

**MEDICAL AND HEALTH (REGISTRATION OF PHARMACIES)
REGULATIONS 2008**

**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**

Amending enactments	Relevant current provisions	Commencement date
LN. 2013/196	rr. 2, 3, 4(3), (4), 5(2), (3), (4), (5), (6), 6, 7(1)-(9), 7A, 8(1), (3)-(7), 9(1), (2), (3), 10, 11	19.12.2013

EU Legislation/International Agreements involved:

ARRANGEMENT OF REGULATIONS.

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Medical and Health

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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—

“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;

“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;

“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.

(2) Terms used in these Regulations but not defined shall be construed in accordance with the provisions of the Medical and Health Act, 1997 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 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.

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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,

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 Trade Licensing Authority may, in its absolute discretion waive or modify this requirement in cases where the Trade Licensing Authority 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 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.

Conditions of grant.

5.(1) Applications under regulation 3 shall be granted only if the Trade Licensing Authority, after consultation with the administrator of the Medical Group Practice Scheme, is satisfied that it is necessary or desirable in order to secure the adequate provision of pharmaceutical services in Gibraltar.

(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.

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(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.

(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.

Criteria for grant.

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.

Consideration of objections

7.(1) The Trade Licensing Authority 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 Trade Licensing Authority 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.

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(3) The Trade Licensing Authority 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 Trade Licensing Authority.

(5) Upon receipt of a notice of objection under sub-regulation (4), the Trade Licensing Authority shall give the objector an opportunity to be heard.

(6) Where the Trade Licensing Authority is to hear oral representations pursuant to sub-regulation (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 Trade Licensing Authority for the purposes of this regulation, shall be made in such form as the Trade Licensing Authority may, from time to time, require.

(8) Any person making oral representations under this regulation may be assisted at any such hearing by counsel.

(9) The Board may, if it thinks fit, object to an application under regulation 3 in accordance with this regulation.

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.

Decisions of the Board.

8.(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.

(2) A notice under sub-regulation (1) shall include details of the reasons for the decision.

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(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.

Removal of premises registered as a pharmacy from register.

9.(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

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

(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.

(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.

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.