STATUTORY INSTRUMENTS.

**S.I. No. 744 of 2021**

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# HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2021

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

1. These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2021.

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)

*Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of* 31*st December,* 2021.

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

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

"certificate of free sale" means –

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

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

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

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

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

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

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

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

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

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

"device" means –

(a) a medical device,

(b) an accessory for a medical device,

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

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

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

but does not include-

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

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

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

(iv) an in-house device;

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

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

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

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

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

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

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

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

"*in vitro* diagnostic medical device" has the meaning assigned to it by Article 2(2) of the IVD Medical Devices Regulation or by Article 1(2)(b) of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[2];

"IVD Medical Devices Regulation" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[3];

"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.

1 OJ No. L 311, 28.11.2001, p. 67.
2 OJ No. L 331, 7.12.1998, p. 1
3 OJ No. L 117, 5.5.2017, p. 176.

No. 81 of 2021)) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

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

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

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

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

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

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

as applicable;

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

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

(a) manufactures a device,

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

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

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

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

"medical device" has the meaning—

(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[4], as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020[5];

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

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

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

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

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

as applicable;

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

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

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

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

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

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

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

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4 OJ No. L 117, 5.5.2017, p. 1.
5 OJ No. L 130, 24.4.2020, p. 18.

"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[6],

as applicable;

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

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

"type IA variation", "type IB variation" and "type II standard variation" refer to classifications by the Authority in accordance with Commission Regulation (EC) No. 1234/2008 of 24 November 2008[7];

"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 2020 (S.I. No. 654 of 2020) are revoked.

6 OJ No. L 169, 12.7.1993, p. 1.
7 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 | 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 – 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** | 1,245 |
| Related company | |
| 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 scheme | 190 |
| 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 cancellation/rescheduling fee | 500 |

**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 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<br>- with more than 150 employees | 30,600 |
| Manufacturer or system and procedure pack producer or manufacturing facility<br>- with 100-150 employees | 20,400 |
| Manufacturer or system and procedure pack producer or manufacturing facility<br>- with 50-99 employees | 15,300 |
| Manufacturer or system and procedure pack producer or manufacturing facility<br>- with 16-49 employees | 5,100 |
| Manufacturer or system and procedure pack producer or manufacturing facility<br>- with 5-15 employees | 1,275 |
| Manufacturer or system and procedure pack producer or manufacturing facility<br>- with less than 5 employees or annual turnover of less than €500,000 | 250 |

**Authorised Representatives – annual fees**

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

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

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

| | |
|---|---|
| **Distributors and Importers – annual fees** | |
| Large distributor/importer (turnover greater than €15 million) | 4,590 |
| Medium distributor/importer (turnover €3-€15 million) | 2,550 |
| Small distributor/importer (turnover under €3 million) | 1,275 |
| Distributor/importer turnover less than €500,000 | 250 |
| Additional supplement – Entities acting as both a distributor and importer where turnover is more than €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** | |
| Devices using starting materials for which a TSE certificate of suitability has been submitted | 2,500 |
| Devices using starting materials for which a TSE certificate of suitability has not been submitted | 5,000 |
| **Certificates of free sale or letters confirming the location of the manufacturing facility in Ireland for Devices** | |
| Certificate of free sale/letter confirming the location of the manufacturing facility in Ireland (4 certificates per request) | 255 |
| Each additional certificate of free sale/letter confirming the location of the manufacturing facility in Ireland – (available at time of request) | 25 |

L.S.

GIVEN under my Official Seal,
21 December, 2021.

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 2020 (S.I. No. 654 of 2020).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2021.

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