STATUTORY INSTRUMENTS.

S.I. No. 602 of 2016

HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2016

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HEALTH PRODUCTS REGULATORY AUTHORITY (FEES) REGULATIONS 2016

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 2016.

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);

"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 to 2009, the European Communities (Active Implantable Medical Devices) Regulations 1994 to 2009, or the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 to 2012;

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

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 16*th December*, 2016.

"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 to 2016;

"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 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 2001[1], as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003[2], Commission Directive 2003/63/EC of 25 June 2003[3], Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004[4], Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[5], Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006[6], Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007[7], Directive 2008/29/EC of the

[1]OJ No. L 311, 28.11.2001, p. 67.
[2]OJ No. L 33, 8.2.2003, p. 30.
[3]OJ No. L 159, 27.6.2003, p. 46.
[4]OJ No. L 136, 30.4.2004, p. 85.
[5]OJ No. L 136, 30.4.2004, p. 34.
[6]OJ No. L 378, 27.12.2006, p. 1.
[7]OJ No. L 324, 10.12.2007, p. 121.

European Parliament and of the Council of 11 March 2008[8], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[9], Commission Directive 2009/120/EC of 14 September 2009[10], Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[11], Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[12] and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012[13].

"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 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 to 2016;

"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;

[8]OJ No. L 81, 20.3.2008, p. 51.
[9]OJ No. L 168, 30.6.2009, p. 33.
[10]OJ No. L 242, 15.9.2009, p. 3.
[11]OJ No. L 348, 31.12.2010, p. 74.
[12]OJ No. L 174, 1.7.2011, p. 74.
[13]OJ No. L 299, 27.10.2012, p. 1.

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

"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 an authorisation granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014;

"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 to 2012, and

(ii) an active implantable medical device in accordance with the European Communities (Active Implantable Medical Devices) Regulations 1994 to 2009;

"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;

"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 to 2009, the European Communities (Active Implantable Medical Devices) Regulations 1994 to 2009, or the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 to 2012;

"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 2016;

"project authorisation" means an authorisation granted pursuant to the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2016;

"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 2016;

"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 2008[14], as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012[15];

"user authorisation" means an authorisation granted to a user pursuant to the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2016;

"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.

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 2015 (S.I. No. 599 of 2015) are revoked.

[14]OJ No. L 334, 12.12.2008, p. 7.
[15]OJ No. L 209, 4.8.2012, p. 4.

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for national applications for marketing authorisations	**€**
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
Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure	
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 — dual pack registration	831
Dual pack 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 — 1st marketing authorisation within a range	900
Change of ownership — related company — each additional marketing authorisation within a range	321
Change of ownership — non-related company — 1st marketing authorisation within a range	1,316
Change of ownership — non-related company — each additional marketing authorisation within a range	321

Other fees relating to the granting of marketing authorisations

Service item	612

Notification to become a listed organisation

Notification Fee	10

Fees for applications for wholesaler's authorisations

Application fee	555
Variation to authorisation — minor site technical	400
Variation to authorisation — 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

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 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	2,287

time)	
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 licence	113
Parallel import licence — Dual pack registration	55
Certificate of registration — homeopathic medicinal products	55
Certificate of traditional-use registration — 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
Minor establishment (less than 5 employees)	1,000

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	10,500

holders

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

Per day (per member of the inspection team)	1,489
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.)

Fees in relation to medical devices

Manufacturers and authorised representatives — annual fees

Manufacturer — more than 150 employees	30,000
Manufacturer — 50-150 employees	25,000
Manufacturer — 15-49 employees	15,000
Manufacturer — 5-15 employees	5,000
Manufacturer — less than 5 employees or annual turnover of less than €500,000	250
Manufacturer/authorised representative fee per entity (subject to a maximum of €10,000)	1,000
Authorised representative which is not a manufacturer (of medical devices) (maximum of €30,000)	5,000

(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)	5,500
Medium distributor (turnover €3-€15 million)	3,500
Small distributor (turnover under €3 million)	1,250
Distributor turnover less than €500,000	250
Notified Body — annual fees	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,
6 December 2016.

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 2015 (S.I. No. 599 of 2015).

These Regulations may be cited as the Health Products Regulatory Authority (Fees) Regulations 2016.

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)
nó trí aon díoltóir leabhar.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4064-5603-5

€4.06

9 781406 456035

Wt. (B32447). 285. 12/16. Essentra. Gr 30-15.