



STATUTORY INSTRUMENTS.

S.I. No. 542 of 2007



EUROPEAN COMMUNITIES (AMENDMENT OF THE IRISH
MEDICINES BOARD ACT 1995) REGULATIONS 2007

(Prn. A7/1463)

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MEDICINES BOARD ACT 1995) REGULATIONS 2007

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2001/83/EC¹, hereby make the following Regulations:

1. These Regulations may be cited as the European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007.
2. These Regulations shall come into operation on the 23rd July 2007.
3. Section 4(1)(b) of the Irish Medicines Board Act 1995 (as substituted by section 11(a)(ii) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) is hereby amended by inserting “other than those powers conferred by Article 5.3 of the said Directive,” after “6 November 2001,”.
4. For the purposes of Article 5.3 of Directive 2001/83/EC, as amended by Directive 2004/27/EC², the competent authority shall be the Minister for Health and Children.



GIVEN under my Official Seal,
20 July 2007

MARY HARNEY
Minister for Health and Children

¹OJ No. L.311, 28.11.2001, p.67 - 128.

²OJ No. L.136, 30.04.2004, p. 34 - 57.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 31st July, 2007.*

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 enable the recommendations or requirements, in respect of the use of a medicinal product otherwise than for their authorised indications or in respect of the use of an unauthorised medicinal product, in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear reaction any of which could cause harm, to be laid down by the Minister for Health and Children, rather than by the Irish Medicines Board.

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ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
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