STATUTORY INSTRUMENTS.

S.I. No. 614 of 2020

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 6) REGULATIONS 2020

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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. 6) Regulations 2020.

(2) The citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2020" includes these Regulations.

2. These regulations shall come into operation on 1 January 2021.

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 2014" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014);

"Regulations of 2015" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015);

"Regulations of 2020" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020).

4. Regulation 4(1) (as amended by Regulation 3 of the Regulations of 2020) of the Principal Regulations is amended—

(*a*) by inserting after the definition of "hospital" the following definition:

"'information society services' has the meaning assigned to it by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015[1];", and

[1] OJ No. L 241, 17.9.2015, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 22*nd December,* 2020.

(*b*) in the definition of "prescription"—

(i) in subparagraph (c), by deleting "or",

(ii) in subparagraph (d), by substituting "order, or" for "order;", and

(iii) by inserting after subparagraph (d) the following subparagraph:

"(*e*) a practitioner, of status equivalent to a registered medical practitioner, a registered dentist or a registered nurse, practising in the United Kingdom, who is legally entitled to issue a prescription for the medicinal product concerned in the United Kingdom, if the prescription has not been issued with a view to enabling the supply of a medicinal product by mail order and the prescription has not been issued by means of information society services;".

5. Regulation 7(1A) (inserted by Regulation 4 of the Regulations of 2014) of the Principal Regulations is amended—

(a) by inserting "or in the United Kingdom," after "in an EEA state other than the State,",

(b) by inserting ", or a practitioner of status equivalent to a registered nurse who is legally entitled to issue a prescription for the medicinal product concerned in the United Kingdom," after "EEA state in which the prescription is issued,", and

(c) in subparagraph (c), by deleting "EEA".

6. Regulation 7A(1) (inserted by Regulation 5 of the Regulations of 2014) of the Principal Regulations is amended by inserting ", or in the United Kingdom," after "in an EEA state other than the State".

7. Regulation 19A(16) (inserted by Regulation 8 of the Regulations of 2015) of the Principal Regulations is amended by deleting the definition of "information society services".

L.S.

GIVEN under my Official Seal,
11 December, 2020.

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 (S.I. No. 540 of 2003) as follows:

- they amend the definition of "prescription", following the departure of the United Kingdom from the European Union, to enable the recognition of prescriptions written by registered medical practitioners, registered dentists and registered nurse prescribers, including midwife prescribers, in the United Kingdom for dispensing in the State, as long as such prescriptions have not been issued by means of information society services or for the purpose of enabling the supply of a medicinal product by mail order; and
- they enable a prescription issued in the State to be recognised in the United Kingdom.

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D02 DR67.

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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 978-1-4468-8478-2

€ 3.00

(DH-147) 75. 12/20. Propylon.