STATUTORY INSTRUMENTS.

S.I. No. 401 of 2020

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 5) REGULATIONS 2020

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I, STEPHEN DONNELLY, 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) (No. 5) Regulations 2020.

(2) The citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2020" includes these Regulations.

2. In these Regulations "Principal Regulations" means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

3. The Principal Regulations are amended by substituting for Regulation 4B (inserted by Regulation 4 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015)) the following:

"*Supply and administration of certain medicinal products by authorised persons*

4B. It shall not be a contravention of a provision of these Regulations for an authorised person, in the course of his or her professional practice as an authorised person, to supply a person with, and to administer to the person, a medicinal product specified in column 1 of the Eighth Schedule if, and only if—

(*a*) a body recognised by the Council of the Pharmaceutical Society of Ireland has issued to the authorised person a certificate stating that he or she has satisfactorily completed a course of training approved by the Registrar of the Pharmaceutical Society of Ireland relating to the supply and administration of the product and the management of any immediate adverse reaction that may follow from such administration,

(*b*) the product is administered in accordance with the requirements specified in columns 2 to 5 of the Eighth Schedule opposite the mention of the product specified in column 1 of that Schedule, and

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 6th *October,* 2020.

(*c*) the product is administered at the place specified in column 6 of the Eighth Schedule opposite the mention of the product specified in column 1 of that Schedule.".

4. The Principal Regulations are amended by substituting for the Eighth Schedule (as amended by Regulation 2 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020 (S.I. No. 241 of 2020)) the following:

"EIGHTH SCHEDULE

MEDICINAL PRODUCTS WHICH MAY BE SUPPLIED AND ADMINISTERED BY AUTHORISED PERSONS PURSUANT TO REGULATION 4B

Medicinal Product	Form and presentation of product administered	Route of administration	Indication for which the medicinal product may be administered	Dosage and conditions of administration	Place of administration
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Epinephrine (adrenaline) Injection	Epinephrine (adrenaline) injection presented as a pre-filled syringe or ampoule	Intramuscular or subcutaneous injection	Adults and Children: For the emergency treatment of anaphylactic shock	In accordance with the summary of product characteristics of the product administered and relevant national guidelines	Any place
Glucagon for injection	Glucagon hydrochloride for injection	Intramuscular or subcutaneous injection	Adults and children: For the emergency treatment of hypoglycaemia	In accordance with the summary of product characteristics of the product administered	Any place
Glyceryl trinitrate aerosol	Glyceryl trinitrate sublingual spray	Sublingual spray	Adults: For the emergency treatment of severe	In accordance with the summary of product characteristic	Any place

			angina attack	s of the product administered	
Herpes zoster vaccine for injection	Live, attenuated, varicella-zoster virus powder and solvent for the suspension for injection	By intramuscular or subcutaneous injection	Prevention of zoster and zoster-related post-herpetic neuralgia	0.65ml for single administration in accordance with the summary of product characteristics of the product administered and Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland	The premises of the retail pharmacy business in which the authorised person carries on professional practice
Influenza vaccine of a composition that has been approved for use in the European Union for the season in question	Influenza vaccine suspension for injection presented as a pre-filled syringe	By intramuscular injection only	Prevention of seasonal influenza	0.5ml or less for a single administration. In accordance with the summary of product characteristics of the product administered and Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory	Any suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public and safely administer the product.

				Committee of the Royal College of Physicians of Ireland. Only to be administered in connection with the carrying on of the registered retail pharmacy business in which the authorised person is employed or engaged.	
Influenza vaccine (live attenuated) nasal spray suspension of a composition that has been approved for use in the European Union for the season in question	Influenza vaccine nasal spray, suspension	By intranasal administration only	Prevention of seasonal influenza	Children and adolescents from 24 months: 0.2 ml (administered as 0.1 ml per nostril). For children who have not previously been vaccinated against seasonal influenza, a second dose should be given after an interval of at least 4 weeks. In accordance with the summary of product characteristics of the product administered and	Any suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public and safely administer the product.

				Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland. Only to be administered in connection with the carrying on of the registered retail pharmacy business in which the authorised person is employed or engaged.	
Naloxone injection	Naloxone hydrochloride dihydrate 1mg/ml pre-filled injection	Intramuscular injection	Adults and children: Respiratory depression secondary to known or suspected narcotic overdose	In accordance with the summary of product characteristics of the product administered and relevant national guidelines	Any place
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	Any place

				national guidelines	
Pneumococcal Polysaccharide Vaccine solution for injection	Pneumococcal Polysaccharide Vaccine solution for injection 25mcg/0.5 ml in a pre-filled syringe or vial.	By intramuscular or subcutaneous injection	Active immunization against disease caused by the pneumococcal serotypes included in the vaccine	0.5ml for single administration, in accordance with the summary of product characteristics of the product administered and the specific timing of, and need for re-vaccination as determined by the Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland	The premises of the retail pharmacy business in which the authorised person carries on professional practice
Salbutamol 100 mcg multi-dose inhaler	Salbutamol pressurised inhalation solution 100mcg multi-dose inhaler	Oral inhalation	Adults and children: For the emergency treatment of acute asthmatic attack	In accordance with the summary of product characteristics of the product administered or relevant national guidelines	Any place

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L.S.

GIVEN under my Official Seal,
30 September, 2020.

STEPHEN DONNELLY,
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 allow for influenza vaccination to be administered by registered pharmacists in places other than the premises of the retail pharmacy business in which they carry on their professional practice.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020.

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