



STATUTORY INSTRUMENTS.

S.I. No. 245 of 2021



MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 7) REGULATIONS 2021

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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 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. 4) of 2021” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 (S.I. No. 155 of 2021);

“Regulations (No. 6) of 2021” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2021 (S.I. No. 81 of 2021).

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

“(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,

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 21st May, 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),
- (vii) a registered optometrist,
- (viii) a registered dentist,
- (ix) a person registered in the register of the Radiographers Registration Board established under section 36(1)(a) of the Health and Social Care Professionals Act 2005, or
- (x) a person registered in the register of dental hygienists established and maintained by the Dental Council under section 53 of the Dentists Act 1985,

and has received training in the administration of the product, as approved by the regulatory body for the profession concerned, or, in the case of a regulatory body that does not have legal authority to approve such training, as approved by the Health Service Executive following consultation with the regulatory body,”.

4. The Principal Regulations are amended by inserting after Regulation 4F (as amended by Regulation 4 of the Regulations (No. 4) of 2021) the following Regulation:

“Administration of Covid-19 vaccinations by students in health professions

4G. It shall not be a contravention of a provision of these Regulations for a person to administer to another person a medicinal product specified in column 1 of the Twelfth Schedule (other than epinephrine (adrenaline) injection) if, and only if—

- (a) the medicinal product is administered as part of the vaccination programme implemented in the State to address the Covid-19 emergency,
- (b) the medicinal product is administered in accordance with the directions of a registered medical practitioner,
- (c) the person administering the medicinal product is a student in—
 - (i) a programme of basic medical education and training approved by the Medical Council under section 88(2) of the Medical Practitioners Act 2007,
 - (ii) a Masters degree in pharmacy recognised and approved by the Pharmaceutical Society of Ireland under Regulation 6 of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No. 377 of 2014),

- (iii) a programme of nursing or midwifery education and training approved by the Nursing and Midwifery Board of Ireland under section 85(2) of the Nurses and Midwives Act 2011,
- (iv) a course leading to a primary qualification in dentistry listed in the Second Schedule to the Dentists Act 1985,
- (v) a physiotherapy education and training programme approved by the Physiotherapists Registration Board under section 48 of the Health and Social Care Professionals Act 2005, or
- (vi) an optometry education and training programme approved by the Optical Registration Board under section 48 of the Health and Social Care Professionals Act 2005,

and has successfully undertaken training in the administration of the product, as approved by the Health Service Executive,

- (d) the medicinal product is supplied and administered in a vaccination centre established as part of the programme referred to in paragraph (a), and
- (e) 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.”.

5. Regulation 10D (as re-numbered by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2021 (S.I. No. 130 of 2021)) of the Principal Regulations is amended—

- (a) by inserting “or Regulation 4G” after “(except in the case of epinephrine (adrenaline))”, and
- (b) by substituting for paragraph (f) the following paragraphs:
- (c)

“(f) in the case of administration under Regulation 4F, 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;

(fa) in the case of administration under Regulation 4G, the name, home address, email and telephone number of the person who administered the product and, in the case of a nursing or midwifery student, the candidate number attached to his or her registration in the candidate register maintained by the Nursing and Midwifery Board of Ireland;”.

6. The Eighth Schedule (as amended by Regulation 3 of the Regulations (No. 6) of 2021) to the Principal Regulations is amended, in the entry for the medicinal product “COVID-19 Vaccine AstraZeneca, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant])” (inserted by Regulation 3 of the Regulations of 2021), by substituting “Vaxzevria (also known as COVID-19 Vaccine AstraZeneca)” for “COVID-19 Vaccine AstraZeneca” in both places it occurs.

7. The Twelfth Schedule (as amended by Regulation 4 of the Regulations (No. 6) of 2021) to the Principal Regulations is amended, in the entry for the medicinal product “COVID-19 Vaccine AstraZeneca, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant])” (inserted by Regulation 4 of the Regulations of 2021), by substituting “Vaxzevria (also known as COVID-19 Vaccine AstraZeneca)” for “COVID-19 Vaccine AstraZeneca” in both places it occurs.



GIVEN under my Official Seal,
13 May, 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—

- (1) provide for the supply and administration of Covid-19 vaccines by additional health care professionals,
- (2) provide for the administration of Covid-19 vaccines by health care students, and
- (3) update the name of the Covid-19 vaccination produced by AstraZeneca in the Eighth and Twelfth Schedules to the Regulations of 2003.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021.

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