



STATUTORY INSTRUMENTS.

S.I. No. 529 of 2018



MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE
MARKET) (AMENDMENT) REGULATIONS 2018

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2018

I, SIMON HARRIS, 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), hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018.

(2) These Regulations shall be construed as one with the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014 and may be cited together with those Regulations as the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2018.

2. In these Regulations “Principal Regulations” means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

3. Regulation 3(1) (as amended by Regulation 3 of the Medicinal Products (Control of Placing on the Market) Regulations (Amendment) Regulations 2014 (S.I. No. 151 of 2014)) of the Principal Regulations is amended—

(a) by substituting for the definition of “practitioner” the following definition:

“‘practitioner’ means a registered dentist, a registered medical practitioner, a registered nurse prescriber or a registered midwife prescriber;”,

(b) by inserting after the definition of “product authorisation” the following definition:

“‘register of nurses and midwives’ means the register of nurses and midwives established under section 46(1)(a) of the Nurses and Midwives Act 2011 (No. 41 of 2011);”,

(c) by substituting for the definition of “registered nurse” the following definitions:

“‘registered nurse’ means a person registered in the nurses division of the register of nurses and midwives;

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 14th December, 2018.

‘registered nurse prescriber’ means a person registered in the nurse prescribers division of the register of nurses and midwives”, and

(d) by inserting after the definition of “registered medical practitioner” the following definitions:

“‘registered midwife’ means a person registered in the midwives division of the register of nurses and midwives;

‘registered midwife prescriber’ means a person registered in the midwife prescribers division of the register of nurses and midwives;”.

4. Regulation 8(5) of the Principal Regulations is amended by inserting after subparagraph (iv) the following subparagraph:

“(iva) registered midwives, or”.

5. Paragraph 1 of Schedule 1A (inserted by Regulation 12 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009)) to the Principal Regulations is amended by substituting “registered medical practitioner” for “medical practitioner”.



GIVEN under my Official Seal,
11 December 2018.

SIMON HARRIS,
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 Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

The main purpose of these Regulations is to amend the definition of “practitioner” to include registered nurse prescribers and registered midwife prescribers. The Regulations also update paragraph 1 of Schedule 1A of the Principle Regulations to refer to “registered medical practitioner” and amend Regulation 8(5) to include “registered midwives” in the list of health professionals.

These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018.

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