STATUTORY INSTRUMENTS.

S.I. No. 422 of 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 5) REGULATIONS 2023

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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. 5) Regulations 2023.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2023" 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 2023" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023 (S.I. No. 284 of 2023).

3. Regulation 4F (as amended by Regulation 4 of the Regulations of 2023) of the Principal Regulations is amended—

(a) by substituting for the heading the following:

"*Supply and administration of certain medicinal products by certain health professionals as part of HSE vaccination programme*",

(b) by substituting for paragraph (a) the following:

"(a) the medicinal product is supplied and administered as part of a vaccination programme that is being coordinated, overseen and implemented in the State by the Health Service Executive for the purpose of immunising members of the public against an infectious disease that is listed in the Schedule to the Infectious Diseases Regulations 1981 (S.I. No. 390 of 1981), including where a public health emergency has been declared,", and

(c) in paragraph (b), by inserting "or as provided by another body recognised by the said regulatory body for this purpose" after "the profession concerned".

4. The Principal Regulations are amended by revoking Regulation 4G.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 29*th August*, 2023.

5. Regulation 10D (as amended by Regulation 5 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021 (S.I. No. 245 of 2021)) of the Principal Regulations is amended—

(a) in the heading, by substituting "*medicinal products under Regulation 4F*" for "*Covid-19 vaccination*",

(b) by deleting "or Regulation 4G", and

(c) by substituting for paragraphs (f) and (fa) the following paragraph:

"(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;".

6. The Twelfth Schedule (as amended by Regulation 9 of the Regulations of 2023) to the Principal Regulations is amended by inserting the following entries:

"

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 (live attenuated) nasal spray suspension of a composition that has been approved for use in the European Union for the season in question	Nasal spray, suspension.	By intranasal administration only.	Prevention of seasonal influenza.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee.

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**
VARIVAX powder and solvent for suspension for injection in a pre-filled syringe Varicella Vaccine (live)	Powder and solvent for suspension for injection. White to off-white powder and clear, colourless liquid solvent.	Intramuscular or subcutaneous injection.	Vaccination against varicella.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee.
IMVANEX suspension for injection Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Suspension for injection. Light yellow to pale white, milky suspension.	Subcutaneous injection.	Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in adults.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee.
BCG VACCINE AJV	Powder and solvent for suspension for injection. White crystalline powder	Intradermal injection.	Active immunisation against tuberculosis.	In accordance with the summary of product characteristics of the product administered

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**
	(might be difficult to see due to the small amount of powder in the vial). The solvent is a colourless solution without any visible particles.			and/or relevant national guidelines issued by the National Immunisation Advisory Committee.
Tuberculin PPD RT23 2 T.U./0.1 mL	Solution for injection (injection). Clear, colourless to pale-yellow solution.	Intradermal injection.	Used for Mantoux tuberculin skin testing.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee.
M-M-R vaxPro powder and solvent for suspension for injection	Powder and solvent for suspension for injection. Before reconstitution, the powder is a	Intramuscular or subcutaneous injection.	Vaccination against measles, mumps and rubella.	In accordance with the summary of product characteristics of the product administered and/or

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**
Measles, Mumps and Rubella vaccine (live)	light yellow compact crystalline cake and the solvent is a clear colourless liquid.			relevant national guidelines issued by the National Immunisation Advisory Committee
Priorix - Powder and solvent for solution for injection in a pre-filled syringe Measles, Mumps and Rubella vaccine (live)	Powder and solvent for solution for injection in a pre-filled syringe.	Subcutaneous or intramuscular injection.	Active immunisation against Measles, Mumps and Rubella.	In accordance with the summary of product characteristics of the product administered and/or relevant national guidelines issued by the National Immunisation Advisory Committee.

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L.S.

GIVEN under my Official Seal,
23 August, 2023.

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 provide for the supply and administration of medicinal products as part of HSE vaccination programmes under Regulation 4F, to add additional products to the list of products to which that provision applies and to update and remove other provisions introduced in response to the Covid-19 pandemic.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2023.

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