STATUTORY INSTRUMENTS.

S.I. No. 654 of 2020

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2020

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HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2020

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 2020.

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" –

(a) 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),

(b) has the meaning assigned to it by Article 2(32) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 [1],

[1] OJ L117, 5.5.2017, p.1

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1st *January,* 2021.

(c) has the meaning assigned to it by Article 2(25) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2];

"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 (S.I. No. 164 of 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, or

(b) a certificate of free sale issued under Article 60 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[3], or

(c) a certificate of free sale issued under Article 55 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[4];

"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;

[2] OJ L117, 5.5.2017, p.176
[3] OJ L117, 5.5.2017, p.1
[4] OJ L117, 5.5.2017, p.176

"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;

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[5];

"distributor", in the context of medical 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;

"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. 2) Regulations 2015 (S.I. No. 449 of 2015)) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

"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;

"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;

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

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

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

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

"manufacturer", in the context of medical devices,

(a) means—

(i) a person who is responsible for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his or her own name, regardless of whether these operations are carried out by that person himself or herself or on his or her behalf by a third party, or

(ii) 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 medical device with a view to their being placed on the market under his or her own name, but not including a person who assembles or adapts medical devices already on the market to their intended purpose for an individual patient, or

(b) has the meaning assigned to it by-

(i) Article 2(30) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[6], or

(ii) Article 2(23) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[7];

"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 medical devices, means a place where an entity, which does not place medical devices on the market under its own name or under its own trademark—

[6] OJ L117, 5.5.2017, p.1
[7] OJ L117, 5.5.2017, p.176

(a) manufactures a medical device, or

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

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

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

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

"medical device"

(a) means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,

- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) or has the meaning assigned to it by Article 2(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[8];

(c) or has the meaning assigned to "device" by Regulation 2 (1) of the European Communities (Medical Devices) Regulations, 1994 (SI 252/1994) which transposed Directive 93/42/EEC of 14th June 1993 into Irish Law

(d) or has the meaning assigned to "device" by Regulation 2 (1) of the European Communities (Active Implantable Medical Devices) Regulations, 1994 (SI 253/1994) which transposed Directive 90/385/EEC of 20th June 1990 into Irish Law

(e) or has the meaning assigned to "device" by Regulation 2 (1) of the European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001 (S.I. No. 304/2001) which

[8] OJ L117, 5.5.2017, p.1

transposed Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[9] into Irish law

(f) or has the meaning assigned to it by Article 2(2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[10];

"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"-

(a) 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

(b) has the meaning assigned to it by Article 2(42) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[11], or

(c) has the meaning assigned to it by Article 2(34) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[12];

"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;

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[9] OJ L331, 7.12.1998, p.1
[10] OJ L117, 5.5.2017, p.176
[11] OJ L117, 5.5.2017, p.1
[12] OJ L117, 5.5.2017, p.176

"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;

"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[13];

"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.

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[13] OJ No. L 334, 12.12.2008, p. 7.

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 2019 (S.I. No. 700 of 2019) are revoked.

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for national applications for marketing authorisations	*€*
Complex dossier	
National application	20,400
Each additional form (same time)	7,140
Each additional strength (same time)	1,020
Additional drug master file submitted	4,080
Reduced dossier – complex	
National application	15,300
Each additional form (same time)	7,140
Each additional strength (same time)	1,020
Additional drug master file submitted	4,080
Reduced dossier – standard	
National application	10,200
Each additional form (same time)	7,140
Each additional strength (same time)	1,020
Additional drug master file submitted	4,080
Subsequent extension applications	
First additional form	10,200
Each additional form (same time)	7,140
First additional strength (existing form)	3,060
Each additional strength (same time)	1,020
Additional drug master file submitted	4,080

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

Complex dossier

Mutual recognition incoming	14,280
Each additional form (same time)	5,100
Each additional strength (same time)	1,020
Outgoing mutual recognition supplement	15,300
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	15,300
Decentralised incoming	20,400
Decentralised outgoing	51,000
Each additional form (same time)	7,140
Each additional strength (same time)	1,020
Additional supplement where there are 15 or more concerned Member States	1,530

Reduced dossier – complex

Mutual recognition incoming	10,200
Each additional form (same time)	5,100
Each additional strength (same time)	1,020
Outgoing mutual recognition supplement	15,300
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	10,200
Decentralised incoming	15,300
Decentralised outgoing	40,800
Each additional form (same time)	7,140
Each additional strength (same time)	1,020
Additional supplement where there are 15 or more concerned Member States	1,530

Reduced dossier – standard	
Mutual recognition incoming	7,140
Each additional form (same time)	4,080
Each additional strength (same time)	1,020
Outgoing mutual recognition supplement	10,200
Outgoing mutual recognition supplement – mutual recognition applied for within twelve months of the national procedure ending	6,120
Decentralised incoming	10,200
Decentralised outgoing	26,520
Each additional form (same time)	7,140
Each additional strength (same time)	1,020
Additional supplement where there are 15 or more concerned Member States	1,530
Subsequent extension applications	
Mutual recognition incoming (first additional form)	7,140
Mutual recognition incoming (first additional strength)	2,040
Mutual recognition incoming (subsequent additional strength)	1,020
Outgoing mutual recognition/decentralised supplement (additional form)	3,060
Outgoing mutual recognition/decentralised supplement (additional strength)	1,020
Decentralised incoming (first additional form)	10,200
Decentralised outgoing (first additional form)	26,520
Each additional form (same time)	7,140
First additional strength (existing form)	3,060
Each additional strength (same time)	1,020
Additional supplement where there are 15 or more concerned Member States	1,530

Switching applications

Switching applications	5,200

Fees for parallel import licences

Application fee - per country at the same time or by variation	1,870
Each additional strength per country	555
Each additional form per country	555
Parallel imports - dual pack registration	935
Dual pack registration of parallel imports - each additional strength or form	555
Parallel imports where the originator is not on the Irish market	5,620
Change of ownership per product range	590

Fees for variations to national marketing authorisations

Type IB variation	525
Type IB variation - reduced rate	265
Type II complex variation	2,920
Type II complex variation – reduced rate	570
Type II standard variation	570
Type II standard variation - reduced rate	285
Notifications under Article 61(3) of Directive 2001/83/ EC	280
Notifications under Article 61(3) of Directive 2001/83/EC - reduced rate	140
Multiple variations capped fee (per product range)	5,395
Multiple variations capped fee (per product)	3,485
Worksharing capped fee	5,845

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

Type IA variation outgoing mutual recognition / decentralised supplement	280
Type IB variation outgoing mutual recognition / decentralised supplement	390
Type IB variation - mutual recognition incoming	380
Type IB variation - mutual recognition incoming - reduced rate	195
Type II complex variation - outgoing mutual recognition / decentralised supplement	590
Type II complex variation - mutual recognition incoming	2,020
Type II complex variation – mutual recognition incoming – reduced rate	380
Type II standard variation - mutual recognition incoming	380
Type II standard variation - mutual recognition incoming - reduced rate	195
Type II standard variation - outgoing mutual recognition / decentralised supplement	380
Notifications made under Article 61(3) of Directive 2001/83/EC	280
Notifications made under Article 61(3) of Directive 2001/83/EC – reduced rate	140

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

Change of ownership - related company – 1st marketing authorisation within a range	1,010
Change of ownership - related company – each additional marketing authorisation within a range	360
Change of ownership - non-related company – 1st marketing authorisation within a range	1,480
Change of ownership - non-related company – each additional marketing authorisation within a range	360

Other fees relating to the granting of marketing authorisations

Service item	685

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	625
Variation to authorisation - minor site technical	450
Variation to authorisation – administrative	245
Variation to authorisation – technical	675

Fees for applications for manufacturer's authorisations

Application fee	2,080
Variation to authorisation – administrative	310
Variation to authorisation – technical	865
Variation to authorisation – investigational medicinal product – fast track	1,225

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

Registration fee – importers and distributors of active substances and brokers	280
Registration fee – manufacturers of active substances	495
Immediate notification of a change which may impact on the quality or safety of the active substances	865
Notification of an administrative change to the active substances register	155
Notification of any change to the brokers register	155

Fees for applications for organ establishment authorisations

Application charge	2,080
Variation to authorisation – administrative	310
Variation to authorisation – technical	865
Appeal to amend/revoke an authorisation	560
Scientific opinion on the non-viability of the cells/tissue, donation, procurement testing	3,000

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation	
Related company	1,245
Unrelated company	2,080
Wholesaler's authorisation, registration on brokers register and registration on active substances register	
Related company	410
Unrelated company	625

Fees for applications in relation to cosmetic products

Certificates of free sale – standard (4 certificates per request)	165
Certificates of free sale – fast track (4 certificates per request)	310
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	760
New national / decentralised registration standard charge - 2 or more stocks	1,140
New application - national rules scheme standard fee - single stock	1,140
New application - national rules scheme standard fee - 2 or more stocks	1,685
Mutual recognition incoming application standard fee - single stock	510
Mutual recognition incoming application standard fee - 2 or more stocks	760
Outgoing mutual recognition / decentralised supplement	635
National variation – registration and national rules scheme	380
National variation – reduced rate – registrations and national rules	190

scheme	
Mutual recognition incoming variation	255
Mutual recognition incoming variation - reduced rate	125
Variation – outgoing mutual recognition / decentralised supplement	190
Bulk variation for multiple changes to the masterfile	2,290

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	5,495
National application where there is a monograph	3,370
Each additional form (same time)	4,575
Each additional strength (same time)	590
Additional drug master file submitted	3,655

Extension applications

First additional form	5,495
Each additional form (same time)	4,575
First additional strength	2,480
Each additional strength (same time)	590

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

Mutual recognition incoming	3,840
Mutual recognition incoming - each additional form (same time)	2,570
Mutual recognition incoming - each additional strength (same time)	590
Outgoing mutual recognition / decentralised supplement	4,995
Decentralised outgoing/incoming	5,495
Each additional form (same time)	4,575
Each additional strength (same time)	590

Traditional herbal medicinal products – national variations

Type IB variation – national	420
Type IB variation – reduced rate	215
Type II standard variation	450
Type II standard variation – reduced rate	225
Type II complex variation	2,360
Bulk variation for multiple changes	4,720

Traditional herbal medicinal products – mutual recognition variations

Type IB variation – mutual recognition incoming	305
Type IB variation – mutual recognition incoming - reduced rate	155
Type IB variation – outgoing mutual recognition supplement	310
Type II standard – mutual recognition incoming	305
Type II standard – mutual recognition incoming - reduced rate	155
Type II standard – outgoing mutual recognition supplement	305
Type II complex – mutual recognition incoming	1,615
Type II complex – outgoing mutual recognition supplement	470

Fees for export certificates and certification of documents

Standard	165
Fast track	310

Annual maintenance fees

Marketing authorisations and registrations

First 10 marketing authorisations	730

Additional marketing authorisation	910
Dormant marketing authorisation	463
Parallel import licence	125
Parallel import licence - Dual pack	60
Certificate of registration - homeopathic medicinal products	60
Certificate of traditional-use registration - traditional herbal medicinal products	125

Manufacturer's authorisations

Major site (more than 250 employees)	22,000
Large site (150-250 employees)	15,000
Medium site (50-149 employees)	10,000
Small site (less than 50 employees)	4,500
Homeopathic manufacturing site	1,125

Wholesaler's authorisations

Large full line	3,115
Medium full line / short line	1,770
Small short line	675
Minor site / Procure & supply	450

Active substances register

Active substances distributor	280
Active substances importer	560
Active substances manufacturer	1,125

Organ establishment authorisations

Major establishment (more than 250 employees)	18,730
Large establishment (150-250 employees)	12,485
Medium establishment (50-149 employees)	8,325
Small establishment (less than 50 employees)	4,160
Minor establishment (less than 5 employees)	1,125

Fees in relation to protection of animals used for scientific purposes

Project fees

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

Breeder/Supplier/User Authorisation fees

Band 1: Small establishment with no animal facilities or establishment with 1-3 individual authorisation holders	305
Band 2: Establishment with 4-10 individual authorisation holders	605
Band 3: Establishment with 11-20 individual authorisation holders	935
Band 4: Establishment with 21-50 individual authorisation holders	1,760
Band 5: Establishment with 51-100 individual authorisation holders	3,575
Band 6: Establishment with 101-150 individual authorisation holders	6,050
Band 7: Establishment with 151 – 200 individual authorisation holders	8,800
Band 8: Establishment with >201 individual authorisation holders	11,550

Individual authorisation fees

Application fee	295
Annual fee	295
Once-off authorisation - procedural training for a period of two months or less (reduced fee)	100

Fees for follow-up inspections

Per day (per member of the inspection team)	1,675
Part of day (per hour, per member of the inspection team)	240

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)	1,675
Part of day (per hour, per member of the inspection team)	240
Inspection booking fee	1,000

Enforcement fees

Manufacturers

Major site (more than 250 employees)	2,695
Large site (150-250 employees)	2,025
Medium site (50-149 employees)	675
Small site (less than 50 employees)	225

Wholesalers

Large full line	675
Medium full line / short line	225

Marketing authorisation / parallel import licence holders

> 50 marketing authorisations / parallel import licences	3,540
31-50 marketing authorisations / parallel import licences	1,125
16-30 marketing authorisations / parallel import licences	675
6-15 marketing authorisations / parallel import licences	225

(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 medical devices

Manufacturer / manufacturing facility located in Ireland – annual fees

Manufacturer or manufacturing facility - with more than 150 employees	30,600
Manufacturer or manufacturing facility - with 100-150 employees	20,400
Manufacturer or manufacturing facility - with 50-99 employees	15,300
Manufacturer or manufacturing facility - with 16-49 employees	5,100
Manufacturer or manufacturing facility - with 5-15 employees	1,275
Manufacturer or manufacturing facility - with less than 5 employees or annual turnover of less than €500,000	250

(Note: Where one entity has multiple manufacturing facilities based in the State, the entity will be charged per manufacturing facility to a maximum fee of €61,200.)

Authorised Representatives – annual fees

Type I Authorised Representative – representing a non-EU manufacturer that manufactures low risk* devices (fee per manufacturer)	1,100

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

(Note: * low risk devices means Class I general medical devices (as described in Council Directive 93/42/EEC of 14 June 1993[14] ('MDD') / Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 [15] ('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[16] ('IVDD')) / Class A (as described in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[17] ('IVDR').)

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

Distributors and Importers – annual fees

Large distributor/importer (turnover greater than €15 million)	4,590
Medium distributor/importer (turnover €3-€15 million)	2,550
Small distributor/importer (turnover under €3 million)	1,275
Distributor/importer turnover less than €500,000	250
Additional supplement – Entities acting as both a distributor and importer where turnover is more than €500,000	1,000
Additional supplement – Entities acting as both a distributor and importer where turnover is less than €500,000	250

Notified Body – annual fees 5,100

Summary evaluation review fees

[14] OJ L169, 12.7.1993, p.1
[15] OJ L117, 5.5.2017, p.1
[16] OJ L331, 7.12.1998, p.1
[17] OJ L117, 5.5.2017, p.176

Medical devices using starting materials for which a TSE certificate of suitability has been submitted	2,500
Medical devices using starting materials for which a TSE certificate of suitability has not been submitted	5,000

Certificates of free sale or letters confirming the location of the manufacturing facility in Ireland for medical devices

Certificate of free sale/letter confirming the location of the manufacturing facility in Ireland (4 certificates per request)	255
Each additional certificate of free sale/letter confirming the location of the manufacturing facility in Ireland – (available at time of request)	25

L.S.

GIVEN under my Official Seal,
17 December, 2020.

STEPHEN DONNELLY,
Minister for Health.

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 2019 (S.I. No. 700 of 2019).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2020.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2,
D02 DR67.

Tel: 076 110 6834
E-mail: publications@opw.ie

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ISBN 978-1-4468-8518-5

9 781446 885185

€ 6.50

(DH-162) 75. 12/20. Propylon.