STATUTORY INSTRUMENTS

S.I. No. 866 of 2007

IRISH MEDICINES BOARD (FEES) REGULATIONS 2007

(Prn. A7/2411)

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IRISH MEDICINES BOARD (FEES) REGULATIONS 2007

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 2007.

2. These Regulations shall come into force on the 1st day of January 2008.

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.617 of 2006) are hereby revoked.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 25*th January*, 2008.

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for National Applications for Product Authorisations	€
National application — complex dossier, new active substance	14,500
Each additional form (same time)	4,852
Each additional strength (same time)	625
Additional drug master file submitted with any of the above	3,099
National application — reduced complex	10,800
Each additional form (same time)	4,852
Each additional strength (same time)	625
Additional drug master file submitted with any of the above	3,099
National application — reduced dossier standard	7,300
Each additional form (same time)	4,852
Each additional strength (same time)	625
Additional drug master file submitted with any of the above	3,099
Subsequent extension applications — first additional form	7,300
Each additional form (same time)	4,852
First additional strength (existing form)	2,627
Each additional strength (same time)	625
Fees for Applications for Product Authorisations using European Mutual Recognition procedure	€
Mutual recognition incoming — complex dossier, new active substance	10,150
Each additional form (same time)	3,489
Each additional strength (same time)	625
Outgoing mutual recognition/decentralised supplement	10,450
Decentralised Outgoing/Incoming	14,500
Each additional form (same time)	4,852
Each additional strength (same time)	625
Mutual recognition incoming — reduced complex	7,700
Each additional form (same time)	3,099
Each additional strength (same time)	625
Outgoing mutual recognition / decentralised supplement	10,450
Decentralised Outgoing/Incoming	10,800

Each additional form (same time)	4,852
Each additional strength (same time)	625
Mutual recognition incoming — reduced dossier standard	5,100
Each additional form (same time)	2,725
Each additional strength (same time)	625
Outgoing mutual recognition / decentralised supplement	6,793
Decentralised Outgoing/Incoming	7,300
Each additional form (same time)	4,852
Each additional strength (same time)	625
Subsequent extension applications	
— mutual recognition incoming (first additional form)	5,100
— mutual recognition incoming (first additional strength)	1,839
— mutual recognition incoming (subsequent additional strength)	625
Outgoing mutual recognition/decentralised supplement (additional form)	2,725
Outgoing mutual recognition/decentralised supplement (additional strength)	625
Decentralised Outgoing / Incoming First Additional Form	7,300
Each additional form (same time)	4,852
First additional strength (existing form)	2,627
Each additional strength (same time)	625
Change of address for Product Authorisation holder: 1 to 20 Product Authorisations	113
Change of address for Product Authorisation holder: more than 20 Product Authorisations	563

Fees for Parallel Product Authorisations	€
Application fee — per country at the same time or by variation	1,584
Each additional strength per country	472
Each additional form per country	472
Dual pack registration of parallel imports	538
Each additional strength or form	270
Change of Ownership	500

Fees for Variations to Product Authorisations that are nationally licensed	€
Type IA variation	348
Type IA variation — reduced rate	175
Type IB variation	472
Type IB variation — reduced rate	236
Type II complex variation	3,099
Type II standard variation	603
Type II standard variation — reduced rate	301
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC	472
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC—reduced rate	236
Bulk variation to multiple changes to the SPC (per product range)	8,000
Introduction of standard statements from PHV working party — 0 to 50 licences	15,000
Introduction of standard statements from PHV working party — 51 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	348
Type IA variation — mutual recognition incoming	300
Type IA variation — mutual recognition incoming — reduced rate	175
Type IB variation outgoing mutual recognition / decentralised supplement	348
Type IB variation — mutual recognition incoming	402
Type IB variation — mutual recognition incoming — reduced rate	208
Type II complex variation — outgoing mutual recognition / decentralised supplement	625
Type II complex variation — mutual recognition incoming	2,141
Type II standard variation — mutual recognition incoming	402
Type II standard variation — mutual recognition incoming — reduced rate	208
Type II standard variation — outgoing mutual recognition / decentralised supplement	402
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC	472
Notifications made under Article 61 (3) of Directive 2001 / 83 / EC—reduced rate	236

Fees for the granting of a Product Authorisation on transfer to another company	€
Change of ownership — related company — per form	1,071
Change of ownership — related company — per strength	306
Change of ownership — non-related company — per form	1,568
Change of ownership — non-related company — per strength	306

Other fees relating to the granting of Product Authorisations	€
Service item	583

Fees for Wholesale Licences	€
Application fee	529
Annual fee — large site	2,642
Annual fee — medium site	1,502
Annual fee — minor site	529
Variation to licence — administrative	209
Variation to licence — technical	575

Fees for Manufacturing Licences	€
Application fee	1,766
Annual fee — major site (more than 250 employees)	15,890
Annual fee — large site (150 — 250 employees)	10,593
Annual fee — medium site (50 — 149 employees)	7,063
Annual fee — small site (less than 50 employees)	3,530
Variation to licence — administrative	261
Variation to licence — technical	732

Fees for the granting of a Manufacturing Licence or a Wholesale Licence on transfer to another company	€
Manufacture — related companies	1,055
Manufacture — unrelated companies	1,766
Wholesale — related companies	348
Wholesale — unrelated companies	529

Fees for Notifications of Exempt Medicinal Products	€
1-50 Notifications (per notification)	6
51-500 Notifications (per notification)	5
501-1,000 Notifications (per notification)	4
1,001-5,000 Notifications (per notification)	3
5,001-20,000 Notifications (per notification)	2
20,001 and above Notifications (per notification)	1

Fees for Medical Devices	€
Certificates of free sale	
Certificates of free sale issued within 2 days (4 certs per request)	140
Certificates of free sale issued within 1 day (4 certs per request)	264
Additional certificates (available at the time of the initial request)	22

Registration of Devices	€
Registration of In-vitro Diagnostic medical device	146
First registration of a general medical device	146
Re-registration of items currently on the market	146
Changes to registration thereafter	146
Electronic registration	125
Annual Verification Fee — up to 5 employees	146
Annual Verification Fee — between 6-20 employees	366
Annual Verification Fee — between 21-100 employees	732
Annual Verification Fee — Over 100 employees	1,568

Clinical Investigations	€
Clinical Investigations — active implatable medical devices	3,658
Clinical Investigations — Class III and class IIb medical devices	3,658
Clinical Investigations — Class IIa and class I medical device	1,568
Clinical Investigations — Amendment to a previously approved clinical Investigation	1,076

Audits / Inspections	€
Audits/ Inspections (including Notified Body) per day	1,419
Audits/Inspections (including Notified Body) per hour	223

Classifications	€
Classification of a product (1 product per request)	209
Classification of additional products (available at the time of the intial request)	157
Appeal of a classification decision	209

Designation Fee for a Notified Body	€
Designation Fee	3,500
Extension to the scope (per extension)	1,750

Medicinal Product/Medical Device — Drug Consultation fees	€
New active substance	40,000
Established active in new therapeutic area	32,000
Established active and therapeutic area	28,000
Variations — Minor	800
Variations — Major	3,600

L.S.

GIVEN under my Official Seal,
21 December 2007

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
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
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
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2
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ISBN 978-1-4064-3582-5

€3.05

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Wt. (B25922). 285. 1/08. Cahill. Gr. 30-15.