MEDICAL AND HEALTH (REGISTRATION OF PHARMACIES) REGULATIONS 2008

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Subsidiary 2008/037

Subsidiary Legislation made under s. 66 of the Medical and Health Act.

MEDICAL AND HEALTH (REGISTRATION OF PHARMACIES) REGULATIONS 2008

(LN. 2008/037)

Commencement 15.5.2008

ARRANGEMENT OF REGULATIONS.

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In exercise of the powers conferred on me by section 66 of the Medical and Health Act, and of all other enabling powers, I have made the following Regulations—

Title and commencement.

1 These Regulations may be cited as the Medical and Health (Registration of Pharmacies) Regulations 2008 and come into operation on the day of publication.

Interpretation.

- 2.(1) In these Regulations and unless the context otherwise requires—
 - "pharmacy" means any premises where medicinal products are lawfully provided by a registered pharmacist;
 - "pharmaceutical services" means the retail sale of medicinal products, or the supply of such products or services supplementary to such products in circumstances corresponding to retail sale, in the course of carrying on business as a pharmacist;
- (2) Terms used in these Regulations but not defined shall be construed in accordance with the provisions of the Medical and Health Act as amended from time to time.

Application for registration as a pharmacy.

3. A pharmacist, or more than one pharmacist in partnership, or eligible owner or proposed owner of a pharmacy who wishes to register any business as a pharmacy or to register any premises as a pharmacy in order to provide pharmaceutical services from premises in Gibraltar shall apply to the Board in such form as the Board may, from time to time, direct.

Form of application.

- 4.(1) A person who knowingly—
 - (a) gives any false information in connection with an application under regulation 3; or
 - (b) makes any false entry in the form in respect of any such application,

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shall be guilty of an offence and punishable on summary conviction to a fine at level 3 on the standard scale.

- (2) An application under regulation 3 on behalf of a partnership may be made by one partner in the name of all partners jointly.
- (3) An application under regulation 3 on behalf of a company incorporated in Gibraltar or elsewhere shall be signed by all the directors thereof provided that the Board may, in its absolute discretion waive or modify this requirement in cases where the Board is satisfied about the repute of the applicant and that compliance is unduly onerous in practice.
- (4) An application under regulation 3 shall not be entertained by the Board unless it is accompanied by such evidence as the Board may require that notice of the application has been published in the Gibraltar Gazette and in a newspaper circulating in Gibraltar.

Conditions of grant.

- 5.(1) Applications under regulation 3 shall be granted only if the Board is satisfied that it is necessary or desirable in order to secure the adequate provision of pharmaceutical services in Gibraltar.
- (2) Applications under regulation 3 shall be granted subject to the applicant complying with the provisions of sub-regulations (4) and (5) below, in default of which the validity of the grant shall lapse.
- (3) An application under regulation 3 made by a person who qualifies to have his name registered under section 8(1)(b) or section 23(1) of the Act shall not, in the public interest, be granted unless the applicant satisfies the Board that his knowledge of the English Language is adequate for the safe provision of pharmaceutical services in Gibraltar.
- (4) Where an application under regulation 3 is granted by the Board, the applicant shall commence the provision of pharmaceutical services within such time or times as the Board may, in its absolute discretion, see fit to notify the applicant.
- (5) Where the Board fails to notify the applicant under subsection (3), the applicant shall commence the provision of pharmaceutical services within six months after the date on which the Board notified the applicant that the application has been granted.

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(6) Without prejudice to the provisions of sub-regulations (1) to (5) above, an application under regulation 3 may be granted subject to such conditions as the Board may deem reasonable in the circumstances.

Criteria for grant.

- 6.(1) In considering any application to register any business as a pharmacy, and to register any premises as a pharmacy under section 69 of the Act, the Board shall have regard to the following matters—
 - (a) whether or not adequate pharmaceutical services are already provided in the neighbourhood in which the premises named in the application are located;
 - (b) whether or not adequate pharmacy services are already provided in Gibraltar generally;
 - (c) any information available to the Board which, in its opinion, is relevant to the consideration of the application;
 - (d) whether or not the grant of the application is likely to adversely affect the stocking and supply of medicinal products in Gibraltar to the prejudice of the quality, nature or extent of pharmacy services in Gibraltar generally;
 - (e) any objections to the application received by the Board.

Consideration of objections

- 7.(1) The Board shall, in the case where objections to an application under regulation 3 have been received, determine the application under regulation 3 with a hearing of oral representations.
- (2) Where the Board is to hear oral representations under sub-regulation (1) it shall give the applicant and any person from whom it has received objections not less than 14 days notice of the time and place at which the oral representations are to be heard.
- (3) The Board may, if it thinks fit, consider two or more applications under regulation 3 together in relation to each other, and, where it proposes to do so, it shall give 14 days' notice in writing to the applicants.
- (4) An applicant who objects to a notice under sub-regulation (3) may, within 7 days of receipt of the notice, send a written notice of objection to the Board.

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- (5) Upon receipt of a notice of objection under sub-regulation (4), the Board shall give the objector an opportunity to be heard.
- (6) Where the Board is to hear oral representations pursuant to subregulation (5), it shall give the objector not less than 14 days notice of the time and place where the hearing is to take place.
- (7) Objections addressed to the Board for the purposes of this regulation, shall be made in such form as the Board may, from time to time, require.
- (8) Any person making oral representations under this regulation may be assisted at any such hearing by counsel.

Decisions of the Board.

- 8.(1) The Board shall, as soon as practicable following an application under regulation 3, give notice in writing of its decision to the applicant and to any person who has objected to the grant of the application.
- (2) A notice under sub-regulation (1) shall include details of the reasons for the decision.

Lapse of Registration.

- 9.(1) Any registration under these Regulations shall lapse and be null and void if the Board decides that—
 - (a) the continued use of the premises as a pharmacy would constitute a breach of the Act; or
 - (b) the premises have not been used to provide pharmaceutical services for a period of six months without the Board's prior consent;

and the Board considers that the registration should lapse in the public interest.

- (2) Before making any determination under sub-regulation (1) the Board shall–
 - (a) give the owner not less than 28 days notice of its intention; and

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- (b) afford the owner an opportunity of making written representations to the Board or, if he so decides, oral representations.
- (3) Where, under sub-regulation (1), the Board determines that a registration shall lapse, it shall give notice in writing of its decision to the owner.