, if he prefers that to paying the cost. Fees for such applications are pursuant to para.5.

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 authorisation

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 on 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.

The fees 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

Annual fees

The marketing authorisation holder shall, in accordance with Annex I to this Tariff, and before 1 March each year, pay an annual fee pursuant to Article 3, Para.4 of the Medicinal Products Act No 93/1994 for each pharmaceutical form and strength of a proprietary medicinal product, a parallel-imported medicinal product, a herbal medicinal product and a medicinal product pursuant to Article 8, Para.2 of the Medicinal Products Act, which has a marketing authorisation on 1 January each year, in accordance with an invoice from the Icelandic Medicines Agency. The annual fees shall be paid to the State Treasury. 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, his national representative is responsible for paying the annual fee.

Art. 4

Certifications etcetera.

Pharmaceutical companies shall pay the Icelandic Medicines Agency a fee in accordance with Article 3, para.6 of the Medicinal Products Act No 93/1994, for issuing a Certificate of a Pharmaceutical Product for which they intend to apply a marketing authorisation for in other countries, in addition to a Certificate of Authorisation for Manufacturers of Medicinal Products and a Statement of Licensing Status of Pharmaceutical Products. The fees shall be based on the expert work undertaken in issuing them.

The Icelandic Medicines Agency collects a fee for licenses and exemptions in accordance with Act on narcotic and psychotropic substances cf. Article 3, para.1.1.2 of the Medicinal Products Act.

The Icelandic Medicines Agency is authorised, in accordance with Article 3, para.7 of the Medicinal Products Act No 93/1994, to collect special fees for scientific advice in respect of a product's marketing authorisation which pharmaceutical companies request.

The Icelandic Medicines Agency collects special fees per hour for GMP (Good Manufacturing Practice) inspections at companies requesting such inspections but which are not subject to regular supervision according to the Medicinal Products Act.

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

Art. 5

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 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.

Art. 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 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.

Art. 7

Classification of products/substances.

The applicant requesting an evaluation of whether a product is considered to be a medicinal product in accordance with Article 5 of the Medicinal Products Act No 93/1994, due to its intended distribution and resale, shall, in accordance with Article 3, para.5 of the Medicinal Products Act No 93/1994, pay the Icelandic Medicines Agency a fee to cover the cost of the evaluation. The fee shall be in accordance with Annex I to this Regulation.

The fee for an evaluation, in accordance with para.1, is non-refundable.

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.

Article 9

Medicinal products which have not been granted an authorisation

The Icelandic Medicines Agency shall collect a fee in accordance with Article 3, para.8 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 this country, cf. Article 3, 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 subsequently collected the following year. These fees will, however, never exceed the amount of ISK 200,000.

Article 10
Special marketing authorisations.

In instances when the Icelandic Medicines Agency invites applications for a marketing authorisation of a medicine in order to ensure to the extent possible access to the medicine, the Agency can request a minimum fee for the application, which shall not be higher than a fee for an application for a change in labelling/leaflet for medicinal products for human use, not being a part of another application, when Iceland is a CMS.

Article 11
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 12
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.

Article 13
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 14
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 305/2009 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, 6 April 2018.

Svandís Svavarsdóttir.

Áslaug Einarsdóttir

ANNEX I

	RMS in DCP	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	5.630.000	4.500.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	4.500.000	3.950.000
Generic/Informed consent, Art. 10 (1)/10c/13(1)/13c	3.380.000	3.265.000
Additional pharmaceutical form and strengths applied at the same time	395.000	395.000
Additional application (duplicate)	1.420.000	1.420.000
Additional pharmaceutical form and strengths applied at the same time	395.000	395.000
Annex I[1)] New pharmaceutical forms/strengths (line extensions)	1.420.000	1.420.000
Additional pharmaceutical forms and strengths applied at the same time	395.000	395.000
Other annex I applications [1)]	1.180.000	1.180.000
Additional pharmaceutical forms and strengths applied at the same time	335.000	335.000
Annex I for products previously approved for food producing animals [1)]		560.000
Additional pharmaceutical forms and strengths applied at the same time		157.000
Annual fee for each marketing authorisation number	34.000	22.500
Variation Type IA_{IN} and IA	56.000	55.000
Variation Type IB	90.000	87.000
Variation Type II; change in therapeutic indication	710.000	710.000
Variation Type II; change in posology	395.000	395.000
Other variation Type II	337.000	337.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	90.000	
Renewals	710.000	710.000
Additional pharmaceutical forms and strengths	190.000	190.000
PSUR assessment - one fee per PSUR	430.000	430.000

	RMS in MRP	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b [3)]	5.630.000	4.500.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) [3)]	4.500.000	3.950.000
Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c [3)]	3.380.000	3.265.000
Additional pharmaceutical forms and strengths applied at the same time [3)]	395.000	395.000
Additional application (duplicate) [3)]	1.420.000	1.420.000
Additional pharmaceutical forms and strengths applied at the same time [3)]	395.000	395.000
Repeat procedure	1.290.000	
Additional pharmaceutical forms and strengths applied for at the same time	395.000	
Annex I[1)] New pharmaceutical forms/strengths (line extensions) [3)]	1.420.000	1.420.000
Additional pharmaceutical forms and strengths applied at the same time [3)]	395.000	395.000
Other annex I applications [1)]	1.180.000	1.180.000

Additional pharmaceutical forms and strengths applied at the same time	335.000	335.000
Annex I for products previously approved for food producing animals [1)]		560.000
Additional pharmaceutical forms and strengths applied at the same time		157.000
Annual fee for each marketing authorisation number	34.000	22.500
Variation Type IA_{IN} and IA	56.000	55.000
Variation Type IB	90.000	87.000
Variation Type II; change in therapeutic indication	710.000	710.000
Variation Type II; change in posology	395.000	395.000
Other variation Type II	337.000	337.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	90.000	
Renewals	710.000	710.000
Additional pharmaceutical forms and strengths	190.000	190.000
PSUR assessment - one fee per PSUR	430.000	430.000

	CMS in DCP/MRP	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	360.000	102.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	307.000	61.000
Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	307.000	61.000
Additional pharmaceutical forms and strengths applied at the same time	51.000	25.500
Additional application (duplicate)	133.000	30.500
Additional pharmaceutical forms and strengths applied at the same time	31.000	15.500
Annex I[1)] New pharmaceutical forms /strengths (line extensions)	102.000	41.000
Additional pharmaceutical forms and strengths applied at the same time	20.500	10.500
Other annex I applications [1)]	61.000	25.500
Additional pharmaceutical forms and strengths applied at the same time	20.500	10.500
Annex I for products previously approved for food producing animals [1)]		25.500
Additional pharmaceutical forms and strengths applied at the same time		10.500
Annual fee for each marketing authorisation number	31.000	20.500
Variation Type IA_{IN} and IA	15.500	10.500
Variation Type IB	31.000	16.500
Variation Type II; change in therapeutic indication	61.000	20.500
Variation Type II; change in posology	61.000	20.500
Other variation Type II	51.000	15.500
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	41.000	
Renewals	133.000	51.000
Additional pharmaceutical forms and strengths	31.000	20.500
PSUR - one fee per PSUR	16.500	11.500

	National	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	4.090.000	3.070.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	3.070.000	2.560.000

Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	2.050.000	1.860.000
Additional pharmaceutical forms and strengths applied at the same time	204.000	204.000
Additional application (duplicate)	921.000	921.000
Additional pharmaceutical forms and strengths applied at the same time	204.000	204.000
Annex I[1)] New pharmaceutical forms /strengths (line extensions)	921.000	921.000
Additional pharmaceutical forms and strengths applied at the same time	204.000	204.000
Other annex I applications [1)]	614.000	614.000
Additional pharmaceutical forms and strengths applied at the same time	51.000	51.000
Annex I for products previously approved for food producing animals [1)]		410.000
Additional pharmaceutical forms and strengths applied at the same time		41.000
Annual fee for each marketing authorisation number	31.000	20.500
Variation Type IA_{IN} and IA [4)]	31.000	15.500
Variation Type IB [4)]	41.000	20.500
Variation Type II; change in therapeutic indication [4)]	410.000	153.000
Variation Type II; change in posology [4)]	235.000	87.000
Other variation Type II [4)]	153.000	76.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	41.000	
Renewals [4)]	307.000	307.000
Additional pharmaceutical forms and strengths [4)]	76.000	76.000
PSUR assessment - one fee per PSUR [4) 6)] (except PSUSA)	395.000	280.000

Other changes		
Variation Type II, Change in legal status (prescription/non-prescription) [5)]	225.000	225.000
Transfer to CTD format, without any substantial changes [5)]	11.500	
Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number [5)]	29.000	29.000
Request for a temporary exemption from approved Labelling/PIL requirements, with or without repackaging/over stickering - not a part of an ongoing application [5)]	13.500	11.500
Withdrawal of a marketing authorisation - one fee per product [5)]	13.500	11.500
Deletion from the Icelandic Drug Catalogue and the Price List - one fee per request and product name [5)]	13.500	11.500
RMS transfer to IMA	180.000	
Corrections / improvements of texts	13.500	13.500
IMA as lead RMS. IMA takes on the lead in variation for a group of marketing authorizations in different member states.	17.000	

Authorisation to place a product on the market cf. Directive 2001/83/EC Article 126(a)		
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	337.000	
Additional pharmaceutical forms and strengths	56.000	
Variation, Type IA_{IN} and IA	17.000	

Variation, Type IB	34.000	
Variation, Type II; change in therapeutic indication	67.000	
Variation, Type II; change in posology	67.000	
Other variation, Type II	56.000	
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL)[2)]	45.000	
Renewal	146.000	
Additional pharmaceutical forms and strengths [5)]	34.000	
Annual fee for each authorisation number	34.000	

Parallel import		
Parallel import (one country of origin)	177.000	157.500
Additional pharmaceutical forms and strengths applied at the same time	31.500	28.000
Variations	37.000	34.000
Renewals	177.000	157.000
Additional pharmaceutical forms and strengths	31.500	28.000
Annual fee for each marketing authorisation number	37.000	22.500

Traditional herbal medicines		
With monograph	1.520.000	
Without monograph	1.915.000	
Additional application (duplicate) applied at the same time	560.000	
Application for MRP, with or without monograph – all forms, strengths and routes of administration applied at the same time – (CMS)	215.000	
Renewal – all pharmaceutical forms, strengths and routes of administration – national and RMS	450.000	
Renewal – one fee for all pharmaceutical forms and strengths– CMS	56.000	
Annual fee	36.000	
Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number	31.500	

Homeopathic preparations		
Application for registration for Homeopathic preparations when Iceland is RMS and National	281.000	281.000
Application for registration for Homeopathic preparations when Iceland is CMS	22.500	17.000
Application for a homeopathic product which has been granted a marketing authorisation within the European Economic Area	14.000	13.000
Annual fee (all variations IA/IB and II) reg/national	11.500	11.500
Annual fee (DCP and MRP)	2.250	2.250

Classification to decide if a product is covered by the Pharmaceutical Act		
Classification to decide if a product is covered by the Pharmaceutical Act.	85.000	85.000

Clinical trial applications		
Clinical trials	238.000	238.000
Substantial amendments	108.000	108.000

Bioavailability study	78.000	78.000

Officinal formula		
Application for an assessment of an official formula	112.000	112.000

Certificates		
Certificate of a Pharmaceutical Product	20.000	20.000
GMP certificate	13.500	13.500
Statement of Licensing Status of Pharmaceutical Products	12.500	12.500

Issuing of certicficate for licencing required operation according to Pharmaceutical Act No 93/1994		
One license	11.500	11.500

Licenses and exemptions according to Act on narcotic and psychotropic substances		
One license	11.500	11.500

Scientific advice - hourly based fee		
Scientific advice. Fee per hour	17.000	17.000
Inspection Unit – hourly fee		
Specialist. Fee per hour	15.000	15.000
Service agent. Fee per hour	12.000	12.000

[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, a fee corresponding to the difference between RMS fee and the fee originally paid for the national marketing authorisation will be invoiced.

[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)] 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