



STATUTORY INSTRUMENTS.

**S.I. No. 531 of 2018**



HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) (NO. 2)  
REGULATIONS 2018

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I, SIMON HARRIS, 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) (No. 2) Regulations 2018.

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);

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

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 14th December, 2018.*

“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 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;

“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;

“Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001<sup>1</sup>;

“distributor”, in the context of medical devices, means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a medical device available on the market;

“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;

<sup>1</sup>OJ No. L 311, 28.11.2001, p. 67.

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

“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, means—

- (a) 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
- (b) 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;

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

“manufacturing site”, in the context of medical devices, means a site where an entity—

- (a) manufactures a medical device,
- (b) manufactures critical components of a medical device to a set of specifications,
- (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” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of—

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease,

- (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- (c) investigation, replacement or modification of the anatomy or of a physiological process, or
- (d) control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes—

- (i) an in vitro diagnostic medical device in accordance with the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001, and
- (ii) an active implantable medical device in accordance with the European Communities (Active Implantable Medical Devices) Regulations 1994;

“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;

“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 (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 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<sup>2</sup>;

“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 2018 (S.I. No. 208 of 2018) are revoked.

<sup>2</sup>OJ No. L 334, 12.12.2008, p. 7.

SCHEDULECOLUMN 1COLUMN 2Fees for national applications for marketing authorisations

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**Complex dossier**

National application	20,000
Each additional form (same time)	7,000
Each additional strength (same time)	1,000
Additional drug master file submitted	4,000

**Reduced dossier — complex**

National application	15,000
Each additional form (same time)	7,000
Each additional strength (same time)	1,000
Additional drug master file submitted	4,000

**Reduced dossier — standard**

National application	10,000
Each additional form (same time)	7,000
Each additional strength (same time)	1,000
Additional drug master file submitted	4,000

**Subsequent extension applications**

First additional form	10,000
Each additional form (same time)	7,000
First additional strength (existing form)	3,000
Each additional strength (same time)	1,000
Additional drug master file submitted	4,000

Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure**Complex dossier**

Mutual recognition incoming	14,000
Each additional form (same time)	5,000
Each additional strength (same time)	1,000
Outgoing mutual recognition supplement	15,000
Decentralised incoming	20,000
Decentralised outgoing	50,000
Each additional form (same time)	7,000
Each additional strength (same time)	1,000
Additional supplement where there are 15 or more concerned Member States	1,500

**Reduced dossier — complex**

Mutual recognition incoming	10,000
Each additional form (same time)	5,000
Each additional strength (same time)	1,000
Outgoing mutual recognition supplement	15,000
Decentralised incoming	15,000
Decentralised outgoing	40,000

Each additional form (same time)	7,000
Each additional strength (same time)	1,000
Additional supplement where there are 15 or more concerned Member States	1,500
<b>Reduced dossier — standard</b>	
Mutual recognition incoming	7,000
Each additional form (same time)	4,000
Each additional strength (same time)	1,000
Outgoing mutual recognition supplement	10,000
Decentralised incoming	10,000
Decentralised outgoing	26,000
Each additional form (same time)	7,000
Each additional strength (same time)	1,000
Additional supplement where there are 15 or more concerned Member States	1,500
<b>Subsequent extension applications</b>	
Mutual recognition incoming (first additional form)	7,000
Mutual recognition incoming (first additional strength)	2,000
Mutual recognition incoming (subsequent additional strength)	1,000
Outgoing mutual recognition/decentralised supplement (additional form)	3,000
Outgoing mutual recognition/decentralised supplement (additional strength)	1,000
Decentralised incoming (first additional form)	10,000
Decentralised outgoing (first additional form)	26,000
Each additional form (same time)	7,000
First additional strength (existing form)	3,000
Each additional strength (same time)	1,000
Additional supplement where there are 15 or more concerned Member States	1,500
<b>Switching applications</b>	
Switching applications	5,100
 <b><u>Fees for parallel import licences</u></b>	
Application fee — per country at the same time or by variation	1,831
Each additional strength per country	545
Each additional form per country	545
Parallel imports — dual pack registration	915
Dual pack registration of parallel imports — each additional strength or form	545
Parallel imports where the originator is not on the Irish market	5,508
Change of ownership per product range	578



**Fees for variations to national marketing authorisations**

Type IB variation	516
Type IB variation — reduced rate	258
Type II complex variation	2,865
Type II complex variation — reduced rate	558
Type II standard variation	558
Type II standard variation — reduced rate	278
Notifications under Article 61(3) of Directive 2001/83/ EC	275
Notifications under Article 61(3) of Directive 2001/83/EC — reduced rate	138
Multiple variations capped fee (per product range)	5,288
Multiple variations capped fee (per product)	3,415
Worksharing capped fee	5,728

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

Type IB variation outgoing mutual recognition / decentralised supplement	380
Type IB variation — mutual recognition incoming	372
Type IB variation — mutual recognition incoming — reduced rate	192
Type II complex variation — outgoing mutual recognition / decentralised Supplement	578
Type II complex variation — mutual recognition incoming	1,980
Type II complex variation — mutual recognition incoming — reduced rate	372
Type II standard variation — mutual recognition incoming	372
Type II standard variation — mutual recognition incoming — reduced rate	192
Type II standard variation — outgoing mutual recognition / decentralised Supplement	372
Notifications made under Article 61(3) of Directive 2001/83/EC	275
Notifications made under Article 61(3) of Directive 2001/83/EC — reduced rate	138

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

Change of ownership — related company — 1 <sup>st</sup> marketing authorisation within a range	991
Change of ownership — related company — each additional marketing authorisation within a range	354
Change of ownership — non-related company — 1 <sup>st</sup> marketing authorisation within a range	1,450

Change of ownership — non-related company — each additional marketing authorisation within a range	354
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**Other fees relating to the granting of marketing authorisations**

Service item	674
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**Notification to become a listed organisation**

Notification Fee	10
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**Fees for applications for wholesaler's authorisations**

Application fee	611
Variation to authorisation — minor site technical	441
Variation to authorisation — administrative	241
Variation to authorisation — technical	664

**Fees for applications for manufacturer's authorisations**

Application fee	2,041
Variation to authorisation — administrative	302
Variation to authorisation — technical	846
Variation to authorisation — investigational medicinal product — fast track	1,200

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

Registration fee — importers and distributors of active substances and Brokers	275
Registration fee — manufacturers of active substances	486
Immediate notification of a change which may impact on the quality or safety of the active substances	846
Notification of an administrative change to the active substances register	150
Notification of any change to the brokers register	150

**Fees for applications for organ establishment authorisations**

Application charge	2,041
Variation to authorisation — administrative	302
Variation to authorisation — technical	846
Appeal to amend/revoke an authorisation	551

**Fees for transferring of authorisation/registration to another company**

**Manufacturer's authorisation and organ establishment authorisation**

Related companies	1,219
Unrelated companies	2,041

**Wholesaler's authorisation, registration on brokers register and registration on active substances register**

Related companies	402
Unrelated companies	611

**Fees for applications in relation to cosmetic products**

Certificates of free sale — standard (4 certs per request)	162
Certificates of free sale — fast track (4 certs per request)	305
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	747
New national / decentralised registration standard charge — 2 or more stocks	1,119
New application — national rules scheme standard fee — single stock	1,119
New application — national rules scheme standard fee — 2 or more stocks	1,652
Mutual recognition incoming application standard fee — single stock	498
Mutual recognition incoming application standard fee — 2 or more stocks	747
Outgoing mutual recognition / decentralised supplement	621
National variation — registration and national rules scheme	373
National variation — reduced rate — registrations and national rules scheme	187
Mutual recognition incoming variation	249
Mutual recognition incoming variation — reduced rate	124
Variation — outgoing mutual recognition / decentralised supplement	187
Bulk variation for multiple changes to the masterfile	2,245

**Fees for applications in relation to traditional herbal medicinal products**

**National applications for certificates of traditional-use registration**

National application	5,385
National application where there is a monograph	3,305
Each additional form (same time)	4,486
Each additional strength (same time)	579
Additional drug master file submitted	3,581

**Extension applications**

First additional form	5,385
Each additional form (same time)	4,485
First additional strength	2,429
Each additional strength (same time)	579

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

Mutual recognition incoming	3,765
Mutual recognition incoming — each additional form (same time)	2,520
Mutual recognition incoming — each additional strength (same time)	579
Outgoing mutual recognition / decentralised supplement	4,897
Decentralised outgoing/incoming	5,385
Each additional form (same time)	4,486
Each additional strength (same time)	579

**Traditional herbal medicinal products — national variations**

Type IB variation — national	413
Type IB variation — reduced rate	210
Type II standard variation	441
Type II standard variation — reduced rate	220
Type II complex variation	2,313
Bulk variation for multiple changes	4,627

**Traditional herbal medicinal products — mutual recognition variations**

Type IB variation — mutual recognition incoming	297
Type IB variation — mutual recognition incoming — reduced rate	154
Type IB variation — outgoing mutual recognition supplement	303
Type II standard — mutual recognition incoming	297
Type II standard — mutual recognition incoming — reduced rate	154
Type II standard — outgoing mutual recognition supplement	297

Type II complex — mutual recognition incoming	1,581
Type II complex — outgoing mutual recognition supplement	462

### **Fees for export certificates and certification of documents**

Standard	162
Fast track	305

### **Annual maintenance fees**

Marketing authorisations and registrations	
First 10 marketing authorisations	716
Additional marketing authorisations	894
Dormant marketing authorisations	463
Parallel import licence	124
Parallel import licence — Dual pack	61
Certificate of registration — homeopathic medicinal products	61
Certificate of traditional-use registration — traditional herbal medicinal products	124

### **Manufacturer's authorisations**

Major site (more than 250 employees)	18,363
Large site (150-250 employees)	12,241
Medium site (50-149 employees)	8,162
Small site (less than 50 employees)	4,079
Homeopathic manufacturing site	1,102

### **Wholesaler's authorisations**

Large full line	3,053
Medium full line/ short line	1,736
Small short line	661
Minor site / Procure & supply	441

### **Active substances register**

Active substances distributor	275
Active substances importer	551
Active substances manufacturer	1,102

### **Organ establishment authorisations**

Major establishment (more than 250 employees)	18,363
Large establishment (150-250 employees)	12,241
Medium establishment (50-149 employees)	8,162
Small establishment (less than 50 employees)	4,079
Minor establishment (less than 5 employees)	1,102

### **Project fees**

Project application without ethical approval	2,000
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Fast track project application	2,000
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**Breeder/Supplier/User Authorisation fees**

Band 1: Small establishment with no animal facilities or establishment with 1-3 individual authorisation holders	275
Band 2: Establishment with 4-10 individual authorisation holders	550
Band 3: Establishment with 11-20 individual authorisation holders	850
Band 4: Establishment with 21-50 individual authorisation holders	1,600
Band 5: Establishment with 51-100 individual authorisation holders	3,250
Band 6: Establishment with 101-150 individual authorisation holders	5,500
Band 7: Establishment with 151 — 200 individual authorisation holders	8,000
Band 8: Establishment with >201 individual authorisation holders	10,500

**Individual authorisation fees**

Application fee	260
Annual fee	260
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)	1,640
Part of day (per hour, per member of the inspection team)	235

**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)	1,640
Part of day (per hour, per member of the inspection team)	235

**Enforcement fees**

**Manufacturers**

Major site (more than 250 employees)	2,644
Large site (150-250 employees)	1,983
Medium site (50-149 employees)	661
Small site (less than 50 employees)	220

**Wholesalers**

Large full line	661
Medium full line / short line	220

**Marketing authorisation / parallel import licence holders**

> 50 marketing authorisations / parallel import licences	3,470
31-50 marketing authorisations / parallel import licences	1,102
16-30 marketing authorisations / parallel import licences	661
6-15 marketing authorisations / parallel import licences	220

(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****Manufacturers and authorised representatives — annual fees**

Manufacturer — more than 150 employees	30,000
Manufacturer — 100-150 employees	20,000
Manufacturer — 50-99 employees	15,000
Manufacturer — 16-49 employees	5,000
Manufacturer — 5-15 employees	1,250
Manufacturer — less than 5 employees or annual turnover of less than €500,000	250
Authorised representative/legal manufacturer which is not a manufacturer (of medical devices) (maximum of €5,000)	1,250

(Note: Where one organisation has multiple manufacturing sites based in the State, the organisation will be charged per manufacturing site to a maximum fee of €60,000.)

**Distributors — annual fees**

Large distributor (turnover greater than €15 million)	4,500
Medium distributor (turnover €3-€15 million)	2,500
Small distributor (turnover under €3 million)	1,250
Distributor turnover less than €500,000	250

<b>Notified Body — annual fees</b>	5,000
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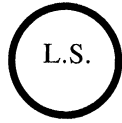
**Summary evaluation review fees**

Medical Devices using starting materials for which a TSE certificate of suitability has been submitted	1,000
Medical Devices using starting materials for which a TSE certificate of suitability has not been submitted	3,000

**Certificates of free sale for medical devices**

Certificate of free sale (4 certificates per request) 250

Duplicate certificates of free sale — each (available at time  
of request) 23



Given under my official seal,  
11 December 2018.

SIMON HARRIS,  
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 2018 (S.I. No. 208 of 2018).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) (No. 2) Regulations 2018.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ó  
FOILSEACHÁIN RIALTAIS,  
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2  
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)  
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