STATUTORY INSTRUMENTS.

S.I. No. 531 of 2018

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


“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);


“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;

“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;

“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.
## SCHEDULE

<table>
<thead>
<tr>
<th>COLUMN 1</th>
<th>COLUMN 2</th>
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<tbody>
<tr>
<td><strong>Fees for national applications for marketing authorisations</strong></td>
<td>€</td>
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<tr>
<td><strong>Complex dossier</strong></td>
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<tr>
<td>National application</td>
<td>20,000</td>
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<tr>
<td>Each additional form (same time)</td>
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<td>Each additional strength (same time)</td>
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<td>Additional drug master file submitted</td>
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<tr>
<td><strong>Reduced dossier — standard</strong></td>
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<td>Additional drug master file submitted</td>
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</table>

| **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 | 1,500 |
| Member States | |
| **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 1,500

Member States

**Reduced dossier — standard**
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 1,500

Member States

**Subsequent extension applications**
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 1,500

Member States

**Switching applications**
Switching applications 5,100

**Fees for parallel import licences**
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

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<th>Type I variation</th>
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<td>Type I variation — reduced rate</td>
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<td>Type II complex variation</td>
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<td>Type II complex variation — reduced rate</td>
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<tr>
<td>Type II standard variation</td>
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<td>Type II standard variation — reduced rate</td>
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<td>Notifications under Article 61(3) of Directive 2001/83/EC</td>
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<td>Notifications under Article 61(3) of Directive 2001/83/EC — reduced rate</td>
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<td>Multiple variations capped fee (per product range)</td>
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<td>Worksharing capped fee</td>
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</table>

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

| Type I variation outgoing mutual recognition / decentralised supplement | 380 |
| Type I variation — mutual recognition incoming | 372 |
| Type I 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 — 1st 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 — 1st marketing authorisation within a range | 1,450 |
Change of ownership — non-related company — each additional marketing authorisation within a range

**Other fees relating to the granting of marketing authorisations**

Service item

**Notification to become a listed organisation**

Notification Fee

**Fees for applications for wholesaler’s authorisations**

Application fee
Variation to authorisation — minor site technical
Variation to authorisation — administrative
Variation to authorisation — technical

**Fees for applications for manufacturer’s authorisations**

Application fee
Variation to authorisation — administrative
Variation to authorisation — technical
Variation to authorisation — investigational medicinal product — fast track

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

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

**Fees for applications for organ establishment authorisations**

Application charge
Variation to authorisation — administrative
Variation to authorisation — technical
Appeal to amend/revoke an authorisation
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

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Fee</th>
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</thead>
<tbody>
<tr>
<td>Standard</td>
<td>162</td>
</tr>
<tr>
<td>Fast track</td>
<td>305</td>
</tr>
</tbody>
</table>

### 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
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 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

Notified Body — annual fees
5,000

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

Given under my official seal,
11 December 2018.

L.S.

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.