MEDICAL (GROUP PRACTICE SCHEME) (PHARMACEUTICAL SERVICES) REGULATIONS

Regulations made under section 22 of the Medical (Group Practice Scheme) Act.

MEDICAL (GROUP PRACTICE SCHEME) (PHARMACEUTICAL SERVICES) REGULATIONS

Repealed by LN. 2008/036 as from 15.5.2008

(LN. 1999/107)

23.8.1999

Amending enactments	Relevant current provisions	Commencement date
2000/083	r. 6(6)	2.11.2000
2001/007	r. 18(3)(c)	1.2.2001

ARRANGEMENT OF REGULATIONS

MEDICAL (GROUP PRACTICE SCHEME) (PHARMACEUTICAL SERVICES) REGULATIONS

1973-14
Repealed
Subsidiary
1999/107

MEDICAL (GROUP PRACTICE SCHEME) (PHARMACEUTICAL SERVICES) REGULATIONS

PART 1
PRELIMINARY

Title and commencement.

1. These Regulations may be cited as the Medical (Group Practice Scheme) (Pharmaceutical Services) Regulations and shall come into effect on the 23rd August, 1999.

Interpretation.

2. In these Regulations and unless the context otherwise requires–

"appliances" shall include dressings;

"board" means the Scheme Pharmacists Board constituted under section 12 of the principal Act;

"Authority" means the Gibraltar Health Authority;

"formulary" means such list of medicinal products and appliances available for prescribing and dispensing under the Scheme, being medicinal products and appliances listed in the Gibraltar National Formulary published on behalf of the Authority, as the Authority may from time to time notify pharmacists;

"Gibraltar Drug Tariff" means the statement published in accordance with regulation 11, as amended from time to time;

"medicinal product" means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways,–

(a) by being administered to one or more human beings or animals for a medicinal purpose;

(b) in any of the following circumstances –

(i) in a pharmacy or hospital;

(ii) by a practitioner; or

(iii) in the course of a business which consists of or includes the retail sale or the supply in circumstances corresponding to retail sale, of herbal remedies;

(iv) as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose;

However, "medicinal product" does not include –

(a) substances used in dental surgery for filling dental cavities;

(b) bandages and other surgical dressings, except medicated dressings where the medication has a curative function which is not limited to sterilising the dressing;

(c) substances and articles of such other descriptions or classes as may be specified by an order made by the Minister for the purposes of this regulation;

"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;

"pharmacist" means any person registered as a pharmacist under Part III of the register established pursuant to section 7 of the Medical and Health Act 1997;

"pharmacy" means any premises where medicinal products are lawfully provided by a registered pharmacist;

"proceedings" means any proceedings before the board;

"registered dentist" means a dentist registered in Part II of the register established pursuant to section 7 of the Medical and Health Act 1997;

"registered doctor" means a doctor registered under Parts I, IA or IB of the register established pursuant to section 7 of the Medical and Health Act 1997;

"sale by retail" means selling a substance or article to a person who buys it otherwise than for –

(a) selling or supplying it; or

(b) administering it, or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(2) Terms used in these Regulations but not defined shall be construed in accordance with the provisions of the Medical (Group Practice Scheme) Act as amended from time to time.

PART II
APPLICATIONS

Scheme Members List.

3.(1) The board shall maintain a Scheme Members List.

(2) The board shall, in January of each year, cause the Scheme Members List to be published in the Gazette.

Amendments to list.

4.(1) A pharmacist, or more than one pharmacist in partnership, or owner or proposed owner of a pharmacy –

(a) who wishes to become a Scheme Member in order to provide pharmaceutical services from premises in Gibraltar; or

(b) who is already a Scheme Member but who wishes –

(i) to open additional premises from which to provide pharmaceutical services; or

(ii) to change the address from which he provides pharmaceutical services,

shall apply to the board in such form as the board may, from time to time, direct.

(2) In considering an application under sub-regulation (1), where the applicant intends –

(a) to change the address from which he provides pharmaceutical services, and the board is satisfied that the change is a minor relocation; or

(b) to provide pharmaceutical services from a pharmacy from which those services are, at the time of the application, provided by a Scheme Member and the board is satisfied that such services will continue to be provided from that pharmacy,

the board may, in its discretion, grant the applicant provisional authority to provide pharmaceutical services as a Scheme Member according to the terms of the application, until such time as the application is finally determined.

Form of application.

5.(1) A person who knowingly –

(a) gives any false information in connection with an application under regulation 4(1); 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 4(1) on behalf of a partnership may be made by one partner in the name of all partners jointly.

(3) An application under regulation 4(1) 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 4(1) 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.

6.(1) Applications under regulation 4(1) 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 for the purposes of the Scheme.

(2) Applications under regulation 4(1) 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 4(1) made by a person who qualifies to have his name registered under section 8(1)(b) or section 23(1) of the

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Medical and Health Act 1997[1] 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 4(1) 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.

(6) Without prejudice to the provisions of sub-regulations (1) to (5) above, an application under regulation 4(1) may be granted subject to such conditions as the Board may deem reasonable in the circumstances.

Criteria for grant.

7.(1) In considering any application under regulation 4(1), the board shall have regard to the following matters –

(a) whether or not adequate pharmaceutical services are already provided by Scheme Members in the neighbourhood in which the premises names in the application are located;

(b) whether or not adequate pharmacy services are already provided by Scheme Members in Gibraltar generally;

(c) any information available to the board which, in its opinion, is relevant to the consideration of the application; and

(d) any objections to the application received by the board.

(2) The board shall, in the case where objections to an application under regulation 4(1) have been received, determine the application under regulation 4(1) with a hearing of oral representations.

(3) Where the board is to hear oral representations under sub-regulation (2) 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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(4) The board may, if it thinks fit, consider two or more applications under regulation 4(1) together in relation to each other, and, where it proposes to do so, it shall give 14 days' notice in writing to the applicants.

(5) An applicant who objects to a notice under sub-regulation (4) may, within, 7 days of receipt of the notice, send a written notice of objection to the board.

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

(7) Where the board is to hear oral representations pursuant to sub-regulation (6), it shall give the objector not less than 14 days notice of the time and place where the hearing is to take place.

(8) Objections addressed to the board for the purposes of this regulation, shall be made on such form as the board may, from time to time, require.

(9) 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 4(1), 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.

Removal and substitution from Scheme Members List.

9.(1) Where a Scheme Member has died and the board has decided not to exercise its discretion under sub-regulations (2) and (3), the board shall remove the Scheme Member's name from the Scheme Members List.

(2) Where the board determines that a Scheme Member has died (the "first Scheme Member") and that the executors or personal representatives of his estate intend the deceased's business to be taken over by a pharmacist who is not a Scheme Member, the board may, in its absolute discretion, amend the Scheme Members List to include that pharmacist as a Scheme Member in substitution for the first Scheme Member.

(3) Where the board determines that a Scheme Member has ceased to practice by reason of ill health (the "first Scheme Member"), and that he intends, his business to be taken over by a pharmacist who is not a Scheme Member, the board may, in its absolute discretion, amend the Scheme

Members List to include that pharmacist as a Scheme Member in substitution for the first Scheme Member.

(4) Where the board determines that a Scheme Member has not, for a period of six months, provided pharmaceutical services, the board may, in its absolute discretion, remove the pharmacist's name from the Scheme Members List.

(5) Before making any determination under sub-regulation (4), the board shall –

(a) give the Scheme Member not less than 28 days notice of its intention;

(b) afford the Scheme Member an opportunity of making written representations to the board or, if he so decides, oral representations.

(6) Where, under sub-regulation (4), the board determines to remove a Scheme Member from a Scheme Members List, it shall give notice in writing of its decision to the Scheme Member.

(7) Nothing in this regulation shall prejudice the right of a person from making a fresh application to be included in a Scheme Members List.

Sanctions for breaches of statutory duty.

10.(1) The board may take such action as it deems necessary to investigate compliance by Scheme Members with the provisions of these Regulations and of the principal Act.

(2) Where prima facie evidence exists of a failure in compliance by a Scheme Member with the provisions of these Regulations or of the principal Act, the board may suspend the Scheme Member from the Scheme Members List for a period not exceeding four months, pending the investigation and determination of the case.

(3) The board may, in the course of its investigations under this regulation, require the Scheme Member to attend before the board or before such person as the board may appoint to answer questions and otherwise to furnish information and to require the production of such books or papers as the board may require.

(4) Following the conclusion of its investigation, the board may determine–

(a) that no further action need be taken;

(b) that the Scheme Member should be issued with a written warning;

(c) that a fine not exceeding a sum equivalent to level 1 on the standard scale be recovered from the Scheme Member whether by deduction from payments due or which may become due to him or otherwise;

(d) that a payment made to the Scheme Member in circumstances where it was not due be recovered by deduction from other payments due or which may become due to him or otherwise;

(e) that the Scheme Member be suspended from the Scheme Members List for a period not exceeding 12 months either generally or in respect of a specified pharmacy;

(f) that the Scheme Member be removed from the Scheme Members List either generally or in respect of a specified pharmacy;

(g) that no further application by the Scheme Member or shareholder thereof be considered for a period not exceeding five years.

(5) The board shall, as soon as practicable, notify the Scheme Member notice in writing of a determination under sub-regulation (4) and shall include with the notice a statement of the reasons for the determination.

PART III
TERMS OF SERVICE

Interpretation of Part.

11. In this Part unless the context otherwise requires –

"bank holiday" shall be construed in accordance with the Banking and Financial Dealings Act;

"basic price" means either the price of any item stated in the Gibraltar Drug Tariff published on behalf of the Authority or, if the price of the item is not stated in the Gibraltar Drug Tariff, the price published by the manufacturer or supplier or, in default, the price determined by the Minister with responsibility for health;

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"Chief Executive" means the Chief Executive or Deputy Chief Executive of the Gibraltar Health Authority;

"Head Pharmacist" means the Head Pharmacist of the Gibraltar Health Authority;

"item" means any product which is in the formulary;

"normal hours" means; on days other than bank or public holidays, the hours of:

9.00 a.m. to 7.00 p.m. Monday to Friday, and

9.00 p.m. to 1.00 p.m. Saturday,

or such other hours as the Chief Executive may, from time to time, require;

"prescription" or "prescriptions" means an item or items on a prescriptions form as the case may be;

"prescription form" means such form issued by the Authority from time to time for the purposes of recording items that have been prescribed;

"prohibited schedule" means the list of medicinal products not available for prescription which the Authority may publish from time to time;

"public holiday" shall be construed in accordance with the Interpretation and General Clauses Act.

General duties of Scheme Members.

12.(1) Scheme Members shall comply with the provisions of these Regulations, the principal Act, the Medical and Health Act 1997 and with any rule of law for the time being in force relating to his professional duties.

(2) Scheme Members shall not engage in conduct prejudicial or discreditable to his profession or to the Authority.

(3) Scheme Members shall make their practice as pharmacists their primary occupation, unless the Chief Executive has otherwise approved.

Indemnity insurance.

13.(1) Scheme Members shall have and maintain professional indemnity insurance in respect of claims for damages, of up to a minimum of £4.5 million, including £500,000 on any single claim for damages.

(2) In this Regulation, "professional indemnity insurance" means indemnity insurance against loss or damage arising from claims in respect of civil liability incurred:

(a) in the supply of a medicinal product which is the subject of a prescription under the Scheme;

(b) in the failure to supply a medicinal product which is the subject of a prescription under the Scheme; or

(c) in the giving of pharmaceutical advice to customers regarding the proper treatment to soothe or cure any ailment, taking all reasonable circumstances into account.

Duty to maintain good faith and reasonable competence.

14.(1) Scheme Members shall act with reasonable competence and good faith in all their professional activities.

(2) Scheme Members shall ensure that their pharmacies are efficiently and properly administered and particularly ensure that an adequate stock of pharmaceutical products is kept.

(3) Scheme Members shall ensure that their pharmacies are, when open, supervised by a registered pharmacist.

Sub-contracting of work.

15.(1) Scheme Members shall not sub-contract the provision of services under the Scheme to another pharmacy or pharmacist.

(2) Sub-regulation (1) shall not act to prevent Scheme Members from employing pharmacists for the purpose of operating or managing pharmacies.

Duty to prepare and dispense prescriptions.

16.(1) Scheme Members who have available the medicinal products and appliances necessary to prepare a prescription issued under the Scheme shall accept, prepare and dispense the prescription.

(2) Scheme Members shall supply all items included in a single prescription which they are authorised to supply under the Scheme and,

should they be unable to do so, shall redirect the patient to another pharmacy which is for the time being included in the Scheme Members List.

(3) Scheme Members who have dispensed medicinal products pursuant to sub-regulation (1) shall submit all prescriptions and other forms for payment as directed by the Authority.

Length of prescription.

17. Scheme Members shall, only with the prior written approval of the Head Pharmacist, provide items on a prescription to cover a period of more than one month.

Payment of Scheme Members.

18.(1) Scheme Members shall be paid by the Authority in accordance with the provisions of sub-regulations (2) and (3) for medicinal products supplied to patients.

(2) In order to qualify for payment under sub-regulation (1), medicinal products dispensed must not be excluded by the prohibited schedule and must be written by a registered doctor or dentist on a prescription form issued by the Authority under the Scheme.

(3) Scheme Members will be paid the following in respect of each item dispensed –

(a) the basic price;

(b) an additional 15 % to the basic price;

(c) a dispensing fee of £1.80.

Other charges.

19. Scheme Members shall charge and receive, on behalf of the Authority, from every person presenting a prescription form issued by the Authority under the Scheme (other than persons on whose prescription it is indicated that they are entitled to free or reduced cost medicines), such payment as may be prescribed from time to time under the principal Act.

Opening hours.

20.(1) The Authority may stipulate the hours during which Scheme Members shall open their pharmacy to the public outside normal hours.

(2) The Authority shall submit to Scheme Members notice of which pharmacy shall be open during such hours and every Scheme Member shall display in his pharmacy window in a prominent position for the benefit of the public the name and address of the pharmacy which is so open.

(3) The Scheme Member due to open outside normal hours under sub-regulation (1) shall be under a duty to do so.

(4) The Scheme Member whose duty it is to open outside normal hours shall be under a duty to make up prescriptions in cases of emergency at all times when no other pharmacy is open and shall provide the Authority with a contact telephone number and address in Gibraltar for the purpose thereof.

(5) The Scheme Member whose duty it is to open his pharmacy outside normal hours under this regulation shall be paid the sum of £500 for every 7 day week in respect of which the services specified in this regulation are actually provided.

Licensing of medicines.

21.(1) For the purposes of the Scheme and, subject to sub-regulation (2), no Scheme Member shall sell, supply or export any medicinal product or procure the sale or supply of a medicinal product unless there is in existence in relation to the medicinal product –

(a) a current product licence granted under the provisions of the Medicines Act 1968 of the United Kingdom;

(b) a current marketing authorisation issued under the Medicines for Human Use (Marketing Authorisation etc.) Regulations 1994 of the United Kingdom (S.I. 1994/3144); or

(c) a current marketing authorisation issued by the European Agency for the Evaluation of Medicinal Products pursuant to Council Regulation (EEC) No: 2309/93.

(2) The restrictions imposed by sub-regulation (1) shall not apply in respect of a medicinal product listed in the Gibraltar National Formulary which has been prescribed by a doctor or dentist for administration to a particular patient of his.

Supply of information.

22. Scheme Members shall supply, in response to a request from the Minister or the board, within 30 days of the notification of the request, any information which may be relevant to the purpose of conducting an inquiry into any matter covered by these regulations, or any other subsidiary legislation made under the principal Act.

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Voluntary removal of name from list.

23. Scheme Members wishing to cease their membership shall give two months' written notice of the same to the Chief Executive.

PART IV
FINAL PROVISIONS

Revocation.

24. Regulation 11(2) of the Medical (Group Practice Scheme) Regulations is hereby revoked.

Transitional provisions.

25.(1) A person who, on a date before the coming into effect of these Regulations was a Scheme Member as defined in regulation 11 of the Medical (Group Practice Scheme) Regulations as amended, shall be a Scheme Member for the purposes of these Regulations.

(2) Any agreement made with a Scheme Member for the purposes of regulation 11 of the Medical (Group Practice Scheme) Regulations as amended, shall, if in force at the date of coming into force of these Regulations and unless a contrary intention appears, remain in force, to the extent that the agreement is consistent with these Regulations, and shall hereinafter be deemed for all purposes to have been made for the purposes of these Regulations.