STATUTORY INSTRUMENTS.

S.I. No. 418 of 2025

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO.2) REGULATIONS 2025

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO.2) REGULATIONS 2025

I, JENNIFER CARROLL MACNEILL, 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) and section 9 of the Irish Medicines Board (Miscellaneous Provisions) Act 2024 (No. 4 of 2024)) 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 2025.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2025" 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);

"Regulations of 2024" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2024 (S.I. No. 582 of 2024).

"Regulations of 2025" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2025 (S.I. No. 353 of 2025).

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 5th September, 2025.

3. The Eight Schedule (as amended by Regulation 3 of the Regulations of 2024) to the Principal Regulations is amended by removing the Eight Schedule in its entirety and inserting the following entry wherever it appears:

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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 angina attack	In accordance with the summary of product characteristics of the product administered	Any place
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 as approved by the Minister for Health. Only to be administered in connection with the carrying on of the registered	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.

				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 2 to 17 years: 0.2 ml (administered as 0.1 ml per nostril). 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 as approved by the Minister for Health. 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.	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
Naloxone injection	Naloxone hydrochloride dihydrate 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 or relevant national guidelines	Any place
Naloxone Nasal Spray	Naloxone hydrochloride dihydrate 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	Any place

				administered or 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 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 as approved by the Minister for Health.	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
Shingrix powder and suspension for suspension for injection Herpes zoster vaccine (recombinant, adjuvanted)	Adjuvanted recombinant Varicella Zoster Virus glycoprotein E antigen Powder and suspension for suspension for injection.	Intramuscular (IM) injection only	Prevention of zoster and zoster-related post- herpetic neuralgia	Two doses of 0.5 mL each 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 as approved by the Minister for Health.	The premises of the retail pharmacy business in which the authorised person carries on professional practice.
Comirnaty KP.2 30 micrograms/dose dispersion	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent	In accordance with the summary of product	Any suitable and appropriate place, having

for injection COVID-19 mRNA Vaccine			COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older	characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.	regard to public convenience and the need to protect the health and safety of the public and safely administer the product.
Comirnaty KP.2 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.	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.
Comirnaty KP.2 3 micrograms/dose concentrate for dispersion COVID-19 mRNA Vaccine	Concentrate for dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.	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.
Nuvaxovid JN.1 5 micrograms/dose dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.	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.
Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-	In accordance with the summary of product characteristics and the relevant recommendatio	Any suitable and appropriate place, having regard to public

mRNA Vaccine			2, in individuals 12 years of age and older	ns or guidelines issued by the National Immunisation Advisory Committee and approved by the Minister for Health.	convenience and the need to protect the health and safety of the public and safely administer the product.
Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 – 11 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and approved by the Minister for Health.	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.
Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion COVID-19 mRNA Vaccine	Concentrate for dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and approved by the Minister for Health.	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

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4. The Twelfth Schedule (as amended by Regulation 2 of the Regulations of 2025) to the Principal Regulations is amended by removing the Twelfth Schedule in its entirety and inserting the following entry wherever it appears:

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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
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 Committee as approved by the Minister for Health.
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 2 to 17 years: 0.2 ml (administered as 0.1 ml per nostril). In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
VARIVAX powder and solvent for suspension for injection in a pre-filled syringe. Varicella Vaccine (live)	Powder and solvent for suspension for injection. White to off-white powder and clear, colourless liquid solvent.	Intramuscular or subcutaneous injection.	Vaccination against varicella.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
IMVANEX suspension for injection Smallpox and monkeypox vaccine (Live	Suspension for injection. Light yellow to pale white, milky suspension.	Subcutaneous injection.	Active immunisation against smallpox, monkeypox and disease caused	In accordance with the summary of product characteristics of the product administered

Modified Vaccinia Virus Ankara)			by vaccinia virus in adults.	and/or relevant national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
BCG VACCINE AJV	Powder and solvent for suspension for injection. White crystalline powder (might be difficult to see due to the small amount of powder in the vial). The solvent is a colourless solution without any visible particles.	Intradermal injection.	Active immunisation against tuberculosis.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
Tuberculin PPD RT23 2 T.U./0.1 mL	Solution for injection (injection). Clear, colourless to pale-yellow solution.	Intradermal injection.	Used for Mantoux tuberculin skin testing.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
M-M-RvaxPro powder and solvent for suspension for injection Measles, Mumps and Rubella vaccine (live)	Powder and solvent for suspension for injection. Before reconstitution, the powder is a light yellow compact crystalline cake and the solvent is a clear colourless liquid.	Intramuscular or subcutaneous injection.	Vaccination against measles, mumps and rubella.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
Priorix - Powder and solvent for solution for injection in a pre-filled syringe Measles, Mumps	Powder and solvent for solution for injection in a pre-filled syringe.	Subcutaneous or intramuscular injection.	Active immunisation against Measles, Mumps and Rubella.	In accordance with the summary of product characteristics of the product administered and/or relevant

and Rubella vaccine (live)				national guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
Comirnaty KP.2 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
Comirnaty KP.2 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
Comirnaty KP.2 3 micrograms/dose concentrate for dispersion COVID-19 mRNA Vaccine	Concentrate for dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the Minister for Health.
Nuvaxovid JN.1 5micrograms/dose dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee as approved by the

				Minister for Health.
Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and approved by the Minister for Health.
Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 – 11 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and approved by the Minister for Health.
Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion COVID-19 mRNA Vaccine	Concentrate for dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and approved by the Minister for Health.
Nirsevimab	50mg in 0.5mL pre-filled syringe; 100mg in 1mL pre-filled syringe.	Intramuscular (IM) injection.	Passive immunisation with nirsevimab of all infants who are born during the RSV season. Passive immunisation with nirsevimab of all *high-risk infants aged ≤12 months at the start of their first RSV season. Passive immunisation	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and as approved by the Minister for Health. Infants weight<5kg: A

			with nirsevimab of all infants who are aged ≤6 months at the start of the RSV season. Passive immunisation with nirsevimab of all ex-preterm infants under 24 months of age with Chronic Lung Disease in their second RSV season.	single dose of 50mg (0.5ml) administered intramuscularly. Infants weight≥ 5kg: A single dose of 100mg (1.0ml) administered intramuscularly. Children up to 24 months entering their second season: 200 mg given as 2 x 100 mg intramuscular injections.

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L.S.

GIVEN under my Official Seal,
1 September, 2025.

JENNIFER CARROLL MACNEILL,
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 make amendments and additions to the lists of medicinal products in the Eighth and Twelfth Schedules.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2025.

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