STATUTORY INSTRUMENTS.

S.I. No. 525 of 2011

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2011

(Prn. A11/1829)

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I, JAMES REILLY, 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), make the following regulations:

1. These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011.

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

3. Regulation 4(1) of the Principal Regulations is amended by inserting the following definitions:

" 'pharmacy owner' and 'retail pharmacy business' shall have the meanings they have in the Pharmacy Act 2007 (No. 20 of 2007);".

4. The Principal Regulations are amended by inserting the following after Regulation 4A:

"Supply and administration of influenza vaccine, etc., by authorised persons.

4B. It shall not be a contravention of a provision of these Regulations for an authorised person, in the course of his or her professional practice as an authorised person and at the premises of the retail pharmacy business in which he or she carries on that professional practice (or, in the case of epinephrine (adrenaline), at any place), to supply a person with, and to administer to the person, a medicinal product specified in column 1 of the Eighth Schedule if, and only if—

(*a*) a body recognised by the Council of the Pharmaceutical Society of Ireland has issued to the authorised person a certificate stating that he or she has satisfactorily completed a course of training approved by the Council relating to the administration of the product and the management of any adverse reaction that may follow from such administration, and

(*b*) the product is administered in accordance with the requirements specified in columns 2 to 5 of the Eighth Schedule opposite the mention of the product specified in column 1 of that Schedule.".

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 18*th October*, 2011.

5. Regulation 5 of the Principal Regulations is amended by inserting the following after paragraph (5):

"(6) Paragraph (1) shall not apply as respects a medicinal product specified in column 1 of the Eighth Schedule in any case where it is to be, and is, administered by an authorised person pursuant to Regulation 4B.".

6. The Principal Regulations are amended by inserting the following after Regulation 10:

"Keeping of records in relation to supply and administration of influenza vaccine, etc.

10A. (1) Subject to paragraph (4), an authorised person who administers a medicinal product pursuant to Regulation 4B shall make an entry, in a register kept for the purpose by the pharmacy owner (who may be that authorised person) at the premises of the retail pharmacy business in which the authorised person carries on his or her professional practice as an authorised person, recording the following particulars in respect of such administration:

(*a*) the date of administration;

(*b*) the name, address, date of birth and sex of the person to whom the product was administered;

(*c*) the personal public service number (within the meaning of section 262 of the Social Welfare Consolidation Act 2005 (No. 26 of 2005)) of the person to whom the product was administered unless that person fails to provide such particular to the authorised person;

(*d*) the name, dosage, marketing authorisation number, batch number and expiry date of the product;

(*e*) the name of the authorised person and the number of his or her certificate of registration issued under section 20 of the Pharmacy Act 2007;

(*f*) the address of the premises of the retail pharmacy business in which the authorised person carries on his or her professional practice; and

(*g*) the name, address and contact particulars of the general medical practitioner (if any) of the person to whom the product was administered unless that person fails to provide such particulars to the authorised person.

(2) An authorised person who administers a medicinal product to a person pursuant to Regulation 4B shall, within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in the register referred to in paragraph (1) in respect of such administration, to—

(*a*) the Health Service Executive, and

(*b*) the general medical practitioner (if any) of the person to whom the product was administered unless that person fails to provide the authorised person with the particulars referred to in paragraph (1)(*g*).

(3) A pharmacy owner (including any successor pharmacy owner to the first-mentioned pharmacy owner) shall—

(*a*) preserve, or cause to be preserved, an entry made in a register kept by him or her pursuant to paragraph (1) until at least the eighth anniversary of the date on which the entry was made, and

(*b*) keep the register available for inspection at the premises of the retail pharmacy business to which it relates for a period of at least two years from such date unless (and without prejudice to paragraph (*a*)) such business ceases to be carried on in those premises before the expiration of that two years.

(4) The requirements of paragraph (1) shall be satisfied in the case of a register referred to in that paragraph kept in the form of computerised records if—

(*a*) there is a print-out, for each day on which the premises of the retail pharmacy business to which the register relates is open for such business, of the particulars recorded in the register pursuant to that paragraph during that day, and

(*b*) the authorised person (or, if more than one, each of them) certifies, not later than 24 hours after the print-out is made, such of the particulars in the print-out as he or she recorded in the register, to be true and correct to the best of his or her knowledge and belief.".

7. Regulation 19 of the Principal Regulations is amended by substituting the following for paragraph (4):

"(4) The provisions of this Regulation shall not apply to a medicinal product (not being a medicinal product specified in column 1 of the Eighth Schedule) which by virtue of these Regulations may be supplied otherwise than in accordance with a prescription.".

8. The Principal Regulations are amended by inserting the following after the Seventh Schedule:

"EIGHTH SCHEDULE

ADMINISTRATION OF CERTAIN MEDICINAL PRODUCTS BY AUTHORISED PERSONS PURSUANT TO REGULATION 4B

Medicinal product	**Form and presentation of product administered**	**Route of administration**	**Indication for which the medicinal product may be administered**	**Dosage and conditions of administration**
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Influenza vaccine of a composition that has been approved for use in the European Union for the season in question	Influenza vaccine suspension for injection presented as a prefilled syringe	By intramuscular injection only	Prevention of seasonal influenza	0.5ml or less for single administration. In accordance with the summary of product characteristics of the product administered
Epinephrine (adrenaline) injection	Epinephrine (adrenaline) 1 mg/ml injection presented as a prefilled syringe or epinephrine (adrenaline) 1.7 mg/ml injection presented as a prefilled syringe	Intramuscular or subcutaneous injection	For the emergency treatment of anaphylactic shock arising as a result of the administration of seasonal influenza vaccine	0.5mg repeated every 5 to 10 minutes to a maximum of 3 doses and otherwise in accordance with the summary of product characteristics of the product administered

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L.S.

GIVEN under my Official Seal,
14 October 2011.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The purpose of these Regulations is to provide for the supply and administration of seasonal influenza vaccine, and where appropriate epinephrine (adrenaline) injection, to a person by a pharmacist, where that pharmacist has completed approved training regarding the administration of such products and the management of any adverse reaction.

The Regulations also set out the records to be kept by pharmacists and pharmacy owners in respect of each administration of a seasonal influenza vaccine or epinephrine (adrenaline) injection. In addition the Regulations provide for the forwarding of copies of these records to the Health Service Executive and general medical practitioners.

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CONTAE MHAIGH EO,
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
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