STATUTORY INSTRUMENTS.

S.I. No. 2 of 2021

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) 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) Regulations 2021.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007), Part 4 of the Regulations of 2007, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (S.I. No. 512 of 2008), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009 (S.I. No. 442 of 2009), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. No. 530 of 2018), Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2020, the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2020, the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020, the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020 S.I. No. (401 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020 (S.I. No. 614 of 2020), the Regulations of 2020 and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2021.

2. In these Regulations—

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

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 8th *January,* 2021.

"Regulations of 2007" means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

"Regulations of 2020" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020).

3. Regulation 20 of the Principal Regulations is amended by inserting after paragraph (9) (inserted by Regulation 23 of the Regulations of 2007) the following paragraph:

"(9A) The provisions of Regulations 5 and 6 of these Regulations, shall not apply as respects supply of a medicinal product specified in column 1 of the Twelfth Schedule to a person referred to in Regulation 4F for the purpose of supply and administration in accordance with that Regulation.".

4. The Eighth Schedule (as amended by Regulation 5 of the Regulations of 2020) to the Principal Regulations is amended, in Column 2, by deleting "One vial (0.45 mL) contains 5 doses of 0.3 mL after dilution.".

5. The Twelfth Schedule (inserted by Regulation 6 of the Regulations of 2020) to the Principal Regulations is amended, in Column 2, by deleting "One vial (0.45 mL) contains 5 doses of 0.3 mL after dilution.".

L.S.

GIVEN under my Official Seal,
4 January, 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 exempt from certain requirements the supply of Covid-19 vaccinations to persons administering such vaccines as part of the vaccination programme implemented in the State to address the Covid-19 emergency.

In addition, these Regulations amend certain requirements in relation to doses of Covid-19 vaccinations.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2021.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2,
D02 DR67.

Tel: 076 110 6834
E-mail: publications@opw.ie

ISBN 978-1-4468-8593-2

€ 3.00

(DH-188) 75. 1/21. Propylon.