STATUTORY INSTRUMENTS

S.I. No. 542 of 2008

IRISH MEDICINES BOARD (FEES) REGULATIONS 2008

(Prn. A8/1995)

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IRISH MEDICINES BOARD (FEES) REGULATIONS 2008

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by sections 13 and 32 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as adapted by the Health (Alteration of Name of Department and Title of Minister) Order 1997, (S.I. No. 308 of 1997) and of all other powers enabling me in that behalf, hereby make the following Regulations:

1. These Regulations may be cited as the Irish Medicines Board (Fees) Regulations 2008.

2. These Regulations shall come into force on the 1st day of January 2009.

3. In these Regulations—

"Board" means the Irish Medicines Board;

"manufacturing licence" means a licence granted pursuant to the Medical Preparations (Licensing of Manufacture) Regulations 1993 to 1996;

"product authorisation" means an authorisation granted pursuant to the Medical Preparations (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998);

"wholesale licence" means a licence granted pursuant to the Medical Preparations (Wholesale Licences) Regulations 1993 to 1996.

4. These Regulations shall apply to the fees that may be charged by the Board, in pursuit of its statutory duties, in relation to applications for the grant or renewal of manufacturing licences, wholesale licences and product authorisations in respect of medicinal products for human use.

5. Subject to Regulation 6 hereof, there shall be paid to the Board in respect of each and every matter set out in column 1 of the schedule hereto the fee as set out in column 2 of the said schedule.

6. The Board 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 5 hereof.

7. The Irish Medicines Board (Fees) Regulations 2007 (S.I. No. 866 of 2007) are hereby revoked.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 19*th December*, 2008.

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for National Applications for Product Authorisations	€
National application — complex dossier, new active substance	15,211
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted with any of the above	3,251
National application — reduced complex	11,329
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted with any of the above	3,251
National application — reduced dossier standard	7,658
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted with any of the above	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 with any of the above	3,251
Fees for Applications for Product Authorisations using European	
Mutual Recognition procedure	
Mutual recognition incoming — complex dossier, new active substance	10,647
Each additional form (same time)	3,660
Each additional strength (same time)	656
Outgoing mutual recognition/decentralised supplement	10,962
Decentralised Outgoing/Incoming	15,211
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional supplement DCP outgoing greater than 10 countries	5,000
Mutual recognition incoming — reduced complex	8,077
Each additional form (same time)	3,251
Each additional strength (same time)	656
Outgoing mutual recognition / decentralised supplement	10,962
Decentralised Outgoing/Incoming	11,329
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional supplement DCP outgoing greater than 10 countries	5,000
Mutual recognition incoming — reduced dossier standard	5,350
Each additional form (same time)	2,859
Each additional strength (same time)	656
Outgoing mutual recognition / decentralised supplement	7,126
Decentralised Outgoing/Incoming	7,658
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional supplement DCP outgoing greater than 10 countries	5,000
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 Outgoing / Incoming 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 supplement DCP outgoing greater than 10 countries	5,000
Change of address for Product Authorisation holder: 1 to 20	

Product Authorisations	119
Change of address for Product Authorisation holder: more than 20 Product Authorisations	591

Fees for Parallel Product Authorisations

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
Dual pack registration of parallel imports	564
Each additional strength or form	283
Change of Ownership	525

Fees for Variations to Product Authorisations that are nationally licensed

Type IA variation	365
Type IA variation — reduced rate	184
Type IB variation	495
Type IB variation — reduced rate	248
Type II complex variation	3,251
Type II standard variation	633
Type II standard variation — reduced rate	316
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC	495
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC— reduced rate	248
Bulk variation to multiple changes to the SPC (per product range)	8,000
Bulk variation for multiple changes to the same document	6,000
Introduction of standard statements from PHV working party — 1 to 5licences	1,500
Introduction of standard statements from PHV working party — 6 to 10 licences	3,000
Introduction of standard statements from PHV working party — 11 to 20 licences	6,000
Introduction of standard statements from PHV working party — 21 to 40 licences	12,000
Introduction of standard statements from PHV working party — 41 to 100 licences	20,000
Introduction of standard statements from PHV working party — 101 and above	30,000

Fees for Variations to Product Authorisations licensed under European Mutual Recognition procedure

Type IA variation — outgoing mutual recognition / decentralised supplement	365
Type IA variation — mutual recognition incoming	315
Type IA variation — mutual recognition incoming — reduced rate	184
Type IB variation outgoing mutual recognition / decentralised supplement	365
Type IB variation — mutual recognition incoming	422
Type IB variation — mutual recognition incoming — reduced rate	218
Type II complex variation — outgoing mutual recognition / decentralised supplement	656
Type II complex variation — mutual recognition incoming	2,246
Type II standard variation — mutual recognition incoming	422
Type II standard variation — mutual recognition incoming — reduced rate	218
Type II standard variation — outgoing mutual recognition / decentralised supplement	422
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC	495
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC— reduced rate	248

Fees for the granting of a Product Authorisation on transfer to another company

Change of ownership — related company — per form	1,123
Change of ownership — related company — per strength	321
Change of ownership — non-related company — per form	1,645
Change of ownership — non-related company — per strength	321

Other fees relating to the granting of Product Authorisations

Service item	612

Fees for Wholesale Licences

Application fee	555
Annual fee — large site	2,771
Annual fee — medium site	1,576
Annual fee — minor site	555
Variation to licence — administrative	219
Variation to licence — technical	603

Fees for Manufacturing Licences

Application fee	1,853
Annual fee — major site (more than 250 employees)	16,669
Annual fee — large site (150 — 250 employees)	11,112
Annual fee — medium site (50 — 149 employees)	7,409
Annual fee — small site (less than 50 employees)	3,703
Variation to licence — administrative	274
Variation to licence — technical	768

Fees for Blood and Tissue Establishments

Application fee	1,853
Annual fee — major site (more than 250 employees)	16,669
Annual fee — large site (150 — 250 employees)	11,112
Annual fee — medium site (50 — 149 employees)	7,409
Annual fee — small site (less than 50 employees)	3,703
Variation to licence — administrative	274
Variation to licence — technical	768

Fees for Laboratory Approvals

Application fee	555
Annual fee — minor site	555
Variation to licence — administrative	219
Variation to licence — technical	603

Fees for the granting of a Manufacturing Licence or a Wholesale Licence on transfer to another company

Manufacture — related companies	1,107
Manufacture — unrelated companies	1,853
Wholesale — related companies	365
Wholesale — unrelated companies	555

Fees for Notifications of Exempt Medicinal Products

Per notification	2
Cap on total notifications	10,000

Fees for Medical Devices

Certificates of free sale

Certificates of free sale issued within 2 days (4 certs per request)	147
Certificates of free sale issued within 1 day (4 certs per request)	277
Additional certificates (available at the time of the initial request)	23

Registration of Devices

Registration of In-vitro Diagnostic medical device	153
First registration of a general medical device	153
Re-registration of items currently on the market	153
Changes to registration thereafter	153
Electronic registration	131
Annual Verification Fee — up to 5 employees	153
Annual Verification Fee — between 6-20 employees	384
Annual Verification Fee — between 21-100 employees	768
Annual Verification Fee — Over 100 employees	1,645

Clinical Investigations	
Clinical Investigations — active implantable medical devices	3,837
Clinical Investigations — Class III and class IIb medical devices	3,837
Clinical Investigations — Class IIa and class I medical device	1,645
Clinical Investigations — Technical amendment to a previously approved clinical investigation	1,129
Clinical Investigations — Administrative amendment to a previously approved clinical investigation	219
Audits / Inspections	
Audits/ Inspections (including Notified Body) per day	1,489
Audits/Inspections (including Notified Body) per hour	234
Classifications	
Classification of a product (1 product per request)	250
Classification of additional products (available at the time of the initial request)	200
Appeal of a classification decision	250
Designation Fee for a Notified Body	
Designation Fee	3,672
Extension to the scope (per extension)	1,836
Medicinal Product/Medical Device — Drug Consultation fees	
New active substance	41,960
Established active in new therapeutic area	33,568
Established active and therapeutic area	29,372
Variations — Minor	839
Variations — Major	3,776

L.S.

GIVEN under my Official Seal ,
15 December 2008

MARY HARNEY.
Minister for Health and Children.

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 Irish Medicines Board pursuant to Section 13 of the Irish Medicines Board Act 1995.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
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TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
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(Tel: 01 - 6476834/37 or 1890 213434; Fax: 01 - 6476843 or 094 - 9378964)
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ISBN 978-1-4064-4411-7

€2.54

9 781406 444117

Wt. (B26565). 285. 12/08. Cahill. Gr. 30-15.