



STATUTORY INSTRUMENTS.

S.I. No. 162 of 2024



MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 3) REGULATIONS 2024

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**MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 3) REGULATIONS 2024**

I, STEPHEN DONNELLY, 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. 3) Regulations 2024.

(2) The collective citation “the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2024” 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 2023” means the Medicinal Products (Prescription and Control of Supply) (No. 7) Regulations 2023 (S.I. No. 584 of 2023).

3. The Eighth Schedule (as amended by Regulation 3 of the Regulations of 2023) to the Principal Regulations is amended—

(a) in column 5 of the entry for “Comirnaty 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Paediatric pack”, by deleting “Administered as a course of 3 doses of (0.2ml) each”,

(b) by substituting for column 5 of the entry for “Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)” the following:

“In accordance with the summary of product characteristics of the product administered and/or relevant guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.”,

(c) in column 2 of the entry for “Naloxone injection”, by deleting “1mg/ml”,

(d) in column 2 of the entry for “Naloxone Nasal Spray”, by deleting “1.8 mg”, and

(e) by inserting the following entry:

“

Medicinal Product	Form and presentation of product administered	Route of administration	Indication for which the medicinal product may be	Dosage and conditions of administration	Place of administration

*Notice of the making of this Statutory Instrument was published in
"Iris Oifigiúil" of 23rd April, 2024.*

			administered		
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine	Concentrate for dispersion for injection.	Intramuscular injection	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 of the product administered and/or relevant guidelines issued by the National Immunisation Advisory Committee and accepted 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 Tenth Schedule (as amended by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023 (S.I. No. 238 of 2023)) to the Principal Regulations is amended—

- (a) in column 2 of the entry for “Naloxone injection”, by deleting “1mg/ml”, and
- (b) in column 2 of the entry for “Naloxone Nasal Spray”, by deleting “1.8 mg”

5. The Twelfth Schedule (as amended by Regulation 4 of the Regulations of 2023) to the Principal Regulations is amended—

- (a) in column 5 of the entry for “Comirnaty 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Paediatric pack”, by deleting “Administered as a course of 3 doses of (0.2ml) each”,
- (b) by substituting for column 5 of the entry for “Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)” the following:
“In accordance with the summary of product characteristics of the product administered and/or relevant guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.”, and
- (c) 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

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
Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine	Concentrate for dispersion for injection.	Intramuscular injection	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 of the product administered and/or relevant guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.

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GIVEN under my Official Seal,
22 April, 2024.

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

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2024.

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