STATUTORY INSTRUMENTS.

S.I. No. 451 of 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 6) REGULATIONS 2023

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 6) REGULATIONS 2023

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. 6) Regulations 2023.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2023" 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 Eighth Schedule (as amended by Regulation 8 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023 (S.I. No. 284 of 2023)) 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	Place of administration
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
COMIRNATY Omicron XBB.1.5 30 mcg/dose	Dispersion for injection	Intramuscular injection	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 of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee	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.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 19*th September,* 2023.

COMIRNATY Omicron XBB.1.5 10 mcg/dose	Concentrate for dispersion for injection	Intramuscular injection	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 of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee	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 Omicron XBB.1.5 10 mcg/dose	Dispersion for injection	Intramuscular injection	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 of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee	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 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2023 (S.I. No. 422 of 2023)) 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**
COMIRNATY Omicron XBB.1.5 30 mcg/dose	Dispersion for injection	Intramuscular injection	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 of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee.

COMIRNATY Omicron XBB.1.5 10 mcg/dose	Concentrate for dispersion for injection	Intramuscular injection	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 of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee
COMIRNATY Omicron XBB.1.5 10 mcg/dose	Dispersion for injection	Intramuscular injection	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 of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee

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L.S.

GIVEN under my Official Seal,
14 September, 2023.

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 update the relevant schedules in relation to the COVID-19 vaccines to include the COMIRNATY Omicron XBB.1.5 vaccine.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2023.

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