STATUTORY INSTRUMENTS.

S.I. No. 1 of 2021

MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2021

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MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) 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), and for the purpose of giving further effect to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[1], hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2021.

(2) The Principal Regulations, the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 2 of 2009), the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 286 of 2010), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012 (S.I. No. 274 of 2012), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013 (S.I. No. 164 of 2013), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2019 (S.I. No. 217 of 2019) and these Regulations may be cited together as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2007 to 2021.

2. In these Regulations "Principal Regulations" means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

3. Regulation 6 of the Principal Regulations is amended by inserting after paragraph (c) the following paragraph:

"(d) the supply of a medicinal product specified in column 1 of the Twelfth Schedule to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (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 a person referred to in Regulation 4F of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (inserted by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020) for the purpose of supply and administration in accordance with that Regulation.".

[1] OJ No. L 311, 28.11.2001, p. 67.

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

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 (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

The purpose of these Regulations is to exempt the supply of Covid-19 vaccinations from the prohibition on the sale by wholesale of medicinal products by registered pharmacists in nominated public and private hospital pharmacy departments, who do not hold a wholesaler's authorisation.

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