STATUTORY INSTRUMENTS.

S.I. No. 698 of 2020

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 7) REGULATIONS 2020

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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. 7) Regulations 2020.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2020" 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 Principal Regulations are amended by inserting after Regulation 4E (inserted by Regulation 4 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015)) the following Regulation:

"*Supply and administration of Covid-19 vaccinations and epinephrine (adrenaline)*

4F. It shall not be a contravention of a provision of these Regulations for a person to supply another person with, and to administer to that person, a medicinal product specified in column 1 of the Twelfth Schedule if, and only if—

(a) the medicinal product is supplied and administered as part of the vaccination programme implemented in the State to address the Covid-19 emergency,

(b) the person supplying and administering the medicinal product is—

(i) a registered nurse (including a registered midwife),

(ii) a registered pharmacist,

(iii) an advanced paramedic,

(iv) a paramedic,

(v) an emergency medical technician, or

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 5*th January,* 2021.

(vi) a person registered in the register of the Physiotherapists Registration Board established under section 36(1)(a) of the Health and Social Care Professionals Act 2005 (No. 27 of 2005),

and has received training in the administration of the product, as approved by the regulatory body for the profession concerned,

(c) the medicinal product is supplied and administered in a suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public and safely administer the product, and

(d) the product is administered in accordance with the requirements specified in columns 2 to 5 of the Twelfth Schedule opposite the mention of the product specified in column 1 of that Schedule."

4. The Principal Regulations are amended by inserting after Regulation 10A (inserted by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011)) the following Regulation:

"*Keeping of records in relation to supply and administration of Covid-19 vaccination*

10B. A person who administers a medicinal product pursuant to Regulation 4F (except in the case of epinephrine (adrenaline)) shall within 7 days of the administration, forward to the Health Service Executive, by electronic means or otherwise, the following particulars in respect of such administration:

(a) the date of administration;

(b) the name, address, contact number(s), email address(es), ethnicity, pregnancy status, date of birth and sex of the person to whom the product was administered, to the extent that the person can provide such particulars;

(c) confirmation that prior to the administration of the product—

(i) consent was obtained from the person to whom the product was administered for its administration, or

(ii) if he or she was unable to give such consent, the will and preferences of the person was established and the administration was for the benefit of the person;

(d) the personal public service number (within the meaning of section 262 of the Social Welfare Consolidation Act 2005) of the person to whom the product was administered, or, where that person does not have, or is unable to give, a personal public service number, other identifying particulars as defined in section 2 of the Health Identifiers Act (No. 15 of 2014);

(e) the name, batch number and expiry date of the product;

(f) the name, business address, email and telephone number of the person who supplied and administered the product and the number of his or her certificate of registration issued by his or her professional regulatory body;

(g) the name, address and telephone number of the general medical practitioner (if any) of the person to whom the product was administered to the extent that the person can give such particulars; and

(h) such other relevant and necessary information as may be specified by the Minister.

5. The Eighth Schedule (as substituted by Regulation 4 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020 (S.I. No. 401 of 2020)) 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	Place of administration
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Concentrate for dispersion for injection (sterile concentrate) in a multidose vial and must be diluted before use. One vial (0.45 mL) contains 5 doses of 0.3 mL after dilution. One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in	Comirnaty is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each) at least 21 days apart	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older	In accordance with the summary of product characteristics of the product administered and relevant national guidelines	Any suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public and safely administer the product.

	lipid nanoparticles).				

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6. The Principal Regulations are amended by inserting after the Eleventh Schedule (as substituted by Regulation 4 of the Regulations of 2020) the following Schedule:

“**TWELFTH SCHEDULE**

Regulation 4F

MEDICINAL PRODUCTS WHICH MAY BE SUPPLIED AND ADMINISTERED BY CERTAIN PERSONS PURSUANT TO REGULATION 4F

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**
Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	Concentrate for dispersion for injection (sterile concentrate) in a multidose vial and must be diluted before use. One vial (0.45 mL) contains 5 doses of 0.3 mL after dilution. One dose (0.3 mL) contains	Comirnaty is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each) at least 21 days apart	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older	In accordance with the summary of product characteristics of the product administered and relevant national guidelines

	30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).			
Epinephrine (adrenaline) injection	Epinephrine (adrenaline) injection presented as a pre-filled syringe or ampoule	Intramuscular or subcutaneous injection	Adults and Children: For the emergency treatment of anaphylactic shock	In accordance with the summary of product characteristics of the product administered and relevant national guidelines

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L.S.

GIVEN under my Official Seal,
24 December, 2020.

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 Covid-19 vaccinations to be administered by pharmacists, nurses and midwives, advanced paramedics, paramedics, emergency medical technicians and physiotherapists.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020.

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