STATUTORY INSTRUMENTS.

S.I. No. 605 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 13) REGULATIONS 2021

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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. 13) 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. 12) Regulations 2021 (S.I. No. 578 of 2021).

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

(a) by substituting for the text in column 5 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following:

"In accordance with the summary of product characteristics of the product administered and relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.

Notwithstanding any guidance to the contrary in the summary of product characteristics, an additional or booster dose may be administered to—

(a) immunocompromised persons who are 12 years of age or older,
(b) persons who are 50 years of age or older,

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 23rd *November*, 2021.

(c) persons who reside in long term care facilities and are 16 years of age or older,
(d) persons who have underlying conditions associated with very high risk or high risk of severe COVID-19 disease and are 16 years of age or older, and
(e) health care workers,

at such volumes, intervals and manner as may be specified in such recommendations or guidelines and subject to informed consent being obtained.", and

(b) by substituting for the text 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)" the following:

"In accordance with the summary of product characteristics of the product administered and relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.
An additional or booster dose may be administered to—
(a) persons who are 50 years of age or older, and
(b) persons who are 30 years of age or older and—
(i) reside in long term care facilities,
(ii) have underlying conditions associated with very high risk or high risk of severe COVID-19 disease, or
(iii) are health care workers,

at such volumes, intervals and manner as may be specified in such recommendations or guidelines and subject to informed consent being obtained.".

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

(a) by substituting for the text in column 5 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" the following:

"In accordance with the summary of product characteristics of the product administered and relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.
Notwithstanding any guidance to the contrary in the summary of product characteristics, an additional or booster dose may be administered to—
(a) immunocompromised persons who are 12 years of age or older,
(b) persons who are 50 years of age or older,

(c) persons who reside in long term care facilities and are 16 years of age or older,
(d) persons who have underlying conditions associated with very high risk or high risk of severe COVID-19 disease and are 16 years of age or older, and
(e) health care workers,

at such volumes, intervals and manner as may be specified in such recommendations or guidelines and subject to informed consent being obtained.", and

(b) by substituting for the text 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)" the following:

"In accordance with the summary of product characteristics of the product administered and relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.
An additional or booster dose may be administered to—
(a) persons who are 50 years of age or older, and
(b) persons who are 30 years of age or older and—
(i) reside in long term care facilities,
(ii) have underlying conditions associated with very high risk or high risk of severe COVID-19 disease, or
(iii) are health care workers,

at such volumes, intervals and manner as may be specified in such recommendations or guidelines and subject to informed consent being obtained.".

L.S.

GIVEN under my Official Seal,
19 November, 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 amend the relevant schedules in relation to the Comirnaty and Spikevax COVID-19 vaccines to take account of updated NIAC advice in relation to booster and additional doses.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 13) 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

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r-phost: publications@opw.ie

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