STATUTORY INSTRUMENTS.

S.I. No. 57 of 2022

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2022

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2022

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. 2) Regulations 2022.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2022" 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 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2022 (S.I. No. 32 of 2022)) 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
Nuvaxovid dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)	Dispersion for injection, colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles in a multidose vial. One dose (0.5 mL) contains 5 micrograms of the SARS-CoV-2 spike protein	Administered intramuscularly	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health. Administered as a course of 2 doses (0.5 mL each) at such interval as may be specified	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 18*th February,* 2022.

	and is adjuvanted with Matrix-M			in such recommendations or guidelines. Notwithstanding any directions to the contrary in the summary of product characteristics— (a) a dose may be administered as part of a heterologous primary schedule, (b) an additional dose may be administered to immunocompromised persons who are 18 years of age or older and have already received a primary vaccine course against Covid-19, and (c) a booster dose may be administered to— (i) persons who are 18 years of age or older and have already received a primary vaccine course against Covid-19, and (ii) immunocompromised persons who are 18 years of age or older and have already received an additional dose of a Covid-19 vaccine, in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy or otherwise), as may be specified in such	

				recommendations or guidelines, and subject to informed consent being obtained.	

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4. The Twelfth Schedule (as amended by Regulation 4 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021 (S.I. No. 718 of 2021)) to the Principal Regulations is amended by inserting the following entry:

“

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**
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Nuvaxovid dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)	Dispersion for injection, colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles in a multidose vial. One dose (0.5 mL) contains 5 micrograms of the SARS-CoV-2 spike protein and is adjuvanted with Matrix-M	Administered Intramuscularly	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health. Administered as a course of 2 doses (0.5 mL each) at such interval as may be specified in such recommendations or guidelines. Notwithstanding any directions to the contrary in the summary of product characteristics— (a) a dose may be administered as part of a heterologous primary schedule, (b) an additional dose may be administered to immunocompromised persons who are 18 years of age or older and have already received a primary

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**
				vaccine course against Covid-19, and (c) a booster dose may be administered to— (i) persons who are 18 years of age or older and have already received a primary vaccine course against Covid-19, and (ii) immunocompromised persons who are 18 years of age or older and have already received an additional dose of a Covid-19 vaccine, in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy or otherwise), as may be specified in such recommendations or guidelines, and subject to informed consent being obtained.

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L.S.

GIVEN under my Official Seal,
15 February, 2022.

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 Nuvaxovid vaccine.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2022.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

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r-phost: publications@opw.ie

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