STATUTORY INSTRUMENTS.

S.I. No. 624 of 2025

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2025

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

1. These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2025.

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 Distribution) (Amendment) Regulations 2013) of the Control of Wholesale Distribution Regulations;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 30*th December,* 2025.

"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 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—

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

(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 2024 (S.I. No. 751 of 2024) 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	25,625
Additional drug master file submitted	4,855
Reduced dossier – complex	
National application	19,375
Additional drug master file submitted	4,855
Reduced dossier – standard	
National application	13,835
Additional drug master file submitted	4,855
Subsequent extension applications	
First additional form	12,145
Each additional form (same time)	8,500
First additional strength (existing form)	3,645
Each additional strength (same time)	1,210
Additional drug master file submitted	4,855
Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure	
Complex dossier	
Mutual recognition incoming	18,965
Outgoing mutual recognition supplement	18,215
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	19,710
Decentralised incoming	25,625
Decentralised outgoing	63,550
Additional supplement where there are 15 or more concerned Member States	1,825
Reduced dossier – complex	
Mutual recognition incoming	13,325
Outgoing mutual recognition supplement	18,215

Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	13,665
Decentralised incoming	19,375
Decentralised outgoing	51,250
Additional supplement where there are 15 or more concerned Member States	1,825

Reduced dossier – standard

Mutual recognition incoming	9,740
Outgoing mutual recognition supplement	12,145
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	8,865
Decentralised incoming	14,350
Decentralised outgoing	34,850
Additional Supplement where there are 15 or more concerned Member States	1,825

Subsequent extension applications

Mutual recognition incoming (first additional form)	8,500
Mutual recognition incoming (first additional strength)	2,435
Mutual recognition incoming (subsequent additional strength)	1,210
Outgoing mutual recognition/decentralised supplement (additional form)	3,645
Outgoing mutual recognition/decentralised supplement (additional strength)	1,210
Decentralised incoming (first additional form)	12,145
Decentralised outgoing (first additional form)	31,575
Each additional form (same time)	8,500
First additional strength incoming (existing form)	3,645
First additional strength outgoing (existing form)	8,500
Each additional strength (same time)	1,210
Additional supplement where there are 15 or more concerned Member States	1,825

Switching applications

Switching applications	6,195

Fees for parallel import licences

Application fee - per country at the same time or by variation	2,230
Each additional strength per country	660
Each additional form per country	660
Parallel imports - dual pack registration	1,110
Dual pack registration of parallel imports - each additional strength or form	660
Parallel imports where the originator is not on the Irish market	6,690
Change of ownership per product range	705

Fees for variations to national marketing authorisations

Type IB variation	625
Type IB variation - reduced rate	320
Type II complex variation	3,480
Type II complex variation – reduced rate	675
Type II standard variation	675
Type II standard variation - reduced rate	340
Notifications under Article 61(3) of Directive 2001/83/ EC	335
Notifications under Article 61(3) of Directive 2001/83/EC - reduced rate	170
Multiple variations capped fee (per product range)	6,425
Multiple variations capped fee (per product)	4,150
Worksharing capped fee	6,960

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

Type IA variation outgoing mutual recognition / decentralised supplement	335
Type IB variation outgoing mutual recognition / decentralised supplement	460
Type IB variation - mutual recognition incoming	450
Type IB variation - mutual recognition incoming - reduced rate	235
Type II complex variation - outgoing mutual recognition / decentralised supplement	705
Type II complex variation - mutual recognition incoming	2,405

Type II complex variation – mutual recognition incoming – reduced rate	450
Type II standard variation - mutual recognition incoming	450
Type II standard variation - mutual recognition incoming - reduced rate	235
Type II standard variation - outgoing mutual recognition / decentralised supplement	490
Notifications made under Article 61(3) of Directive 2001/83/EC	335
Notifications made under Article 61(3) of Directive 2001/83/EC – reduced rate	170

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

Change of ownership - related company – 1st marketing authorisation within a range	1,200
Change of ownership - related company – each additional marketing authorisation within a range	425
Change of ownership - non-related company – 1st marketing authorisation within a range	1,765
Change of ownership - non-related company – each additional marketing authorisation within a range	425

Other fees relating to the granting of marketing authorisations

Service item	815

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	745
Variation to authorisation - minor site technical	535
Variation to authorisation – administrative	290
Variation to authorisation – technical	800

Fees for applications for manufacturer's authorisations

Application fee	2,475
Variation to authorisation – administrative	370
Variation to authorisation – technical	1,035
Variation to authorisation – fast track	1,460

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

Registration fee – importers and distributors of active substances and brokers	335
Registration fee – manufacturers of active substances	595
Immediate notification of a change which may impact on the quality or safety of the active substances	1,035
Notification of an administrative change to the active substances register	190
Notification of any change to the brokers register	190

Fees for applications for organ establishment authorisations

Application charge	2,475
Variation to authorisation – administrative	370
Variation to authorisation – technical	1,035
Appeal to amend/revoke an authorisation	665
Scientific opinion on the non-viability of the cells/tissue, donation, procurement testing	3,570

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation	
Related company	1,480
Unrelated company	2,475
Wholesaler's authorisation, registration on brokers register and registration on active substances register	
Related company	485
Unrelated company	745

Fees for applications in relation to cosmetic products

Certificates of free sale – standard (4 certificates per request)	200
Certificates of free sale – fast track (4 certificates per request)	370
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	900
New national / decentralised registration standard charge - 2 or more stocks	1,365
New application - national rules scheme standard fee - single stock	1,365
New application - national rules scheme standard fee - 2 or more stocks	2,010
Mutual recognition incoming application standard fee - single stock	610
Mutual recognition incoming application standard fee - 2 or more stocks	900
Outgoing mutual recognition / decentralised supplement	755
National variation – registration and national rules scheme	450
National variation – reduced rate – registrations and national rules scheme	225
Mutual recognition incoming variation	310
Mutual recognition incoming variation - reduced rate	145
Variation – outgoing mutual recognition / decentralised supplement	225
Bulk variation for multiple changes to the Masterfile	2,720

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	6,545
National application where there is a monograph	4,015
Each additional form (same time)	5,450
Each additional strength (same time)	705
Additional drug master file submitted	4,350

Extension applications

First additional form	6,545
Each additional form (same time)	5,450
First additional strength	2,950
Each additional strength (same time)	705

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

Mutual recognition incoming	4,575
Mutual recognition incoming - each additional form (same time)	3,055
Mutual recognition incoming - each additional strength (same time)	705
Outgoing mutual recognition / decentralised supplement	5,945
Decentralised outgoing/incoming	6,545
Each additional form (same time)	5,450
Each additional strength (same time)	705

Traditional herbal medicinal products – national variations

Type IB variation – national	500
Type IB variation – reduced rate	255
Type II standard variation	535
Type II standard variation – reduced rate	270
Type II complex variation	2,810
Bulk variation for multiple changes	5,615

Traditional herbal medicinal products – mutual recognition variations

Type IB variation – mutual recognition incoming	360
Type IB variation – mutual recognition incoming - reduced rate	190
Type IB variation – outgoing mutual recognition supplement	370
Type II standard – mutual recognition incoming	360
Type II standard – mutual recognition incoming - reduced rate	190
Type II standard – outgoing mutual recognition supplement	360
Type II complex – mutual recognition incoming	1,920
Type II complex – outgoing mutual recognition supplement	560

Fees for export certificates and certification of documents

Standard	200
Fast track	370

Annual maintenance fees

Marketing authorisations and registrations

First 10 marketing authorisations	865
Additional marketing authorisation	1,080
Dormant marketing authorisation	463
Parallel import licence	145
Parallel import licence - Dual pack	70
Certificate of registration - homeopathic medicinal products	70
Certificate of traditional-use registration - traditional herbal medicinal Products	145

Manufacturer's authorisations

Major site (more than 250 employees)	26,195
Large site (150-250 employees)	17,860
Medium site (50-149 employees)	11,910
Small site (less than 50 employees)	5,360
Homeopathic manufacturing site	1,340

Wholesaler's authorisations

Large full line	3,705
Medium full line / short line	2,110
Small short line	800
Minor site / Procure & supply	535

Active substances register

Active substances distributor	335
Active substances importer	665
Active substances manufacturer	1,340

Organ establishment authorisations

Major establishment (more than 250 employees)	22,300
Large establishment (150-250 employees)	14,870
Medium establishment (50-149 employees)	9,910
Small establishment (less than 50 employees)	4,955

Minor establishment (less than 5 employees)	1,340

Fees in relation to protection of animals used for scientific purposes

Project authorisation fees	
Project application without ethical approval	2,445
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	355
Band 2: Establishment with 4-10 individual authorisation holders	705
Band 3: Establishment with 11-20 individual authorisation holders	1,080
Band 4: Establishment with 21-40 individual authorisation holders	2,045
Band 5: Establishment with 41-70 individual authorisation holders	3,110
Band 6: Establishment with 71-100 individual authorisation holders	4,155
Band 7: Establishment with 101-150 individual authorisation holders	7,025
Band 8: Establishment with 151-200 individual authorisation holders	10,225
Band 9: Establishment with >200 individual authorisation holders	13,420
Individual authorisation fees	
Application fee	345
Annual fee	345
Once-off authorisation - procedural training for a period of two months or less (reduced fee)	120
Fees for follow-up inspections	
Per day (per member of the inspection team)	1,995
Part of day (per hour, per member of the inspection team)	285

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)	1,995
Part of day (per hour, per member of the inspection team)	285

Enforcement fees

Manufacturers	
Major site (more than 250 employees)	3,215
Large site (150-250 employees)	2,410
Medium site (50-149 employees)	800
Small site (less than 50 employees)	270
Wholesalers	
Large full line	800
Medium full line / short line	270
Marketing authorisation / parallel import licence holders	
> 50 marketing authorisations / parallel import licences	4,220
31-50 marketing authorisations / parallel import licences	1,340
16-30 marketing authorisations / parallel import licences	800
6-15 marketing authorisations / parallel import licences	270

(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.)

<u>Fees for medical device organisations</u>
Manufacturer or system or procedure pack producer or manufacturing facility located in Ireland – annual fees

Manufacturer or system or procedure pack producer or manufacturing facility - with more than 150 employees	33,430
Manufacturer or system or procedure pack producer or manufacturing facility - with 100-150 employees	22,285
Manufacturer or system or procedure pack producer or manufacturing facility - with 50-99 employees	16,715
Manufacturer or system or procedure pack producer or manufacturing facility - with 16-49 employees	5,570
Manufacturer or system or procedure pack producer or manufacturing facility - with 5-15 employees	1,395
Manufacturer or system or procedure pack producer or manufacturing facility - with less than 5 employees or annual turnover of less than €500,000	275

Authorised Representatives – annual fees

Type I Authorised Representative – representing a non-EU manufacturer that manufactures low risk* devices (fee per manufacturer)	1,200
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)	1,635
Cap on type I Authorised Representative	6,000
Cap on type II Authorised Representative	8,175

(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)	5,015
Medium distributor/importer (turnover €3-€15 million)	2,790
Small distributor/importer (turnover under €3 million)	1,395
Distributor/importer turnover less than €500,000	275
Additional supplement – Entities acting as both a distributor and importer where turnover is more than €3 million	1,090

Notified Body – annual fees 5,570

Summary evaluation review fees

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

Devices using starting materials for which a TSE certificate of suitability has been submitted	2,725
Devices using starting materials for which a TSE certificate of suitability has not been submitted	5,465

European Union Reference Laboratories

European Union Reference Laboratory (EURL) Application Verification	2,945

Certificates of free sale or letters confirming the location of the manufacturing facility in Ireland or export documents for system or procedure pack producers

Certificate of free sale/letter confirming the location of the manufacturing facility in Ireland and export documents for system or procedure pack producers (4 certificates per request)	280
Each additional certificate of free sale/letter confirming the location of the manufacturing facility in Ireland and export documents for system or procedure pack producers– (available at time of request)	25
Letter confirming that a device or a list of devices are registered with the HPRA	130
Digitally signed/sent certificate of free sale/letter confirming the location of the manufacturing facility in Ireland and export documents for system or procedure pack producers (4 certificates per request)	200

Registration of Medical Device Organisations

Online Registration – Administration fee	150

Clinical Investigations and IVDR performance studies

Class III and Class IIb medical devices, including relevant MDR Annex XVI clinical investigations	4,700
Class IIa and Class I devices, including relevant MDR Annex XVI clinical investigations	2,075
Notifications and substantial modifications to notifications in accordance with MDR Article 74(1), Article 82, IVDR Article 58(2) and IVDR Article 70(1)	220
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)	2,725

Substantial modifications and technical amendment to a previously approved clinical investigation/performance study	1,360
Resubmission of a clinical investigation/performance study following a withdrawal or objection or if the application has lapsed	2,075
Resubmission of a clinical investigation/performance study - Academic Sponsor	560

Determination of classification within the medical devices regulations

Determination not requiring a complex technical review (one device per request)	335
Complex classification requests	1,210
MDR Article 51 / IVDR Article 47 referral	10,760
Appeal of a classification opinion	655

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	11,145
Extensions to the scope (per extension)	5,570

Medicinal Product / Medical Device - Drug Consultation Fees

New active substance	52,470
Established active in new therapeutic area	13,115
Established active and therapeutic area	7,610
Variations - Minor	1,100
Variations - Major	4,955

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

Assessment fee	4,370

Miscellaneous - Medical Devices

Daily charge-out rate for Technical Services	1,830

Hourly charge-out rate for Technical Services	290
Hourly charge-out rate for Administrative Services	85

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	4,075
Ireland – Reporting Member State	9,410
Ireland - Concerned Member State, initial, transitional or additional applications	3,800
Supplement – Where Ireland subsequently becomes the Reporting Member State	5,695
Reporting Member State – 2nd & subsequent waves	1,090

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

Mono National	2,795
Ireland – Reporting Member State	8,120
Ireland - Concerned Member State, initial, transitional or additional applications	2,455
Supplement – Where Ireland subsequently becomes the Reporting Member State	5,495
Reporting Member State – 2nd & subsequent waves	1,090

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

Mono National	1,545
Ireland – Reporting Member State	1,795
Ireland - Concerned Member State	1,485

Substantial Modifications – other

Mono National	1,015

Ireland – Reporting Member State	1,350
Ireland- Concerned Member State	925

Substantial Modifications – Part II only

Substantial Modification	440

Fees for Appeals

Appeal of clinical trial decision – Commercial	2,745

Fees for Inspections

per day (per member of the inspection team)	1,995
per hour (per member of the inspection team)	285

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	310
Amendment to registered details	170

L.S.

GIVEN under my Official Seal,
17 December, 2025.

DR. JENNIFER CARROLL MACNEILL,
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 2024 (S.I. No. 751 of 2024).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2025.

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