



STATUTORY INSTRUMENTS.

S.I. No. 284 of 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 4) REGULATIONS 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 4) 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. 4) 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);

“Regulations of 2020” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020);

“Regulations of 2021” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021 (S.I. No. 511 of 2021);

“Regulations of 2023” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023 (S.I. No. 105 of 2023).

3. Regulation 4(1) (as amended by Regulation 3(a) of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023 (S.I. No. 238 of 2023)) of the Principal Regulations is amended by substituting for the definition of “Covid-19 emergency” the following definition:

“‘Covid-19 situation’ means the situation resulting from the spread in the State of the disease caused by infection with the virus SARS-CoV-2, being a disease specified as an infectious disease in accordance with Regulation 6 of, and the Schedule to, the Infectious Diseases Regulations 1981 (S.I. No. 390 of 1981), or any variant of the disease so specified as an infectious disease in those Regulations;”

4. Regulation 4F (as amended by Regulation 3 of the Regulations of 2021) of the Principal Regulations is amended—

(a) by substituting for the heading the following:

“Supply and administration of certain medicinal products by health professions in context of Covid-19 situation”, and

- (b) in paragraph (a), by substituting “Covid-19 situation” for “Covid-19 emergency”.

5. Regulation 4G (as amended by Regulation 4 of the Regulations of 2021) of the Principal Regulations is amended—

- (a) by substituting for the heading the following:

“Administration of certain medicinal products by students in health professions in context of Covid-19 situation”, and

- (b) in paragraph (a), by substituting “Covid-19 situation” for “Covid-19 emergency”.

6. Regulation 7(2A) (inserted by Regulation 4 of the Regulations of 2020) of the Principal Regulations is amended by substituting “Covid-19 situation” for “Covid-19 emergency” in both places it occurs.

7. Regulation 8(4) (inserted by Regulation 5 of the Regulations of 2020) of the Principal Regulations is amended by substituting “Covid-19 situation” for “Covid-19 emergency” in each place it occurs.

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

- (a) in columns 4 and 5 of the entry for “Nuvaxovid dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)”, by substituting “12 years” for “18 years” in each place it occurs, and

- (b) 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
VidPrevtn Beta solution and emulsion for emulsion for injection COVID-19 vaccine (recombinant,	Solution and emulsion for emulsion for injection. The antigen solution is a	Administered intramuscularly only after mixing.	Indicated as a booster vaccine for active immunisation to prevent COVID-19 caused by SARS-CoV-2	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the	Any suitable and appropriate place, having regard to public convenience and the need to protect the health

adjuvanted). The adjuvant emulsion is a whitish to yellowish homogenous milky liquid. These are two multidose vials (antigen vial and adjuvant vial) that must be mixed before use.	colourless, clear liquid.		virus, in individuals 18 years of age and older who have previously received an mRNA or adenoviral vector COVID-19 vaccine.	Minister for Health. VidPrevtn Beta is administered intramuscularly as a single dose of 0.5 mL	and safety of the public and safely administer the product.
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9. The Twelfth Schedule (as amended by Regulation 4 of the Regulations of 2023) to the Principal Regulations is amended—

- (a) in columns 4 and 5 of the entry for “Nuvaxovid dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)”, by substituting “12 years” for “18 years” in each place it occurs, and
- (b) 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
VidPrevtn Beta solution and emulsion for emulsion for injection COVID-19 vaccine (recombinant, adjuvanted).	Solution and emulsion for emulsion for injection. The antigen solution is a colourless, clear liquid.	Administered intramuscularly only after mixing.	Indicated as a booster vaccine for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the

	<p>The adjuvant emulsion is a whitish to yellowish homogeneous milky liquid.</p> <p>These are two multidose vials (antigen vial and adjuvant vial) that must be mixed before use.</p>		<p>and older who have previously received an mRNA or adenoviral vector COVID-19 vaccine.</p>	<p>Minister for Health.</p> <p>VidPrevyn Beta is administered intramuscularly as a single dose of 0.5 mL</p>
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L.S.

GIVEN under my Official Seal,
1 June, 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 (1) remove references to the “Covid-19 emergency”, (2) change the age limit in the relevant Schedules in respect of the Covid-19 vaccine Nuvaxovid and (3) update the relevant schedules in relation to the COVID-19 vaccines to include the VidPrevyn Beta vaccine.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023.

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