# SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 4047 of 19 December, 2013

LEGAL NOTICE NO. 196 OF 2013.

#### **MEDICAL AND HEALTH ACT, 1997**

## MEDICAL AND HEALTH (REGISTRATION OF PHARMACIES) (AMENDMENT) REGULATIONS 2013

In exercise of powers conferred upon him by section 66 of the Medical and Health Act, 1997 and all other enabling powers, the Minister has made the following Regulations—

#### Title and commencement.

1. These Regulations may be cited as the Medical and Health (Registration of Pharmacies) (Amendment) Regulations 2013 and shall come into operation on the day of publication.

## Amendment of the Medical and Health (Registration of Pharmacies) Regulations 2008.

- 2.(1) The Medical and Health (Registration of Pharmacies) Regulations 2008 are amended in accordance with the provisions of these Regulations.
  - (2) In regulation 2(1)–
    - (a) before the definition of "pharmacy" insert-
      - ""Applicant" means a person applying to the Board to have the premises registered as a pharmacy under Part VII of the Act;
      - "Medical Group Practice Scheme" means the Scheme established under section 3 of the Medical (Group Practice Scheme) Act;";
    - (b) after the definition of "pharmaceutical services" insert-
    - ""premises" means the premises which are the subject of an application under regulation 3;

"Trade Licensing Authority" means the Trade Licensing Authority established under section 26 of the Trade Licensing Act.".

- (3) In regulation 2(2) after Medical and Health Act insert ", 1997".
- (4) For regulation 3 substitute–
  - "3. A pharmacist, or more than one pharmacist in partnership, or eligible owner or proposed owner of a pharmacy who wishes to register any premises as a pharmacy in order to provide pharmaceutical services from premises in Gibraltar shall apply to the Trade Licensing Authority in the prescribed form as the Trade Licensing Authority may, from time to time, direct."
- (5) In regulation 4(3)–
  - (a) for "Board" substitute "Trade Licensing Authority" on the 2 occasions it appears;
  - (b) for "applicant" substitute "Applicant".
- (6) For regulation 4(4) substitute–
  - "(4) An application under regulation 3 shall not be entertained by the Trade Licensing Authority unless it is accompanied by evidence that—
    - (a) notice of the application has been published in the Gibraltar Gazette and in a newspaper circulating in Gibraltar not less than 14 days before the application to register the premises as a pharmacy is made; and
    - (b) notice of the application has been served on the Board.".
- (7) In regulation 5(1) for "Board" substitute "Trade Licensing Authority, after consultation with the administrator of the Medical Group Practice Scheme,".
  - (8) For regulation 5(2) substitute–

- "(2) An application under regulation 3 shall not be granted unless the registered pharmacist, who will be working in the premises, satisfies the Trade Licensing Authority that his knowledge of the English language is adequate for the safe provision of pharmaceutical services in Gibraltar.".
- (9) For regulation 5(3) substitute–
  - "(3) An application granted under regulation 3 shall not be valid for the provision of pharmaceutical services until the Board has certified to the Trade Licensing Authority that the premises are suitable for use as a pharmacy."
- (10) For regulation 5(4) substitute-
  - "(4) Without prejudice to the provisions of sub-regulation (1) to (3) above, an application under regulation 3 may be granted subject to such conditions as the Trade Licensing Authority may deem reasonable in the circumstances."
- (11) Delete regulations 5(5) and 5(6).
- (12) For regulation 6 substitute-
  - "6.(1) In considering any application to register any premises as a pharmacy under section 69 of the Act, the Trade Licensing Authority shall have regard to—
    - (a) any information in their possession in relation to an application for a licence or an objection to an application for a licence made under the Trade Licensing Act with respect to the same business or premises; and
    - (b) the following matters—
      - (i) whether or not, after consultation with the administrator of the Medical Group Practice Scheme, 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;

- (ii) any objections to the application received by the Trade Licensing Authority; and
- (iii) any information available to the Trade Licensing Authority which, in its opinion, is relevant to the consideration of the application.".
- (13) In regulation 7-
  - (a) in sub-regulation (1) for "Board" substitute "Trade Licensing Authority";
  - (b) in sub-regulation (2)-
    - (i) for "Board" substitute "Trade Licensing Authority";
    - (ii) for "applicant" substitute "Applicant";
  - (c) in sub-regulation (3)-
    - (i) for "Board" substitute "Trade Licensing Authority";
    - (ii) for "applicants" substitute "Applicants";
  - (d) in sub-regulation (4)-
    - (i) for "applicant" substitute "Applicant";
    - (ii) for "Board" substitute "Trade Licensing Authority";
  - (e) in sub-regulation (5) for "Board" substitute "Trade Licensing Authority";
  - (f) in sub-regulation (6) for "Board" substitute "Trade Licensing Authority";
  - (g) in sub-regulation (7) for "Board" substitute "Trade Licensing Authority" on the 2 occasions it appears;
  - (h) after sub-regulation (8) insert-

- "(9) The Board may, if it thinks fit, object to an application under regulation 3 in accordance with this regulation."
- (14) After regulation 7 insert-

#### "Trade Licensing Act.

7A. The Trade Licensing Authority may, if it thinks fit, consider an application under these Regulations or objections received to an application under these Regulations, together with any application or objections received by it in relation to an application or objection to an application made under the Trade Licensing Act with respect to the same premises or business."

#### (15) For regulation 8(1) substitute-

"(1) The Trade Licensing Authority shall, as soon as practicable following an application under regulation 3, give notice in writing of its decision to the Applicant, the Board and to any person who has objected to the grant of the application."

#### (16) After regulation 8(2) insert-

- "(3) Where the decision of the Trade Licensing Authority is that an application be granted, the Trade Licensing Authority shall direct the Applicant to contact the Board (within the stipulated time frame contained in sub-regulation (4) below) so that the Board can certify suitability of premises as a pharmacy in accordance with regulation 5(3).
- (4) The Applicant is to contact the Board within 6 months from the date the Trade Licensing Authority notified the Applicant pursuant to sub-regulation (3).
- (5) During the 6 months period specified in sub-regulation (4), the Applicant shall notify the Board in writing of—
  - (a) commencement of works to the premises; and
  - (b) completion of works once the premises are ready to operate as a pharmacy.

- (6) Where the Board receives notice from the Applicant in writing pursuant to sub-regulation (5)(b) above, the Board shall satisfy itself that the premises are suitable for use as a pharmacy in accordance with regulation 5(3) and, if satisfied, shall—
  - (a) proceed to register the premises as a pharmacy under section 69 of the Act; and
  - (b) notify the Trade Licensing Authority of its decision in writing.
- (7) After the expiry of 6 months pursuant to sub-regulation (4), the Board shall, in circumstances where it has been notified under sub-regulation (5)(a), proceed to notify the Trade Licensing Authority if the premises have not been registered as a pharmacy under section 69 of the Act.".
- (17) For the heading appearing before regulation 9 ("Lapse of Registration.") substitute "Removal of premises registered as a pharmacy from register.".
  - (18) For regulation 9(1) substitute-
    - "(1) Any registration of premises registered as a pharmacy under these Regulations shall lapse and be null and void if the Trade Licensing Authority, after consultation with 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 6 months

and the Trade Licensing Authority, after consultation with the Board, considers that the registration should lapse in the public interest."

- (19) For regulation 9(2) substitute-
  - "(2) Before making any determination under sub-regulation (1) the Trade Licensing Authority shall—

- (a) give the owner not less than 28 days' notice of its intention; and
- (b) afford the owner an opportunity of making written representations to the Trade Licensing Authority or, if he so decides, oral representation.".
- (20) For regulation 9(3) substitute-
  - "(3) Where, under sub-regulation (1) the Trade Licensing Authority determines that a registration shall lapse, it shall give notice in writing of its decision to—
    - (a) the owner; and
    - (b) the Board

who shall act accordingly.

(21) After regulation 9(3) insert-

### "Appeals.

- 10.(1) Any person who is aggrieved by any decision made under these Regulations may appeal to the Magistrate Court and that court may confirm, vary or reverse any such decision.
- (2) An appeal from the decision of the Magistrate Court may be made to the Supreme Court on a point of law only.

#### Savings and transitional provisions.

11. Any applications made but not determined shall be continued by the Trade Licensing Authority under the new regime established under these Regulations.".

Dated 19th December, 2013.

DR. J CORTES, Minister with responsibility for Health.

#### EXPLANATORY MEMORANDUM

These regulations amend the Medical and Health (Registration of Pharmacies) Regulations 2008 as follows-

Regulations 3, 5 and 6 provide that the Trade Licensing Authority, in consultation with the administrator of the Medical Group Practice Scheme, shall now be responsible for approving the establishing of new pharmacies.

Registration of premises as a pharmacy will remain with the Board in accordance with section 69 of the Act, who shall only proceed to register the premises once it is satisfied that the premises are suitable for use as a pharmacy in accordance with regulation 5(3).

A newly inserted regulation 7A provides that the Trade Licensing Authority can consider applications or objections under the Medical and Health (Registration of Pharmacies) Regulations 2008 together with applications or objections under the Trade Licensing Act.

Regulation 8 introduces a time frame which the applicant must adhere to when carrying out works to the premises and must notify the Board once this is done. If the Board is satisfied that the premises are suitable for use as a pharmacy, it shall proceed to register the premises.

An appeal provision is introduced under regulation 10 which was absent in the Medical and Health (Registration of Pharmacies) Regulations 2008.