



STATUTORY INSTRUMENTS.

**S.I. No. 411 of 2021**



MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF  
SUPPLY) (AMENDMENT) (NO. 8) REGULATIONS 2021

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MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 8) 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. 8 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).

3. The Eighth Schedule (as amended by Regulation 5 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020)), to the Principal Regulations is amended, in Column 4 in the entry for “Indication for which the medicinal product may be administered” (inserted by Regulation 5 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020), by substituting “12 years of age” for “16 years of age”.

4. The Twelfth Schedule (as inserted by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020)), to the Principal Regulations is amended, in Column 4 in the entry for “Indication for which the medicinal product may be administered” (inserted by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020), by substituting “12 years of age” for “16 years of age”.

5. The Eighth Schedule (as inserted by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021 (S.I. No. 8 of 2021)), to the Principal Regulations is amended, in Column 4 in the entry for “Indication for which the medicinal product may be administered” (inserted by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021), by substituting “12 years of age” for “18 years of age”.

6. The Twelfth Schedule (as inserted by Regulation 4 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021 (S.I. No. 8 of 2021)), to the Principal Regulations is amended, in Column 4 in the entry for “Indication for which the medicinal product may be administered” (inserted by Regulation 4 of the Medicinal

*Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 3rd August, 2021.*

Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021), by substituting “12 years of age” for “18 years of age”.



GIVEN under my Official Seal,  
30 July, 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 change the age from 18 years and 16 years and older, to 12 years and older for the Pfizer (Comirnaty) and Moderna (Spikevax) vaccine.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 8) Regulations 2021.

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