



STATUTORY INSTRUMENTS.

S.I. No. 530 of 2018



MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) REGULATIONS 2018

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (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 (Prescription and Control of Supply) (Amendment) Regulations 2018.

(2) The Principal Regulations, the Regulations of 2005, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007), Part 4 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (S.I. No. 512 of 2008), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009 (S.I. No. 442 of 2009), the Regulations of 2011, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015), the Regulations of 2015 and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2018 and shall be construed together as one.

2. In these Regulations—

“Principal Regulations” means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

“Regulations of 2005” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005);

“Regulations of 2011” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011);

“Regulations of 2015” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015).

3. Regulation 11 of the Principal Regulations is revoked.

4. The First Schedule to the Principal Regulations (as amended by Regulation 3(p) and (q) of the Regulations of 2005) is amended by—

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

- (a) substituting “A” for “C” in column 2 of the entry for “Gemeprost”, and
- (b) substituting “A” for “C” in column 2 of the entry for “Mifepristone”.

5. The Eighth Schedule to the Principal Regulations (inserted by Regulation 8 of the Regulations of 2011 and amended by Regulation 12 of the Regulations of 2015) is amended—

- (a) by substituting “or” for “and” in Column 5 of the entry for “Epinephrine (adrenaline) injection”,
- (b) by substituting “By intramuscular or subcutaneous injection” for “By subcutaneous injection only” in Column 3 of the entry for “Herpes zoster vaccine for injection”,
- (c) by substituting “Naloxone hydrochloride dihydrate 1mg/ml pre-filled injection” for “Naloxone hydrochloride 1mg/ml pre-filled injection” in Column 2 of the entry for “Naloxone injection”,
- (d) by substituting “or” for “and” in Column 5 of the entry for “Naloxone injection”,
- (e) by inserting after the entry for “Naloxone injection” the following entry:

“Naloxone Nasal Spray	Naloxone hydrochloride dihydrate 1.8 mg Nasal Spray Solution	Nasal administration	Adults and children: Respiratory depression secondary to known or suspected narcotic overdose	In accordance with the summary of product characteristics of the product administered or relevant national guidelines”,
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- (f) by substituting “By intramuscular or subcutaneous injection” for “By intramuscular injection only” in Column 3 of the entry for “Pneumococcal Polysaccharide Vaccine solution for injection”, and
- (g) by inserting “or relevant national guidelines” after “product administered” in Column 5 of the entry for “Salbutamol 100 mcg multi-dose inhaler”.

6. The Tenth Schedule to the Principal Regulations (inserted by Regulation 13 of the Regulations of 2015) is amended by substituting for the entry for “Naloxone hydrochloride 1mg/ml pre-filled injection” the following entries:

“Naloxone
hydrochloride dihydrate
1mg/ml pre-filled
injection

Intramuscular injection

Adults and children:
For the emergency
treatment of respiratory
depression secondary to
known or suspected
narcotic overdose in
accordance with
Clinical Practice
Guidelines approved by
the Pre-Hospital
Emergency Care
Council, or by another
body nominated by the
Minister.

Naloxone hydrochloride
dihydrate 1.8mg nasal
spray

Nasal administration

Adults and children:
For the emergency
treatment of respiratory
depression secondary to
known or suspected
narcotic overdose in
accordance with
Clinical Practice
Guidelines approved by
the Pre-Hospital
Emergency Care
Council, or by another
body nominated by the
Minister.”.



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 (Prescription and Control of Supply) Regulations 2003.

The purpose of these Regulations is to: (a) remove the requirement for the keeping of a register by a person who supplies or administers a medicinal product which consists of or contains mifepristone; (b) amend the First Schedule to update the Part of the Schedule in which medicinal products containing mifepristone and gemeprost are listed; (c) amend the Eighth Schedule to update the route of administration for Herpes zoster vaccine for injection and Pneumococcal Polysaccharide Vaccine solution for injection to reflect updates to the respective Summaries of Product Characteristics; (d) amend the Eighth Schedule to update the dosage and conditions of administration for Salbutamol 100 mcg multi-dose inhaler; (e) amend the Eighth and Tenth Schedules to update the entries for Naloxone injection and insert entries for Naloxone Nasal Spray.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018.

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nó trí aon díoltóir leabhar.

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

€2.54



Wt. (B33848). 285. 12/18. Essentra. Gr 30-15.