



STATUTORY INSTRUMENTS.

S.I. No. 495 of 2008

PHARMACEUTICAL SOCIETY OF IRELAND (RETAIL PHARMACY
BUSINESSES) (REGISTRATION) RULES 2008

(Prn. A8/1897)

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PHARMACEUTICAL SOCIETY OF IRELAND (RETAIL PHARMACY
BUSINESSES) (REGISTRATION) RULES 2008

The Council of the Pharmaceutical Society of Ireland, in exercise of the functions conferred on the said Society by section 11 of the Pharmacy Act 2007 (No. 20 of 2007), hereby makes the following rules.

Dated this 28 day of November 2008

BERNARD LEDDY

President

AMBROSE McLOUGHLIN

Registrar

I consent to the making of these Rules.



GIVEN under my Official Seal,
28 November 2008

MARY HARNEY,
Minister for Health and Children.

S.I. No. 495 of 2008

PHARMACEUTICAL SOCIETY OF IRELAND (RETAIL PHARMACY
BUSINESSES) (REGISTRATION) RULES 2008

ARRANGEMENT OF RULES

1. Citation.
2. Commencement.
3. Interpretation.
4. Applications for registration.
5. Examination of applications.
6. Notifications of changes in personnel and premises.
7. Cancellation of registration.
8. Restoration of registration.

SCHEDULE 1

PARTICULARS REQUIRED IN AN APPLICATION FOR REGISTRATION OF A RETAIL
PHARMACY BUSINESS.

SCHEDULE 2

PROCEDURAL PROVISIONS RELATING TO PROPOSALS TO REFUSE AN APPLICATION FOR
REGISTRATION OF A RETAIL PHARMACY BUSINESS.

PHARMACEUTICAL SOCIETY OF IRELAND (RETAIL PHARMACY
BUSINESSES) (REGISTRATION) RULES 2008

The Council of the Pharmaceutical Society of Ireland, in exercise of the functions conferred on the said Society by section 11 of the Pharmacy Act 2007 (No. 20 of 2007), hereby makes the following rules:—

Citation

1. These Rules may be cited as the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008.

Commencement

2. These rules shall come into force on 29 November 2008.

Interpretation

3. (1) In these Rules—

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

“certificate of registration” means a certificate issued under section 20 of the Act and which is for the time being in force;

“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;

“public limited company”, has the meaning assigned to it in section 2(1) of the Companies (Amendment) Act 1983 (No. 13 of 1983);

“registered pharmaceutical assistant” means a person registered in the register of pharmaceutical assistants kept by the Council under section 13(1) of the Act;

“registered pharmacist” means a person registered in the register of pharmacists kept by the Council under section 13(1) of the Act;

“registered pharmacy” means a retail pharmacy business that has been registered in the retail pharmacy businesses’ register kept by the Council under section 13(1) of the Act;

“registrar” means the Registrar of the Pharmaceutical Society of Ireland;

“Regulation of Retail Pharmacy Businesses Regulations” means the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008);

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

“superintendent pharmacist” means a registered pharmacist acting in the capacity specified in section 27(b), 28(a) or 29(b) of the Act, who is in personal control of the management and administration of the sale and supply of medicinal products, either where such control is exercised 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.

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

Applications for registration

4. (1) Every application for the registration of a retail pharmacy business, or for the continued registration of such a business, under section 17 of the Act shall be made in writing and shall be sent to the registrar and shall be made not later than 60 days before—

- (a) the date on which the retail pharmacy business is intended to open to the public or,
- (b) in the case of an application for the continued registration of a retail pharmacy business, the date on which the registration of the retail pharmacy business is due to expire.

(2) Every such application shall be signed by or on behalf of the pharmacy owner, whether in ink or by means of an electronic signature.

(3) Every such application shall contain or be accompanied by—

- (a) the particulars specified in Schedule 1, and
- (b) any fee which may be payable in connection with that application.

(4) A separate application for registration as aforesaid shall be made in respect of each premises in which a retail pharmacy business is, or is to be, carried on.

(5) Where an application for the registration of a retail pharmacy business, or for the continued registration of such a business, is not made within the period specified in paragraph (1) then such application shall in addition be subject to the payment of a late fee.

Examination of applications

5. (1) Subject to the provisions of this Rule, the Council shall consider a valid application for registration in the register of retail pharmacy businesses or for

the continued registration of such a business within a period not exceeding 30 days from the date the application is received.

- (2) Where the Council considers it necessary to—
- (a) require verification of anything contained in the application,
 - (b) require the supply of further information in relation to the application, or
 - (c) conduct an inspection in accordance with Section 19 of the Act,

it shall give a notice of same in writing to the applicant.

(3) Where the Council gives a notice pursuant to paragraph (2) the period specified in paragraph (1) shall be suspended from the date the notice is given and shall recommence only on receipt of the information requested, or on completion of the inspection or both, as the case may be. Such inspection shall take place not later than 30 days from the date the said notice is given.

(4) The provisions of Schedule 2 shall have effect where the Council proposes to refuse an application for the registration of a retail pharmacy business or for the continued registration of such a business.

(5) In this Rule, “valid application” means an application which complies with the provisions of Rule 4.

Notifications of changes in personnel and premises

6. (1) The pharmacy owner or, as the case may be, the superintendent pharmacist shall forthwith notify the registrar of—

- (a) any changes of any registered pharmacist or registered pharmaceutical assistant specified in the application for registration referred to in Rule 4, and
- (b) any material changes made or proposed to be made in respect of the registered pharmacy from those set out in the application for registration made under Rule 4.

(2) Every such notification shall be accompanied by any fee which may be payable in connection with the notification of any change—

- (a) referred to in paragraph (1)(a) in respect of any of the registered pharmacists as it relates to the superintendent pharmacist or supervising pharmacist in the retail pharmacy business, or
- (b) referred to in paragraph (1)(b).

Cancellation of registration

7. An application for the cancellation of the registration of a retail pharmacy business under section 59 of the Act shall be made by the pharmacy owner in

writing to the registrar setting out the arrangements made, or to be made, in respect of—

- (a) the disposal of any medicinal products held at that pharmacy, and
- (b) the records of the dispensing or supply of medicinal products conducted at that pharmacy, having regard to the reasonable needs of patients to continue to have access to such records,

and shall be accompanied by any fee which may be payable in connection with that application.

Restoration of registration

8. Every application for restoration under section 61 of the Act shall be made in the same manner as is provided in these Rules in respect of the continued registration of a retail pharmacy business and shall set out any changes that may have taken place in respect of the retail pharmacy business concerned and shall be accompanied by any fee which may be payable in connection with that application and, in the case of an application under section 61(1)(b), the unpaid fee.

SCHEDULE 1

Particulars required in an application for registration of a retail pharmacy business

1. (1) Name of the pharmacy owner, being the person carrying on, or intending to carry on, a retail pharmacy business, and his or her private residential address.

(2) In the case of a partnership carrying on, or intending to carry on, such a business, the names and such addresses of all of the partners.

(3) In the case of a corporate body carrying on, or intending to carry on, such a business—

(i) the registered name and the address of the registered office of the body, or, in the case of a corporate body which is not a body controlled under the Companies Acts 1963 to 2006, the name and address of the body,

(ii) the Companies Office Registration Number of the body, or, in the case of a corporate body which is not a body controlled under the Companies Acts 1963 to 2006, the name of the statute, charter or regulation under which the said body was established, and

(iii) the name of the superintendent pharmacist who is or is to be in personal control of the retail pharmacy business and who has provided the registrar with the statement prescribed by section 28(a) of the Act.

(4) In the case where a retail pharmacy business is being carried on by a representative of a pharmacist, as defined in section 25(2) of the Act, and the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist in accordance with section 29(b) of the Act and who in these Rules is referred to as the superintendent pharmacist, the latter pharmacist's name and the number of his or her certificate of registration.

2. Where a person or, as the case may be, a partnership or corporate body is carrying on, or intends to carry on, such a business under a name which does not correspond to the name of the person or, as the case may be, the names of the partners or the name of the corporate body, the business name under which such business is being, or is to be, carried out.

3. The name of the superintendent pharmacist under whose personal control the retail pharmacy business is, or is to be, carried out and, in respect of such pharmacist, the number of his or her certificate of registration and a statement setting out his or her 3 year minimum post-registration experience.

4. The name of the supervising pharmacist who is, or is to be, in whole-time charge of carrying on the retail pharmacy business at the premises to which the application relates and, where such pharmacist is not acting as the superintendent pharmacist for the said business, the number of his or her certificate of registration and a statement setting out his or her 3 year minimum post-registration experience.

5. The name of any other registered pharmacist or registered pharmaceutical assistant employed or engaged in the retail pharmacy business on an ongoing basis whether in a whole-time or part-time capacity.

6. The full postal address of the premises to which the application relates.

7. (1) Subject to subparagraph (2), a brief description of the premises including the internal layout of the premises as respects the areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored, together with—

(a) a site map to identify the location of the premises,

(b) a statement setting out the arrangements so as to enable—

(i) personal supervision to be exercised by a pharmacist of any preparation, dispensing or compounding and of the sale of medicinal products, at one and the same time,

(ii) a pharmacist to review and discuss in private with a person for whom a prescription has been issued, or with the carer of such a person, matters relating to the medicine therapy of the individual for whom the prescription was issued, and

(c) a sketch plan, drawn to scale, showing the areas and the layout to which this paragraph relates.

(2) Subparagraph (1)(b)(ii) of this paragraph shall not apply until 1 September 2010 in the case of retail pharmacy businesses that have been established by the pharmacy owner concerned in the relevant premises on the date on which these Rules came into force.

8. In the case of an application for the registration of a retail pharmacy business being made for the first time, a statement setting out the details of the ownership of that business including—

(a) the names of all the owners or co-owners of the retail pharmacy business, and

(b) in the case of a retail pharmacy business that is, or is to be, carried on by a corporate body, being a body controlled under the Companies Acts 1963 to 2006 and not being a public limited company, the legal and beneficial ownership of the body including a statement of the ownership of any shares issued in such body.

9. In the case of an application in relation to a retail pharmacy business in respect of which there has been, or is to be, a change in the ownership of the pharmacy, as defined in section 17(6) of the Act—

- (a) a statement showing all of the owners or co-owners of the retail pharmacy business and, in the case of a retail pharmacy business that is or is to be carried on by a corporate body, being a body controlled under the Companies Acts 1963 to 2006 and not being a public limited company, a brief statement setting out the legal and beneficial ownership of the body including a statement of the ownership of any shares issued in such body,
- (b) the name and address of the immediate former owner of that business,
- (c) the date of such change of ownership, and
- (d) the date or the intended date of opening of such business to the public.

10. In the case of an application in respect of the continued registration of a retail pharmacy business where no change in the ownership of the said business (as referred to in section 17 of the Act) has taken place since the provision of a statement under either of paragraphs 8 or 9, a statement that no such change has taken place in respect of the retail pharmacy business to which the application relates.

11. (1) Where the application relates to a retail pharmacy business which is a member of a group of such businesses having a common ownership, the name and address of each of those businesses and the relationship between those businesses including, in the case of any corporate body, being a body controlled under the Companies Acts 1963 to 2006 and not being a public limited company, that may be established for the conduct of one or more of the businesses concerned, the relationship between those bodies and any other body exercising a management or controlling role in the operation of the businesses concerned.

(2) A statement setting out the role of the superintendent pharmacist in the context of the retail pharmacy businesses referred to in subparagraph (1) and the manner in which such role is or will be discharged, having regard, in particular, to the role of the superintendent pharmacist as set out in Regulation 5 of the Regulation of Retail Pharmacy Businesses Regulations.

(3) In this paragraph the expression “common ownership” includes ownership as a pharmacy owner or as a director or shareholder of a corporate body which is a pharmacy owner.

12. A statement setting out the arrangements that the pharmacy owner has put in place in respect of all registered pharmacists employed or engaged in the retail pharmacy business so as to ensure that those pharmacists—

- (a) obtain and maintain appropriate experience in the practice of pharmacy, and

- (b) undertake appropriate continuing education and continuing professional development

with a view to protecting, maintaining and promoting the health and safety of the public.

13. A statement setting out the arrangements that the pharmacy owner has put in place in respect of the segregation, storage and disposal of any medicinal products, including veterinary medicinal products, that have expired or that have been accepted as a return under Regulation 6(3) of the Regulation of Retail Pharmacy Businesses Regulations.

14. A statement setting out the various services of a professional nature, which are provided or are to be provided by the retail pharmacy business.

15. A statement that the retail pharmacy business will be conducted in accordance with regulations under section 18 of the Act and that the applicant is satisfied as to the identity and current registration status 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.

16. A statement setting out the details of any professional indemnity insurance cover or other means of personal or collective protection with regard to professional liability.

SCHEDULE 2

Procedural provisions relating to proposals to refuse an application for registration of a retail pharmacy business

1. If the Council proposes to refuse an application for registration of a retail pharmacy business or for the continued registration of such a business, the Council shall notify the applicant accordingly.
2. Any notification given under paragraph (1) shall include:
 - (a) a statement of the proposal of the Council,
 - (b) a statement setting out in detail the reasons on which the said proposal is based, and
 - (c) a statement that the applicant has the right to make representations to the Council in response to the notification.
3. A person to whom notification has been given under paragraph (1) may, within the time allowed after the notification was issued, give notice to the Council of his or her wish to do so, and make representations to the Council with respect to the proposal referred to in the notification.
4. The Council shall, after consideration of the representations, decide whether to grant the application for the registration of the retail pharmacy business or confirm or alter its proposal to refuse the application, as the case may be.
5. In this Schedule, “time allowed” means the period of 28 days or such extended period as the Council may in any particular case allow.

EXPLANATORY NOTE

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

These Rules set out the procedures that must be complied with by persons making application for the registration of retail pharmacy businesses under the Pharmacy Act 2007.

The Rules also set out the procedures for the examination of applications, for the notification of material changes to premises and of certain personnel, for the cancellation of registrations and for restorations to the Register.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
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TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
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