STATUTORY INSTRUMENTS.

S.I. No. 165 of 2013

IRISH MEDICINES BOARD (FEES) (AMENDMENT) REGULATIONS 2013

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I, JAMES REILLY, 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) and for the purpose of giving effect to Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1], hereby make the following regulations:

1. (1) These Regulations may be cited as the Irish Medicines Board (Fees) (Amendment) Regulations 2013.

(2) These Regulations shall be construed as one with the Irish Medicines Board (Fees) Regulations 2012 (S.I. No. 572 of 2012) and may be cited together with those Regulations as the Irish Medicines Board (Fees) Regulations 2012 to 2013.

2. In these Regulations "Principal Regulations" means the Irish Medicines Board (Fees) Regulations 2012 (S.I. No. 572 of 2012).

3. Regulation 2(1) of the Principal Regulations is amended—

(*a*) by inserting after the definition of "Act" the following definition:

"'active substances register' means the register of importers, manufacturers and distributors of active substances maintained by the Board in pursuance of Regulation 14D (as inserted by 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. 539 of 2007);", and

(*b*) by inserting after the definition of "Board" the following definitions:

"'broker' means a person carrying out the brokering of medicinal products, as defined in Regulation 4(1) (as amended by 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 Board in pursuance of Regulation 14D (as inserted by the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013

[1]OJ No. L 174, 1.7.2011, p. 74.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 28*th May*, 2013.

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

4. The Schedule to the Principal Regulations is amended by inserting before the heading "Inspections fees" the following headings and entries:

COLUMN 1	COLUMN 2
"**Fees for broker registration**	
Fee for registration in the brokers register	250
Fees for active substances registration	
Fee for registration in the active substances register	250
Fee for immediate notification of a change which may have an impact on the quality or safety of the active substances	768".

L.S.

GIVEN under my Official Seal,
22 May 2013.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the Irish Medicines Board (Fees) Regulations 2012 (S.I. No. 572 of 2012).

These Regulations give effect to Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 with regard to fees for registration in the brokers register, registration in the active substances register and immediate notification of a change to the active substances register which may have an impact on the quality or safety of the active substances.

These Regulations may be cited as the Irish Medicines Board (Fees) (Amendment) Regulations 2013.

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