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medicinal products in accordance with para.1 or their renewal are non-refundable even though an application has been withdrawn or rejected.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to the work undertaken in evaluating an authorisation application in accordance with para.1 which is subsequently withdrawn.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

A half fee is collected for each consequential variation.

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, 27 May 2011.

Guðbjartur Hannesson.

Vilborg Ingólfssdóttir

ANNEX I

	RMS in DCP	
	Human	Veterinary
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	4.000.000	4.000.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	3.500.000	3.500.000
Generic/Informed concent, Art. 10 (1)/10c/13(1)/13c	2.900.000	2.900.000
Additional formulations and strengths applied at the same time	350.000	350.000
Additional application (duplicate)	1.260.000	1.260.000
Additional formulations and strengths applied at the same time	350.000	350.000
Annex I ¹⁾ New formulations/strengths (line extensions)	1.260.000	1.260.000
Additional formulations and strengths applied at the same time	350.000	350.000
Other annex I applications ¹⁾	1.050.000	1.050.000
Additional formulations and strengths applied at the same time	300.000	300.000
Annex I for products previously approved for food producing animals ¹⁾		500.000
Additional formulations and strengths applied at the same time		140.000
Annual fee for each marketing authorisation number	30.000	20.000
Variation Type IA _{IN} and IA	49.000	49.000
Variation Type IB	77.000	77.000
Variation Type II; change in therapeutic indication	630.000	630.000
Variation Type II; change in posology	350.000	350.000
Other variation Type II	300.000	300.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) ²⁾	77.000	
Renewals	630.000	630.000
Additional formulations and strengths	168.000	168.000
PSUR assessment - one fee per PSUR	385.000	385.000

	RMS in MRP	
	Human	Veterinary
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b ³⁾	4.000.000	4.000.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) ³⁾	3.500.000	3.500.000
Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c ³⁾	2.900.000	2.900.000
Additional formulations and strengths applied at the same time ³⁾	350.000	350.000
Additional application (duplicate) ³⁾	1.260.000	1.260.000
Additional formulations and strengths applied at the same time ³⁾	350.000	350.000
Annex I ¹⁾ New formulations/strengths (line extensions) ³⁾	1.260.000	1.260.000
Additional formulations and strengths applied at the same time ³⁾	350.000	350.000
Other annex I applications ¹⁾	1.050.000	1.050.000
Additional formulations and strengths applied at the same time	300.000	300.000
Annex I for products previously approved for food producing animals ¹⁾		500.000
Additional formulations and strengths applied at the same time		140.000
Annual fee for each marketing authorisation number	30.000	20.000

Variation Type IA _{IN} and IA	49.000	49.000
Variation Type IB	77.000	77.000
Variation Type II; change in therapeutic indication	630.000	630.000
Variation Type II; change in posology	350.000	350.000
Other variation Type II	300.000	300.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) ²⁾	77.000	
Renewals	630.000	630.000
Additional formulations and strengths	168.000	168.000
PSUR assessment - one fee per PSUR	385.000	385.000

	CMS in DCP/MRP	
	Human	Veterinary
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	300.000	100.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	260.000	60.000
Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	260.000	60.000
Additional formulations and strengths applied at the same time	50.000	25.000
Additional application (duplicate)	130.000	30.000
Additional formulations and strengths applied at the same time	30.000	15.000
Annex I ¹⁾ New formulations/strengths (line extensions)	100.000	40.000
Additional formulations and strengths applied at the same time	20.000	10.000
Other annex I applications ¹⁾	60.000	25.000
Additional formulations and strengths applied at the same time	20.000	10.000
Annex I for products previously approved for food producing animals ¹⁾		25.000
Additional formulations and strengths applied at the same time		10.000
Annual fee for each marketing authorisation number	30.000	20.000
Variation Type IA _{IN} and IA	12.000	10.000
Variation Type IB	25.000	16.000
Variation Type II; change in therapeutic indication	50.000	20.000
Variation Type II; change in posology	50.000	20.000
Other variation Type II	40.000	15.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) ²⁾	30.000	
Renewals	130.000	50.000
Additional formulations and strengths	30.000	20.000
PSUR - one fee per PSUR	16.000	11.000

	National	
	Human	Veterinary
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	3.000.000	3.000.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	2.500.000	2.500.000
Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	1.820.000	1.820.000
Additional formulations and strengths applied at the same time	200.000	200.000
Additional application (duplicate)	900.000	900.000
Additional formulations and strengths applied at the same time	200.000	200.000

Annex I ¹⁾ New formulations/strengths (line extensions)	900.000	900.000
Additional formulations and strengths applied at the same time	200.000	200.000
Other annex I applications ¹⁾	600.000	600.000
Additional formulations and strengths applied at the same time	50.000	50.000
Annex I for products previously approved for food producing animals ¹⁾		400.000
Additional formulations and strengths applied at the same time		40.000
Annual fee for each marketing authorisation number	30.000	20.000
Variation Type IA _{IN} and IA	25.000	15.000
Variation Type IB	36.000	20.000
Variation Type II; change in therapeutic indication	400.000	150.000
Variation Type II; change in posology	230.000	85.000
Other variation Type II	150.000	75.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) ²⁾	30.000	
Renewals	300.000	300.000
Additional formulations and strengths	75.000	75.000
PSUR assessment - one fee per PSUR ⁵⁾	275.000	275.000
Other changes		
Variation Type II, Change in legal status (prescription/non-prescription) ⁴⁾	200.000	200.000
Transfer to CTD format, without any substantial changes ⁴⁾	10.000	
Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number ⁴⁾	26.000	26.000
Request for a temporary exemption from approved Labelling/PIL requirements, with or without repackaging/oversticking - not a part of an ongoing application ⁴⁾	10.000	10.000
Withdrawal of a marketing authorisation - one fee per product ⁴⁾	10.000	10.000
Deletion from the Icelandic Drug Catalogue and the Price List - one fee per request and product name ⁴⁾	10.000	10.000
Authorisation to place a product on the market		
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	260.000	
Additional formulations and strengths	50.000	
Variations and other changes - same fees as when Iceland is CMS in DCP/MRP		
Renewal	130.000	
Additional formulations and strengths ⁴⁾	30.000	
Annual fee for each authorisation number	30.000	
Parallel import		
Parallel import (one country of origin)	140.000	140.000
Additional formulations and strengths applied at the same time	25.000	25.000
Variations	30.000	30.000
Renewals	140.000	140.000

Additional formulations and strengths	25.000	25.000
Annual fee for each marketing authorisation number	30.000	20.000

Traditional herbal medicines		
With monography	200.000	
Additional formulations and strengths	20.000	
Without monography	300.000	
Additional formulations and strengths	30.000	
Reclassification from traditional herbal medicine to well established use	60.000	
Variations - fees in accordance with purely nationally authorised medicinal products.		
Renewals	200.000	
Additional formulations and strengths	20.000	
Annual fee	30.000	
Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number	26.000	

Homeopathic preparations		
Application for a homeopathic product which has been granted a marketing authorisation within the Euroean Economic Area	11.500	11.500
Application for a homeopathic product which has not been granted a marketing authorisation within the Euroean Economic Area	40.000	40.000

Classification to decide if a product is covered by the Pharmaceutical Act		
Classification to decide if a product is covered by the Pharmaceutical Act.	70.000	70.000

Clinical trial applications		
Clinical trials	212.000	212.000
Substantial amendments	96.000	96.000
Bioavailatality study	70.000	76.000

Officinal formula		
Application for an assessment of an officinal formula	100.000	100.000

Certificates		
Certificate of a Pharmaceutical Product	18.000	18.000
GMP certificate	12.000	12.000
Statement of Licensing Status of Pharmaceutical Products	11.000	11.000

Licenses and exemptions according to Act on narcotic and psychotropic substances		
One license	12.500	12.5000

Scientific advice and other hourly based fees		
Scientific advice. Fee per hour	20.000	20.000

GMP certification requested by manufacturers which do not fall under the Icelandic Medicines Agency's inspection, cf. Article 3 in the Pharmaceutical Act No 93/1994. Fee per hour	20.000	20.000
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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⁾ This fee is valid for DCP and MRP products where Iceland is a RMS or a CMS, as well as for purely national products.

⁵⁾ 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