

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 presentatio n of product administer ed	Route of administra tion	Indication for which the medicinal product may be administer ed	Dosage and conditions of administration	Place of administra tion
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	Intramusc ular or subcutane ous injection	Adults and Children: For the emergency treatment of anaphylact ic shock	In accordance with the summary of product characteristic s of the product administered and relevant national guidelines	Any place
Glucagon for injection	Glucagon hydrochlor ide for injection	Intramusc ular or subcutane ous injection	Adults and children: For the emergency treatment of hypoglyca emia	In accordance with the summary of product characteristic s of the product administered	Any place
Glyceryl trinitrate aerosol	Glyceryl trinitrate sublingual spray	Sublingua l spray	Adults: For the emergency treatment of severe	In accordance with the summary of product characteristic	Any place

			angina	s of the	
			attack	product administered	
Hampag	Livo	Du	Prevention	0.65ml for	The
Herpes zoster	Live, attenuated,	By intramusc	of zoster	single	premises
vaccine	varicella-	ular or	and zoster-	administratio	of the
for	zoster	subcutane	related	n in	retail
injection	virus	ous	post-	accordance	pharmacy
injection	powder	injection	herpetic	with the	business
	and	injection	neuralgia	summary of	in which
	solvent for		neurungiu	product	the
	the			characteristic	authorised
	suspension			s of the	person
	for			product	carries on
	injection			administered	profession
				and	al practice
				Immunisation	_
				Guidelines	
				for Ireland, as	
				published and	
				updated by	
				the National	
				Immunisation	
				Advisory	
				Committee of	
				the Royal	
				College of Physicians of	
				Ireland	
Influenza	Influenza	By	Prevention	0.5ml or less	Any
vaccine of	vaccine	intramusc	of	for a single	suitable
a	suspension	ular	seasonal	administratio	and
compositi	for	injection	influenza	n. In	appropriat
on that has	injection	only		accordance	e place,
been	presented			with the	having
approved	as a pre-			summary of	regard to
for use in	filled			product	public
the	syringe			characteristic	convenien
European				s of the	ce and the
Union for				product	need to
the season				administered	protect the
in				and	health and
question				Immunisation	safety of
				Guidelines	the public
				for Ireland, as	and safely administer
				published and updated by	the
				the National	product.
				Immunisation	product.
				Advisory	
				Auvisory	

				Committee of the Royal College of Physicians of Ireland. Only to be administered in connection with the carrying on of the registered retail pharmacy	
Influenza vaccine (live attenuated) nasal spray suspension of a compositi on that has been approved for use in the European Union for the season in question	Influenza vaccine nasal spray, suspension	By intranasal administra tion only	Prevention of seasonal influenza	which the authorised person is employed or engaged. 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 characteristic s of the product administered and	Any suitable and appropriat e place, having regard to public convenien ce and the need to protect the health and safety of the public and safely administer the product.

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				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	Naloxone	Intramusc	Adults and	In accordance	Any place
injection	hydrochlor	ular	children:	with the	
0	ide	injection	Respirator	summary of	
	dihydrate	0	y	product	
	1mg/ml		depression	characteristic	
	pre-filled		secondary	s of the	
	injection		to known	product	
	-		or	administered	
			suspected	and relevant	
			narcotic	national	
			overdose	guidelines	
Naloxone	Naloxone	Nasal	Adults and	In	Any place
Nasal	hydrochlor	administra	children:	accordance	
Spray	ide	tion	Respirator	with the	
	dihydrate		y	summary of	
	1.8		depression	product	
	mg Nasal		secondary	characteristic	
	Spray		to	S	
	Solution		known or	of the	
			suspected	product	
			narcotic	administered	
			overdose	or relevant	
	1	1			

				national	
				guidelines	
Pneumoco	Pneumoco	By	Active	0.5ml for	The
ccal	ccal	intramusc	immunizat	single	premises
Polysacch	Polysaccha	ular or	ion against	administratio	of the
aride	ride	subcutane	disease	n, in	retail
Vaccine	Vaccine	ous	caused by	accordance	pharmacy
solution	solution	injection	the	with the	business
for	for		pneumoco	summary of	in which
injection	injection		ccal	product	the
	25mcg/0.5		serotypes	characteristic	authorised
	ml in a		included	s of the	person
	pre-filled		in the	product	carries on
	syringe or		vaccine	administered	profession
	vial.			and the	al practice
				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	
Salbutamo	Salbutamo	Oral	Adults and	In accordance	Any place
1 100 mcg	1	inhalation	children:	with the	
multi-dose	pressurised		For the	summary of	
inhaler	inhalation		emergency	product	
	solution		treatment	characteristic	
	100mcg		of acute	s of the	
	multi-dose		asthmatic	product	
	inhaler		attack	administered	
				or relevant	
				national	
				guidelines	

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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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