STATUTORY INSTRUMENTS.

S.I. No. 679 of 2022

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2022

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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by sections 13 and 32 (as amended by sections 15 and 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995), hereby make the following regulations:

1. These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2022.

2. In these Regulations—

"Act of 1995" means the Irish Medicines Board Act 1995 (No. 29 of 1995);

"Act of 2006" means the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006);

"active substances register" has the meaning assigned to it by Regulation 3(1) (inserted by Regulation 3(a) of the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 (S.I. No. 163 of 2013)) of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

"authorised representative" means a person established within the European Economic Area who, explicitly designated by the manufacturer, acts for the manufacturer and may be addressed by authorities and bodies in the European Economic Area instead of the manufacturer with respect to the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994), the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. No. 253 of 2004), or the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), or has the meaning assigned to it by—

(a) Article 2(32) of the Medical Devices Regulation, or

(b) Article 2(25) of the IVD Medical Devices Regulation,

as applicable;

"Authority" means the Health Products Regulatory Authority;

"breeder authorisation" has the meaning assigned to it by Regulation 3(1) of the Protection of Animals Regulations;

"broker" means a person carrying out the brokering of medicinal products, as defined in Regulation 4(1) (as amended by Regulation 3(a)

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 20*th December*, 2022.

of the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013 (S.I. No. 164 of 2013)) of the Control of Wholesale Distribution Regulations;

"brokers register" has the meaning assigned to it by Regulation 4(1) (as amended by Regulation 3(a) of the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013) of the Control of Wholesale Distribution Regulations;

"certificate of free sale" means –

(a) a certificate of free sale issued under section 4(1)(k)(ii) (as amended by section 11(a)(iii) of the Act of 2006) of the Act of 1995,

(b) a certificate of free sale issued under Article 60 of the Medical Devices Regulation, or

(c) a certificate of free sale issued under Article 55 of the IVD Medical Devices Regulation;

"certificate of registration" has the meaning assigned to it by Regulation 3(1) of the Control of Placing on the Market Regulations;

"certificate of traditional-use registration" has the meaning assigned to it by Regulation 3(1) of the Control of Placing on the Market Regulations;

"certification of documents" means the certification, under section 4(1)(k)(ii) (as amended by section 11(a)(iii) of the Act of 2006) of the Act of 1995, of documents not being certificates of free sale or export certificates;

"complex dossier" refers to an application accompanied by a full dossier in accordance with Directive 2001/83/EC;

"Control of Placing on the Market Regulations" means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

"Control of Wholesale Distribution Regulations" means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007);

"decentralised procedure" means the decentralised procedure for human medicinal products provided for in Directive 2001/83/EC;

"device" means –

(a) a medical device,

(b) an accessory for a medical device,

(c) a product listed in Annex XVI to the Medical Devices Regulation, provided that the Medical Devices Regulation applies to such product pursuant to Article 1(2) thereof,

(d) an *in vitro* diagnostic medical device, or

(e) an accessory for an *in vitro* diagnostic medical device,

but does not include-

(i) a product or other substance excluded by Article 1(6)(b) to (i) of the Medical Devices Regulation,

(ii) a product or other substance excluded from the scope of the IVD Medical Devices Regulation by Article 1(3) thereof,

(iii) a device referred to in the second subparagraph of Article 1(8), (9) or (10) of the Medical Devices Regulation, or

(iv) an in-house device;

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[1];

"distributor", in the context of devices, means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

"export certificate" means an export certificate issued under section 4(1)(k)(ii) (as amended by section 11(a)(iii) of the Act of 2006) of the Act of 1995;

"European Union Reference Laboratory" means a laboratory designated under Article 100 of the IVD Medical Devices Regulation.

"follow-up inspections" means inspections other than routine inspections;

"homeopathic medicinal product" has the meaning assigned to it by Regulation 3(1) of the Control of Placing on the Market Regulations;

"importer", in the context of devices, means any natural or legal person established within the European Economic Area that places a device from a third country on the market in the European Economic Area;

"individual authorisation" means an authorisation granted to an individual under Part 8 of the Protection of Animals Regulations;

"investigational medicinal product" has the meaning assigned to it by Regulation 3(1) of the Medicinal Products (Control of Manufacture) Regulations 2007;

"*in vitro* diagnostic medical device" has the meaning assigned to it by—

(a) Article 2(2) of the IVD Medical Devices Regulation, or

(b) Regulation 2(1) of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001),

as applicable;

[1] OJ No. L 311, 28.11.2001, p. 67.

"IVD Medical Devices Regulation" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2] as amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022;

"listed organisation" has the meaning assigned to it by Regulation 4(1) (as amended by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 (S.I. No. 81 of 2021)) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

"manufacturer", in the context of devices, means a person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his or her own name, but not including a person which assembles or adapts devices already on the market to their intended purpose for an individual patient, or has the meaning assigned to it by—

(a) Regulation 2(1) of the European Communities (Medical Devices) Regulations 1994,

(b) Regulation 2(1) of the European Communities (Active Implantable Medical Devices) Regulations 1994,

(c) by Regulation 2(1) of the European Communities (*In vitro* Diagnostic Medical Devices) Regulations 2001,

(d) Article 2(30) of the Medical Devices Regulation, or

(e) Article 2(23) of the IVD Medical Devices Regulation,

as applicable;

"manufacturer's authorisation" has the meaning assigned to it by Regulation 3(1) of the Medicinal Products (Control of Manufacture) Regulations 2007;

"manufacturing facility", in the context of devices, means a place where an entity, which does not place devices on the market under its own name or under its own trademark—

(a) manufactures a device,

(b) manufactures one or more critical components of a device to a set of specifications,

(c) carries out packaging activities in relation to a device, or

(d) carries out labelling activities in relation to a device;

"marketing authorisation" means a marketing authorisation granted pursuant to the Control of Placing on the Market Regulations;

"medical device" has the meaning—

[2] OJ No. L 117, 5.5.2017, p. 176.

(a) assigned to it by Article 2(1) of the Medical Devices Regulation,

(b) assigned to it by Article 2(2) of the IVD Medical Devices Regulation,

(c) assigned to the term "device" by Regulation 2(1) of the European Communities (Medical Devices) Regulations 1994, or

(d) assigned to the term "device" by Regulation 2(1) of the European Communities (Active Implantable Medical Devices) Regulations 1994,

as applicable;

"Medical Devices Regulation" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[3], as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020[4]

"mutual recognition procedure" means the mutual recognition procedure for human medicinal products provided for in Directive 2001/83/EC;

"national rules scheme" means the national rules governing the granting of marketing authorisation in respect of homeopathic medicinal products, as provided in Regulation 11 of the Control of Placing on the Market Regulations;

"notified body" means, in relation to any task, a body designated and notified in respect of that task in accordance with the European Communities (Medical Devices) Regulations 1994, the European Communities (Active Implantable Medical Devices) Regulations 1994, or the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001, or has the meaning assigned to it by—

(a) Article 2(42) of the Medical Devices Regulation, or

(b) Article 2(34) of the IVD Medical Devices Regulation,

as applicable;

"organ establishment authorisation" means an authorisation granted pursuant to Regulation 6 of the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012);

"parallel import licence" has the meaning assigned to it by Regulation 3(1) of the Control of Placing on the Market Regulations;

"project" and "project authorisation" have the meanings assigned to them by Regulation 3(1) of the Protection of Animals Regulations;

"Protection of Animals Regulations" means the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (S.I. No. 543 of 2012);

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[3] OJ No. L 117, 5.5.2017, p. 1.
[4] OJ No. L 130, 24.4.2020, p. 18.

"reduced dossier – complex" refers to an application for a generic medicinal product accompanied by a reduced dossier but containing additional data in circumstances required by Directive 2001/83/EC;

"reduced dossier – standard" refers to an application for a generic medicinal product accompanied by a reduced dossier in accordance with Directive 2001/83/EC;

"service item" means an application for a medicinal product designated by the Authority as qualifying for a reduced application fee on the basis that the product has limited but important uses for which no alternative authorised product exists;

"subsequent extension applications" means applications in relation to additional pharmaceutical forms and strengths of a medicinal product, made subsequent to the first application in relation to that product;

"supplier authorisation" has the meaning assigned to it by Regulation 3(1) of the Protection of Animals Regulations;

"system or procedure pack producer" means a natural or legal person referred to in—

(a) Article 22(1), (2) or (3) of the Medical Devices Regulation, or

(b) Article 12 of Council Directive 93/42/EEC of 14th June 1993[5],

as applicable;

"switching applications" means applications for a change in the classification of medicinal products under Title VI of Directive 2001/83/EC;

"traditional herbal medicinal product" has the meaning assigned to it by Regulation 3(1) of the Control of Placing on the Market Regulations;

"type IA variation", "type IB variation" and "type II standard variation" refer to classifications by the Authority in accordance with Commission Regulation (EC) No. 1234/2008 of 24 November 2008[6];

"user authorisation" has the meaning assigned to it by Regulation 3(1) of the Protection of Animals Regulations;

"wholesaler's authorisation" has the meaning assigned to it by Regulation 4(1) of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007.

3. Subject to Regulation 4, there shall be paid to the Authority in respect of each and every matter set out in column 1 of the Schedule the corresponding fee set out in column 2 of the Schedule.

[5] OJ No. L 169, 12.7.1993, p. 1.
[6] OJ No. L 334, 12.12.2008, p. 7.

4. The Authority may, in circumstances where it considers it appropriate to do so, waive, remit or refund, either in whole or in part, any fee that would otherwise be payable to it under Regulation 3.

5. The Health Products Regulatory Authority (Fees) Regulations 2021 (S.I. No. 744 of 2021) are revoked.

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for national applications for marketing authorisations	**€**
Complex dossier	
National application	22,235
Each additional form (same time)	7,785
Each additional strength (same time)	1,110
Additional drug master file submitted	4,445
Reduced dossier – complex	
National application	16,675
Each additional form (same time)	7,785
Each additional strength (same time)	1,110
Additional drug master file submitted	4,445
Reduced dossier – standard	
National application	11,120
Each additional form (same time)	7,785
Each additional strength (same time)	1,110
Additional drug master file submitted	4,445
Subsequent extension applications	
First additional form	11,120
Each additional form (same time)	7,785
First additional strength (existing form)	3,335
Each additional strength (same time)	1,110
Additional drug master file submitted	4,445
Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure	
Complex dossier	
Mutual recognition incoming	15,565
Each additional form (same time)	5,560
Each additional strength (same time)	1,110

Outgoing mutual recognition supplement	16,675
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	16,675
Decentralised incoming	22,235
Decentralised outgoing	55,590
Each additional form (same time)	7,785
Each additional strength (same time)	1,110
Additional supplement where there are 15 or more concerned Member States	1,670
Reduced dossier – complex	
Mutual recognition incoming	11,120
Each additional form (same time)	5,560
Each additional strength (same time)	1,110
Outgoing mutual recognition supplement	16,675
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	11,120
Decentralised incoming	16,675
Decentralised outgoing	44,470
Each additional form (same time)	7,785
Each additional strength (same time)	1,110
Additional supplement where there are 15 or more concerned Member States	1,670
Reduced dossier – standard	
Mutual recognition incoming	7,785
Each additional form (same time)	4,445
Each additional strength (same time)	1,110
Outgoing mutual recognition supplement	11,120
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	6,670
Decentralised incoming	11,120
Decentralised outgoing	28,905
Each additional form (same time)	7,785
Each additional strength (same time)	1,110

Additional supplement where there are 15 or more concerned Member States	1,670
Subsequent extension applications	
Mutual recognition incoming (first additional form)	7,785
Mutual recognition incoming (first additional strength)	2,225
Mutual recognition incoming (subsequent additional strength)	1,110
Outgoing mutual recognition/decentralised supplement (additional form)	3,335
Outgoing mutual recognition/decentralised supplement (additional strength)	1,110
Decentralised incoming (first additional form)	11,120
Decentralised outgoing (first additional form)	28,905
Each additional form (same time)	7,785
First additional strength (existing form)	3,335
Each additional strength (same time)	1,110
Additional supplement where there are 15 or more concerned Member States	1,670
Switching applications	
Switching applications	5,670

Fees for parallel import licences

Application fee - per country at the same time or by variation	2,040
Each additional strength per country	605
Each additional form per country	605
Parallel imports - dual pack registration	1,020
Dual pack registration of parallel imports - each additional strength or form	605
Parallel imports where the originator is not on the Irish market	6,125
Change of ownership per product range	645

Fees for variations to national marketing authorisations

Type IB variation	570
Type IB variation - reduced rate	290
Type II complex variation	3,185
Type II complex variation – reduced rate	620
Type II standard variation	620
Type II standard variation - reduced rate	310
Notifications under Article 61(3) of Directive 2001/83/ EC	305
Notifications under Article 61(3) of Directive 2001/83/EC - reduced rate	155
Multiple variations capped fee (per product range)	5,880
Multiple variations capped fee (per product)	3,800
Worksharing capped fee	6,370

Fees for variations to marketing authorisations under mutual recognition procedure and decentralised procedure

Type IA variation outgoing mutual recognition / decentralised supplement	305
Type IB variation outgoing mutual recognition / decentralised supplement	425
Type IB variation - mutual recognition incoming	415
Type IB variation - mutual recognition incoming - reduced rate	215
Type II complex variation - outgoing mutual recognition / decentralised	645
Supplement	
Type II complex variation - mutual recognition incoming	2,200
Type II complex variation – mutual recognition incoming – reduced rate	415
Type II standard variation - mutual recognition incoming	415
Type II standard variation - mutual recognition incoming - reduced rate	215
Type II standard variation - outgoing mutual recognition / decentralised	415

Supplement

Notifications made under Article 61(3) of Directive 2001/83/EC	305
Notifications made under Article 61(3) of Directive 2001/83/EC – reduced rate	155

Fees for the granting of a marketing authorisation on transfer to another company

Change of ownership - related company – 1st marketing authorisation within a range	1,100
Change of ownership - related company – each additional marketing authorisation within a range	390
Change of ownership - non-related company – 1st marketing authorisation within a range	1,615
Change of ownership - non-related company – each additional marketing authorisation within a range	390

Other fees relating to the granting of marketing authorisations

Service item	745

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	680
Variation to authorisation - minor site technical	490
Variation to authorisation – administrative	265
Variation to authorisation – technical	735

Fees for applications for manufacturer's authorisations

Application fee	2,265
Variation to authorisation – administrative	340
Variation to authorisation – technical	945
Variation to authorisation – fast track	1,335

Fees for applications in relation to brokers register and active substances register

Registration fee – importers and distributors of active substances and brokers	305
Registration fee – manufacturers of active substances	540
Immediate notification of a change which may impact on the quality or safety of the active substances	945
Notification of an administrative change to the active substances register	170
Notification of any change to the brokers register	170

Fees for applications for organ establishment authorisations

Application charge	2,265
Variation to authorisation – administrative	340
Variation to authorisation – technical	945
Appeal to amend/revoke an authorisation	610
Scientific opinion on the non-viability of the cells/tissue, donation, procurement testing	3,270

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation	
Related company	1,355
Unrelated company	2,265
Wholesaler's authorisation, registration on brokers register and registration on active substances register	
Related company	445
Unrelated company	680

Fees for applications in relation to cosmetic products

Certificates of free sale – standard (4 certificates per request)	180
Certificates of free sale – fast track (4 certificates per request)	340
Duplicate certificates of free sale – each (available at time of initial request)	25

Fees for applications in relation to homeopathic medicinal products

New national / decentralised registration standard charge - single stock	830
New national / decentralised registration standard charge - 2 or more stocks	1,245
New application - national rules scheme standard fee - single stock	1,245
New application - national rules scheme standard fee - 2 or more stocks	1,835
Mutual recognition incoming application standard fee - single stock	555
Mutual recognition incoming application standard fee - 2 or more stocks	830
Outgoing mutual recognition / decentralised supplement	690
National variation – registration and national rules scheme	415
National variation – reduced rate – registrations and national rules scheme	205

Mutual recognition incoming variation	280
Mutual recognition incoming variation - reduced rate	135
Variation – outgoing mutual recognition / decentralised supplement	205
Bulk variation for multiple changes to the Masterfile	2,495

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	5,990
National application where there is a monograph	3,675
Each additional form (same time)	4,985
Each additional strength (same time)	645
Additional drug master file submitted	3,985

Extension applications

First additional form	5,990
Each additional form (same time)	4,985
First additional strength	2,705
Each additional strength (same time)	645

Applications for certificates of traditional-use registration under mutual recognition procedure and decentralised procedure

Mutual recognition incoming	4,185
Mutual recognition incoming - each additional form (same time)	2,800
Mutual recognition incoming - each additional strength (same time)	645
Outgoing mutual recognition / decentralised supplement	5,445
Decentralised outgoing/incoming	5,990
Each additional form (same time)	4,985
Each additional strength (same time)	645

Traditional herbal medicinal products – national variations	
Type IB variation – national	460
Type IB variation – reduced rate	235
Type II standard variation	490
Type II standard variation – reduced rate	245
Type II complex variation	2,570
Bulk variation for multiple changes	5,145

Traditional herbal medicinal products – mutual recognition variations	
Type IB variation – mutual recognition incoming	330
Type IB variation – mutual recognition incoming - reduced rate	170
Type IB variation – outgoing mutual recognition supplement	340
Type II standard – mutual recognition incoming	330
Type II standard – mutual recognition incoming - reduced rate	170
Type II standard – outgoing mutual recognition supplement	330
Type II complex – mutual recognition incoming	1,760
Type II complex – outgoing mutual recognition supplement	510

Fees for export certificates and certification of documents	
Standard	180
Fast track	340
Annual maintenance fees	
Marketing authorisations and registrations	
First 10 marketing authorisations	795
Additional marketing authorisation	990
Dormant marketing authorisation	463
Parallel import licence	135
Parallel import licence - Dual pack	65
Certificate of registration - homeopathic medicinal products	65
Certificate of traditional-use registration - traditional herbal medicinal products	135
Manufacturer's authorisations	

Major site (more than 250 employees)	23,980
Large site (150-250 employees)	16,350
Medium site (50-149 employees)	10,900
Small site (less than 50 employees)	4,905
Homeopathic manufacturing site	1,225

Wholesaler's authorisations

Large full line	3,395
Medium full line / short line	1,930
Small short line	735
Minor site / Procure & supply	490

Active substances register

Active substances distributor	305
Active substances importer	610
Active substances manufacturer	1,225

Organ establishment authorisations

Major establishment (more than 250 employees)	20,415
Large establishment (150-250 employees)	13,610
Medium establishment (50-149 employees)	9,075
Small establishment (less than 50 employees)	4,535
Minor establishment (less than 5 employees)	1,225

Fees in relation to protection of animals used for scientific purposes

Project fees

Project application without ethical approval	2,270
Fast track project application	2,100

Breeder/Supplier/User Authorisation fees	
Band 1: Small establishment with no animal facilities or establishment with 1-3 individual authorisation holders	330
Band 2: Establishment with 4-10 individual authorisation holders	655
Band 3: Establishment with 11-20 individual authorisation holders	1,005
Band 4: Establishment with 21-40 individual authorisation holders	1,900
Band 5: Establishment with 41-70 individual authorisation holders	2,890
Band 6: Establishment with 71-100 individual authorisation holders	3,860
Band 7: Establishment with 101-150 individual authorisation holders	6,530
Band 8: Establishment with 151 – 200 individual authorisation holders	9,500
Band 9: Establishment with >201 individual authorisation holders	12,470
Individual authorisation fees	
Application fee	315
Annual fee	315
Once-off authorisation - procedural training for a period of two months or less (reduced fee)	110
Fees for follow-up inspections	
Per day (per member of the inspection team)	1,825
Part of day (per hour, per member of the inspection team)	260
Inspection/Audit fees (other than inspections in relation to the protection of animals used for scientific purposes)	
Per day (per member of the inspection team)	1,825
Part of day (per hour, per member of the inspection team)	260
Inspection cancellation/rescheduling fee	500

Enforcement fees

Manufacturers

Major site (more than 250 employees)	2,940
Large site (150-250 employees)	2,205
Medium site (50-149 employees)	735
Small site (less than 50 employees)	245

Wholesalers

Large full line	735
Medium full line / short line	245

Marketing authorisation / parallel import licence holders

> 50 marketing authorisations / parallel import licences	3,860
31-50 marketing authorisations / parallel import licences	1,225
16-30 marketing authorisations / parallel import licences	735
6-15 marketing authorisations / parallel import licences	245

(Note: Companies classed as both manufacturer and wholesaler are charged the higher of the two applicable charges. Marketing authorisation holders pay the marketing authorisation holder fee in addition to any manufacturer's authorisation / wholesaler's authorisation fee.)

Fees in relation to devices

Manufacturer or system and procedure pack producer or manufacturing facility located in Ireland – annual fees

Manufacturer or system and procedure pack producer or manufacturing facility - with more than 150 employees	30,600
Manufacturer or system and procedure pack producer or manufacturing facility - with 100-150 employees	20,400
Manufacturer or system and procedure pack producer or manufacturing facility - with 50-99 employees	15,300

Manufacturer or system and procedure pack producer or manufacturing facility - with 16-49 employees	5,100
Manufacturer or system and procedure pack producer or manufacturing facility - with 5-15 employees	1,275
Manufacturer or system and procedure pack producer or manufacturing facility - with less than 5 employees or annual turnover of less than €500,000	250

Authorised Representatives – annual fees

Type I Authorised Representative – representing a non-EU manufacturer that manufactures low risk* devices (fee per manufacturer)	1,100
Type II Authorised Representative – representing a non-EU manufacturer that manufactures high risk** devices or a mix of high risk** & low risk* devices (fee per manufacturer)	1,500
Cap on type I Authorised Representative	5,500
Cap on type II Authorised Representative	7,500

(Note: * low risk devices means Class I general medical devices (as described in Council Directive 93/42/EEC of 14 June 1993[6] ('MDD') / the Medical Devices Regulation ('MDR')) and/or general category IVDs (as described in Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[2] ('IVDD')) / Class A (as described in the IVD Medical Devices Regulation ('IVDR').)

(Note: ** high risk devices means Class IIa, IIb, III general medicinal devices (as described in MDD/MDR), active implantable medicinal devices, self-test IVD, Annex II IVD (as described in IVDD) or Class B, C and D (as described in IVDR).)

Distributors and Importers – annual fees

Large distributor/importer (turnover greater than €15 million)	4,590
Medium distributor/importer (turnover €3-€15 million)	2,550

Small distributor/importer (turnover under €3 million)	1,275
Distributor/importer turnover less than €500,000	250
Additional supplement – Entities acting as both a distributor and importer where turnover is more than €3 million	1,000
Notified Body – annual fees	5,100
Summary evaluation review fees	
Devices using starting materials for which a TSE certificate of suitability has been submitted	2,500
Devices using starting materials for which a TSE certificate of suitability has not been submitted	5,000
European Union Reference Laboratories	
European Union Reference Laboratory (EURL) Application Verification	2,700
Certificates of free sale or letters confirming the location of the manufacturing facility in Ireland for Devices	
Certificate of free sale/letter confirming the location of the manufacturing facility in Ireland (4 certificates per request)	255
Each additional certificate of free sale/letter confirming the location of the manufacturing facility in Ireland – (available at time of request)	25
Letter confirming that a device or a list of devices are registered with the HPRA	120
Registration of Devices	
Online Registration – Administration fee	140
Clinical Investigations and IVDR performance studies	
Class III and Class IIb medical devices, including relevant MDR Annex XVI clinical investigations	4,300
Class IIa and Class I devices, including relevant MDR Annex	1,900

XVI clinical investigations	
Notifications and substantial modifications to notifications in accordance with MDR article 74(1), Article 82, IVDR Article 58(2) and IVDR Article 70(1)	200
Application for authorisation of in vitro diagnostic medical device (IVD) performance study under IVDR Article 58(1) (first submission) and PMPF study under IVDR Article 70(2)	2,500
Notification of Performance study involving Companion Diagnostic IVD using left over samples (IVDR Article 58(2))	265
Substantial modifications and technical amendment to a previously approved clinical investigation/performance study	1,240
Resubmission of a clinical investigation/performance study following a withdrawal or objection or if the application has lapsed	1,900
Resubmission of a clinical investigation/performance study - Academic Sponsor	510

Determination of classification within the medical devices regulations

Determination not requiring a complex technical review (one device per request)	280
Complex classification requests	1,020
Arbitration Fee	5,000
Appeal of a classification opinion	600

Designation Fee for a Notified Body

Initial designation of a notified body and to the re-assessment of the notified body under the new Device Regulations 745 and 746 of 2017	10,200
Extensions to the scope (per extension)	5,100

Medicinal Product / Medical Device - Drug Consultation Fees

New active substance	48,030
Established active in new therapeutic area	12,005

Established active and therapeutic area	6,965
Variations - Minor	1,010
Variations - Major	4,535

Assessments under Article 59 of the MDR and Article 54 of the IVDR

Assessment fee	4,000

Miscellaneous - Medical Devices

Search fee of medical devices data base	65
Daily charge-out rate for Technical Services	1,675
Hourly charge-out rate for Technical Services	265
Hourly charge-out rate for Administrative Services	80

Fees in relation to clinical trials under European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004)

Request for authorisation under Regulation 14 – Phase I, II, III or IV clinical trials

Investigational medicinal product containing an established active substance	605
Investigational medicinal product containing a new active substance	1,620

Amendment to authorisation under Regulation 21

Notice of amendment	410
Notice of amendment to include a new investigational medicinal product dossier	880

Fees in relation to clinical trials under European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (S.I. No. 99 of 2022)

Applications with an investigational medicinal product dossier

Mono National	3,420
Ireland – Reporting Member State	8,700

Ireland - Concerned Member State, initial, transitional or additional applications	3,200
Supplement – Where Ireland subsequently becomes the Reporting Member State	5,280
Reporting Member State – 2nd & subsequent waves	1,000
Non Commercial/Academic Trials	300

Applications with no investigational medicinal product dossier or with a simplified investigational medicinal product dossier

Mono National	2,405
Ireland – Reporting Member State	7,500
Ireland - Concerned Member State, initial, transitional or additional applications	2,135
Supplement – Where Ireland subsequently becomes the Reporting Member State	5,095
Reporting Member State – 2nd & subsequent waves	1,000
Non Commercial/Academic Trials	300

Substantial Modifications (Parts I & II or Part I only) – with the addition of a new investigational medicinal product dossier

Mono National	1,380
Ireland – Reporting Member State	1,600
Ireland - Concerned Member State	1,325
Non Commercial/Academic Trials	100

Substantial Modifications – other

Mono National	910
Ireland – Reporting Member State	1,210
Ireland- Concerned Member State	830
Non Commercial/Academic Trials	100

Substantial Modifications – Part II only

Substantial Modification	400
Non Commercial/Academic Trials	50

Fees for Appeals

Appeal of clinical trial decision – Commercial	1,200
Appeal of clinical trial decision – Non-commercial	100

Fees for Safety Reports

Review of Annual Safety reports/ Drug safety update reports	220
Review of drug safety update reports where Ireland is the lead member state under a work sharing procedure or Safety assessment member state (saMS)	1,125

Fees for Inspections

per day (per member of the inspection team)	1,825
per hour (per member of the inspection team)	260

Fees for applications in relation to Exemptions under Article 61(5) of Regulation (EU) No. 536/2014 of the European Parliament and of the Council[7]

Registration fee	280
Amendment to registered details	155

L.S.

GIVEN under my Official Seal,
15 December, 2022.

STEPHEN DONNELLY,
Minister for Health.

[7] OJ No. L 158, 27.5.2014, p. 1.

EXPLANATORY NOTE

(*This note is not part of the instrument and does not purport to be a legal instrument*.)

The purpose of these Regulations is to provide for the revision of fees payable to the Health Products Regulatory Authority (formerly the Irish Medicines Board) pursuant to Section 13 of the Irish Medicines Board Act 1995.

These Regulations revoke the Health Products Regulatory Authority (Fees) Regulations 2021 (S.I. No. 744 of 2021).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2022.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

Teil: 046 942 3100
r-phost: publications@opw.ie

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