STATUTORY INSTRUMENTS.

S.I. No. 442 of 2009

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2009

(Prn. A9/1560)

S.I. No. 442 of 2009

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2009

I, MARY HARNEY, Minister for Health and Children, 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 (Alteration of Name of Department and Title of Minister) Order 1997 (S.I. No. 308 of 1997), hereby make the following regulations:

1. These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009.

2. The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) are amended—

(*a*) by substituting the following for Regulation 4A (inserted by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005)):

"4A. (1) It shall not be a contravention of the provisions of these Regulations for—

(*a*) Any person to administer to another any medicinal product which is not subject to prescription control by virtue of these Regulations;

(*b*) A registered medical practitioner or registered dentist to administer to a patient any medicinal product subject to control by virtue of these Regulations;

(*c*) Any person, other than a registered medical practitioner or registered dentist, to administer to a patient, in accordance with the directions of a registered medical practitioner or registered dentist, any medicinal product subject to control by virtue of these Regulations.

(2) In paragraph (1) a reference to a registered dentist shall be construed as a reference to a registered dentist acting in the course of his or her practice as a dentist.",

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 10*th November*, 2009.

and

(*b*) by substituting the following for Regulation 18:

"18. (1) Subject to paragraph (2) a person shall not supply any medicinal product for use after the date specified thereon by the manufacturer thereof as its expiry date.

(2) Paragraph (1) shall not apply to a medicinal product where the body which has authorised the placing on the market of that product has determined that the expiry date may be extended and the product is supplied for use within such extended period, and any condition or restriction relating to that determination is complied with.".

L.S.

GIVEN under my Official Seal,
6 November 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 purposes of these Regulations are—

(*a*) to clarify provisions relating to the administration of medicinal products by registered dentists; and

(*b*) to amend the provision regarding the offence of supplying a medicinal product after its expiry date to take account of circumstances where the body which has authorised the placing of the product on the market has determined that the expiry date may be extended.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
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