STATUTORY INSTRUMENTS.

S.I. No. 718 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 15) REGULATIONS 2021

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The Minister for Health, in exercise of the powers conferred on him 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 makes the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2021" 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 2021" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 14) Regulations 2021 (S.I. No. 692 of 2021).

3. The Eighth Schedule (as amended by Regulation 3 of the Regulations of 2021) to the Principal Regulations is amended—

(a) by substituting for the text in column 5 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following:

"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—

(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 16 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,

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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.",

(b) by substituting for the text in column 5 of the entry for the medicinal product "Spikevax (previously Covid-19 Vaccine Moderna) dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following:

"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—

(a) an additional dose may be administered to immunocompromised persons who are 30 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 30 years of age or older and have already received a primary vaccine course against Covid-19, and

(ii) immunocompromised persons who are 30 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.", and

(c) by inserting the following additional 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**
Comirnaty 10 micrograms/dose concentrate for dispersion for injection	Concentrate for dispersion for injection (sterile concentrate)	Comirnaty is administered intra muscularly after dilution.	Indicated for active immunisation to prevent COVID-19	In accordance with relevant recommendations or guidelines issued by the	Any suitable and appropriate place, having regard to public

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
COVID-19 mRNA Vaccine (nucleoside modified) Paediatric pack	in a multidose vial that must be diluted before use. One dose (0.2 mL) contains 10 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).		caused by SARS-CoV-2 virus, in individuals aged 5 to 11 years at the time of their first dose.	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 2 doses (0.2 mL each) at least 19 days apart. An additional dose should be administered to children aged 5 to 11 years who are severely immunocompromised at least 28 days after the second dose to complete the primary series. The additional dose should be administered in such manner and order of prioritisation (whether by reference to age, immune status, living arrangements or otherwise), as may be specified in such recommendations or guidelines.	convenience and the need to protect the health and safety of the public and safely administer the product.

”.

4. The Twelfth Schedule (as amended by Regulation 4 of the Regulations 2021) to the Principal Regulations is amended—

(a) by substituting for the text in column 5 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following:

"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 chaacteristics—

(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 16 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,

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.",

(b) by substituting for the text in column 5 of the entry for the medicinal product "Spikevax (previously Covid-19 Vaccine Moderna) dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following:

"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—

(a) an additional dose may be administered to immunocompromised persons who are 30 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 30 years of age or older and have already received a primary vaccine course against Covid-19, and

(ii) immunocompromised persons who are 30 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.", and

(c) by inserting the following additional 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**
Comirnaty 10 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. One dose (0.2 mL) contains 10 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).	Comirnaty is administered intramuscularly after dilution.	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals aged 5 to 11 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 2 doses (0.2 mL each) at least 19 days apart. An additional dose should be administered to children aged 5 to 11 years who are severely immunocompromised at least 28 days after the second dose to complete the primary series. The additional dose should be administered in such manner and order of prioritisation (whether by reference to age, living arrangements or otherwise), as may be specified in such recommendations or guidelines.

”.

GIVEN under the Official Seal of the Minister for Health,
16 December, 2021.

MUIRIS O'CONNOR,
A person authorised under section 15 of the Ministers and Secretaries Act 1924 to authenticate the seal of the 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, by taking account of the extension of the vaccination programme to include children aged 5 to 11 years being administered Comirnaty COVID-19 Vaccine, Paediatric Formulation, as per NIAC recommendations of 7 December 2021, and to provide for boosters in accordance with NIAC recommendations of 13 December 2021.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021.

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