STATUTORY INSTRUMENTS.

S.I. No. 458 of 2024

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 4) REGULATIONS 2024

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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. 4) Regulations 2024.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2024" includes these Regulations.

2. These Regulations shall come into operation on 16th September 2024.

3. In these Regulations –

"Principal Regulations" means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

"Regulations of 2024" means the Medicinal Products (Prescription and Control of Supply) (No. 3) Regulations 2024 (S.I. No. 162 of 2024).

4. Regulation 10A of the Principal Regulations is amended –

(a) by deleting paragraph (1)(g),

(b) by substituting for paragraph (1)(h) the following:

"(g) confirmation that prior to the administration of the product, consent was —

(i) obtained from the person to whom the product was administered, 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, or

(iii) in the case of a child under 16 years of age, informed consent was obtained from a parent or guardian.",

(c) by substituting for paragraph (2) the following:

"(2) An authorised person who administers a medicinal product to a person pursuant to Regulation 4B shall, within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in the register referred to in paragraph (1) in respect of such

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 13*th September,* 2024.

administration, to the Health Service Executive (except in the case of epinephrine (adrenaline), glucagon, glyceryl trinitrate, naloxone or salbutamol).",

(d) by substituting for paragraph (3) the following:

"(3) A pharmacy owner (including any successor pharmacy owner to the first-mentioned pharmacy owner) shall preserve, or cause to be preserved, and keep readily available for inspection, in electronic form, an entry made in a register kept pursuant to paragraph (1) at the premises of the retail pharmacy business, for a period of two years from the date of the supply and administration of the medicinal product", and

(e) by deleting paragraph (4).

5. Regulation 10C of the Principal Regulations is amended by substituting for paragraph (1)(c) the following:

"(c) confirmation that prior to the administration of the product –

(i) Consent was obtained from the person to whom the product was administered, 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, or

(iii) in the case of a child under 16 years of age, informed consent was obtained from a parent or guardian;".

6. Regulation 10D of the Principal Regulations is amended –

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

"(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, or

(iii) in the case of a child under 16 years of age, informed consent was obtained from a parent or guardian;"

(b) by deleting paragraph (g) and consequently re-numbering paragraph (h) as paragraph (g).

7. The Eighth Schedule (as amended by Regulation 3 of the 2024 Regulations) to the Principal Regulations is amended by inserting the following entry:

“

Medicinal product	**Form and presentation of the 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 JN.1 30 micrograms/dose dispersion for injection	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.	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.
Comirnaty JN.1 10 micrograms/dose dispersion for injection	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.	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.
Comirnaty JN.1 3 micrograms/dose concentrate for dispersion for injection	Concentrate for dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.	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.

”

8. The Twelfth Schedule (as amended by Regulation 5 of the 2024 Regulations) 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**
Comirnaty JN.1 30 micrograms/dose dispersion for injection	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.
Comirnaty JN.1 10 micrograms/dose dispersion for injection	Dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.
Comirnaty JN.1 3 micrograms/dose concentrate for dispersion for injection	Concentrate for dispersion for injection	Intramuscular injection	Indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.	In accordance with the summary of product characteristics and the relevant recommendations or guidelines issued by the National Immunisation Advisory Committee and accepted by the Minister for Health.

”

L.S.

GIVEN under my Official Seal,
11 September, 2024.

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 align the consent requirements in relation to the provision of vaccinations and certain emergency medicines. These Regulations also update the requirements regarding the keeping of records in relation to the supply and administration of medicinal products pursuant to Regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulations 2003. The relevant schedules in relation to the COVID-19 vaccines are updated to include the Comirnaty JN.1 COVID-19 vaccine.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2024.

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