TARIFF NO 250/2017

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 relating to 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medicinal products in accordance with para.1 or their renewal are non-refundable even though an application has been withdrawn or rejected.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to the work undertaken in evaluating an authorisation application in accordance with para.1 which is subsequently withdrawn.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 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 141/2011 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 is collected according to Annex I to this Tariff when the role as a RMS is transferred to Iceland.

A special fee is collected according to Annex I to this Tariff when it is requested that Iceland takes on the role of a lead RMS in a IA supergroup application. One single fee is collected for each variation, irrespective of the number of medicinal products or strengths.

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

Medicinal products that 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 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 220,000.

Article 4

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 5

Annual fees

The marketing authorisation holder shall, in accordance with Annex I to this Tariff, pay an annual fee pursuant to Article 3, Para.5 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.

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 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 relating to clinical trial applications.

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 Icelandic Medicines Agency 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 relating to inspections.

Article 9

Fee for processing an application for a licence

The Icelandic Medicines Agency collects a fee in accordance with Article 3, para.3 of the Medicinal Products Act No 93/1994, for issuing a licence for operations where a licence is the legal requirement. The fees according to this article shall be in accordance with Annex I to this Tariff.

Article 10

Fee for a necessary inspection of planned licence-only operations.

The applicant for a manufacturing licence, wholesaler licence, licence to import and/or manufacture of medicated feed a fee or a pharmacy licence shall pay the Icelandic Medicines Agency a fee in accordance with Article 3, para.3 of the Medicinal Products Act No 93/1994, to cover the costs of a necessary inspection of the planned operations.

Before a necessary inspection of the planned operations takes place according to para.1, the applicant shall be made aware of the estimated scale of the inspection.

Upon a completed inspection, the Icelandic Medicines Agency invoices the applicant based on the number of work-hours put in by an expert and/or representative of the Icelandic Medicines Agency during the inspection.

This fee or fees are collected as a fee per hour this article and shall be in accordance with Annex I to this Tariff.

Article 11

Fee for quality inspections and certifications of manufacturing processes of pharmaceutical companies in Iceland and abroad.

The Icelandic Medicines Agency collects a fee in accordance with Article 3, para.8 of the Medicinal Products Act No 93/1994, for quality inspections and certifications of manufacturing processes of pharmaceutical companies in Iceland and abroad, based on a request thereof and/or according to the Medicinal Products Act No 93/1994, applicable EEA/EU legislation and under the European Free Trade Association (EFTA) Treaty.

Before a quality inspection and/or certification of the manufacturing processes of pharmaceutical company takes place according to para.1, the pharmaceutical company shall be made aware of the estimated scale of the inspection and/or certification. Upon a completed inspection, the Icelandic Medicines Agency invoices the pharmaceutical company based on the number of work-hours put in by an expert and/or representative of the Icelandic Medicines Agency during the inspection.

This fee or fees are collected as a fee per hour and shall be in accordance with Annex I to this Tariff.

Article 12

Fee for issuing of licences and exemptions according to the Act on Narcotic and Psychotropic Substances.

The Icelandic Medicines Agency collects a fee for issuing of licenses and exemptions in accordance with the Act on Narcotic and Psychotropic Substances cf. Article 3, para.1.1.2 of the Medicinal Products Act.

CHAPTER IV

Fees relating to services.

Article 13

Certifications etc.

A fee is payable to the Icelandic Medicines Agency a fee in accordance with Article 3, para.7 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 the issuing of a *Certificate of GMP Compliance of a Manufacturer*, a *Certificate of Authorisation for Manufacturers of Medicinal Products* and a *Statement of Licensing Status of Pharmaceutical Products*.

The amount of these fees are collected as a fee per hour and shall be in accordance with Annex I to this Tariff.

Article 14

Scientific Advice.

The Icelandic Medicines Agency collects, in accordance with Article 3, para.8 of the Medicinal Products Act No 93/1994, a special fee for scientific advice in respect of a product's marketing authorisation which pharmaceutical companies request. This fee is collected as a fee per hour this article and shall be in accordance with Annex I to this Tariff.

Article 15

Classification of products/substances.

An applicant, requesting an assessment of whether a product or substance classifies as a medicinal product or not, 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 assessment. The fee shall be in accordance with Annex I to this Tariff, and is non-refundable.

If the aforementioned assessment requires exceptional preparation, i.e., data collection on behalf of the Icelandic Medicines Agency, or that work carrying out the assessment turns out to be exceptionally extensive, the Icelandic Medicines Agency can choose to collect fee to cover the costs of the assessment. This fee is added to the standard fee for classification of products or substances.

When additional work is considered necessary to complete a classification application, the applicant shall be made aware of the estimated scale of the additional work and the applicant given an opportunity to withdraw is application. Under such circumstances, the Icelandic Medicines Agency is authorised to collect a proportionate fee, never exceeding the amount of 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 force.

Article 18

Collection of fees

The Icelandic Medicines Agency collects fees in accordance with this Tariff. Payment is due 30 days from the date of issuance of the invoice. Interest on fees is collected in cases where fees are not paid before the final due date.

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 460/2016 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, 13 March 2017

Óttarr Proppé.
Minister of Health

Margrét Björnsdóttir

ANNEX I

	RMS in DCP	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	5.500.000	4.400.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	4.400.000	3.850.000
Generic/Informed consent, Art. 10 (1)/10c/13(1)/13c	3.300.000	3.190.000
Additional pharmaceutical form and strengths applied at the same time	385.000	385.000
Additional application (duplicate)	1.386.000	1.386.000
Additional pharmaceutical form and strengths applied at the same time	385.000	385.000
Annex I[1)] New pharmaceutical forms/strengths (line extensions)	1.386.000	1.386.000
Additional pharmaceutical forms and strengths applied at the same time	385.000	385.000
Other annex I applications [1)]	1.155.000	1.155.000
Additional pharmaceutical forms and strengths applied at the same time	330.000	330.000
Annex I for products previously approved for food producing animals [1)]		550.000
Additional pharmaceutical forms and strengths applied at the same time		154.000
Annual fee for each marketing authorisation number	33.000	22.000
Variation Type IA_{IN} and IA	55.000	53.900
Variation Type IB	88.000	84.700
Variation Type II; change in therapeutic indication	693.000	693.000
Variation Type II; change in posology	385.000	385.000
Other variation Type II	330.000	330.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	88.000	
Renewals	693.000	693.000
Additional pharmaceutical forms and strengths	184.800	184.800
PSUR assessment - one fee per PSUR	423.500	423.500

	RMS in MRP	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b [3)]	5.500.000	4.400.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) [3)]	4.400.000	3.850.000
Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c [3)]	3.300.000	3.190.000
Additional pharmaceutical forms and strengths applied at the same time[3)]	385.000	385.000
Additional application (duplicate) [3)]	1.386.000	1.386.000
Additional pharmaceutical forms and strengths applied at the same time [3)]	385.000	385.000
Repeat procedure	1.259.500	
Additional pharmaceutical forms and strengths applied for at the same time	385.000	
Annex I[1)] New pharmaceutical forms/strengths (line extensions) [3)]	1.386.000	1.386.000
Additional pharmaceutical forms and strengths applied at the same time [3)]	385.000	385.000
Other annex I applications [1)]	1.155.000	1.155.000
Additional pharmaceutical forms and strengths applied at the same time	330.000	330.000

Annex I for products previously approved for food producing animals [1)]		550.000
Additional pharmaceutical forms and strengths applied at the same time		154.000
Annual fee for each marketing authorisation number	33.000	22.000
Variation Type IA_{IN} and IA	55.000	53.900
Variation Type IB	88.000	84.700
Variation Type II; change in therapeutic indication	693.000	693.000
Variation Type II; change in posology	385.000	385.000
Other variation Type II	330.000	330.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	88.000	
Renewals	693.000	693.000
Additional pharmaceutical forms and strengths	184.800	184.800
PSUR assessment - one fee per PSUR	423.500	423.500

	CMS in DCP/MRP	
	Human	**Veterinary**
Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b	350.000	100.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	300.000	60.000
Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	300.000	60.000
Additional pharmaceutical forms and strengths applied at the same time	50.000	25.000
Additional application (duplicate)	130.000	30.000
Additional pharmaceutical forms and strengths applied at the same time	30.000	15.000
Annex I[1)] New pharmaceutical forms /strengths (line extensions)	100.000	40.000
Additional pharmaceutical forms and strengths applied at the same time	20.000	10.000
Other annex I applications [1)]	60.000	25.000
Additional pharmaceutical forms 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 pharmaceutical forms 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	15.000	10.000
Variation Type IB	30.000	16.000
Variation Type II; change in therapeutic indication	60.000	20.000
Variation Type II; change in posology	60.000	20.000
Other variation Type II	50.000	15.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	40.000	
Renewals	130.000	50.000
Additional pharmaceutical forms 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	4.000.000	3.000.000
Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4)	3.000.000	2.500.000

Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c	2.000.000	1.820.000
Additional pharmaceutical forms and strengths applied at the same time	200.000	200.000
Additional application (duplicate)	900.000	900.000
Additional pharmaceutical forms and strengths applied at the same time	200.000	200.000
Annex I[1)] New pharmaceutical forms /strengths (line extensions)	900.000	900.000
Additional pharmaceutical forms and strengths applied at the same time	200.000	200.000
Other annex I applications [1)]	600.000	600.000
Additional pharmaceutical forms 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 pharmaceutical forms 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 [4)]	30.000	15.000
Variation Type IB [4)]	40.000	20.000
Variation Type II; change in therapeutic indication [4)]	400.000	150.000
Variation Type II; change in posology [4)]	230.000	85.000
Other variation Type II [4)]	150.000	75.000
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	40.000	
Renewals [4)]	300.000	300.000
Additional pharmaceutical forms and strengths [4)]	75.000	75.000
PSUR assessment - one fee per PSUR [4) 6)] (except PSUSA)	385.000	275.000

Other changes		
Variation Type II, Change in legal status (prescription/non-prescription) [5)]	220.000	220.000
Transfer to CTD format, without any substantial changes [5)]	11.000	
Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number [5)]	28.600	28.600
Request for a temporary exemption from approved Labelling/PIL requirements, with or without repackaging/over stickering - not a part of an ongoing application [5)]	13.200	11.000
Withdrawal of a marketing authorisation - one fee per product [5)]	13.200	11.000
Deletion from the Icelandic Drug Catalogue and the Price List - one fee per request and product name [5)]	13.200	11.000
RMS transfer to IMA	176.000	
Corrections/improvements of texts	13.200	13.200
IMA as lead RMS. IMA takes on the lead in variation for a group of marketing authorizations in different member states.	16.500	

Authorisation to place a product on the market according to Directive 2001/83/EC Article 126(a)		
Application to place a product on the market cf. Article 6 of Regulation No 141/2011, cf. article 126(a) of Directive 2001/83	330.000	
Additional pharmaceutical forms and strengths	55.000	
Variation, Type IA_{IN} and IA	16.500	

Variation, Type IB	33.000	
Variation, Type II; change in therapeutic indication	66.000	
Variation, Type II; change in posology	66.000	
Other variation, Type II	55.000	
Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL)[2)]	44.000	
Renewal	143.000	
Additional pharmaceutical forms and strengths [5)]	33.000	
Annual fee for each authorisation number	33.000	

Parallel import		
Parallel import (one country of origin)	172.700	154.000
Additional pharmaceutical forms and strengths applied at the same time	30.800	27.500
Variations	36.300	33.000
Renewals	172.700	154.000
Additional pharmaceutical forms and strengths	30.800	27.500
Annual fee for each marketing authorisation number	36.300	22.000

Traditional herbal medicines		
With monograph	1.485.000	
Without monograph	1.870.000	
Additional application (duplicate) applied at the same time	550.000	
Application for MRP, with or without monograph – all forms, strengths and routes of administration applied at the same time – CMS	66.000	
Renewal – all pharmaceutical forms, strengths and routes of administration – national and RMS	440.000	
Renewal – one fee for all pharmaceutical forms and strengths – CMS	55.000	
Annual fee	35.200	
Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number	30.800	

Homeopathic preparations		
Application for MA for homeopathic preparations - Iceland as RMS or national MA	275.000	275.000
Application for MA for homeopathic preparations – Iceland as CMS	22.000	16.500
Application for a registration of homeopathic medicinal product which has a marketing authorisation in another EEA Member State	13.750	12.650
Annual fee (all variations IA/IB and II) regarding RMS/nat. and CMS	11.000	11.000
Annual fee (registration based on a marketing authorisation in another EEA Member State)	2.200	2.200

Classification to decide if a product is covered by the Pharmaceutical Act		
Classification to decide if the Pharmaceutical Act covers a product.	83.600	83.600

Clinical trial applications		
Clinical trials	233.200	233.200

Substantial amendments	105.600	105.600
Bioavailability study	77.000	77.000

Officinal formula		
Application for an assessment of an official formula	110.000	110.000

Certificates		
Certificate of a Pharmaceutical Product	19.800	19.800
GMP certificate	13.200	13.200
Statement of Licensing Status of Pharmaceutical Products	12.100	12.100

Fee for a necessary inspection of planned licence-only operations according to the Medicinal Products Act		
One license	11.000	11.000

Licenses and exemptions according to the Act on Narcotic and Psychotropic Substances		
One license	11.000	11.000

Scientific advice and other hourly based fees		
Scientific advice. Fee per hour	16.500	16.500
Expert. Fee per hour	14.500	14.500
Representative. Fee per hour	11.500	11.500

[1)] Annex I to 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 based on an assessment carried out by IMA (cf. the portion of this Annex on national registration), a fee amounting to the difference between a RMS fee and the fee originally paid for the national marketing authorisation will be invoiced. In all other circumstances a full MRP application fee 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