



STATUTORY INSTRUMENTS.

**S.I. No. 11 of 2023**

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF  
SUPPLY) (AMENDMENT) REGULATIONS 2023

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## MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) 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) Regulations 2023.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007), Part 4 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (S.I. No. 512 of 2008), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009 (S.I. No. 442 of 2009), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. No. 530 of 2018), Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2020 (S.I. No. 177 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2020 (S.I. No. 204 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020 (S.I. No. 241 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020 (S.I. No. 401 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020 (S.I. No. 614 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2021 (S.I. No. 2 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021 (S.I. No. 8 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2021 (S.I. No. 43 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 (S.I. No. 81 of 2021), the Medicinal Products (Prescription and Control of Supply)

*Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 27th January, 2023.*

(Amendment) (No. 5) Regulations 2021 (S.I. No. 130 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2021 (S.I. No. 155 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021 (S.I. No. 245 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 8) Regulations 2021 (S.I. No. 411 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021 (S.I. No. 492 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021 (S.I. No. 511 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 11) Regulations 2021 (S.I. No. 558 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 12) Regulations 2021 (S.I. No. 578 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 13) Regulations 2021 (S.I. No. 605 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 14) Regulations 2021 (S.I. No. 692 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021 (S.I. No. 718 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2022 (S.I. No. 32 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2022 (S.I. No. 57 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2022 (S.I. No. 84 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2022 (S.I. No. 402 of 2022), the Regulations of 2022 and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2023.

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. 5) Regulations 2022 (S.I. No. 467 of 2022).

3. The Eighth Schedule (as amended by Regulation 3 of the Regulations of 2022) to the Principal Regulations is amended by inserting the following additional entries:

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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 3 micrograms /dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Paediatric pack	Concentrate for dispersion for injection (sterile concentrate) in a multidose vial that must be diluted before use.  After dilution, one dose (0.2 mL) contains 3 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles)	Intramuscular (IM) Injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals aged 6 months to 4 years at the time of their first dose.	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health, subject to informed consent being obtained from a parent or guardian.  Administered as a course of 3 doses of (0.2ml) each.	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 Original/Omicron BA.4-5 (5/5 micrograms )/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Concentrate for dispersion for injection (sterile concentrate) in a multidose vial that must be diluted before use.  After dilution one dose (0.2 mL) contains 5 micrograms of tozinameran and 5 micrograms of famtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles)	Intramuscular (IM) Injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years 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 administered to eligible individuals who are 5 -11 years of age and have previously received at least a primary vaccination course against COVID-19.  Notwithstanding any directions to the contrary in the summary of product characteristics, a booster dose may be administered to children aged 5 to	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.

				<p>11 years who—</p> <p>(a) are immunocompromised and have already received an additional dose of a COVID-19 vaccine, or</p> <p>(b) have already received a primary vaccine course against COVID-19 and have become immunocompromised since the administration of that primary vaccine course.</p> <p>The booster doses should be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, immune status, living arrangements or otherwise), as may be specified in such recommendations or guidelines.</p>	
<p>Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms /50 micrograms )/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)</p>	<p>One dose (0.5 mL) contains 25 micrograms of elasmomeran and 25 micrograms of davesomeran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles)</p>	<p>Intramuscular (IM) injection</p>	<p>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.</p>	<p>In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.</p> <p>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</p>	<p>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.</p>

				<p>have previously received at least a primary vaccination course against COVID-19.</p> <p>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.</p>	
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4. The Twelfth Schedule (as amended by Regulation 4 of the Regulations of 2022) to the Principal Regulations is amended by inserting the following additional entries:

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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
Column 1	Column 2	Column 3	Column 4	Column 5
Comirnaty 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside	<p>Concentrate for dispersion for injection (sterile concentrate) in a multidose vial that must be diluted before use.</p> <p>After dilution, one dose (0.2 mL) contains 3 micrograms of</p>	Intramuscular (IM) Injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals aged 6 months to 4 years at the time of	In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health, subject to informed consent being obtained from a

modified) Paediatric pack	tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).		their first dose.	parent or guardian.  Administered as a course of 3 doses (0.2 mL each).
Comirnaty Original/Omi cron BA.4-5 (5/5 micrograms)/ dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Concentrate for dispersion for injection (sterile concentrate) in a multidose vial that must be diluted before use.  After dilution one dose (0.2 mL) contains 5 micrograms of tozinameran and 5 micrograms of famtzinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles)	Intramuscular (IM) Injection	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years 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 administered to eligible individuals who are 5 -11 years of age and have previously received at least a primary vaccination course against COVID-19.  Notwithstanding any directions to the contrary in the summary of product characteristics, a booster dose may be administered to children aged 5 to 11 years who—  (a) are immunocompromised and have already received an additional dose of a COVID-19 vaccine, or  (b) have already received a primary vaccine course against COVID-19 and have become immunocompromised since the administration of that primary vaccine course.  The booster doses should be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, immune status, living arrangements or

				otherwise), as may be specified in such recommendations or guidelines.
Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	One dose (0.5 mL) contains 25 micrograms of elasomeran and 25 micrograms of davesomeran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).	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.	<p>In accordance with relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.</p> <p>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.</p> <p>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.</p>

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GIVEN under my Official Seal,  
23 January, 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 amend the relevant schedules in relation to the COVID-19 vaccines to provide for the administration of a bivalent adapted Covid vaccine, to add an additional paediatric product formulation of Comirnaty product to facilitate vaccination of children from 6 months to 4 years, and to provide for a further bivalent adapted Covid vaccine as a booster dose for persons aged 5 to 11.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2023.

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

Teil: 046 942 3100  
r-phost: publications@opw.ie

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