



STATUTORY INSTRUMENTS.

S.I. No. 449 of 2015



MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2015

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2015

I, LEO VARADKAR, 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. 2) Regulations 2015.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 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 Regulations of 2014, the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014), the Regulations of 2015 and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2015 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 2011” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011);

“Regulations of 2014” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014);

“Regulations of 2015” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015).

3. Regulation 4(1) (as amended by Regulation 4 of the Regulations of 2015) of the Principal Regulations is amended—

(a) by inserting after the definition of “EEA Agreement” the following definitions:

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 23rd October, 2015.

“‘emergency’, for the purposes of Regulations 4C, 4D, 4E and 20(10) and (11), means a situation in which the physical state of an individual reasonably leads another to suspect that the first individual is experiencing a life-threatening event that requires the provision of immediate care to assist the physiological functioning of that person;

‘emergency rescue organisation’ means an organisation whose functions include provision of rescue services to persons who cannot, without specialised assistance, remove themselves from danger or entrapment, due to injury, illness or environmental conditions;”,

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

“‘listed organisation’ means an organisation or emergency rescue organisation listed in the list of organisations maintained by the Health Products Regulatory Authority pursuant to Regulation 4D(3);”,

(c) by inserting after the definition of “Opticians Board” the following definition:

“‘organisation’ includes—

(a) an organisation, body, person or group in control of a place of worship, a place of hospitality, an entertainment venue, a place of work, a sports venue, a sports club, a train station, a bus station, a ferry port, an airport or aerodrome, a commercial aircraft, a passenger ferry, a supermarket, a shopping centre, an educational establishment, a childcare facility, a crèche, a museum, an art gallery, an exhibitions centre,

(b) An Garda Síochána,

(c) the Courts Service,

(d) a local authority,

(e) the Health Service Executive,

(f) a fire service,

(g) an emergency rescue organisation;”, and

(d) by substituting for the definition of “premises” the following definition:

“‘premises’ includes any aircraft, hovercraft, ship, stall, land, building or vehicle;”.

4. The Principal Regulations are amended by substituting for Regulation 4B (inserted by Regulation 4 of the Regulations of 2011) the following Regulations:

“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 and at the premises of the retail pharmacy business in which he or she carries on that professional practice (or, in the case of epinephrine (adrenaline), glucagon, glyceryl trinitrate, naloxone or salbutamol at any place), 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, and
- (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.

Supply and administration of medicinal products in emergencies by persons engaged or employed by listed organisations

4C. It shall not be a contravention of a provision of these Regulations for a person to supply another person with, and to administer to that person, a medicinal product specified in column 1 of the Tenth Schedule if, and only if—

- (a) the medicinal product is used in an emergency,
- (b) the person to whom the product is administered—
 - (i) has previously been prescribed the medicinal product or has been diagnosed as having the particular medical condition in respect of which the medicinal product is to be administered, provided that it is reasonable to expect this information to be obtained in the circumstances, or
 - (ii) where the product is a medical gas mixture consisting of 50% nitrous oxide and 50% oxygen, requires management of severe pain,
- (c) the person supplying and administering the medicinal product has been issued with a certificate stating that he or she has satisfactorily completed a course of training, approved by the Pre-Hospital Emergency Care Council or another body nominated by

the Minister for that purpose, in the use of the specific medicinal product, relating to the administration of the medicinal product, the management of any immediate adverse reaction that may follow from such administration, the storage and safe keeping of the medicinal product and the clinical practice guidelines and record-keeping requirements for administration of the medicinal product,

- (d) the certificate certifying completion of the course of training referred to in paragraph (c) is valid for a period not longer than 2 years from the date of issuance,
- (e) the product is administered in accordance with the requirements specified in columns 2 and 3 of the Tenth Schedule opposite the product listing in column 1 of that Schedule, and
- (f) the person supplying and administering the medicinal product is employed or engaged by a listed organisation, or in the case of a medical gas mixture consisting of 50% nitrous oxide and 50% oxygen by a listed emergency rescue organisation, including in a voluntary capacity, and supplies and administers the medicinal product in the course of that engagement or employment.

Listed organisations

4D. (1) An organisation which wishes to procure a medicinal product specified in column 1 of the Tenth Schedule for use in emergencies, in accordance with Regulation 4C, shall notify the Health Products Regulatory Authority, prior to the first such procurement, in accordance with this Regulation.

(2) A notification under paragraph (1) shall—

- (a) be made to the Health Products Regulatory Authority in such electronic form as that Authority shall accept,
- (b) be accompanied by any fee which may be payable in connection with that notification,
- (c) include at least the particulars listed in the Eleventh Schedule, and
- (d) be made for each individual premises, should the organisation wish to procure the medicinal product for more than one premises.

(3) The Health Products Regulatory Authority shall establish and maintain a list of organisations that have provided a valid notification to it in accordance with this Regulation.

(4) The Health Products Regulatory Authority shall enter in the list referred to in paragraph (3)—

- (a) the name of each organisation which has made a valid notification in accordance with this Regulation to procure a medicinal product specified in Column 1 of the Tenth Schedule,
- (b) the address of the organisation by which the medicinal product shall be procured,
- (c) the business name or trading style, if different to the name referred to in paragraph (a), used in connection with such procurement,
- (d) the medicinal product or products in respect of which procurement has been notified,
- (e) the address of the premises, which shall not be a dwelling, where the medicinal product shall be stored, and
- (f) the name of the accountable person(s) pursuant to Regulation 4E.

(5) The Health Products Regulatory Authority shall publish the list referred to in paragraph (3) on its website.

(6) A listed organisation shall ensure that information provided at the time of notification under paragraph (1) remains up to date and must notify any change to that information to the Health Products Regulatory Authority within 4 weeks of that change taking place.

Accountable person in listed organisation

4E. (1) A listed organisation shall appoint an individual or individuals employed or engaged by that organisation, including in a voluntary capacity, as the “accountable person” for the purpose of this Regulation.

(2) An accountable person referred to in paragraph (1) shall, on behalf of the listed organisation by which he or she is employed or engaged,—

- (a) oversee and manage the appropriate storage of any medicinal product procured by the listed organisation for use in an emergency pursuant to Regulation 4C,
- (b) oversee and manage the appropriate conditions for storage of such medicinal product,
- (c) ensure that medicinal product is procured from a registered retail pharmacy business or where the product is a medical gas mixture consisting of 50% nitrous oxide and 50% oxygen, from the holder of a wholesaler’s authorisation.
- (d) ensure that such medicinal product is only supplied to a person or persons (who may also be the accountable person) employed by or engaged by that organisation, including in a voluntary capacity, for supply and administration in an emergency,

- (e) maintain confidential records at the premises of the listed organisation in relation to the procurement and storage of such medicinal product,
- (f) ensure that the person(s) with responsibility for supplying and administering such medicinal product in an emergency is appropriately trained in accordance with Regulation 4C(c) and that his or her training certificate is valid, and
- (g) assist An Garda Síochána or any other investigative body with its investigations in the event of an adverse event or incident relating to the procurement, storage, supply or administration of the medicinal product.”

5. Regulation 5 (as amended by Regulation 5 of the Regulations of 2011) of the Principal Regulations is amended by inserting the following after paragraph (6):

“(7) Paragraph (1) shall not apply as respects a medicinal product specified in column 1 of the Tenth Schedule in any case where it is to be, and is, administered by a person pursuant to Regulation 4C.”.

6. The Principal Regulations are amended by inserting after Regulation 9 the following Regulations:

“Labelling of medicinal products supplied to listed organisations

9A. Where a medicinal product is supplied by or under the supervision of an authorised person pursuant to Regulation 20(10), the container or outer package of the medicinal product shall be labelled to show the following particulars:

- (a) the name of the listed organisation to which the product was supplied;
- (b) the name and address of the person by whom the product was supplied;
- (c) the date on which the product was supplied;
- (d) the name of the product, being either the proprietary name or the non-proprietary name, with the name of the manufacturer or of the person responsible for placing the product on the market;
- (e) the words “Keep out of the reach of children”; and
- (f) such of the cautionary and warning notices specified in the Fifth Schedule as are, in the opinion of the authorised person, deemed to be appropriate.”

7. Regulation 10A (inserted by Regulation 6 of the Regulations of 2011) of the Principal Regulations is amended—

- (a) in the heading, by substituting “*certain medicinal products*” for “*influenza vaccine, etc.*”,
- (b) in paragraph (1)(b), by inserting “(except in the case of epinephrine (adrenaline), glucagon, glyceryl trinitrate, naloxone or salbutamol, where that person fails, or is unable, to provide such particulars to the authorised person)” after “administered”,
- (c) in paragraph (1)(f), by deleting “and”,
- (d) in paragraph (1)(g), by substituting “authorised person; and” for “authorised person.”, and
- (e) by inserting after paragraph (1)(g) the following subparagraph:
 - “(h) confirmation that prior to the administration of the product, consent was—
 - (i) obtained from the person to whom the product was administered, or
 - (ii) if he or she was unable to give such consent—
 - I. obtained from his or her representative, such as a family member, friend or colleague, or
 - II. implied through the interaction with the person to whom the product was administered or the circumstances in which the product was administered.”, and
- (f) in paragraph (2)(a), by inserting “(except in the case of epinephrine (adrenaline), glucagon, glyceryl trinitrate, naloxone or salbutamol)” after “Executive”.

8. The Principal Regulations are amended by inserting after Regulation 10A the following Regulations:

“Keeping of records in relation to supply to listed organisations

10B. (1) Subject to paragraph (4), an authorised person who supplies a medicinal product to a listed organisation pursuant to Regulation 20(10) shall make an entry, in a register kept for the purpose by the pharmacy owner (who may be that authorised person) at the premises of the retail pharmacy business in which the authorised person carries on his or her professional practice as an authorised person, recording the following particulars in respect of such supply:

- (a) the date of supply;
- (b) the name and address of the listed organisation for which the medicinal product is required;

- (c) the name of the accountable person appointed by the listed organisation to ensure compliance with these Regulations;
- (d) the permanent address of the premises at which the medicinal product is to be stored and from which it is to be supplied, where this differs from the address at (b);
- (e) the name, and except where it is apparent from the name, the pharmaceutical form and strength of the product;
- (f) the marketing authorisation number, batch number and expiry date of the product;
- (g) the total quantity supplied; and
- (h) the address of the premises of the retail pharmacy business in which the authorised person carries on his or her professional practice.

(2) An authorised person who supplies a medicinal product to a listed organisation pursuant to Regulation 20(10) shall preserve and keep readily available for inspection the signed order as required under subparagraph (e) of that paragraph for a period of two years.

(3) A pharmacy owner (including any successor pharmacy owner to the first-mentioned pharmacy owner) shall keep the register referred to in paragraph (1) available for inspection at the premises of the retail pharmacy business to which it relates for a period of at least two years from the date on which the last entry is made in the register.

(4) The requirements of paragraph (1) shall be satisfied in the case of a register referred to in that paragraph kept in the form of computerised records if—

- (a) there is a print-out, for each day on which the premises of the retail pharmacy business to which the register relates is open for such business, of the particulars recorded in the register pursuant to that paragraph during that day, and
- (b) an authorised person certifies, not later than 24 hours after the print-out is made, the particulars in the print-out are true and correct to the best of his or her knowledge and belief.

Keeping of records in relation to supply and administration of medicinal products in emergencies

10C. (1) A person who supplies and administers a medicinal product pursuant to Regulation 4C shall make an entry, in a register kept for the purpose by the listed organisation at its premises, recording the following particulars in respect of each such administration:

- (a) the date of administration;

- (b) the name, address, date of birth and sex of the person to whom the product was administered unless that person fails to provide such particulars;
- (c) confirmation that prior to the administration of the product, consent was—
 - (i) obtained from the person to whom the product was administered, or
 - (ii) if he or she was unable to give such consent—
 - I. obtained from his or her representative, such as a family member, friend or colleague, or
 - II. implied through the interaction with the person to whom the product was administered or the circumstances in which the product was administered;
- (d) the name, form, strength, marketing authorisation number, batch number and expiry date of the product;
- (e) the dose of the product that was administered;
- (f) the name of the person who supplied and administered the product;
- (g) the address of the premises of the listed organisation in which the person who administered the product is engaged or employed; and
- (h) the name, address and telephone number of the general medical practitioner (if any) of the person to whom the product was administered unless that person fails to provide such particulars.

(2) The person referred to in paragraph (1) (including any successor engaged by the listed organisation for the purpose of supply and administration of a medicinal product pursuant to Regulation 4C) shall keep the register referred to in that paragraph available for inspection at the premises of the listed organisation for a period of at least two years from the date on which the last entry is made in the register.”

9. Regulation 19 (as amended by Regulation 7 of the Regulations of 2015) of the Principal Regulations is amended by substituting for paragraph (4) the following:

“(4) The provisions of this Regulation shall not apply to a medicinal product (not being a medicinal product specified in column 1 of the Eighth Schedule or in column 1 of the Tenth Schedule) which by virtue of these Regulations may be supplied otherwise than in accordance with a prescription.”.

10. Regulation 20 (as amended by Regulation 3 of the Regulations of 2014) of the Principal Regulations is amended by inserting after paragraph (9) the following paragraphs:

“(10) The provisions of Regulation 5 shall not apply to the supply to a listed organisation of a medicinal product specified in column 1 of the Tenth Schedule if, and only if—

- (a) the listed organisation complies with these Regulations,
- (b) the medicinal product is for use in emergencies by persons who have successfully completed a course of training in accordance with Regulation 4C(c) and hold a valid certificate,
- (c) the medicinal product is obtained from a supplier who is entitled to supply the listed organisation with the specific medicinal product,
- (d) the medicinal product is authorised for sale or supply in the State or is naloxone pre-filled injection, and
- (e) an order signed by the accountable person, appointed by the listed organisation concerned pursuant to Regulation 4E, is presented stating—
 - (i) the name and address of the listed organisation for which the medicinal product is required,
 - (ii) the name of the accountable person appointed by the listed organisation to ensure compliance with these Regulations,
 - (iii) the permanent address of the premises at which the medicinal product is to be stored and from which they are to be supplied, where this differs from the address at (i),
 - (iv) the name, and except where it is apparent from the name, the pharmaceutical form and strength of the product, and
 - (v) the total quantity required.

(11) The provisions of Regulations 5 shall not apply to the supply, for use in emergencies, of a medicinal product specified in column 1 of the Tenth Schedule by a listed organisation to a person engaged or employed by it if, and only if—

- (a) the listed organisation complies with these Regulations,
- (b) the medicinal product is for use in emergencies by persons who have successfully completed a course of training in accordance with Regulation 4C(c).”

11. The Principal Regulations are amended by deleting Regulation 20A (inserted by Regulation 24 of the Medicinal Products (Control of Placing on the Market) Regulations 2007).

12. The Principal Regulations are amended by substituting for the Eighth Schedule (inserted by Regulation 8 of the Regulations of 2011) 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
Column 1	Column 2	Column 3	Column 4	Column 5
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
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
Glyceryl trinitrate aerosol	Glyceryl trinitrate sublingual spray	Sublingual spray	Adults: For the emergency treatment of severe angina attack	In accordance with the summary of product characteristics of the product administered
Herpes zoster vaccine for injection	Live, attenuated, varicella-zoster virus powder and solvent for suspension for injection	By subcutaneous injection only	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

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
Column 1	Column 2	Column 3	Column 4	Column 5
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 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
Naloxone injection	Naloxone hydrochloride 1 mg/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
Pneumococcal Polysaccharide Vaccine solution for injection	Pneumococcal Polysaccharide Vaccine solution for injection 25mcg/0.5ml in a pre-filled syringe or vial	By intramuscular injection only	Active immunisation 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

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
Column 1	Column 2	Column 3	Column 4	Column 5
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

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13. The Principal Regulations are amended by inserting after the Ninth Schedule the following Schedules:

“TENTH SCHEDULE

MEDICINAL PRODUCTS WHICH MAY BE SUPPLIED AND ADMINISTERED BY PERSONS ENGAGED OR EMPLOYED BY LISTED ORGANISATIONS IN EMERGENCIES PURSUANT TO REGULATION 4C

Medicinal Product	Route of administration	Conditions of administration
Column 1	Column 2	Column 3
Epinephrine (adrenaline) auto-injector presented as a 300 mcg pre-filled syringe	Intramuscular injection	Adults: For the emergency treatment of anaphylactic shock in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council, or by another body nominated by the Minister.
Epinephrine (adrenaline) auto-injector presented as a 150 mcg pre-filled syringe	Intramuscular injection	Children: For the emergency treatment of anaphylactic shock in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council, or by another body nominated by the Minister.
Glucagon hydrochloride for injection	Intramuscular or subcutaneous injection	Adults and children: For the emergency treatment of hypoglycaemia in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council, or by another body nominated by the Minister.

Medicinal Product	Route of administration	Conditions of administration
Column 1	Column 2	Column 3
Glyceryl trinitrate sublingual spray	Sublingual spray	Adults: For the emergency treatment of severe angina attack in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council, or by another body nominated by the Minister.
Medical gas mixture consisting of 50% nitrous oxide and 50% oxygen	By inhalation	Adults and children: Pain relief in emergency rescue situations in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council, or by another body nominated by the Minister.
Naloxone hydrochloride 1 mg/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.
Salbutamol 100 mcg multi-dose inhaler	Oral inhalation	Adults and children: For the emergency treatment of acute asthmatic attack in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council, or by another body nominated by the Minister.

ELEVENTH SCHEDULE

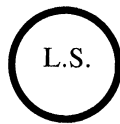
PARTICULARS TO BE INCLUDED IN NOTIFICATION BY ORGANISATION WISHING TO PROCURE MEDICINAL PRODUCTS FOR USE IN EMERGENCIES

Regulation 4D(2)(c)

1. The name of the organisation to be listed.
2. The address of the organisation to be listed.
3. The name of the accountable person(s) that the organisation proposes to appoint in accordance with Regulation 4E to ensuring compliance with these Regulations.
4. The business name or trading style to be used by the organisation, where that name is different to the name required to be provided by paragraph 1.

5. In the case of a corporate body registered under the Companies Act 2014—
 - (a) the registered name of the body,
 - (b) the address of the registered office of the body, and
 - (c) the Companies Registration Office number of the body.
6. The permanent address of the premises at which the medicinal products are to be stored and from which they are to be supplied.
7. The starting date of the activity of holding medicinal products for use in emergencies.
8. The name of the medicinal product or products the organisation wishes to procure.
9. A declaration that the procurement, storage, supply and administration of medicinal products for use in emergencies will be conducted in compliance with these Regulations.

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GIVEN under my Official Seal,
15 October 2015.

LEO VARADKER,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The purpose of these Regulations is to provide for the supply and administration of specified prescription-only medicinal products without a prescription to a person by a pharmacist or by an individual appointed by a listed organisation for the purpose of saving life or reducing severe distress in emergency situations, where that pharmacist or individual has completed an approved course of training regarding the administration of such products and the management of any adverse reaction.

These Regulations provide for the creation of a list of organisations that may procure the specified medicinal products for supply and administration in an emergency by trained persons in the organisation.

The Regulations also set out the records to be kept by pharmacists, pharmacy owners, persons who supply and administer medicinal products in emergencies, listed organisations and accountable persons in such organisations, in respect of each supply and administration of a specified prescription-only medicinal product without a prescription in accordance with these Regulations.

These Regulations also provide for the inclusion of additional vaccines, namely Pneumococcal and Zoster Vaccines, that a Pharmacist may supply and administer in the course of his or her professional practice, subject to the completion of approved training and the Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland.

These Regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015.

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