STATUTORY INSTRUMENTS.

S.I. No. 353 of 2025

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2025

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) 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) 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).

The Twelfth Schedule (as amended by Regulation 3 of the Regulations of 2024) to the Principal Regulations is amended by inserting the following entry:

"

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**
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	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health. Infants weight<5kg: A single dose of 50mg (0.5ml)

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 25th July, 2025.

			first RSV season. Passive immunisation 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.	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.

”.

L.S.

GIVEN under my Official Seal,
22 July, 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 update the schedule of medicinal products which may be supplied and administered pursuant to Regulation 4F of 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) Regulations 2025.

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