

Subsidiary Legislation made under s. 11 of the Medical (Group Practice Scheme) Act.

**MEDICAL (GROUP PRACTICE SCHEME)
(PHARMACEUTICAL SERVICES) REGULATIONS 2008**

(LN. 2008/036)

Commencement **15.5.2008**

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In exercise of the powers conferred on me by section 11 of the Medical (Group Practice Scheme) Act, and of all other enabling powers, I have made the following Regulations—

**PART I
PRELIMINARY**

Title and commencement.

1. These Regulations may be cited as the Medical (Group Practice Scheme) (Pharmaceutical Services) Regulations 2008 and shall come into operation on the date of publication.

Interpretation.

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

“appliances” shall include dressings;

“Authority” means the Gibraltar Health Authority established under section 3 of the Medical (Gibraltar Health Authority) Act;

“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 8, 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;

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- (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; or
- (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;

“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 duly registered under section 69 or other applicable provision of the Medical and Health Act 1997 and the Pharmacy Regulations where medicinal products are lawfully provided by a registered pharmacist;

“Pharmacy Regulations” means the Medical and Health (Registration of Pharmacies) Regulations 2008 or any amended or modified version, or replacement thereof;

“proceedings” means any proceedings before the Authority;

“registered dentist” means a dentist registered under 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;

“Scheme Member” means any pharmacist or pharmacy entered in the Scheme Members’ List maintained under regulation 3;

“Scheme Pharmaceutical Services” means the supply, whether by way of sale by retail or free of charge to the person to whom it is supplied of medicinal products against a prescription issued under the Scheme and for the payment of which the Authority is liable.

(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 SCHEME MEMBERS’ LIST

Scheme Members’ List.

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

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

Notification to be entered in Scheme Members’ List.

4.(1) A pharmacist, or more than one pharmacist in partnership, or owner or proposed owner of a pharmacy carrying on the business of a pharmacy in premises registered under regulation 3 of the Pharmacy Regulations who wishes to be entered in the Scheme Members’ List as a Scheme Member in order to provide Scheme Pharmaceutical Services shall give four weeks notice to the Authority, in such form as the Authority may require, of his desire to be included in the Scheme Members’ List.

(2) A person who has given notice under subsection (1), shall be included by the Authority in the Scheme Members’ list as a Scheme Member with

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effect from the date four weeks from the date notice was given by him under sub-regulation (1).

- (3) A Scheme Member who wishes—
- (a) to open additional premises from which to provide Scheme Pharmaceutical Services; or
 - (b) to change the address from which he provides Scheme Pharmaceutical Services,

shall not be entered in the Scheme Members' List in respect of such additional or other premises unless such premises are registered under regulation 3 of the Pharmacy Regulations.

Form of notification.

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

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

(2) A notification under regulation 4(1) on behalf of a partnership may be made by one partner in the name of all partners jointly.

(3) A notification 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 Authority may, in its absolute discretion waive or modify this requirement in cases where the Authority is satisfied about the repute of the applicant and that compliance is unduly onerous in practice.

Removal and substitution from Scheme Members' List.

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

(2) Where the Authority 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 Authority shall, amend the Scheme Members’ List to include that pharmacist as a Scheme Member in substitution for the first Scheme Member.

(3) Where the Authority 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 Authority shall, amend the Scheme Members’ List to include that pharmacist as a Scheme Member in substitution for the first Scheme Member.

(4) Where the Authority determines that a Scheme Member has not, for a period of six months, provided Scheme Pharmaceutical Services, the Authority 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 Authority shall—

- (a) give the Scheme Member not less than 28 days notice of its intention; and
- (b) afford the Scheme Member an opportunity of making written representations to the Authority or, if he so decides, oral representations.

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

Sanctions for breaches of statutory duty.

7.(1) The Authority 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 Authority 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.

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

(4) Following the conclusion of its investigation, the Authority 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 3 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;

(5) If the Authority determines that a Scheme Member has, in exchange for a Scheme prescription given any person any credit (whether immediate or deferred), or any value or monies worth, or any article or product, or any medicinal product other than the medicinal product specified in such a prescription, the Authority shall (after obtaining the agreement of the Minister) on the first such occasion impose a fine of £5,000, on the second such occasion suspend the Scheme Member for a period of six months and on the third such occasion remove the Scheme Member from the Scheme Members' List.

(6) If any Scheme Member is removed from the Scheme Members' List under sub-regulation (5), then notwithstanding any other provision of these

Regulations neither that Scheme Member nor any pharmacy owned (in whole or in part) by that Scheme Member (or any of them, if more than one) whether in their own name (or names), as partners or by a company in which they or any of them own shares legally or beneficially, shall be entered in the Scheme Members' List, without the consent of the Minister responsible for Finance.

(7) The Authority shall, as soon as practicable, notify the Scheme Member in writing of a determination under this regulation and shall include with the notice a statement of the reasons for the determination.

**PART III
TERMS OF SERVICE**

Interpretation of Part.

8. 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;

“Chief Executive” means the Chief Executive or Deputy Chief Executive of the Authority;

“Head Pharmacist” means the Head Pharmacist of the 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;

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“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.

9.(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.

10.(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.

11.(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.

12.(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.

13.(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.

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14. 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.

15.(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; and
- (c) a dispensing fee of £1.80.

Other charges.

16. 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.

17.(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.

18.(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.

19. Scheme Members shall supply, in response to a request from the Minister responsible for Health or the Authority, 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.

Voluntary removal of name from list.

20. 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.

21. The Medical (Group Practice Scheme) (Pharmaceutical) Regulations are hereby revoked.

Transitional provisions.

22(1). A person who, on the date of the coming into effect of these Regulations was a Scheme Member as defined in the Medical (Group Practice Scheme) Regulations or was established as a pharmacy in Gibraltar registered under the Medical and Health Act 1997, shall be a Scheme Member for the purposes of these Regulations and shall be entered in the Scheme Members' List under these Regulations as of the date that these Regulations come into effect.

(2) For the avoidance of doubt the pharmacies that are automatically entered in the Scheme Members' List under regulation 3 and are thus Scheme Members from the date that these Regulations come into force are the following pharmacies—

- (a) Baglietto Pharmacy, 61 Governor's Street;
- (b) Bell Pharmacy, 27 Bell Lane;
- (c) Calpe ICC Pharmacy, Unit G9 ICC;
- (d) Calpe 93 Pharmacy, 93 Main Street;
- (e) Calpe 232 Pharmacy, 232 Main Street;
- (f) Crown Pharmacy, 4 Casemates Square;
- (g) Louis Pharmacy, F12 ICC;
- (h) Morrison's Pharmacy, Morrisons Westside;
- (i) Mill Pharmacy, 21/2/a City Mill Lane;

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- (j) New Pharmacy, 19 Main Street;
- (k) Trafalgar Pharmacy, 48/50 Main Street;
- (l) Valmar Pharmacy, 11a Main Street.