STATUTORY INSTRUMENTS.

S.I. No. 751 of 2024

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2024

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The Minister for Health, in exercise of the powers conferred on him 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 2024.

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;

"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

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 7th January, 2025.

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);

"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

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

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) 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];

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

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

"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;

[4] OJ No. L 169, 12.7.1993, p. 1.

"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 2023 (S.I. No. 697 of 2023) are revoked.

[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	23,700
Each additional form (same time)	8,295
Each additional strength (same time)	1,180
Additional drug master file submitted	4,735
Reduced dossier – complex	
National application	17,770
Each additional form (same time)	8,295
Each additional strength (same time)	1,180
Additional drug master file submitted	4,735
Reduced dossier – standard	
National application	11,850
Each additional form (same time)	8,295
Each additional strength (same time)	1,180
Additional drug master file submitted	4,735
Subsequent extension applications	
First additional form	11,850
Each additional form (same time)	8,295
First additional strength (existing form)	3,555
Each additional strength (same time)	1,180
Additional drug master file submitted	4,735
Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure	
Complex dossier	
Mutual recognition incoming	16,590
Each additional form (same time)	5,925
Each additional strength (same time)	1,180

Outgoing mutual recognition supplement	17,770
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	17,770
Decentralised incoming	23,700
Decentralised outgoing	59,245
Each additional form (same time)	8,295
Each additional strength (same time)	1,180
Additional supplement where there are 15 or more concerned Member States	1,780
Reduced dossier – complex	
Mutual recognition incoming	11,850
Each additional form (same time)	5,925
Each additional strength (same time)	1,180
Outgoing mutual recognition supplement	17,770
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	11,850
Decentralised incoming	17,770
Decentralised outgoing	47,390
Each additional form (same time)	8,295
Each additional strength (same time)	1,180
Additional supplement where there are 15 or more concerned Member States	1,780
Reduced dossier – standard	
Mutual recognition incoming	8,295
Each additional form (same time)	4,735
Each additional strength (same time)	1,180
Outgoing mutual recognition supplement	11,850
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	7,110
Decentralised incoming	11,850
Decentralised outgoing	30,805
Each additional form (same time)	8,295
Each additional strength (same time)	1,180

Additional supplement where there are 15 or more concerned Member States	1,780
Subsequent extension applications	
Mutual recognition incoming (first additional form)	8,295
Mutual recognition incoming (first additional strength)	2,375
Mutual recognition incoming (subsequent additional strength)	1,180
Outgoing mutual recognition/decentralised supplement (additional form)	3,555
Outgoing mutual recognition/decentralised supplement (additional strength)	1,180
Decentralised incoming (first additional form)	11,850
Decentralised outgoing (first additional form)	30,805
Each additional form (same time)	8,295
First additional strength incoming (existing form)	3,555
First additional strength outgoing (existing form)	8,295
Each additional strength (same time)	1,180
Additional supplement where there are 15 or more concerned Member States	1,780
Switching applications	
Switching applications	6,045

Fees for parallel import licences

Application fee - per country at the same time or by variation	2,175
Each additional strength per country	645
Each additional form per country	645
Parallel imports - dual pack registration	1,085
Dual pack registration of parallel imports - each additional strength or form	645
Parallel imports where the originator is not on the Irish market	6,525
Change of ownership per product range	690

Fees for variations to national marketing authorisations

Type IB variation	610
Type IB variation - reduced rate	310
Type II complex variation	3,395
Type II complex variation – reduced rate	660
Type II standard variation	660
Type II standard variation - reduced rate	330
Notifications under Article 61(3) of Directive 2001/83/ EC	325
Notifications under Article 61(3) of Directive 2001/83/EC - reduced rate	165
Multiple variations capped fee (per product range)	6,270
Multiple variations capped fee (per product)	4,050
Worksharing capped fee	6,790

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

Type IA variation outgoing mutual recognition / decentralised supplement	325
Type IB variation outgoing mutual recognition / decentralised supplement	450
Type IB variation - mutual recognition incoming	440
Type IB variation - mutual recognition incoming - reduced rate	230
Type II complex variation - outgoing mutual recognition / decentralised supplement	690
Type II complex variation - mutual recognition incoming	2,345
Type II complex variation – mutual recognition incoming – reduced rate	440
Type II standard variation - mutual recognition incoming	440
Type II standard variation - mutual recognition incoming - reduced rate	230
Type II standard variation - outgoing mutual recognition / decentralised supplement	440

Notifications made under Article 61(3) of Directive 2001/83/EC	325
Notifications made under Article 61(3) of Directive 2001/83/EC – reduced rate	165

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

Change of ownership - related company – 1st marketing authorisation within a range	1,170
Change of ownership - related company – each additional marketing authorisation within a range	415
Change of ownership - non-related company – 1st marketing authorisation within a range	1,720
Change of ownership - non-related company – each additional marketing authorisation within a range	415

Other fees relating to the granting of marketing authorisations

Service item	795

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	725
Variation to authorisation - minor site technical	520
Variation to authorisation – administrative	285
Variation to authorisation – technical	780

Fees for applications for manufacturer's authorisations

Application fee	2,415
Variation to authorisation – administrative	360
Variation to authorisation – technical	1,010
Variation to authorisation – fast track	1,425

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

Registration fee – importers and distributors of active substances and brokers	325
Registration fee – manufacturers of active substances	580
Immediate notification of a change which may impact on the quality or safety of the active substances	1,010
Notification of an administrative change to the active substances register	185
Notification of any change to the brokers register	185

Fees for applications for organ establishment authorisations

Application charge	2,415
Variation to authorisation – administrative	360
Variation to authorisation – technical	1,010
Appeal to amend/revoke an authorisation	650
Scientific opinion on the non-viability of the cells/tissue, donation, procurement testing	3,485

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation	
Related company	1,445
Unrelated company	2,415
Wholesaler's authorisation, registration on brokers register and registration on active substances register	
Related company	475
Unrelated company	725

Fees for applications in relation to cosmetic products

Certificates of free sale – standard (4 certificates per request)	195
Certificates of free sale – fast track (4 certificates per request)	360
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	880
New national / decentralised registration standard charge - 2 or more stocks	1,330
New application - national rules scheme standard fee - single stock	1,330
New application - national rules scheme standard fee - 2 or more stocks	1,960
Mutual recognition incoming application standard fee - single stock	595
Mutual recognition incoming application standard fee - 2 or more stocks	880
Outgoing mutual recognition / decentralised supplement	735
National variation – registration and national rules scheme	440
National variation – reduced rate – registrations and national rules scheme	220

Mutual recognition incoming variation	300
Mutual recognition incoming variation - reduced rate	140
Variation – outgoing mutual recognition / decentralised supplement	220
Bulk variation for multiple changes to the Masterfile	2,655

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	6,385
National application where there is a monograph	3,915
Each additional form (same time)	5,315
Each additional strength (same time)	690
Additional drug master file submitted	4,245

Extension applications

First additional form	6,385
Each additional form (same time)	5,315
First additional strength	2,880
Each additional strength (same time)	690

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

Mutual recognition incoming	4,465
Mutual recognition incoming - each additional form (same time)	2,980
Mutual recognition incoming - each additional strength (same time)	690
Outgoing mutual recognition / decentralised supplement	5,800
Decentralised outgoing/incoming	6,385
Each additional form (same time)	5,315
Each additional strength (same time)	690

Traditional herbal medicinal products – national variations	
Type IB variation – national	490
Type IB variation – reduced rate	250
Type II standard variation	520
Type II standard variation – reduced rate	265
Type II complex variation	2,740
Bulk variation for multiple changes	5,480

Traditional herbal medicinal products – mutual recognition variations	
Type IB variation – mutual recognition incoming	350
Type IB variation – mutual recognition incoming - reduced rate	185
Type IB variation – outgoing mutual recognition supplement	360
Type II standard – mutual recognition incoming	350
Type II standard – mutual recognition incoming - reduced rate	185
Type II standard – outgoing mutual recognition supplement	350
Type II complex – mutual recognition incoming	1,875
Type II complex – outgoing mutual recognition supplement	545

Fees for export certificates and certification of documents	
Standard	195
Fast track	360

Annual maintenance fees	
Marketing authorisations and registrations	
First 10 marketing authorisations	845
Additional marketing authorisation	1,055
Dormant marketing authorisation	463
Parallel import licence	140
Parallel import licence - Dual pack	70
Certificate of registration - homeopathic medicinal products	70
Certificate of traditional-use registration - traditional herbal medicinal products	140
Manufacturer's authorisations	

Major site (more than 250 employees)	25,555
Large site (150-250 employees)	17,425
Medium site (50-149 employees)	11,620
Small site (less than 50 employees)	5,230
Homeopathic manufacturing site	1,305
Wholesaler's authorisations	
Large full line	3,615
Medium full line / short line	2,060
Small short line	780
Minor site / Procure & supply	520
Active substances register	
Active substances distributor	325
Active substances importer	650
Active substances manufacturer	1,305
Organ establishment authorisations	
Major establishment (more than 250 employees)	21,755
Large establishment (150-250 employees)	14,505
Medium establishment (50-149 employees)	9,670
Small establishment (less than 50 employees)	4,835
Minor establishment (less than 5 employees)	1,305

Fees in relation to protection of animals used for scientific purposes

Project authorisation fees	
Project application without ethical approval	2,385
Fast track project application	2,385
Fast track evaluation of project amendment application	750

Breeder/Supplier/User Authorisation fees	
Band 1: Small establishment with no animal facilities or establishment with 1-3 individual authorisation holders	345
Band 2: Establishment with 4-10 individual authorisation holders	690
Band 3: Establishment with 11-20 individual authorisation holders	1,055
Band 4: Establishment with 21-40 individual authorisation holders	1,995
Band 5: Establishment with 41-70 individual authorisation holders	3,035
Band 6: Establishment with 71-100 individual authorisation holders	4,055
Band 7: Establishment with 101-150 individual authorisation holders	6,855
Band 8: Establishment with 151-200 individual authorisation holders	9,975
Band 9: Establishment with >200 individual authorisation holders	13,095
Individual authorisation fees	
Application fee	335
Annual fee	335
Once-off authorisation - procedural training for a period of two months or less (reduced fee)	115
Fees for follow-up inspections	
Per day (per member of the inspection team)	1,945
Part of day (per hour, per member of the inspection team)	280
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)	1,945
Part of day (per hour, per member of the inspection team)	280
Inspection cancellation/rescheduling fee	530

Enforcement fees

Manufacturers

Major site (more than 250 employees)	3,135
Large site (150-250 employees)	2,350
Medium site (50-149 employees)	780
Small site (less than 50 employees)	265

Wholesalers

Large full line	780
Medium full line / short line	265

Marketing authorisation / parallel import licence holders

> 50 marketing authorisations / parallel import licences	4,115
31-50 marketing authorisations / parallel import licences	1,305
16-30 marketing authorisations / parallel import licences	780
6-15 marketing authorisations / parallel import licences	265

(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	32,615
Manufacturer or system and procedure pack producer or manufacturing facility - with 100-150 employees	21,740
Manufacturer or system and procedure pack producer or manufacturing facility - with 50-99 employees	16,305

Manufacturer or system and procedure pack producer or manufacturing facility - with 16-49 employees	5,435
Manufacturer or system and procedure pack producer or manufacturing facility - with 5-15 employees	1,360
Manufacturer or system and procedure pack producer or manufacturing facility - with less than 5 employees or annual turnover of less than €500,000	270

Authorised Representatives – annual fees

Type I Authorised Representative – representing a non-EU manufacturer that manufactures low risk* devices (fee per manufacturer)	1,170
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)	1,595
Cap on type I Authorised Representative	5,850
Cap on type II Authorised Representative	7,975

(Note: * low risk devices means Class I general medical devices (as described in Council Directive 93/42/EEC of 14 June 1993[4] ('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[6] ('IVDD')) / Class A (as described in the IVD Medical Devices Regulation ('IVDR').)

(Note: ** high risk devices means Class IIa, IIb, III general medical devices (as described in MDD/MDR), active implantable medical 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)	4,895
Medium distributor/importer (turnover €3-€15 million)	2,720

[6] OJ No. L 331, 7.12.1998, p. 1.

Small distributor/importer (turnover under €3 million)	1,360
Distributor/importer turnover less than €500,000	270
Additional supplement – Entities acting as both a distributor and importer where turnover is more than €3 million	1,065

Notified Body – annual fees	5,435

Summary evaluation review fees

Devices using starting materials for which a TSE certificate of suitability has been submitted	2,660
Devices using starting materials for which a TSE certificate of suitability has not been submitted	5,330

European Union Reference Laboratories

European Union Reference Laboratory (EURL) Application Verification	2,875

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)	275
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	125

Registration of Devices

Online Registration – Administration fee	145

Clinical Investigations and IVDR performance studies

Class III and Class IIb medical devices, including relevant MDR Annex XVI clinical investigations	4,585
Class IIa and Class I devices, including relevant MDR Annex	2,025

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)	215
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)	2,660
Substantial modifications and technical amendment to a previously approved clinical investigation/performance study	1,325
Resubmission of a clinical investigation/performance study following a withdrawal or objection or if the application has lapsed	2,025
Resubmission of a clinical investigation/performance study - Academic Sponsor	545

Determination of classification within the medical devices regulations

Determination not requiring a complex technical review (one device per request)	300
Complex classification requests	1,085
MDR Article 51 / IVDR Article 47 referral	10,500
Appeal of a classification opinion	640

Designation Fee for a Notified Body

Initial designation of a notified body and to the re-assessment of the notified body under the IVD Medical Devices Regulation and the Medical Devices Regulation	10,875
Extensions to the scope (per extension)	5,435

Medicinal Product / Medical Device - Drug Consultation Fees

New active substance	51,190
Established active in new therapeutic area	12,795

Established active and therapeutic area	7,425
Variations - Minor	1,075
Variations - Major	4,835

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

Assessment fee	4,265

Miscellaneous - Medical Devices

Daily charge-out rate for Technical Services	1,785
Hourly charge-out rate for Technical Services	285
Hourly charge-out rate for Administrative Services	85

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	3,610
Ireland – Reporting Member State	9,035

Ireland - Concerned Member State, initial, transitional or additional applications	3,370
Supplement – Where Ireland subsequently becomes the Reporting Member State	5,520
Reporting Member State – 2nd & subsequent waves	1,025

Applications with no investigational medicinal product dossier or with a simplified investigational medicinal product dossier	
Mono National	2,495
Ireland – Reporting Member State	7,775
Ireland - Concerned Member State, initial, transitional or additional applications	2,220
Supplement – Where Ireland subsequently becomes the Reporting Member State	5,325
Reporting Member State – 2nd & subsequent waves	1,025

Substantial Modifications (Parts I & II or Part I only) – with the addition of a new investigational medicinal product dossier	
Mono National	1,480
Ireland – Reporting Member State	1,720
Ireland - Concerned Member State	1,420

Substantial Modifications – other	
Mono National	960
Ireland – Reporting Member State	1,290
Ireland- Concerned Member State	875

Substantial Modifications – Part II only	
Substantial Modification	400

Fees for Appeals

Appeal of clinical trial decision – Commercial	1,925

Fees for Inspections

per day (per member of the inspection team)	1,945
per hour (per member of the inspection team)	280

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	300
Amendment to registered details	165

L.S.

GIVEN under the Official Seal of the Minister for Health,
23 December, 2024.

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 2023 (S.I. No. 697 of 2023).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2024.

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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