STATUTORY INSTRUMENTS.

S.I. No. 558 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 11) REGULATIONS 2021

S.I. No. 558 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 11) 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. 11) 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).

3. The Eighth Schedule (as amended by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021 (S.I. No. 492 of 2021)) to the Principal Regulations is amended, in column 5 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)"—

(*a*) in subparagraph (a), by inserting "against Covid-19" after "already received a primary vaccine course",

(*b*) in subparagraph (a)(iv), by substituting "legal guardian)," for "legal guardian), and",

(*c*) in subparagraph (b), by inserting "against Covid-19" after "already received a primary vaccine course",

(*d*) in subparagraph (b)(iii), by substituting "is obtained, and" for "is obtained.", and

(*e*) by inserting after subparagraph (b) the following subparagraph:

"(*c*) a booster or subsequent dose 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 or more have passed since the administration of the said primary vaccine course, and

(iii) informed consent is obtained.".

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 29*th October,* 2021.

4. The Twelfth Schedule (as amended by Regulation 5 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021 (S.I. No. 511 of 2021)) to the Principal Regulations is amended, in column 5 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)"—

(*a*) in subparagraph (a), by inserting "against Covid-19" after "already received a primary vaccine course",

(*b*) in subparagraph (a)(iv), by substituting "legal guardian)," for "legal guardian), and",

(*c*) in subparagraph (b), by inserting "against Covid-19" after "already received a primary vaccine course",

(*d*) in subparagraph (b)(iii), by substituting "is obtained, and" for "is obtained.", and

(*e*) by inserting after subparagraph (b) the following subparagraph:

"(*c*) a booster or subsequent dose 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 or more have passed since the administration of the said primary vaccine course, and

(iii) informed consent is obtained.".

L.S.

GIVEN under my Official Seal,
27 October, 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 allow booster/subsequent doses of the Cominarty COVID-19 vaccine to be supplied and administered to certain persons.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 11) Regulations 2021.

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

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
MOUNTSHANNON ROAD,
KILMAINHAM, DUBLIN 8,
D08 XAO6

Tel: 046 942 3100
E-mail: publications@opw.ie

ISBN 978-1-3993-1176-2

€3.00

(DH-313) 75. 10/21. Propylon.