STATUTORY INSTRUMENTS.

S.I. No. 511 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 10) REGULATIONS 2021

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 10) 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. 10) 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 (No. 7) of 2021" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021 (S.I. No. 245 of 2021);

"Regulations (No. 9) of 2021" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021 (S.I. No. 492 of 2021).

3. Regulation 4F (as amended by Regulation 3 of the Regulations (No. 7) of 2021) of the Principal Regulations is amended by substituting for the heading the following:

"*Supply and administration of certain medicinal products by health professions in context of Covid-19 emergency*".

4. Regulation 4G (inserted by Regulation 4 of the Regulations (No. 7) of 2021) of the Principal Regulations is amended by substituting for the heading the following:

"*Administration of certain medicinal products by students in health professions in context of Covid-19 emergency*".

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 12*th October*, 2021.

5. The Twelfth Schedule (as amended by Regulation 4 of the Regulations (No. 9) of 2021) to the Principal Regulations is amended by inserting the following entry:

"

Medicinal product	**Form and presentation of product administered**	**Route of administration**	**Indication for which the medicinal product may be administered**	**Dosage and conditions of administration**
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Influenza vaccine of a composition that has been approved for use in the European Union for the season in question	Influenza vaccine suspension for injection presented as a pre-filled syringe	By intramuscular injection only	Prevention of seasonal influenza	0.5ml or less for a single administration. In accordance with the summary of product characteristics of the product administered and Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland.

".

L.S.

GIVEN under my Official Seal,
7 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 COVID-19 vaccinators to administer the seasonal influenza vaccines.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021.

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