



STATUTORY INSTRUMENTS.

S.I. No. 578 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 12) REGULATIONS 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 12) REGULATIONS 2021

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. 12) 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. 11) Regulations 2021 (S.I. No. 558 of 2021).

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

- (a) in column 5 of the entry for the medicinal product “Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)”—
- (i) in subparagraph (b), by inserting “(0.3ml/30micrograms)” after “booster or subsequent dose”,
 - (ii) in subparagraph (b)(ii), by substituting “5 months (but preferably 6 months)” for “6 months”,
 - (iii) in subparagraph (b)(iii), by deleting “and”,
 - (iv) in subparagraph (c), by inserting “(0.3ml/30micrograms)” after “booster or subsequent dose”,
 - (v) in subparagraph (c)(ii), by inserting “(but preferably 6 months)” after “5 months”,
 - (vi) in subparagraph (c)(iii), by substituting “is obtained, and” for “is obtained.”, and
 - (vii) by inserting after subparagraph (c) the following subparagraph:

“(d) a booster or subsequent dose (0.3ml/30micrograms) may be administered to a person who has already

received a primary vaccine course against Covid-19 listed in this Schedule where—

- (i) the person is a healthcare worker,
 - (ii) 5 months (but preferably 6 months) or more have passed since the administration of the said primary vaccine course, and
 - (iii) informed consent is obtained.”, and
- (b) in the entry for the medicinal product “COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)”—
- (i) in column 1, by substituting “Spikevax (previously Covid-19 Vaccine Moderna)” for “Covid-19 Vaccine Moderna”, and
 - (ii) in column 5—
 - (I) in subparagraph (a) by inserting “against Covid-19” after “already received a primary vaccine course”,
 - (II) in subparagraph (a)(iv), by substituting “legal guardian,” for “legal guardian), and”,
 - (III) in subparagraph (b), by inserting “(0.25ml/50micrograms)” after “booster or subsequent dose”,
 - (IV) in subparagraph (b)(ii), by substituting “5 months (but preferably 6 months)” for “6 months”,
 - (V) in subparagraph (b)(iii), by substituting “is obtained, and” for “is obtained.”, and
 - (VI) by inserting after subparagraph (b) the following subparagraphs:
 - (c) a booster or subsequent dose (0.25ml/50micrograms) may be administered to a person who has already received a primary vaccine course against Covid-19 listed in this Schedule where—
 - (i) the person is between 60 and 79 years of age,
 - (ii) 5 months (but preferably 6 months) or more have passed since the administration of the said primary vaccine course, and
 - (iii) informed consent is obtained, and
 - (d) a booster or subsequent dose (0.25ml/50micrograms) may be administered to a person who has already received a primary

vaccine course against Covid-19 listed in this Schedule where—

- (i) the person is a healthcare worker,
- (ii) 5 months (but preferably six months) or more have passed since the administration of the said primary vaccine course, and
- (iii) informed consent is obtained.”.

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

- (a) in column 5 of the entry for the medicinal product “Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)”—
 - (i) in subparagraph (b), by inserting “(0.3ml/30micrograms)” after “booster or subsequent dose”,
 - (ii) in subparagraph (b)(ii), by substituting “5 months (but preferably 6 months)” for “6 months”,
 - (iii) in subparagraph (b)(iii), by deleting “and”,
 - (iv) in subparagraph (c), by inserting “(0.3ml/30micrograms)” after “booster or subsequent dose”,
 - (v) in subparagraph (c)(ii), by inserting “(but preferably 6 months)” after “5 months”,
 - (vi) in subparagraph (c)(iii), by substituting “is obtained, and” for “is obtained.”, and
 - (vii) by inserting after subparagraph (c) the following subparagraph:

“(d) a booster or subsequent dose (0.3ml/30micrograms) may be administered to a person who has already received a primary vaccine course against Covid-19 listed in this Schedule where—

 - (i) the person is a healthcare worker,
 - (ii) 5 months (but preferably 6 months) or more have passed since the administration of the said primary vaccine course, and
 - (iii) informed consent is obtained.”, and
- (b) in the entry for the medicinal product “COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)”—
 - (i) in column 1, by substituting “Spikevax (previously Covid-19 Vaccine Moderna)” for “Covid-19 Vaccine Moderna”, and

- (ii) in column 5—
- (I) in subparagraph (a) by inserting “against Covid-19” after “already received a primary vaccine course”,
 - (II) in subparagraph (a)(iv), by substituting “legal guardian),” for “legal guardian), and”,
 - (III) in subparagraph (b), by inserting “(0.25ml/50micrograms)” after “booster or subsequent dose”,
 - (IV) in subparagraph (b)(ii), by substituting “5 months (but preferably 6 months)” for “6 months”,
 - (V) in subparagraph (b)(iii), by substituting “is obtained, and” for “is obtained.”, and
 - (VI) by inserting after subparagraph (b) the following subparagraphs:
- “(c) a booster or subsequent dose (0.25ml/50micrograms) may be administered to a person who has already received a primary vaccine course against Covid-19 listed in this Schedule where—
- (i) the person is between 60 and 79 years of age,
 - (ii) 5 months (but preferably 6 months) or more have passed since the administration of the said primary vaccine course, and
 - (iii) informed consent is obtained, and
- (d) a booster or subsequent dose (0.25ml/50micrograms) may be administered to a person who has already received a primary vaccine course against Covid-19 listed in this Schedule where—
- (i) the person is a healthcare worker,
 - (ii) 5 months (but preferably 6 months) or more have passed since the administration of the said primary vaccine course, and
 - (iii) informed consent is obtained.”.



GIVEN under the Official Seal of the Minister for Health,
5 November, 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 allow booster/subsequent doses of the Cominarty and Spikevax COVID-19 vaccines to be supplied and administered to certain persons.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 12) Regulations 2021.

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