



STATUTORY INSTRUMENTS

S.I. No. 488 of 2008

REGULATION OF RETAIL PHARMACY BUSINESSES
REGULATIONS 2008

(Prn. A8/1883)

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REGULATION OF RETAIL PHARMACY BUSINESSES
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The Minister for Health and Children, in exercise of the powers conferred on her by section 18 of the Pharmacy Act 2007 (No. 20 of 2007), hereby makes the following regulations:—

Citation

1. These Regulations may be cited as the Regulation of Retail Pharmacy Businesses Regulations 2008.

Commencement

2. (1) Subject to paragraph (2), these Regulations shall come into force on 29th November 2008.

(2) Except in the case of a new retail pharmacy business, Regulation 4(3) shall come into force on 1 November 2010.

Interpretation

3. (1) In these Regulations—

“Act” means the Pharmacy Act 2007 (No. 20 of 2007);

“animal remedies authorisation” and “veterinary prescription” have the meaning assigned to them in Regulation 2(1) of the animal remedies regulations;

“animal remedies regulations” means the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007)

“Board” means the Irish Medicines Board established by section 3 of the Irish Medicines Board Act 1995 (No. 29 of 1995);

“certificate of registration”, “certificate of traditional-use registration”, “Community marketing authorisation”, “EEA State”, “homeopathic medicinal product”, “parallel import licence”, “product authorisation”, “summary of product characteristics”, “traditional herbal medicinal product” and “wholesaler’s authorisation” have the meaning assigned to them by the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

“Council” means the Council established by section 10 of the Act;

“manufacturer’s authorisation” means an authorisation granted and in force in pursuance of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 2nd December, 2008.*

“marketing authorisation” means an authorisation granted by the Board under the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), and includes a certificate of registration, a certificate of traditional-use registration, a Community marketing authorisation, a parallel import licence and a product authorisation;

“new retail pharmacy business” means a retail pharmacy business that had not been established by the pharmacy owner concerned in the relevant premises on the date on which these Regulations came into force;

“patient” means the person named on the prescription and in respect of whose treatment the prescription is issued;

“premises”, in relation to a retail pharmacy business means a fixed premises, and includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored;

“sale by wholesale” means sale or supply for the purposes of sale in the course of a business or for administration in the course of a professional practice and cognate words shall be construed accordingly;

“superintendent pharmacist” means a registered pharmacist acting in the capacity specified in section 27(b), 28(a) or 29(b) of the Act and which may be in respect of a single retail pharmacy business or in respect of a number of such businesses;

“supervising pharmacist” means a registered pharmacist acting in the capacity specified in section 27(c), 28(b) or 29(c) of the Act and who is in whole-time charge of carrying on the retail pharmacy business at the premises of the said business;

“veterinary medicinal product” includes an animal remedy as defined in section 1(1) of the Animal Remedies Act 1993 (No. 23 of 1993).

(2) In these Regulations, unless the context otherwise requires, any reference to a Regulation shall be construed as a reference to a Regulation contained in these Regulations, and any reference in a Regulation to a paragraph shall be construed as a reference to a paragraph in that Regulation.

(3) In these Regulations, unless the contrary intention is indicated, these Regulations apply to medicinal products other than veterinary medicinal products.

(4) A word or expression that is used in these Regulations and is used in the Act has, in these Regulations, unless the contrary intention appears, the same meaning as it has in the Act.

(5) Insofar as animal remedies are concerned, these Regulations are in addition to, and not in substitution of, the animal remedies regulations.

Staff, premises, equipment and procedures

4. (1) (a) The pharmacy owner shall provide and maintain such staff, premises, equipment and procedures for the storage, preparation, dispensing, compounding, sale and supply of medicinal products, including veterinary medicinal products, that he or she stores, prepares, dispenses, compounds, sells and supplies in his or her retail pharmacy business, as are necessary to avoid deterioration of the products and he or she shall not use for any such purposes premises other than those that constitute his or her retail pharmacy business and which have been specified in his or her application for registration under section 17 of the Act.

(b) The pharmacy owner shall ensure that, in the conduct of his or her retail pharmacy business and in particular in making provision for the staff, premises and other matters referred to in sub-paragraph (a) of this paragraph, he or she has regard for the health, safety and convenience of the public.

(2) The pharmacy owner shall ensure that the arrangements and layout of the premises are such as to enable personal supervision to be exercised by a registered pharmacist of any preparation, dispensing or compounding and of the sale or supply of medicinal products, including veterinary medicinal products, at one and the same time.

(3) The pharmacy owner shall provide a separate and designated area conveniently located within the pharmacy premises so that a pharmacist may review and discuss in private with the person for whom a prescription has been issued, or with the carer of such a person, such matters relating to the medicine therapy as either of the said persons may request or as the pharmacist, in the exercise of his or her professional judgment, may deem necessary.

(4) The pharmacy owner shall provide and maintain a safe or cabinet that meets the requirements of Regulation 5 of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) (as amended by Regulation 26(2) of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988)) and shall ensure that the said safe or cabinet has a sufficient capacity to permit the orderly storage and safe keeping of all the relevant controlled drugs, including such veterinary medicinal products as are relevant controlled drugs, as required by the aforementioned Regulation 5.

(5) The pharmacy owner shall ensure that any disposal of medicinal products, including veterinary medicinal products, that may be required to be carried out in the course of conducting a retail pharmacy business, is carried out in a manner which will not result in any danger to public health or risk to the environment.

Management and supervision of a retail pharmacy business

5. (1) The pharmacy owner and the superintendent pharmacist shall, inter alia, ensure that—

- (a) the part of the retail pharmacy business that consists of the management and administration of the sale and supply of medicinal products, including veterinary medicinal products, is carried out under his or her personal control and in accordance with all legal requirements,
- (b) at each premises where the retail pharmacy business is carried on, there is a supervising pharmacist who has a 3 year minimum post-registration experience in whole-time charge of the carrying on of the business there,
- (c) an ongoing, contemporaneous and retrievable record of any other registered pharmacist, responsible for the retail pharmacy business or for the personal supervision of the sale and supply of medicinal products, including veterinary medicinal products, at the premises, is maintained,
- (d) the sale or supply of medicinal products, including veterinary medicinal products, and the preparation, dispensing and compounding of prescriptions, including veterinary prescriptions, at the premises, are carried out by or under the personal supervision of a registered pharmacist,
- (e) medicinal products that are subject to prescription control under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) and medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) are not accessible to the public for self-selection,
- (f) veterinary medicinal products that are designated prescription only under the animal remedies regulations and veterinary medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) are not accessible to the public for self-selection,
- (g) he or she cooperates with the directions of the Board, or other such authority, in respect of the withdrawal or recall from sale or supply of any medicinal product, or veterinary medicinal product, as may be given, or as may be implemented, by the Board,
- (h) he or she is satisfied that all of the pharmacists and other staff, employed or engaged by him or her, or under his or her management, have the requisite knowledge, skills, including language skills, and fitness to perform the work for which they are, or are to be, responsible, and
- (i) he or she is satisfied as to the identity of any person employed or engaged as a registered pharmacist in the business and that each such person is the person to whom the relevant certificate of registration as a registered pharmacist relates.

(2) The requirements of subparagraphs (h) and (i) of paragraph (1) shall also apply to persons employed or engaged in a retail pharmacy business that consists of or includes the sale or supply of veterinary medicinal products.

(3) A supervising pharmacist acting as such in respect of a retail pharmacy business shall ensure that his or her current certificate of registration is conspicuously displayed at the premises where he or she is so acting.

Sourcing of medicinal products

6. (1) A person carrying on a retail pharmacy business shall obtain his or her supplies of medicinal products (including medicinal products on a general sales list) from persons—

- (a) who are themselves the holders of a manufacturer's authorisation or a wholesaler's authorisation in respect of such products, or
- (b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.

(2) A person carrying on a retail pharmacy business shall obtain his or her supplies of veterinary medicinal products from persons—

- (a) who are themselves the holders of a manufacturer's licence granted under Regulation 20 of the animal remedies regulations, or an animal remedies wholesaler's licence granted under Regulation 30 of those Regulations, in respect of such products, or
- (b) who are the holders of a licence granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.

(3) Notwithstanding paragraphs (1) and (2), a person carrying on a retail pharmacy business may accept the return of a medicinal product, including a veterinary medicinal product, that had previously been dispensed or supplied, and such product shall be kept in a secure manner that is segregated from other medicinal products, including other such veterinary medicinal products, and shall be disposed of in a manner otherwise than for the purpose of use as a medicinal product or as a veterinary medicinal product.

(4) The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient.

Appropriate storage of medicinal products

7. A person carrying on a retail pharmacy business shall ensure that the quality of the medicinal products, including veterinary medicinal products, that are being handled by him or her, or that are otherwise under his or her control, is

maintained in accordance with the requirements of any marketing authorisation, animal remedies authorisation, or other standard that is applicable to those products.

Medicinal products which may be sold or supplied

8. (1) Subject to paragraph (2), a person carrying on a retail pharmacy business shall not sell or supply a medicinal product (including a medicinal product on a general sales list) unless—

- (a) there has been granted in respect of such product a marketing authorisation which is for the time being in force, or
- (b) the said product is not required to be the subject of such a marketing authorisation by virtue of Regulation 6(4) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

(2) Paragraph (1)(a) shall not apply until the 30 April 2011 in the case of—

- (a) traditional herbal medicinal products, or
- (b) homeopathic medicinal products to which Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) applies,

which were on the market in the State on 20 July 2007.

Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription

9. (1) A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient.

(2) The review provided for in paragraph (1) shall include screening for any potential therapy problems which may arise out of the use of any medicinal product that may have been prescribed and which the registered pharmacist is, or, in the course of his professional practice, ought reasonably to be, aware of. The potential problems to be screened for shall include those which may be due to therapeutic duplication, interactions with other medicinal products (including serious interactions with non-prescription medicinal products, herbal products or foods), incorrect dosage or duration of treatment, allergic reactions, and clinical abuse and/or misuse.

(3) Following completion of the review provided for in paragraph (1) the registered pharmacist shall ensure that each patient has sufficient information and advice for the proper use and storage of the prescribed medicinal product and shall offer to discuss with the patient, or with the carer of such a patient,

all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant, and which may include one or more of the following as may be appropriate—

- (a) the identity of the medicinal product, its dosage form, the method and route of administration and the duration of therapy;
- (b) the therapeutic benefit which may be expected from the use of the medicinal product;
- (c) any special directions and precautions for the correct preparation, administration and use of the medicinal product;
- (d) the importance of the need for compliance with the directions for use including techniques for self-monitoring during therapy;
- (e) any common severe side-effects and adverse reactions or interactions and therapeutic contraindications which may be encountered, including their avoidance and the action to be taken should they occur;
- (f) the action to be taken in the event of a missed dose;
- (g) the methods for the safe disposal of the medicinal product in the event of the course of treatment not being completed, and
- (h) any other matters which may be included or referred to in the summary of product characteristics for the medicinal product concerned.

Counselling in the supply of medicinal products other than on foot of a prescription

10. A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, in the course of the sale or supply of a medicinal product other than on foot of a prescription and prior to such sale or supply, a registered pharmacist is satisfied that the purchaser or other such person is aware of what the appropriate use of the medicinal product is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse.

Veterinary medicinal products which may be sold or supplied

11. A person carrying on a retail pharmacy business shall not sell or supply a veterinary medicinal product unless—

- (a) the sale or supply of the said product is in accordance with the requirements of Regulation 28(1) of the animal remedies regulations,
- (b) the sale or supply of the said product is in accordance with Regulation 28(4)(a) of the animal remedies regulations, except where Regulation 44 of the said regulations applies and has been complied with, and

- (c) (i) there has been granted in respect of such product an animal remedies authorisation which is for the time being in force, or
- (ii) the said product is not required to be the subject of an animal remedies authorisation by virtue of Regulation 3(2) of the animal remedies regulations, or
- (iii) it has been determined by the Board that the said product is not required to be the subject of an animal remedies authorisation by virtue of Regulation 3(3) of the animal remedies regulations, or
- (iv) there has been granted in respect of the product by the Minister for Agriculture, Fisheries and Food, a licence, pursuant to Regulation 18(11)(c) of the animal remedies regulations, which is for the time being in force, or
- (v) it is a product within the meaning of Regulation 18(2)(c)(ii) or Regulation 18(9)(c)(ii) of the animal remedies regulations.

Keeping of records in respect of medicinal products

12. (1) A person carrying on a retail pharmacy business shall keep—

- (a) such records as are prescribed under Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended);
- (b) such register as is prescribed under Regulation 16 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended); and
- (c) such other records in electronic form as will enable the patient in respect of whom a medicinal product has been supplied on foot of a medical prescription to be identified together with the said patient's medication record in respect of his or her previous supplies of such products made by the pharmacy.

(2) Where the records referred in paragraph (1)(a) are retained in electronic format, the computer software in use for the retention of such records shall have been independently validated and certified as being suitable for the retention of such records, having regard to the purpose of such controls under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003). Such certification shall appropriately show the version of the software to which the certificate relates and the date on which it was last updated.

(3) The person responsible for the conduct of such validation and for the issue of the required certification shall be a person approved by the Minister for Health and Children.

(4) A person carrying on a retail pharmacy business shall—

- (a) in the case of records referred to in paragraph (1)(a), keep such records readily available for inspection as required under Regulation

10(3) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), and

- (b) in the case of the certificate referred to in paragraph (2), keep a certified copy of the said certificate readily available for inspection.

Keeping of records, marking of prescriptions and other related matters in respect of veterinary medicinal products

13. A person carrying on a retail pharmacy business shall—

- (a) keep at the premises where such business is conducted, such records as are prescribed in Regulation 34 of the animal remedies regulations which shall be readily available for inspection,
- (b) comply with Regulations 20(3)(b) and 28(5), in relation to labeling, and Regulation 43(7), in relation to the marking of dispensed or partially dispensed prescriptions and other related matters, of the said Regulations.

Publication of guidelines by the Council

14. The Council may, with the prior approval of the Minister, publish detailed guidelines for the purpose of facilitating compliance with these Regulations.

Relevant provisions for the purpose of offences

15. The following provisions of these Regulations are hereby designated as relevant provisions for the purposes of Section 18(3) of the Act:

- (a) Regulations 4(5), 5(1)(c), 5(3), 6, 8, 11, and 12(1)(b), and
- (b) Regulation 5(1)(a), (b), (d) and (f) and Regulation 13, in so far as those Regulations relate to veterinary medicinal products.



GIVEN under the Official Seal of the Minister for Health and
Children
28 November 2008

MARY HARNEY,
Minister for Health and Children.

EXPLANATORY NOTE.

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

These Regulations set out certain requirements to be complied with by persons carrying on retail pharmacy business.

The Regulations lay down requirements in respect of the sourcing, sale, supply, storage and keeping of records in respect of medicinal products including veterinary medicinal products (i.e. animal remedies) by persons carrying on retail pharmacy businesses. Requirements in respect of staff, premises, equipment and procedures are also laid down including certain of the responsibilities that must be discharged by the superintendent and supervising pharmacists in respect of the retail pharmacy businesses for which they are responsible.

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