STATUTORY INSTRUMENTS.

S.I. No. 697 of 2023

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2023

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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 2023.

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)

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

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 26*th December,* 2023.

"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) (as amended by Regulation 4(g) of the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022 (S.I. No. 43 of 2022)) 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;

"IVD Medical Devices Regulation" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2];

"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);

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[1] OJ No. L 311, 28.11.2001, p. 67.
[2] OJ No. L 117, 5.5.2017, p. 176.

"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—

(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];

[3] OJ No. L 117, 5.5.2017, p. 1.

"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);

"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[4], 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[5];

"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.

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 2022 (S.I. No. 679 of 2022) are revoked.

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

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for national applications for marketing authorisations	**€**
Complex dossier	
National application	22,570
Each additional form (same time)	7,900
Each additional strength (same time)	1,125
Additional drug master file submitted	4,510
Reduced dossier – complex	
National application	16,925
Each additional form (same time)	7,900
Each additional strength (same time)	1,125
Additional drug master file submitted	4,510
Reduced dossier – standard	
National application	11,285
Each additional form (same time)	7,900
Each additional strength (same time)	1,125
Additional drug master file submitted	4,510
Subsequent extension applications	
First additional form	11,285
Each additional form (same time)	7,900
First additional strength (existing form)	3,385
Each additional strength (same time)	1,125
Additional drug master file submitted	4,510

Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure

Complex dossier

Mutual recognition incoming	15,800
Each additional form (same time)	5,645
Each additional strength (same time)	1,125
Outgoing mutual recognition supplement	16,925
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	16,925
Decentralised incoming	22,570
Decentralised outgoing	56,425
Each additional form (same time)	7,900
Each additional strength (same time)	1,125
Additional supplement where there are 15 or more concerned Member States	1,695

Reduced dossier – complex

Mutual recognition incoming	11,285
Each additional form (same time)	5,645
Each additional strength (same time)	1,125
Outgoing mutual recognition supplement	16,925
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	11,285
Decentralised incoming	16,925
Decentralised outgoing	45,135
Each additional form (same time)	7,900
Each additional strength (same time)	1,125

Additional supplement where there are 15 or more concerned Member States	1,695
Reduced dossier – standard	
Mutual recognition incoming	7,900
Each additional form (same time)	4,510
Each additional strength (same time)	1,125
Outgoing mutual recognition supplement	11,285
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	6,770
Decentralised incoming	11,285
Decentralised outgoing	29,340
Each additional form (same time)	7,900
Each additional strength (same time)	1,125

Additional supplement where there are 15 or more concerned Member States	1,695
Subsequent extension applications	
Mutual recognition incoming (first additional form)	7,900
Mutual recognition incoming (first additional strength)	2,260
Mutual recognition incoming (subsequent additional strength)	1,125
Outgoing mutual recognition/decentralised supplement (additional form)	3,385
Outgoing mutual recognition/decentralised supplement (additional strength)	1,125
Decentralised incoming (first additional form)	11,285
Decentralised outgoing (first additional form)	29,340
Each additional form (same time)	7,900
First additional strength (existing form)	3,385

Each additional strength (same time)	1,125
Additional supplement where there are 15 or more concerned Member States	1,695

Switching applications

Switching applications	5,755
Application fee - per country at the same time or by variation	2,070
Each additional strength per country	615
Each additional form per country	615
Parallel imports - dual pack registration	1,035
Dual pack registration of parallel imports - each additional strength or form	615
Parallel imports where the originator is not on the Irish market	6,215
Change of ownership per product range	655

Fees for variations to national marketing authorisations

Type IB variation	580
Type IB variation - reduced rate	295
Type II complex variation	3,235
Type II complex variation – reduced rate	630
Type II standard variation	630
Type II standard variation - reduced rate	315
Notifications under Article 61(3) of Directive 2001/83/ EC	310
Notifications under Article 61(3) of Directive 2001/83/EC - reduced rate	155
Multiple variations capped fee (per product range)	5,970

Multiple variations capped fee (per product)	3,855
Worksharing capped fee	6,465

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

Type IA variation outgoing mutual recognition / decentralised supplement	310
Type IB variation outgoing mutual recognition / decentralised supplement	430
Type IB variation - mutual recognition incoming	420
Type IB variation - mutual recognition incoming - reduced rate	220
Type II complex variation - outgoing mutual recognition / decentralised **Supplement**	655
Type II complex variation - mutual recognition incoming	2,235
Type II complex variation – mutual recognition incoming – reduced rate	420
Type II standard variation - mutual recognition incoming	420
Type II standard variation - mutual recognition incoming - reduced rate	220
Type II standard variation - outgoing mutual recognition / decentralized supplement	420
Notifications made under Article 61(3) of Directive 2001/83/EC	310
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	1,115

Change of ownership - related company – each additional marketing authorisation within a range	395
Change of ownership - non-related company – 1st marketing authorisation within a range	1,640
Change of ownership - non-related company – each additional marketing authorisation within a range	395

Other fees relating to the granting of marketing authorisations

Service item	755

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	690
Variation to authorisation - minor site technical	495
Variation to authorisation – administrative	270
Variation to authorisation – technical	745

Fees for applications for manufacturer's authorisations

Application fee	2,300
Variation to authorisation – administrative	345
Variation to authorisation – technical	960
Variation to authorisation – fast track	1,355

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

Registration fee – importers and distributors of active substances and brokers	310
Registration fee – manufacturers of active substances	550
Immediate notification of a change which may impact on the quality or safety of the active substances	960

Notification of an administrative change to the active substances register	175
Notification of any change to the brokers register	175

Fees for applications for organ establishment authorisations

Application charge	2,300
Variation to authorisation – administrative	345
Variation to authorisation – technical	960
Appeal to amend/revoke an authorisation	620
Scientific opinion on the non-viability of the cells/tissue, donation, procurement testing	3,320

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation	
Related company	1,375
Unrelated company	2,300
Wholesaler's authorisation, registration on brokers register and registration on active substances register	
Related company	450
Unrelated company	690
Certificates of free sale – standard (4 certificates per request)	185
Certificates of free sale – fast track (4 certificates per request)	345
Duplicate certificates of free sale – each (available at time of initial request)	25

New national / decentralised registration standard charge - single stock	840
New national / decentralised registration standard charge - 2 or more stocks	1,265
New application - national rules scheme standard fee - single stock	1,265
New application - national rules scheme standard fee - 2 or more stocks	1,865
Mutual recognition incoming application standard fee - single stock	565
Mutual recognition incoming application standard fee - 2 or more stocks	840
Outgoing mutual recognition / decentralised supplement	700
National variation – registration and national rules scheme	420
National variation – reduced rate – registrations and national rules scheme	210

Mutual recognition incoming variation	285
Mutual recognition incoming variation - reduced rate	135
Variation – outgoing mutual recognition / decentralised supplement	210
Bulk variation for multiple changes to the Masterfile	2,530

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	6,080
National application where there is a monograph	3,730
Each additional form (same time)	5,060
Each additional strength (same time)	655
Additional drug master file submitted	4,045

Extension applications

First additional form	6,080
Each additional form (same time)	5,060
First additional strength	2,745
Each additional strength (same time)	655

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

Mutual recognition incoming	4,250
Mutual recognition incoming - each additional form (same time)	2,840
Mutual recognition incoming - each additional strength (same time)	655
Outgoing mutual recognition / decentralised supplement	5,525
Decentralised outgoing/incoming	6,080
Each additional form (same time)	5,060
Each additional strength (same time)	655

Traditional herbal medicinal products – national variations

Type IB variation – national	465
Type IB variation – reduced rate	240
Type II standard variation	495
Type II standard variation – reduced rate	250
Type II complex variation	2,610
Bulk variation for multiple changes	5,220

Traditional herbal medicinal products – mutual recognition variations

Type IB variation – mutual recognition incoming	335
Type IB variation – mutual recognition incoming - reduced rate	175

Type IB variation – outgoing mutual recognition supplement	345
Type II standard – mutual recognition incoming	335
Type II standard – mutual recognition incoming - reduced rate	175
Type II standard – outgoing mutual recognition supplement	335
Type II complex – mutual recognition incoming	1,785
Type II complex – outgoing mutual recognition supplement	520

Fees for export certificates and certification of documents

Standard	185
Fast track	345

Annual maintenance fees

Marketing authorisations and registrations

First 10 marketing authorisations	805
Additional marketing authorisation	1,005
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)	24,340
Large site (150-250 employees)	16,595
Medium site (50-149 employees)	11,065
Small site (less than 50 employees)	4,980

Homeopathic manufacturing site	1,245

Wholesaler's authorisations

Large full line	3,445
Medium full line / short line	1,960
Small short line	745
Minor site / Procure & supply	495

Active substances register

Active substances distributor	310
Active substances importer	620
Active substances manufacturer	1,245

Organ establishment authorisations

Major establishment (more than 250 employees)	20,720
Large establishment (150-250 employees)	13,815
Medium establishment (50-149 employees)	9,210
Small establishment (less than 50 employees)	4,605
Minor establishment (less than 5 employees)	1,245

Fees in relation to protection of animals used for scientific purposes

Project authorisation fees

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

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	655

holders	
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	9,500
holders	
Band 9: Establishment with >200 individual authorisation holders	12,470

Individual authorisation fees

Application fee	320
Annual fee	320
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)	1,850
Part of day (per hour, per member of the inspection team)	265

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)	1,850
Part of day (per hour, per member of the inspection team)	265
Inspection cancellation/rescheduling fee	505

Enforcement fees

Manufacturers

Major site (more than 250 employees)	2,985
Large site (150-250 employees)	2,240
Medium site (50-149 employees)	745
Small site (less than 50 employees)	250

Wholesalers

Large full line	745
Medium full line / short line	250

Marketing authorisation / parallel import licence holders

> 50 marketing authorisations / parallel import licences	3,920
31-50 marketing authorisations / parallel import licences	1,245
16-30 marketing authorisations / parallel import licences	745
6-15 marketing authorisations / parallel import licences	250

(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	31,060
Manufacturer or system and procedure pack producer or manufacturing facility - with 100-150 employees	20,705
Manufacturer or system and procedure pack producer or manufacturing facility - with 50-99 employees	15,530

Manufacturer or system and procedure pack producer or manufacturing facility - with 16-49 employees	5,175
Manufacturer or system and procedure pack producer or manufacturing facility - with 5-15 employees	1,295
Manufacturer or system and procedure pack producer or manufacturing facility - with less than 5 employees or annual turnover of less than €500,000	255

Authorised Representatives – annual fees

Type I Authorised Representative – representing a non-EU manufacturer that manufactures low risk* devices (fee per manufacturer)	1,115
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)	1,520
Cap on type I Authorised Representative	5,575
Cap on type II Authorised Representative	7,600

(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)	4,660
Medium distributor/importer (turnover €3-€15 million)	2,590
Small distributor/importer (turnover under €3 million)	1,295

Distributor/importer turnover less than €500,000	255
Additional supplement – Entities acting as both a distributor and importer where turnover is more than €3 million	1,015
Notified Body – annual fees	5,175
Summary evaluation review fees	
Devices using starting materials for which a TSE certificate of suitability has been submitted	2,535
Devices using starting materials for which a TSE certificate of suitability has not been submitted	5,075
European Union Reference Laboratory (EURL) Application Verification	2,740
Certificate of free sale/letter confirming the location of the manufacturing facility in Ireland (4 certificates per request)	260
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	4,365
Class IIa and Class I devices, including relevant MDR Annex XVI clinical investigations	1,930
Notifications and substantial modifications to notifications in	205

accordance with MDR article 74(1), Article 82, IVDR Article 58(2) and IVDR Article 70(1)	
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)	2,535
Substantial modifications and technical amendment to a previously approved clinical investigation/performance study	1,260
Resubmission of a clinical investigation/performance study following a withdrawal or objection or if the application has lapsed	1,930
Resubmission of a clinical investigation/performance study - Academic Sponsor	520

Determination of classification within the medical devices regulations

Determination not requiring a complex technical review (one device per request)	285
Complex classification requests	1,035
MDR Article 51 / IVDR Article 47 referral	10,000
Appeal of a classification opinion	610

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	10,355
Extensions to the scope (per extension)	5,175

Medicinal Product / Medical Device - Drug Consultation Fees

New active substance	48,750
Established active in new therapeutic area	12,185
Established active and therapeutic area	7,070

Variations - Minor	1,025
Variations - Major	4,605

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

Assessment fee	4,060

Miscellaneous - Medical Devices

Search fee of medical devices data base	65
Daily charge-out rate for Technical Services	1,700
Hourly charge-out rate for Technical Services	270
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)

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

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

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

Substantial Modifications – other

Mono National	910
Ireland – Reporting Member State	1,210
Ireland- Concerned Member State	830

Substantial Modifications – Part II only

Substantial Modification	400

Fees for Appeals	
Appeal of clinical trial decision – Commercial	1,890
Fees for Safety Reports	
Review of Annual Safety reports/ Drug safety update reports	220
Fees for Inspections	
per day (per member of the inspection team)	1,850
per hour (per member of the inspection team)	265
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[6]	
Registration fee	285
Amendment to registered details	155

L.S.

GIVEN under my Official Seal,
21 December, 2023.

STEPHEN DONNELLY,
Minister for Health.

[6] 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 2022 (S.I. No. 679 of 2022).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2023.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
MOUNTSHANNON ROAD,
KILMAINHAM, DUBLIN 8,
D08 XAO6

Tel: 046 942 3100
E-mail: publications@opw.ie

ISBN 978-1-3993-2849-4

€ 6.50

(DH-514) 75. 12/23. Propylon.