



STATUTORY INSTRUMENTS.

S.I. No. 599 of 2015



HEALTH PRODUCTS REGULATORY AUTHORITY (FEES)
REGULATIONS 2015

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I, KATHLEEN LYNCH, Minister of State at the Department of 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) and the Health (Delegation of Ministerial Functions) Order 2014 (S.I. No. 532 of 2014), hereby make the following regulations:

1. These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2015.

2. In these Regulations—

“Act” means the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006), the European Communities (Amendment of the Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007) and section 36 of the Health (Pricing and Supply of Medical Goods) Act 2013;

“active substances register” means the register of importers, manufacturers and distributors of active substances maintained by the Authority in pursuance of Regulation 14D (inserted by Regulation 7 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);

“Authority” means the Health Products Regulatory Authority established by section 3 of the Act;

“breeder authorisation” means an authorisation granted to a breeder under Part 6 of the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (S.I. No. 543 of 2012);

“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.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 5th January, 2016.*

No. 164 of 2013)) of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. 538 of 2007);

“brokers register” means the register maintained by the Authority in pursuance of Regulation 14D (inserted by Regulation 6 of the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013) of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007;

“certificate of free sale” means a certificate of free sale issued under section 4(1)(k)(ii) of the Act;

“certificate of registration” means a certificate of registration granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014;

“certificate of traditional-use registration” means a certificate of traditional-use registration granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014 in respect of a traditional herbal medicinal product;

“certification of documents” means the certification, under section 4(1)(k)(ii) of the Act, 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;

“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 2001¹, as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003², Commission Directive 2003/63/EC of 25 June 2003³, Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004⁴, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004⁵, Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006⁶, Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007⁷, Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008⁸, Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009⁹, Commission Directive 2009/120/EC of 14 September 2009¹⁰, Directive 2010/84/EU of the European Parliament and of the Council of 15 December

¹OJ No. L 311, 28.11.2001, p. 67.

²OJ No. L 33, 8.2.2003, p. 30.

³OJ No. L 159, 27.6.2003, p. 46.

⁴OJ No. L 136, 30.4.2004, p. 85.

⁵OJ No. L 136, 30.4.2004, p. 34.

⁶OJ No. L 378, 27.12.2006, p. 1.

⁷OJ No. L 324, 10.12.2007, p. 121.

⁸OJ No. L 81, 20.3.2008, p. 51.

⁹OJ No. L 168, 30.6.2009, p. 33.

¹⁰OJ No. L 242, 15.9.2009, p. 3.

2010¹¹, Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011¹² and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012¹³;

“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 a certificate issued under section 4(1)(k)(ii) of the Act;

“follow-up inspections” means inspections other than routine inspections;

“homeopathic medicinal product” has the meaning assigned to it by Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

“individual authorisation” means an authorisation granted to an individual under Part 8 of the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (S.I. No. 543 of 2012);

“manufacturer’s authorisation” means an authorisation granted pursuant to the Medicinal Products (Control of Manufacture) Regulations 2007 to 2013;

“marketing authorisation” means an authorisation granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014;

“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 Medicinal Products (Control of Placing on the Market) Regulations 2007;

“organ establishment authorisation” means an authorisation granted pursuant to the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 and 2014;

“parallel import licence” has the meaning assigned to it by Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007;

“project” means a programme of work having a defined scientific objective and involving one or more procedures pursuant to the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2014;

¹¹OJ No. L 348, 31.12.2010, p. 74.

¹²OJ No. L 174, 1.7.2011, p. 74.

¹³OJ No. L 299, 27.10.2012, p. 1.

“project authorisation” means an authorisation granted pursuant to the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2014;

“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” means an authorisation granted pursuant to the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2014;

“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 Medicinal Products (Control of Placing on the Market) Regulations 2007;

“type IB variation” and “type II standard variation” shall be classified by the Authority in accordance with Commission Regulation (EC) No. 1234/2008 of 24 November 2008¹⁴, as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012¹⁵;

“user authorisation” means an authorisation granted to a user pursuant to the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2014;

“wholesaler’s authorisation” means an authorisation granted pursuant to the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013.

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 fee as set out in column 2 of the Schedule.

¹⁴OJ No. L 334, 12.12.2008, p. 7.

¹⁵OJ No. L 209, 4.8.2012, p. 4.

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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 2014 (S.I. No. 607 of 2014) are revoked.

SCHEDULE

Column 1	Column 2
<u>Fees for national applications for marketing authorisations</u>	€
Complex dossier	
National application	15,211
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Reduced dossier — complex	
National application	11,329
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Reduced dossier — standard	
National application	7,658
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Subsequent extension applications	
First additional form	7,658
Each additional form (same time)	5,090
First additional strength (existing form)	2,756
Each additional strength (same time)	656
Additional drug master file submitted	3,251
<u>Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure</u>	
Complex dossier	
Mutual recognition incoming	10,647
Each additional form (same time)	3,660
Each additional strength (same time)	656
Outgoing mutual recognition supplement	10,962
Decentralised incoming	15,211
Decentralised outgoing	40,000
Each additional form (same time)	5,090
Each additional strength (same time)	656

Additional supplement where there are 15 or more concerned Member States	1,000
Reduced dossier — complex	
Mutual recognition incoming	8,077
Each additional form (same time)	3,251
Each additional strength (same time)	656
Outgoing mutual recognition supplement	10,962
Decentralised incoming	11,329
Decentralised outgoing	30,000
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional supplement where there are 15 or more concerned Member States	1,000
Reduced dossier — standard	
Mutual recognition incoming	5,350
Each additional form (same time)	2,859
Each additional strength (same time)	656
Outgoing mutual recognition supplement	7,126
Decentralised incoming	7,658
Decentralised outgoing	20,000
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional supplement where there are 15 or more concerned Member States	1,000
Subsequent extension applications	
Mutual recognition incoming (first additional form)	5,350
Mutual recognition incoming (first additional strength)	1,929
Mutual recognition incoming (subsequent additional strength)	656
Outgoing mutual recognition/decentralised supplement (additional form)	2,859
Outgoing mutual recognition/decentralised supplement (additional strength)	656
Decentralised incoming (first additional form)	7,658
Decentralised outgoing (first additional form)	20,000
Each additional form (same time)	5,090
First additional strength (existing form)	2,756
Each additional strength (same time)	656
Additional supplement where there are 15 or more concerned Member States	1,000
Switching applications	
Switching applications	5,000

Fees for parallel import licences

Application fee — per country at the same time or by variation	1,662
Each additional strength per country	495
Each additional form per country	495
Parallel imports of dual pack registrations	831
Registration of parallel imports — each additional strength or form	495
Parallel imports where the originator is not on the Irish market	5,000
Change of ownership per product range	525

Fees for variations to national marketing authorisations

Type IB variation	468
Type IB variation — reduced rate	234
Type II complex variation	2,601
Type II standard variation	506
Type II standard variation — reduced rate	253
Notifications under Article 61(3) of Directive 2001/83/ EC	250
Notifications under Article 61(3) of Directive 2001/83/EC — reduced rate	125
Multiple variations capped fee (per product range)	4,800
Multiple variations capped fee (per product)	3,100
Worksharing capped fee	5,200

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

Type IB variation outgoing mutual recognition / decentralised supplement	345
Type IB variation — mutual recognition incoming	338
Type IB variation — mutual recognition incoming — reduced rate	174
Type II complex variation — outgoing mutual recognition / decentralised supplement	525
Type II complex variation — mutual recognition incoming	1,797
Type II standard variation — mutual recognition incoming	338
Type II standard variation — mutual recognition incoming — reduced rate	174
Type II standard variation — outgoing mutual recognition / decentralised supplement	338
Notifications made under Article 61(3) of Directive 2001/83/EC	250
Notifications made under Article 61(3) of Directive 2001/83/EC — reduced rate	125

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

Change of ownership — related company — 1 st marketing authorisation within a range	900
Change of ownership — related company — additional marketing authorisations within a range	321
Change of ownership — non-related company — 1 st marketing authorisation within a range	1,316
Change of ownership — non-related company — additional marketing authorisations within a range	321

Other fees relating to the granting of marketing authorisations

Service item	612
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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	555
Variation to authorisation — minor site technical	400
Variation to authorisations — administrative	219
Variation to authorisation — technical	603

Fees for applications for manufacturer's authorisations

Application fee	1,853
Variation to authorisation — administrative	274
Variation to authorisation — technical	768

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

Registration fee	250
Immediate notification of a change which may impact on the quality or safety of the active substances	768
Notification of an administrative change to the active substances register	136

Notification of any change to the brokers register	136
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Fees for applications for organ establishment authorisations

Application charge	1,853
Variation to authorisation — administrative	274
Variation to authorisation — technical	768
Appeal to amend/revoke an authorisation	500

Fees for transferring of authorisation/registration to another company

Manufacturer's authorisation and organ establishment authorisation

Related companies	1,107
Unrelated companies	1,853

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

Related companies	365
Unrelated companies	555

Fees for applications in relation to medical devices and cosmetic products

Certificates of free sale — standard (4 certs per request)	147
Certificates of free sale — fast track (4 certs per request)	277
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	678
New national / decentralised registration standard charge — 2 or more stocks	1,016
New application — national rules scheme standard fee — single stock	1,016
New application — national rules scheme standard fee — 2 or more stocks	1,500
Mutual recognition incoming application standard fee — single stock	452
Mutual recognition incoming application standard fee — 2 or more stocks	678

Outgoing mutual recognition / decentralised supplement	564
National variation — registration and national rules scheme	339
National variation — reduced rate — registrations and national rules scheme	170
Mutual recognition incoming variation	226
Mutual recognition incoming variation — reduced rate	113
Variation — outgoing mutual recognition / decentralised supplement	170
Bulk variation for multiple changes to the masterfile	2,038

Fees for applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration

National application	4,888
National application where there is a monograph	3,000
Each additional form (same time)	4,072
Each additional strength (same time)	525
Additional drug master file submitted	3,251

Extension applications

First additional form	4,888
Each additional form (same time)	4,072
First additional strength	2,205
Each additional strength (same time)	525

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

Mutual recognition incoming	3,418
Mutual recognition incoming — each additional form (same time)	2,287
Mutual recognition incoming — each additional strength (same time)	525
Outgoing mutual recognition / decentralised supplement	4,445
Decentralised outgoing/incoming	4,888
Each additional form (same time)	4,072
Each additional strength (same time)	525

Traditional herbal medicinal products — national variations

Type IB variation — national	375
Type IB variation — reduced rate	190
Type II standard variation	400
Type II standard variation — reduced rate	200
Type II complex variation	2,100
Bulk variation for multiple changes	4,200

Traditional herbal medicinal products — mutual recognition variations

Type IB variation — mutual recognition incoming	270
Type IB variation — mutual recognition incoming — reduced rate	140
Type IB variation — outgoing mutual recognition supplement	275
Type II standard — mutual recognition incoming	270
Type II standard — mutual recognition incoming — reduced rate	140
Type II standard — outgoing mutual recognition supplement	270
Type II complex — mutual recognition incoming	1,435
Type II complex — outgoing mutual recognition supplement	420

Fees for export certificates and certification of documents

Standard	147
Fast track	277

Annual maintenance fees**Marketing authorisations and registrations**

First 10 marketing authorisations	650
Additional marketing authorisations	812
Dormant marketing authorisations	420
Parallel import registration	113
Dual pack registration	55
Homeopathic medicinal products	55
Traditional herbal medicinal products	113

Manufacturer's authorisations

Major site (more than 250 employees)	16,669
Large site (150-250 employees)	11,112
Medium site (50-149 employees)	7,409
Small site (less than 50 employees)	3,703
Homeopathic manufacturing site	1,000

Wholesaler's authorisations

Large full line	2,771
Medium full line/ short line	1,576
Small short line	600
Minor site	400
Procure and supply only	350

Active substances register

Active substances distributor	250
Active substances importer	500
Active substances manufacturer	1,000

Organ establishment authorisations

Major establishment (more than 250 employees)	16,669
Large establishment (150-250 employees)	11,112
Medium establishment (50-149 employees)	7,409
Small establishment (less than 50 employees)	3,703

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	200
Annual fee	200
Once-off authorisation — procedural training for a period of two months or less (reduced fee)	75

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 fees (other than inspections in relation to the protection of animals used for scientific purposes)

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

Enforcement fees**Manufacturers**

Major site (more than 250 employees)	2,400
Large site (150-250 employees)	1,800
Medium site (50-149 employees)	600
Small site (less than 50 employees)	200

Wholesalers

Large full line	600
Medium full line / short line	200

Marketing authorisation / parallel import licence holders

> 50 marketing authorisations / parallel import licences	3,150
31-50 marketing authorisations / parallel import licences	1,000
16-30 marketing authorisations / parallel import licences	600
6-15 marketing authorisations / parallel import licences	200

(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 / wholesaler fee.)

Given under my hand,
17 December 2015.

KATHLEEN LYNCH,
Minister of State at the Department of 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 2014 (S.I. No. 607 of 2014).

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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