STATUTORY INSTRUMENTS.

S.I. No. 105 of 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2023

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) 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) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2023" includes these Regulations.

In these Regulations—

"Principal Regulations" means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

"Regulations of 2023" means the Medicinal Products (Prescription and Control of Supply (Amendment) Regulations 2023 (S.I. No. 11 of 2023).

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

(a) in the entry for "Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)"—

  (i) in column 4, by deleting "and who have previously received at least a primary vaccination course against COVID-19", and

  (ii) in column 5—

    (I) by deleting "and have previously received at least a primary vaccination course against COVID-19", and

    (II) by deleting "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) in the entry for "Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for injection COVID-19 mRNA Vaccine (nucleoside modified)"—

  (i) in column 4, by deleting "who have previously received at least a primary vaccination course against COVID-19", and

  (ii) in column 5, by deleting "and have previously received at least a primary vaccination course against COVID-19".

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 10*th March,* 2023.

3. The Twelfth Schedule (as amended by Regulation 4 of the Regulations of 2023) to the Principal Regulations is amended—

(a) in the entry for "Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)"—

(i) in column 4, by deleting "and who have previously received at least a primary vaccination course against COVID-19", and

(ii) in column 5—

(I) by deleting "and have previously received at least a primary vaccination course against COVID-19", and

(II) by deleting "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) in the entry for "Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for injection COVID-19 mRNA Vaccine (nucleoside modified)"—

(i) in column 4, by deleting "who have previously received at least a primary vaccination course against COVID-19", and

(ii) in column 5, by deleting "and have previously received at least a primary vaccination course against COVID-19".

L.S.

GIVEN under my Official Seal,
7 March, 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 allow for certain bivalent COVID-19 vaccines to be used as the primary vaccination course.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023.

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