STATUTORY INSTRUMENTS.

S.I. No. 582 of 2024

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 5) REGULATIONS 2024

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 5) 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. 5) Regulations 2024.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2024" includes these Regulations.

2. These Regulations shall come into operation on 31st October 2024.

3. 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) (No. 4) Regulations 2024 (S.I. No. 458 of 2024).

The Eighth Schedule (as amended by Regulation 7 of the 2024 Regulations) to the Principal Regulations is amended by inserting the following entry:

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st November,* 2024.

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Medicinal product	**Form and presentation of the 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 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 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.
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 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.
Comirnaty KP.23 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 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.

Nuvaxovid JN.1 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 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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The Twelfth Schedule (as amended by Regulation 8 of the 2024 Regulations) to the Principal Regulations is amended by inserting the following entry:

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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**
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 and accepted 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 and accepted 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 and accepted by the Minister for Health.

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**
Nuvaxovid JN.1 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 and accepted by the Minister for Health.

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L.S.

GIVEN under my Official Seal,
30 October, 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 update the schedules of medicinal products which may be supplied and administered pursuant to Regulation 4B and 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) (No. 5) Regulations 2024.

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