STATUTORY INSTRUMENTS.

S.I. No. 8 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2021

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2021

I, STEPHEN DONNELLY, Minister for Health, 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 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) Regulations 2021 (S.I. No. 2 of 2021).

3. The Eighth Schedule (as amended by Regulation 4 of the Regulations of 2021) to the Principal Regulations is amended by inserting the following entry:

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 15*th January*, 2021.

“

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
COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Dispersion for injection in a multidose vial. One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles). White to off white dispersion.	Intramuscular (IM) injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.	In accordance with the summary of product characteristics of the product administered and relevant national guidelines.	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.

”.

4. The Twelfth Schedule (as amended by Regulation 5 of the Regulations of 2021) 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
Column 1	Column 2	Column 3	Column 4	Column 5
COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Dispersion for injection in a multidose vial. One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles). White to off white dispersion.	Intramuscular (IM) injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.	In accordance with the summary of product characteristics of the product administered and relevant national guidelines.

.”.

L.S.

GIVEN under my Official Seal,
13 January, 2021.

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 add an additional Covid-19 vaccination to the Eighth and Twelfth Schedules to the Regulations of 2003.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021.

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