STATUTORY INSTRUMENTS.

S.I. No. 401 of 2020

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

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

<table>
<thead>
<tr>
<th>Medicinal Product</th>
<th>Form and presentation of product administered</th>
<th>Route of administration</th>
<th>Indication for which the medicinal product may be administered</th>
<th>Dosage and conditions of administration</th>
<th>Place of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine (adrenaline) Injection</td>
<td>Epinephrine (adrenaline) injection presented as a pre-filled syringe or ampoule</td>
<td>Intramuscular or subcutaneous injection</td>
<td>Adults and Children: For the emergency treatment of anaphylactic shock</td>
<td>In accordance with the summary of product characteristics of the product administered and relevant national guidelines</td>
<td>Any place</td>
</tr>
<tr>
<td>Glucagon for injection</td>
<td>Glucagon hydrochloride for injection</td>
<td>Intramuscular or subcutaneous injection</td>
<td>Adults and children: For the emergency treatment of hypoglycaemia</td>
<td>In accordance with the summary of product characteristics of the product administered</td>
<td>Any place</td>
</tr>
<tr>
<td>Glyceryl trinitrate aerosol</td>
<td>Glyceryl trinitrate sublingual spray</td>
<td>Sublingual spray</td>
<td>Adults: For the emergency treatment of severe</td>
<td>In accordance with the summary of product characteristic</td>
<td>Any place</td>
</tr>
<tr>
<td>Vaccine Type</td>
<td>Description</td>
<td>Route of Administration</td>
<td>Indication</td>
<td>Dose</td>
<td>Premises</td>
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<tr>
<td>Herpes zoster vaccine for injection</td>
<td>Live, attenuated, varicella-zoster virus powder and solvent for the suspension for injection</td>
<td>By intramuscular or subcutaneous injection</td>
<td>Prevention of zoster and zoster-related post-herpetic neuralgia</td>
<td>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</td>
<td>The premises of the retail pharmacy business in which the authorised person carries on professional practice</td>
</tr>
<tr>
<td>Influenza vaccine of a composition that has been approved for use in the European Union for the season in question</td>
<td>Influenza vaccine suspension for injection presented as a pre-filled syringe</td>
<td>By intramuscular injection only</td>
<td>Prevention of seasonal influenza</td>
<td>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 Committee of the Royal College of Physicians of Ireland</td>
<td>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.</td>
</tr>
<tr>
<td>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</td>
<td>Influenza vaccine nasal spray, suspension</td>
<td>By intranasal administration only</td>
<td>Prevention of seasonal influenza</td>
<td>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 of the product administered and...</td>
<td>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.</td>
</tr>
<tr>
<td>Naloxone injection</td>
<td>Naloxone hydrochloride dihydrate 1mg/ml pre-filled injection</td>
<td>Intramuscular injection</td>
<td>Adults and children: Respiratory depression secondary to known or suspected narcotic overdose</td>
<td>In accordance with the summary of product characteristics of the product administered and relevant national guidelines</td>
<td>Any place</td>
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<tr>
<td>Naloxone Nasal Spray</td>
<td>Naloxone hydrochloride dihydrate 1.8 mg Nasal Spray Solution</td>
<td>Nasal administration</td>
<td>Adults and children: Respiratory depression secondary to known or suspected narcotic overdose</td>
<td>In accordance with the summary of product characteristics of the product administered or relevant national guidelines</td>
<td>Any place</td>
</tr>
<tr>
<td>Medicine</td>
<td>Description</td>
<td>Administration</td>
<td>Immunity</td>
<td>Notes</td>
<td></td>
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<tr>
<td>Pneumococcal Polysaccharide Vaccine solution for injection</td>
<td>Pneumococcal Polysaccharide Vaccine solution for injection 25mcg/0.5 ml in a pre-filled syringe or vial.</td>
<td>By intramuscular or subcutaneous injection</td>
<td>Active immunization against disease caused by the pneumococcal serotypes included in the vaccine</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Description</th>
<th>Administration</th>
<th>Immunity</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salbutamol 100 mcg multi-dose inhaler</td>
<td>Salbutamol pressurised inhalation solution 100mcg multi-dose inhaler</td>
<td>Oral inhalation</td>
<td>Adults and children: For the emergency treatment of acute asthmatic attack</td>
<td>In accordance with the summary of product characteristics of the product administered or relevant national guidelines.</td>
</tr>
</tbody>
</table>
GIVEN under my Official Seal,

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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