STATUTORY INSTRUMENTS.

S.I. No. 492 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 9) REGULATIONS 2021

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 9) 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. 9) 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. 8) Regulations 2021 (S.I. No. 411 of 2021).

3. The Eighth Schedule (as amended by Regulations 3 and 5 of the Regulations of 2021) to the Principal Regulations is amended—

(*a*) in Column 3 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)", by deleting "as a course of 2 doses (0.3 ml each) at least 21 days apart", and

(*b*) in Column 5 of the entries for the medicinal products "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" and "COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)", by inserting the following additional text:

"Notwithstanding any guidance to the contrary in the summary of product characteristics—

(*a*) an additional dose may be administered to a person who has already received a primary vaccine course listed in this Schedule where—

(i) the person is 12 years of age or older,

(ii) the person is immunocompromised,

(iii) 2 months or more have passed since the administration of the said primary vaccine course, and

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st October,* 2021.

(iv) informed consent is obtained from the person (or, in the case of a person between 12 and 15 years of age, from his or her legal guardian), and

(*b*) a booster or subsequent dose may be administered to a person who has already received a primary vaccine course listed in this Schedule where—

(i) the person is—

(I) 65 years of age or older and a resident of a long-term care facility, or

(II) 80 years of age or older,

(ii) 6 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 Regulations 4 and 6 of the Regulations of 2021) to the Principal Regulations is amended—

(*a*) in Column 3 of the entry for the medicinal product "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)", by deleting "as a course of 2 doses (0.3 ml each) at least 21 days apart", and

(*b*) in Column 5 of the entries for the medicinal products "Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" and "COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)", by inserting the following additional text:

"Notwithstanding any guidance to the contrary in the summary of product characteristics—

(*a*) an additional dose may be administered to a person who has already received a primary vaccine course listed in this Schedule where—

(i) the person is 12 years of age or older,

(ii) the person is immunocompromised,

(iii) 2 months or more have passed since the administration of the said primary vaccine course, and

(iv) informed consent is obtained from the person (or, in the case of a person between 12 and 15 years of age, from his or her legal guardian), and

(*b*) a booster or subsequent dose may be administered to a person who has already received a primary vaccine course listed in this Schedule where—

(i) the person is—

(I) 65 years of age or older and a resident of a long-term care facility, or

(II) 80 years of age or older,

(ii) 6 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,
28 September, 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 for additional or booster/subsequent doses of mRNA 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. 9) Regulations 2021.

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