STATUTORY INSTRUMENTS.

S.I. No. 722 of 2011

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2011

(Prn. A11/2425)

S.I. No. 722 of 2011

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2011

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 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) (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (No. 219 of 2011)), for the purpose of giving further effect to Directive 2001/83/EC of the European Parliament and Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use[1], hereby make the following regulations:

1. These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2011.

2. Regulation 16 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) is amended—

(*a*) in paragraph (1)—

(i) in subparagraph (*a*), by substituting "," for "; and",

(ii) in subparagraph (*b*), by substituting ", and" for ".", and

(iii) by inserting the following subparagraph after subparagraph (*b*):

"(*c*) without prejudice to subparagraphs (*a*) and (*b*), the particulars for the labelling and any package leaflet accompanying the product appear in the English language or in both the Irish language and the English language but this shall not prevent the particulars for the labelling or any package leaflet accompanying the product appearing in other languages also, provided the same information is given in all the languages used.",

and

(*b*) by inserting the following paragraph after paragraph (6):

"(7) Any particulars, statement or information required pursuant to paragraphs (4), (5) or (6) to be included in the outer package, immediate packaging or on the package leaflet, as the case may be, of the products referred to in paragraphs (4), (5) or (6) shall appear in the

[1]OJ No. L 311, 28.11.2001, p.67.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 3rd *January*, 2012.

English language or in both the Irish language and the English language but this shall not prevent the information appearing in other languages also, provided the same information is given in all the languages used."

L.S.

GIVEN under my Official Seal,
22 December 2011.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

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

The purpose of these Regulations is to clarify the language requirements for labelling and package leaflets accompanying medicinal products for human use.

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