STATUTORY INSTRUMENTS.

S.I. No. 402 of 2022

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 4) REGULATIONS 2022

S.I. No. 402 of 2022

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 4) REGULATIONS 2022

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. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2022.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2022" 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 2022" means the Medicinal Products (Prescription and Control of Supply (Amendment) (No. 3) Regulations 2022 (S.I. No. 84 of 2022).

3. The Eighth Schedule (as amended by Regulation 3 of the Regulations of 2022) 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)", by substituting "pregnancy, living arrangements or otherwise" for "pregnancy or otherwise",

(b) 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)", by substituting "pregnancy, living arrangements or otherwise" for "pregnancy or otherwise", and

(c) by substituting for the text in column 5 of the entry for the medicinal product "Comirnaty 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Paediatric pack" the following:

"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.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 2*nd August,* 2022.

An additional dose should be administered to children aged 5 to 11 years who are immunocompromised at least 28 days after the second dose to complete the primary series.

Notwithstanding any directions to the contrary in the summary of product characteristics, a booster dose may be administered to children aged 5 to 11 years who—

(a) are immunocompromised and have already received an additional dose of a Covid-19 vaccine, or

(b) have already received a primary vaccine course against Covid-19 and have become immunocompromised since the administration of that primary vaccine course.

The additional and booster doses should be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, immune status, living arrangements or otherwise), as may be specified in such recommendations or guidelines.".

4. The Twelfth Schedule (as amended by Regulation 4 of the Regulations of 2022) 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)", by substituting "pregnancy, living arrangements or otherwise" for "pregnancy or otherwise",

(b) 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)", by substituting "pregnancy, living arrangements or otherwise" for "pregnancy or otherwise", and

(c) by substituting for the text in column 5 of the entry for the medicinal product "Comirnaty 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Paediatric pack" the following:

"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 immunocompromised at least 28 days after the second dose to complete the primary series.

Notwithstanding any directions to the contrary in the summary of product characteristics, a booster dose may be administered to children aged 5 to 11 years who—

(a) are immunocompromised and have already received an additional dose of a Covid-19 vaccine, or

(b) have already received a primary vaccine course against Covid-19 and have become immunocompromised since the administration of that primary vaccine course.

The additional and booster doses should be administered in such volumes, at such intervals, in such manner and in such order of prioritisation (whether by reference to age, immune status, living arrangements or otherwise), as may be specified in such recommendations or guidelines.".

L.S.

GIVEN under my Official Seal,
29 July, 2022.

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 amend the relevant schedules in relation to the COVID-19 vaccines to provide for booster doses of Comirnaty COVID-19 Vaccine, Paediatric Formulation to immunocompromised persons aged 5 to 11 and to clarify that booster doses of the mRNA vaccines may be prioritised on the basis of living arrangements.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2022.

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 978-1-3993-1806-8

€ 3.00

(SH-435) 75. 7/22. Propylon.