STATUTORY INSTRUMENTS.

S.I. No. 553 of 2009

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) REGULATIONS 2007 (AMENDMENT) (NO. 2) REGULATIONS 2009

(Prn. A9/1895)

S.I. No. 553 of 2009

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) REGULATIONS 2007 (AMENDMENT) (NO. 2) REGULATIONS 2009

The Minister for Health and Children, in exercise of the powers conferred on her by section 32 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and as adapted by the Health (Alteration of Name of Department and Title of Minister) Order 1997 (S.I. No. 308 of 1997), and for the purpose of giving full effect to Directive 2001/83/EC (as amended by Commission Regulation No. 1234/2008[1]) and Commission Directive 2009/35/EC[2], hereby make the following regulations—

Citation

1. These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009.

2. These Regulations shall be construed as one with the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) and Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009) and may be cited together with those Regulations as the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2009.

Interpretation

3. In these Regulations:

"principal regulations" mean the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

4. Regulation 3(1) of the principal regulations is amended in the definition of "relevant Community provisions", by substituting the following for paragraphs (*e*) and (*f*):

> "(*e*) Commission Regulation (EC) No. 1234/2008, concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use;
>
> (*f*) Directive 2009/35/EC of the European Parliament and Council on the colouring matters which may be added to medicinal products;".

[1]OJ No. L334, 12.12.2008, p7
[2]OJ No. L109, 30.04.2009, p10

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 5*th January*, 2010.

Revocation

5. The European Communities (Colouring of Medicinal Products) Regulations, 1981 (S.I. No. 269 of 1981) are hereby revoked.

Commencement

6. The provisions of these Regulations shall come into operation on 1 January 2010.

L.S.

GIVEN under the Official Seal of the Minister for Health and Children,
22 December 2009

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 interpretation.)

The main purpose of these Regulations is to facilitate the operation of Commission Regulation (EC) No. 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and Directive 2009/35/EC of the European Parliament and Council on the colouring matters which may be added to medicinal products.

Regulation 1234/2008 has been adopted to simplify, update and improve the current rules with regard to all variations to Marketing Authorisations and to ensure that all Marketing Authorisations for medicinal products are subject to the same variations procedures.

Directive 2009/35/EC recasts Council Directive 78/25/EC on the colouring matters which may be added to medicinal products. The purpose of this Directive is to remove disparities in national legislation regarding the colouring of medicines across EU Member States.

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