STATUTORY INSTRUMENTS.

S.I. No. 208 of 2018

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) 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) 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 22*nd June*, 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 (No. 540 of 2007);

"Control of Wholesale Distribution Regulations" means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. 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[1];

"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;

[1]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;

"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[2];

"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 2017 (S.I. No. 557 of 2017) are revoked.

[2]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	15,515
Each additional form (same time)	5,192
Each additional strength (same time)	669
Additional drug master file submitted	3,316
Reduced dossier — complex	
National application	11,556
Each additional form (same time)	5,192
Each additional strength (same time)	669
Additional drug master file submitted	3,316
Reduced dossier — standard	
National application	7,811
Each additional form (same time)	5,192
Each additional strength (same time)	669
Additional drug master file submitted	3,316
Subsequent extension applications	
First additional form	7,811
Each additional form (same time)	5,192
First additional strength (existing form)	2,811
Each additional strength (same time)	669
Additional drug master file submitted	3,316
Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure	
Complex dossier	
Mutual recognition incoming	10,860
Each additional form (same time)	3,733
Each additional strength (same time)	669
Outgoing mutual recognition supplement	11,181
Decentralised incoming	15,515
Decentralised outgoing	40,800
Each additional form (same time)	5,192
Each additional strength (same time)	669
Additional supplement where there are 15 or more concerned Member States	1,020
Reduced dossier — complex	
Mutual recognition incoming	8,239
Each additional form (same time)	3,316
Each additional strength (same time)	669
Outgoing mutual recognition supplement	11,181
Decentralised incoming	11,556
Decentralised outgoing	30,600
Each additional form (same time)	5,192
Each additional strength (same time)	669
Additional supplement where there are 15 or more concerned Member States	1,020
Reduced dossier — standard	
Mutual recognition incoming	5,457
Each additional form (same time)	2,916
Each additional strength (same time)	669
Outgoing mutual recognition supplement	7,269
Decentralised incoming	7,811
Decentralised outgoing	20,400
Each additional form (same time)	5,192
Each additional strength (same time)	669
Additional supplement where there are 15 or more concerned Member States	1,020
Subsequent extension applications	
Mutual recognition incoming (first additional form)	5,457
Mutual recognition incoming (first additional strength)	1,968
Mutual recognition incoming (subsequent additional strength)	669
Outgoing mutual recognition/decentralised supplement (additional form)	2,916
Outgoing mutual recognition/decentralised supplement (additional strength)	669
Decentralised incoming (first additional form)	7,811

Decentralised outgoing (first additional form)	20,400
Each additional form (same time)	5,192
First additional strength (existing form)	2,811
Each additional strength (same time)	669
Additional supplement where there are 15 or more concerned Member States	1,020
Switching applications	
Switching applications	5,100

Fees for parallel import licences

Application fee — per country at the same time or by variation	1,695
Each additional strength per country	505
Each additional form per country	505
Parallel imports — dual pack registration	848
Dual pack registration of parallel imports — each additional strength or form	505
Parallel imports where the originator is not on the Irish market	5,100
Change of ownership per product range	536

Fees for variations to national marketing authorisations

Type IB variation	477
Type IB variation — reduced rate	239
Type II complex variation	2,653
Type II standard variation	516
Type II standard variation — reduced rate	258
Notifications under Article 61(3) of Directive 2001/83/ EC	255
Notifications under Article 61(3) of Directive 2001/83/EC — reduced rate	128
Multiple variations capped fee (per product range)	4,896
Multiple variations capped fee (per product)	3,162
Worksharing capped fee	5,304

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

Type IB variation outgoing mutual recognition / decentralised supplement	352
Type IB variation — mutual recognition incoming	345
Type IB variation — mutual recognition incoming — reduced rate	177
Type II complex variation — outgoing mutual recognition / decentralised Supplement	536
Type II complex variation — mutual recognition incoming	1,833
Type II standard variation — mutual recognition incoming	345
Type II standard variation — mutual recognition incoming — reduced rate	177
Type II standard variation — outgoing mutual recognition / decentralised Supplement	345
Notifications made under Article 61(3) of Directive 2001/83/EC	255
Notifications made under Article 61(3) of Directive 2001/83/EC — reduced rate	128

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

Change of ownership — related company — 1st marketing authorisation within a range	918
Change of ownership — related company — each additional marketing authorisation within a range	327
Change of ownership — non-related company — 1st marketing authorisation within a range	1,342
Change of ownership — non-related company — each additional marketing authorisation within a range	327

Other fees relating to the granting of marketing authorisations

Service item	624

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	566
Variation to authorisation — minor site technical	408
Variation to authorisation — administrative	223
Variation to authorisation — technical	615

Fees for applications for manufacturer's authorisations

Application fee	1,890
Variation to authorisation — administrative	279
Variation to authorisation — technical	783

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

Registration fee — importers and distributors of active substances and Brokers	255
Registration fee — manufacturers of active substances	450
Immediate notification of a change which may impact on the quality or safety of the active substances	783
Notification of an administrative change to the active substances register	139
Notification of any change to the brokers register	139

Fees for applications for organ establishment authorisations

Application charge	1,890
Variation to authorisation — administrative	279
Variation to authorisation — technical	783
Appeal to amend/revoke an authorisation	510

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation	
Related companies	1,129
Unrelated companies	1,890

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

Related companies	372
Unrelated companies	566

Fees for applications in relation to cosmetic products

Certificates of free sale — standard (4 certs per request)	150
Certificates of free sale — fast track (4 certs per request)	283
Duplicate certificates of free sale — each (available at time of initial request)	23

Fees for applications in relation to homeopathic medicinal products

New national / decentralised registration standard charge — single stock	692
New national / decentralised registration standard charge — 2 or more stocks	1,036
New application — national rules scheme standard fee — single stock	1,036
New application — national rules scheme standard fee — 2 or more stocks	1,530

Mutual recognition incoming application standard fee — single stock	461
Mutual recognition incoming application standard fee — 2 or more stocks	692
Outgoing mutual recognition / decentralised supplement	575
National variation — registration and national rules scheme	346
National variation — reduced rate — registrations and national rules scheme	173
Mutual recognition incoming variation	231
Mutual recognition incoming variation — reduced rate	115
Variation — outgoing mutual recognition / decentralised supplement	173
Bulk variation for multiple changes to the masterfile	2,079

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	4,986
National application where there is a monograph	3,060
Each additional form (same time)	4,153
Each additional strength (same time)	536
Additional drug master file submitted	3,316

Extension applications

First additional form	4,986
Each additional form (same time)	4,153
First additional strength	2,249
Each additional strength (same time)	536

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

Mutual recognition incoming	3,486
Mutual recognition incoming — each additional form (same time)	2,333
Mutual recognition incoming — each additional strength (same time)	536
Outgoing mutual recognition / decentralised supplement	4,534
Decentralised outgoing/incoming	4,986
Each additional form (same time)	4,153
Each additional strength (same time)	536

Traditional herbal medicinal products — national variations

Type IB variation — national	383
Type IB variation — reduced rate	194
Type II standard variation	408
Type II standard variation — reduced rate	204
Type II complex variation	2,142
Bulk variation for multiple changes	4,284

Traditional herbal medicinal products — mutual recognition variations

Type IB variation — mutual recognition incoming	275
Type IB variation — mutual recognition incoming — reduced rate	143
Type IB variation — outgoing mutual recognition supplement	281
Type II standard — mutual recognition incoming	275
Type II standard — mutual recognition incoming — reduced rate	143
Type II standard — outgoing mutual recognition supplement	275
Type II complex — mutual recognition incoming	1,464
Type II complex — outgoing mutual recognition supplement	428

Fees for export certificates and certification of documents

Standard	150
Fast track	283

Annual maintenance fees

Marketing authorisations and registrations	
First 10 marketing authorisations	663
Additional marketing authorisations	828
Dormant marketing authorisations	428
Parallel import licence	115
Parallel import licence — Dual pack	56
Certificate of registration — homeopathic medicinal products	56
Certificate of traditional-use registration — traditional herbal medicinal products	115
Manufacturer's authorisations	
Major site (more than 250 employees)	17,002
Large site (150-250 employees)	11,334
Medium site (50-149 employees)	7,557
Small site (less than 50 employees)	3,777
Homeopathic manufacturing site	1,020
Wholesaler's authorisations	
Large full line	2,826
Medium full line/ short line	1,608
Small short line	612
Minor site	408
Procure and supply only	357
Active substances register	
Active substances distributor	255
Active substances importer	510
Active substances manufacturer	1,020
Organ establishment authorisations	
Major establishment (more than 250 employees)	17,002
Large establishment (150-250 employees)	11,334
Medium establishment (50-149 employees)	7,557
Small establishment (less than 50 employees)	3,777
Minor establishment (less than 5 employees)	1,020

Project fees

Project application without ethical approval	2,000
Fast track project application	2,000

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	225
Annual fee	225
Once-off authorisation — procedural training for a period of two months or less (reduced fee)	85

Fees for follow-up inspections

Per day (per member of the inspection team)	1,489
Part of day (per hour, per member of the inspection team)	213

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)	1,519
Part of day (per hour, per member of the inspection team)	217

Enforcement fees

Manufacturers	
Major site (more than 250 employees)	2,448
Large site (150-250 employees)	1,836
Medium site (50-149 employees)	612
Small site (less than 50 employees)	204
Wholesalers	
Large full line	612
Medium full line / short line	204
Marketing authorisation / parallel import licence holders	
> 50 marketing authorisations / parallel import licences	3,213
31-50 marketing authorisations / parallel import licences	1,020
16-30 marketing authorisations / parallel import licences	612
6-15 marketing authorisations / parallel import licences	204

(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 Ireland, 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

Notified Body — annual fees	3,000
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

L.S.

GIVEN under my Official Seal,
19 June 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 2017 (S.I. No. 557 of 2017).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2018.

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