No. 2022

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. An applicant for a marketing authorisation for a veterinary medicinal product shall pay a fee pursuant to Article 55, para. 1.a of Act No. 14/2022 on Veterinary Medicinal Products.

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 No. 100/2020, 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medicinal products in accordance with para.1 or their renewal are non-refundable even though an application has been withdrawn or rejected.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to the work undertaken in evaluating an authorisation application, in accordance with para.1, which is subsequently withdrawn.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 19,000.

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 No. 100/2020.

The fees 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, cf. Article 6, para. 1.2 of the Medicinal Products Act No. 100/2020 and Article 6, para 7.b of Act No. 14/2022 on Veterinary Medicinal Products, shall pay the Icelandic Medicines Agency a fee in accordance with Article 89, para. 1.2 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.b of Act No. 14/2022 on Veterinary Medicinal Products, covering the cost of evaluating the variation. 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 19,000, however.

A fee shall be paid in accordance with Annex I to this Tariff for Type IAIN, IA, IB and type II variations cf. Regulation No. 785/2022 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, as well as 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 shall be in accordance with Annex I to this Tariff.

Upon special request, and following an assessment of the project status, the Icelandic Medicines Agency may grant an applicant for a variation to the terms of a national marketing authorisation a special priority in processing the application. Such priority is 14 days at most. Applicants who apply for such priority 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 6, para. 1.3 of the Medicinal Products Act No. 100/2020 and Article 6, para. 7.c of Act No. 14/2022 on Veterinary Medicinal Products, 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 89, para. 1.7 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.f of Act No. 14/2022 on Veterinary Medicinal Products. The Icelandic Medicines Agency collects 2% of the medicinal product's total annual wholesale purchase price. The deadline to apply for a discount on the fee is 20 January each year.

The Icelandic Medicines Agency collects a fee for the publication of a statement declaring that an authorisation according to Article 6, para. 1.3 of the Medicinal Product Act No. 100/2020 and Article 6, para. 7.c of Act No. 14/2022 on Veterinary Medicinal Products had been granted, cf. Article 89, para. 1.7 of the Medicinal Product Act No. 100/2020 and Article 55, para. 1.f of Act No. 14/2022 on Veterinary Medicinal Products. The fees shall be in accordance with Annex I to this Tariff.

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, cf. Article 89, para. 1.11 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.h of Act No. 14/2022 on Veterinary Medicinal Products. This fee shall not be higher than the fee for an application for a change in labelling/leaflet of medicinal products for human use, 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 No. 100/2020 and Article 55, para. 1.c of Act No. 14/2022 on Veterinary Medicinal Products, according to Annex I to this Tariff and pursuant to 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 marketing authorisation in Iceland, cf. Article 11, para. 1 of the Medicinal Products Act No. 100/2020 and Article 7, para. 1 of Act No. 14/2022 on Veterinary Medicinal Products, shall pay the Icelandic Medicines Agency a fee, in accordance with Article 89, para. 1.11 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.h of Act No. 14/2022 on Veterinary Medicinal Products, to bear the cost of their evaluation. 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 withdrawn or 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 and Article 12 of Act No. 14/2022 on Veterinary Medicinal Products, shall pay a fee in accordance with Article 89, para. 1.8 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.h of Act No. 14/2022 on Veterinary Medicinal Products, 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 withdrawn or 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 for the processing of applications for a new authorisation, variations in authorisations and renewals of authorisations for activities that require licencing according to items 5, 6, 8, 17, and 18 of paragraph 1, Article 6 of the Medicinal Products Act No. 100/2020 and items e, f, and i in Article 6, para. 7 of Act No. 14/2022 on Veterinary Medicinal Products. The fee is collected on the basis of Article 89, para 1.11 of the Medicinal Product Act No. 100/2020 and Article 55, para. 1.h of Act No. 14/2022 on Veterinary Medicinal Products and reflects the costs of processing the application for authorisation. The fees shall be in accordance with Annex I to this Tariff.

Article 9
Fee for necessary audits of intended activities that require licensing.

An applicant for a new or renewed authorisation (including applications for variants of items on the basis of which the current authorisation was granted, i.e. new premises, equipment, processes, pharmaceutical form) 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, according to Article 6, para. 1.5 of the Medicinal Product Act No. 100/2020 and items e and f of Article 6, para. 7 of Act No. 14/2022 on Veterinary Medicinal Products, shall pay a fee according to Article 89, para. 1.11 of the Medicinal Product Act No. 100/2020 and Article 55, para. 1.h of Act No. 14/2022 on Veterinary Medicinal Products 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 10
Fee for quality audits and certification of the manufacturing procedures of pharmaceutical companies, in Iceland or abroad.

The Icelandic Medicines Agency collects a fee in accordance with Article 89, para. 1.11 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.h of Act No. 14/2022 on Veterinary Medicinal Products, 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 11

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

For the granting of licences and exceptions in accordance with the Narcotics Act, cf. Article 6, para. 1.12 of the Medicinal Products Act No. 100/2020, the Icelandic Medicines Agency collects a fee according to Article 89, para. 1.9 of the Medicinal Products Act No. 100/2020.

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 12

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, in accordance with Article 6, para. 1.13 of the Medicinal Products Act No. 100/2020.

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 and Article 55, para. 1.g of Act No. 14/2022 on Veterinary Medicinal Products, 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 a fee, cf. Article 89, para. 1.6 of the Medicinal Products Act No. 100/2020 and Article 55, para. 1.e of Act No. 14/2022 on Veterinary Medicinal Products 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.

The Icelandic Medicines Agency is authorised to collect a fee in proportion to the work undertaken in evaluating an application for scientific advice which is subsequently withdrawn or rejected. This fee is never lower than ISK 19,000, however.

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 No. 100/2020, 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 for medicines and medicines without market authorisation.

The Icelandic Medicines Agency is authorised to lower the annual fee of medicines and medicines without market authorisation in exceptional circumstances. The Agency shall decide and publish on its website guidelines for its criteria and arrangements concerning this issue. Applications for such exemptions shall be submitted to the Agency at the beginning of each year, and no later than 20 January. The application shall be supported by information concerning the total wholesale price of the product for the two preceding years.

Article 17

Special reduction of fees.

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

CHAPTER VI
Collection of fees and entry into effect.

Article 18
Collection of fees.

The Icelandic Medicines Agency collects fees in accordance with this Tariff. The final due date for payment is 30 days from the date of issuance of the invoice. In case the fee is not paid before the final due date, interest will be collected. Fees in accordance with this Regulation are enforceable.

Article 19
Entry into force.

This Tariff, which is laid down pursuant to an authorisation in Article 89, para. 2 of the Medicinal Products Act No. 100/2020 and Article 55, para. 2 of Act No. 14/2022 on Veterinary Medicinal Products, in line with proposals from the Icelandic Medicines Agency, enters into effect on 1 January 2023. Concurrently, Tariff No. 133/2022 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 Health, 20 December 2022.

Willum Þór Þórsson.

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Heiða Björg Pálmadóttir

No. 2022

APPENDIX I

		RMS in DCP/MRP	
1		**Human ISK**	**Veterinary ISK**
1.1	Complete dossier/well-established use/fixed combinations, cf. Directive 2001/83/EC. [2) 3)]	6,841,800	5,439,900
1.1.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	488,400	480,600
1.2	Hybrid and biosimilar, cf. Directive 2001/83/EC. [2) 3)]	5,501,700	4,798,800
1.2.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	488,300	480,600
1.3	Generic/Informed consent, cf. Directive 2001/83/EC. [2) 3)]	4,330,900	3,965,900
1.3.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	495,500	480,600
1.4	Additional application (duplicate) [3)]	1,818,100	1,741,000
1.4.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	498,300	481,200
1.5	Repeat Use [3)]	1,592,700	
1.5.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	487,700	
1.6	Annex I [1)] - New pharmaceutical forms/strengths (line extensions)[3)] / VRA-E	1,726,600	1,717,800
1.6.1	Additional pharmaceutical forms and strengths applied at the same time [3)]	481,200	478,400
1.7	Other annex I applications [1)]	1,434,600	1,428,000
1.7.1	Additional pharmaceutical form and strengths applied at the same time	407,600	405,400
1.8	Annex I for products previously approved for food producing animals [1)]		670,300
1.8.1	Additional pharmaceutical form and strengths applied at the same time		188,600
1.9	Variation, Type IA_{IN} and IA / VNRA	53,600	53,600
1.10	Variation, Type IB / VRA-R	80,200	80,200
1.11	Variation, Type II; change in therapeutic indication	710,700	710,700
1.12	Variation, Type II; change in posology	399,300	399,300
1.13	Other variation, Type II / VRA-S	391,000	391,000
1.14	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	110,600	
1.15	Renewals	889,300	859,500
1.15.1	Additional pharmaceutical forms and strengths	236,200	230,600
1.16	PSUR assessment - one fee per PSUR	512,700	509,900

		CMS to DCP/MRP	
2		**Human ISK**	**Veterinary ISK**
2.1	Complete dossier/well-established use/fixed combinations, cf. Directive 2001/83/EC. [2)]	446,300	125,000
2.1.1	Additional pharmaceutical form and strengths applied at the same time	63,600	31,500
2.2	Hybrid and biosimilar, cf. Directive 2001/83/EC. [2)]	387,100	75,700
2.2.1	Additional pharmaceutical form and strengths applied at the same time	64,200	31,500
2.3	Generic/Informed consent, cf. Directive 2001/83/EC. [2)]	390,900	75,800
2.3.1	Additional pharmaceutical form and strengths applied at the same time	64,100	31,500
2.4	Additional application (duplicate)	163,100	37,600
2.4.1	Additional pharmaceutical form and strengths applied at the same time	38,200	19,400
2.5	Repeat Use	387,200	
2.5.1	Additional pharmaceutical form and strengths applied at the same time	64,100	
2.6	Annex I[1)] - New pharmaceutical forms/strengths (line extensions) / VRA-E	125,500	49,200
2.6.1	Additional pharmaceutical form and strengths applied at the same time	26,000	13,300
2.7	Other annex I applications [1)]	74,700	30,400
2.7.1	Additional pharmaceutical form and strengths applied at the same time	24,900	13,300
2.8	Annex I for products previously approved for food producing animals [1)]		30,400
2.8.1	Additional pharmaceutical form and strengths applied at the same time		13,300
2.9	Variation, Type IA_{IN} and IA / VNRA	16,100	11,100
2.10	Variation, Type IB / VRA-R	31,500	16,600
2.11	Variation, Type II; change in therapeutic indication	59,700	20,400
2.12	Variation, Type II; change in posology	59,700	20,400
2.13	Other variation, Type II / VRA-S	51,900	16,600
2.14	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	50,900	
2.15	Renewals	167,000	62,500
2.15.1	Additional pharmaceutical forms and strengths	39,200	25,400
2.16	PSUR assessment - one fee per PSUR	20,500	14,900
2.17	0 day procedure	387,200	75,200
		National	
3		**Human ISK**	**Veterinary ISK**

3.1	Complete dossier/well-established use/fixed combinations, cf. Directive 2001/83/EC. [2)]	4,906,100	3,690,600
3.1.1	Additional pharmaceutical form and strengths applied at the same time	245,600	244,500
3.2	Hybrid and biosimilar, cf. Directive 2001/83/EC. [2)]	3,691,100	3,044,500
3.2.1	Additional pharmaceutical form and strengths applied at the same time	245,600	244,485
3.3	Generic/Informed consent, cf. Directive 2001/83/EC. [2)]	2,477,200	2,208,900
3.3.1	Additional pharmaceutical form and strengths applied at the same time	245,600	244,500
3.4	Additional application (duplicate)	1,110,000	1,104,500
3.4.1	Additional pharmaceutical form and strengths applied at the same time	245,600	244,500
3.5	Annex I[1)] - New pharmaceutical forms/strengths (line extensions) / VRA-E	1,110,000	1,104,500
3.5.1	Additional pharmaceutical form and strengths applied at the same time	245,600	244,400
3.6	Other annex I applications [1)]	737,000	732,900
3.6.1	Additional pharmaceutical form and strengths applied at the same time	61,900	60,800
3.7	Annex I for products previously approved for food producing animals [1)]		486,600
3.7.1	Additional pharmaceutical form and strengths applied at the same time		48,700
3.8	Variation Type IA_{IN} and IA [4)] / VNRA	35,900	16,600
3.9	Variation Type IB [4)] / VRA-R	46,400	21,600
3.10	Variation Type II; change in therapeutic indication [4)]	430,300	157,000
3.11	Variation Type II; change in posology [4)]	251,600	105,700
3.12	Other variation Type II [4)] / VRA-S	162,600	79,600
3.13	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	51,400	
3.14	Renewals [4)]	368,300	366,000
3.14.1	Additional pharmaceutical forms and strengths [4)]	92,400	91,300
3.15	PSUR assessment - one fee per PSUR [4) 7)]	478,900	334,600
4	**Other changes**	**Human ISK**	**Veterinary ISK**
4.1	Variation Type II, Change in legal status (prescription/non-prescription) [5)]	274,900	274,900
4.2	Transfer to CTD format, without any substantial changes [5)]	14,400	
4.3	Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number [5)]	36,500	36,500

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)]	16,600	15,500
4.5	Withdrawal of a marketing authorisation - one fee per product [5)]	16,600	15,500
4.6	Deletion from the Icelandic Drug Catalogue and the Price List - one fee per request and product name [5)]	17,200	16,100
4.7	RMS transfer to IMA[6)] One fee for each marketing authorisation number.	222,300	
4.8	Corrections/improvements of texts. One fee per request.	17,200	17,200
4.9	IMA as lead RMS. IMA takes on the lead in variation for a group of marketing authorisations in different member states.	21,000	
5	**Authorisation to place a product on the market cf. Article 126(a) of Directive 2001/83/EC [2)]**	**Human ISK**	
5.1	Application to place a product on the market cf. article 6 in Regulation (EC) No. 545/2018, cf. article 126(a) of Directive 2001/83/EC[2)]	402,000	
5.1.1	Additional pharmaceutical forms and strengths	67,400	
5.2	Variation, Type IA_{IN} and IA	21,000	
5.3	Variation, Type IB	41,500	
5.4	Variation, Type II; change in therapeutic indication	80,200	
5.5	Variation, Type II; change in posology	80,200	
5.6	Other variation, Type II	67,500	
5.7	Article 61(3) changes in Labelling/PIL (one fee per Labelling/PIL) [2)]	53,900	
5.8	Renewal	174,800	
5.8.1	Additional pharmaceutical forms and strengths	41,500	
6	**Parallel import**	**Human ISK**	**Veterinary ISK**
6,1	Parallel import (one country of origin)	214,600	186,300
6.1.1	Additional pharmaceutical forms and strengths applied at the same time	38,100	33,700
6.2	Changes to the criteria for authorisation	44,800	41,400
6.3	Renewal	210,700	184,200
6.3.1	Additional pharmaceutical forms and strengths	38,700	33,800
6.4	Article 61(3) changes[2)] in Labelling/PIL (one fee per Labelling/PIL)	50,900	50,900

7	**Traditional herbal medicines**	**Human ISK**	
7.1	With monograph	1,805,100	
7.2	Without monograph	2,279,200	
7.3	Additional application (duplicate) applied at the same time.	647,600	
7.4	Application for MRP, with or without monograph – all forms, strengths and routes of administration applied at the same time – CMS	254,900	
7.5	Renewal – all pharmaceutical forms, strengths and routes of administration – national and RMS	532,000	
7.6	Renewal – one fee for all pharmaceutical forms and strengths– CMS	67,469	
7.7	Transfer of a marketing authorisation to a new marketing authorisation holder - one fee for each marketing authorisation number	38,200	
8	**Homeopathic preparations**	**Human ISK**	**Veterinary ISK**
8.1	Application for registration for Homeopathic preparations when Iceland is RMS and National	334,000	331,000
8.2	Application for registration for Homeopathic preparations when Iceland is CMS	27,100	21,000
8.3	Application for a homeopathic product which has been granted a marketing authorisation within the European Economic Area	17,100	16,000
8.4	Annual fee (all variations IA/IB and II) for RMS/national registration and CMS	14,400	14,400
8.5	Annual fee (DCP and MRP)	3,300	3,300
9	**Classification of product**	**Human ISK**	**Veterinary ISK**
9.1	Classification to decide if a product is covered by the Pharmaceutical Act No. 100/2020	102,300	102,300
10	**Clinical trials**	**Human ISK**	**Veterinary ISK**
10.1	Application for authorisation for clinical trial	569,600	569,600
10.2	Substantial amendments	132,200	132,200
10.3	Application for authorisation for bioavailability study	94,500	94,500
11	**Certificates**	**Human ISK**	**Veterinary ISK**
11.1	Certificate of exemption for exempted medicinal product	25,400	25,400
11.2	Certificate of a Pharmaceutical Product (CPP)	25,400	25,400
11.3	GXP certificate	16,600	16,600
11.4	Statement of Licensing Status of Pharmaceutical Products (FSC)	15,500	15,500

11.5	Expedite issue	8,800	8,800
11.6	Accelerated delivery fee	11,600	11,600
12	**Issuing of certicficates for operations that require licencing in accordance with the Medicinal Products Act No. 100/2020**	**Human ISK**	**Veterinary ISK**
12.1	One licence	14,400	14,400
13	**Licences and exemptions according to Act No. 65/1974 on narcotic and psychotropic substances**	**Human ISK**	**Veterinary ISK**
13.1	One licence	14,400	14,400
13.2	Expedite issue	5,500	5,500
14	**Hourly based fee**	**Human ISK**	**Veterinary ISK**
14.1	Expert advice. Fee per hour	21,000	21,000
15	**Inspection Unit – hourly fee**	**Human ISK**	**Veterinary ISK**
15.1	Specialist.	19,400	19,400
15.2	Service agent.	14,900	14,900
16	**Annual fees**	**Human ISK**	**Veterinary ISK**
16.1	Annual fee for each marketing authorisation number - all processes	41,500	27,100

1) Annex I to Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.
2) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
3) When Iceland is acting as RMS for products previously approved nationally (cf. the part of Annex 1 pertaining to purely 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 an 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.