STATUTORY INSTRUMENTS.

S.I. No. 467 of 2022

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 5) REGULATIONS 2022

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

"Regulations of 2022" means the Medicinal Products (Prescription and Control of Supply (Amendment) (No. 4) Regulations 2022 (S.I. No. 402 of 2022).

3. The Eighth Schedule (as amended by Regulation 3 of the Regulations of 2022) to the Principal Regulations is amended—

(a) by inserting after the entry for "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following entries:

"

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 30 micrograms/dose dispersion for	Ready to use dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent	In accordance with relevant recommendations or guidelines issued by the	Any suitable and appropriate place, having

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 23*rd September,* 2022.

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
injection COVID-19 mRNA Vaccine (nucleoside modified)	in a multidose vial One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine.		COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older	National Immunisation Advisory Committee and accepted by the Minister for Health. Notwithstanding any directions to the contrary in the summary of product characteristics— (a) an additional dose may be administered to immunocompromised persons who are 12 years of age or older and have already received a primary vaccine course against Covid-19, and (b) a booster dose may be administered to— (i) persons who are 12 years of age or older and have already received a primary vaccine course against Covid-19, and	regard to public convenience and the need to protect the health and safety of the public and safely administer the product

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**
				(ii) immunocompromised persons who are 12 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, living arrangements or otherwise), as may be specified in such recommendations or guidelines, and subject to informed consent being obtained	
Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA Vaccine	Dispersion for injection in a multidose vial	Intramuscular injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of	In accordance with 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

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**
(nucleoside modified)			age and older who have previously received at least a primary vaccination course against COVID-19	The product is to be given to eligible individuals who are 12 years of age or older and have previously received at least a primary vaccination course against COVID-19. The product is to be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy, living arrangements or otherwise), as may be specified in such recommendations or guidelines with an interval of not less than 4 months , or 3 months in exceptional circumstances, between administration of the product and the last prior dose of a COVID-19 vaccine, or confirmed	the public and safely administer the product.

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**
				SARS-CoV-2 infection.	
Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Dispersion for injection in a multidose vial	Intramuscular injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health The product is to be given to eligible individuals who are 12 years of age or older and have previously received at least a primary vaccination course against COVID-19. The product is to be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy, living arrangements or otherwise), 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.

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**
				in such recommendations or guidelines with an interval of not less than 4 months, or 3 months in exceptional circumstances, between administration of the product and the last prior dose of a COVID-19 vaccine, or confirmed SARS-CoV-2 infection.	

", and

(b) by inserting after the entry for "Spikevax (previously Covid-19 Vaccine Moderna) dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" 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**	**Place of administration**
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50	Dispersion for injection in a multidose vial	Intramuscular injection.	Active immunisation to prevent COVID-19 caused by	In accordance with relevant recommendations or guidelines issued by the National	Any suitable and appropriate place, having regard to

micrograms) /mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)			SARS-CoV-2 in individuals 30 years of age and older who have previously received at least a primary vaccination course against COVID-19	Immunisation Advisory Committee and accepted by the Minister for Health. Notwithstanding any directions to the contrary in the summary of product characteristics, the product shall only be administered to eligible individuals who are 30 years of age or older and have previously received at least a primary vaccination course against COVID-19. The product is to be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy, living	public convenience and the need to protect the health and safety of the public and safely administer the product

				arrangements or otherwise), as may be specified in such recommendations or guidelines with an interval of not less than 4 months, or 3 months in exceptional circumstances, between administration of the product and the last prior dose of a COVID-19 vaccine, or confirmed SARS-CoV-2 infection.	

".

4. The Twelfth Schedule (as amended by Regulation 4 of the Regulations of 2022) to the Principal Regulations is amended—

(a) by inserting after the entry for "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following entries:

"

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**
Comirnaty 30 micrograms/dose dispersion for injection COVID-19 mRNA	Ready for use dispersion for injection in a multidose	Intramuscular Injection	Indicated for active immunisation to prevent COVID-19	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister

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 (nucleoside modified)	vial One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine.		caused by SARS-CoV-2 virus, in individuals 12 years of age and older	for Health. Notwithstanding any directions to the contrary in the summary of product characteristics— (a) an additional dose may be administered to immunocompromised persons who are 12 years of age or older and have already received a primary vaccine course against Covid-19, and (b) a booster dose may be administered to— (i) persons who are 12 years of age or older and have already received a primary vaccine course against Covid-19, and (ii) immunocompromised persons who are 12 years of age or older and have already received an additional dose of a Covid-19 vaccine,

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
				in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy, living arrangements or otherwise), as may be specified in such recommendations or guidelines, and subject to informed consent being obtained.
Comirnaty Original/Omicron BA.1 (15/15 micrograms) /dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Dispersion for injection in a multidose vial	Intramuscular injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health The product is to be given (as a booster dose) to eligible individuals who are 12 years of age or older and have previously received at least a primary vaccination course against COVID-19. The product is to be administered in such volumes, at such intervals, in such manner and in such order of eligibility and prioritisation (whether by reference to age, employment sector, pregnancy, living arrangements or otherwise), as may be

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**
				specified in such recommendations or guidelines with an interval of not less than 4 months, or 3 months in exceptional circumstances between administration of the product and the last prior dose of a COVID-19 vaccine, or confirmed SARS-CoV-2 infection.
Comirnaty Original/Omicron BA.4-5 (15/15 micrograms) /dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Dispersion for injection in a multidose vial	Intramuscular injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health The product is to be given to eligible individuals who are 12 years of age or older and have previously received at least a primary vaccination course against COVID-19. The product is to be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy, living arrangements or otherwise), as may be specified in such recommendations or guidelines with an interval of not less than 4 months or 3 months in exceptional

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
				circumstances, between administration of the product and the last prior dose of a COVID-19 vaccine, or confirmed SARS-CoV-2 infection.

", and

(b) by inserting after the entry for "Spikevax (previously Covid-19 Vaccine Moderna) dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" 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
Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Dispersion for injection in a multidose vial	Intramuscular injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 30 years of age and older who have previously received at least a primary vaccination course against COVID-19	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health. Notwithstanding any directions to the contrary in the summary of product characteristics, the product shall only be

				administered to eligible individuals who are 30 years of age or older and have previously received at least a primary vaccination course against COVID-19. The product is to be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, employment sector, pregnancy, living arrangements or otherwise), as may be specified in such recommendations or guidelines with an interval of not less than 4 months , or 3 months in exceptional circumstances, between administration of the product and the last prior dose of a COVID-19 vaccine, or confirmed SARS-CoV-2 infection.

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GIVEN under my Official Seal,
20 September, 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 amend the relevant schedules in relation to the COVID-19 vaccines to provide for the administration of bivalent adapted Covid vaccines as booster doses, and to add an additional product formulation of the original Comirnaty product.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2022.

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