Regulations made under s.47 of the Medical and Health Act (1973 No.5) saved and deemed to have been made under s.66.

MEDICINES (PRESCRIPTION ONLY) REGULATIONS, 1987

(LN. 1987/142)

5.5.1988

Amending enactments	Relevant current provisions	Commencement date
LNs.1988/085	r.5(2)	1.2.1988
1998/047	r.3(4) and Sch.	25.6.1998
2001/008	Sch	1.3.2001
2007/072	rr. 2, 3(4)(a) & (b), 4(1)(a), (b) & (d), 4(2), 5(2), 7(4)(c), (5) & 8	26.4.2007
2009/043	rr. 3(1) & (2)(c), 9, 10, 11 & Sch.	30.7.2009
2011/199	rr. 2, 3(1)(a) & (b), (4)(b), (5), (6), (7), (8) & (9), 4(da) & (db), 10(2)(b) & (d), Sch. 1, 2 & 3	13.10.2011
2012/084	rr. 2, 3(5) & (9) & Sch. 3	14.6.2012
2013/192	rr. 2 & 3(5)	19.12.2013
2014/030	rr. 2, 3(5) & 4(db)	13.3.2014
2014/151	rr. 2, 3(1)(b), (7), (10) & Sch. 3	7.8.2014
2014/238	rr. 2, 3, 12 & Sch. 3	8.12.2014
2014/250	Sch. 3	11.12.2014

MEDICINES (PRESCRIPTION ONLY) REGULATIONS, 1987

This version is out of date

ARRANGEMENT OF REGULATIONS

Regulation

1. Title and commencement.
2. Interpretation.

PART 1

3. Medicinal products which may only be supplied on prescription.
4. Form of prescription.
5. Provisions as to supply on prescription.
6. Register of prescriptions.
7. Exemptions for Emergency Sale of Supplies.
8. Offences and penalty.

PART 2

9. Patient Group Direction.
10. Exemptions for the supply and administration of prescription only medicines.
11. Persons authorised to sign Patient Group Direction.

PART 3
Exemptions for Midwives

12. Exemption.

SCHEDULE 1
Substances which if included in medicinal products make those products prescription only medicines.

SCHEDULE 2
Particulars to be Included in a Patient Group Direction

SCHEDULE 3

MEDICINES (PRESCRIPTION ONLY) REGULATIONS, 1987

Subsidiary
1987/142

Title and commencement.

1.(1) These Regulations may be cited as the Medicines (Prescription Only) Regulations, 1987.

(2) These Regulations shall come into operation on the 5th day of May, 1988.

Interpretation.

2. In these Regulations–

"appliances" shall including dressings and any devices which are intended to be used for a medicinal purpose;

"approved course" means a course approved by the Chief Executive Officer of the Gibraltar Health Authority;

"British National Formulary" means the medical and pharmaceutical reference book for prescribing, dispensing and administering medicines published under the authority of the Joint Formulary Committee as the same may be amended from time to time;

"dependant" means a person who is unable to administer medicinal products to himself;

"emergency medicinal paramedic product" means a product specified in Part III of Schedule 3 to these Regulations;

"Gibraltar National Formulary" means such list of medicinal products and appliances available for prescribing , dispensing and administering under the Group Practice Scheme published on behalf of the Gibraltar Health Authority, as the same may be amended from time to time;

"GHA Board" means the board established under section 3 of the Medical (Gibraltar Health Authority) Act 1987;

"GHA paramedic" means a person in the employment of the Gibraltar Health Authority;

"GHA Policy" means policy documents authorised by the GHA Board;

"health prescription" means a prescription issued under the provisions of the Medical (Group Practice Scheme) Act;

"midwife" means a person registered under section 28 of the Medical and Health Act, 1997;

"nurse practitioner" means a person–

(a) in the employment of the Gibraltar Health Authority;

(b) entered in the register established under the Register of Nurses, Midwives and Health Visitors Regulations;

(c) against whose name in that register is recorded an annotation by the Nurses and Midwives Registration Board signifying that he is qualified to prescribe, dispense or administer–

(i) appliances and any medicinal products and prescription only medicines from the British National Formulary; and

(ii) appliances and medicinal products contained in List 2 from the Gibraltar National Formulary;

(d) who is subject to such conditions as the Authority may from time to time notify the nurse practitioner in writing;

"prescribing optometrist" means a person–

(a) in the employment of the Gibraltar Health Authority; and

(b) certified by the Chief Executive Officer of the Gibraltar Health Authority, subsequent to his having undertaken a relevant approved course, as competent in the use and prescribing of prescribing optometrist medicinal products,

provided that the Chief Executive Officer of the Gibraltar Health Authority may endorse such certification as to which level of prescribing optometrist medicinal product may be prescribed by such person;

"prescribing optometrist medicinal product" means a product listed in Part II of Schedule 3 to these regulations and references to a particular level of "prescribing optometrist medicinal product" shall be construed accordingly;

"prescription only medicine" has the same meaning as in the 1997 Order;

"pupil" in the context of a midwife, has the meaning given to it in the Midwives Regulations;

"the 1997 Order" means the Prescription Only Medicines (Human Use) Order 1997 of the United Kingdom (S.I. 1997 No.1830) as from time to time amended and includes any order or other instrument in force in substitution for that Order.

PART 1

Medicinal products which may only be supplied on prescription.

3.(1) Subject to the provisions of sub-regulation (2) and regulation 6, Part 2 and Part 3 of these Regulations –

(a) no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product specified or of a description or falling within a class to which this regulation applies, except in accordance with a prescription given by a medical or dental practitioner registered in Gibraltar under the provisions of the Act or (subject to subregulation (5)) a nurse practitioner or (subject to subregulation (6)) a prescribing optometrist; and

(b) subject to sub-regulation (10), no person shall administer (otherwise than to himself and a dependant under his care) any such medicinal products unless he is a medical practitioner, dental practitioner or subject to–

(i) sub-regulation (5) a nurse practitioner;

(ii) sub-regulation (6) a prescribing optometrist; or

(iii) sub-regulation (7) a GHA paramedic.

(2) Subregulation (1) (a) shall not apply–

(a) to the supply of a medicinal product to a patient of his by a practitioner; or

(b) to the sale or supply of a medicinal product for administration to an animal under his care, by a veterinary practitioner;

(c) to the administration of a medicinal product by a person authorised under and in accordance with a Patient Group Direction issued under Part 2 of these Regulations.

(3) For the purpose of this regulation a medicinal product shall not be taken to be sold or supplied in accordance with a prescription unless the provisions of these regulations as to prescriptions are complied with.

(4) This regulation applies, subject to sub-regulation (2) to those medicinal products (hereinafter called "prescription only medicines") which:

(a) are specified for the time being in the 1997 Order and which may only be dealt with in the United Kingdom, in the circumstances described in sub-regulation (1) above in the manner described in that sub-regulation; or

(b) during such period as they are not specified in the 1997 Order, consist of, or contain a substance listed in the Schedule 1 to these Regulations.

(5) Subject to any conditions which the Authority deems appropriate, a nurse practitioner may prescribe, dispense or administer–

(i) appliances and any medicinal products and prescription only medicines from the British National Formulary; and

(ii) appliances and medicinal products contained in List 2 from the Gibraltar National Formulary.

(6) Subject to paragraphs (a), (b), (c) and (d), a prescribing optometrist may only prescribe or administer prescription only medicines which are specified in Part II of Schedule 3 to these regulations–

(a) level 1 prescribing optometrist medicinal products may only be prescribed by a prescribing optometrist who is registered with the General Optical Council of the United Kingdom;

(b) level 2 prescribing optometrist medicinal products may only be prescribed by a prescribing optometrist who is registered on the General Optical Council for the United Kingdom's Specialist Register in Additional Supply;

(c) level 3 prescribing optometrist medicinal products–

(i) are products prescribed in accordance with the conditions listed under Level 3 of Part II of Schedule 3 to these regulations; and

(ii) may only be prescribed by a prescribing optometrist who is registered on the General Optical Council for the United Kingdom's Specialist Register in Supplementary prescribing.

(d) prescribing optometrists may administer but not prescribe topical anaesthetics marked with an "*" in Part II of Schedule 3 to these regulations.

(7) Provided the administration is for the purpose of saving life in an emergency situation, a GHA paramedic may administer emergency medicinal products specified in Part III of Schedule 3 to these Regulations.

(8) Subject to these regulations, for the purposes of Part VII of the Medical and Health Act, 1997, and regulations made under that Part, a prescription given in accordance with this regulation by a nurse practitioner or a prescribing optometrist (as the case may be) shall be deemed to have been made by a medical practitioner.

(9) Prescribing optometrists may not prescribe any drug which is a controlled drug under the Drugs (Misuse) Act, save where that Act or any regulations under it provide to the contrary.

(10) Sub-regulation (1)(b) shall not apply to the administration by a GHA employee of medicinal products in accordance with GHA Policy.

Form of Prescription.

4. (1) Subject to the provisions of these regulations, no person shall issue a prescription containing a medicinal product to which regulation 3 applies unless the prescription complies with the following requirements, that is to say it shall –

(a) be in ink or be otherwise written or printed so as to be indelible and be signed by the person issuing it with his usual signature and dated by him;

(b) in so far as it specifies the information required by paragraph (f) to be specified, be written by the person issuing it in his own handwritting or otherwise written or printed;

(c) except in the case of a health prescription, specify the address of the person issuing it;

(d) have written thereon, if issued by a dentist, the words "for dental treatment only" and if issued by a veterinary practitioner, the words "for animal treatment only";

(da) notwithstanding regulation 3(8), if issued by a prescribing optometrist the words "issued by a prescribing optometrist" shall be included;

(db) *deleted*

(e) specify the name and address of the person for whose treatment it is issued or will be issued by a veterinary practitioner, the person to whom the medicinal product prescribed is to be delivered;

(f) specify the dose to be taken and in the case of a preparation, the form and, where appropriate the strength of the preparation and either the total quantity of the preparation or the number of dosage units, as appropriate, to be supplied; and

(g) in the case of a prescription intended to be dispensed by instalments, contain a direction specifying the amount of the instalments which may be dispensed and the intervals to be observed when dispensing.

(2) In the case of a prescription issued for the treatment of a patient in a hospital or nursing home, it shall be a sufficient compliance with subregulation (1)(e) if the prescription is written or printed on the patient's prescription card.

Provisions as to supply on prescription.

5. (1) Subject to the provisions of regulation 7 below no person shall supply a medicinal product to which regulation 3 applies other than on a prescription unless all of the following criteria are fulfilled;

(a) the prescription complies with the provisions of regulation 4;

(b) the address specified in the prescription as the address of the person issuing it is an address within Gibraltar;

(c) he either is acquainted with the signature of the person by whom it purports to be issued and has no reason to suppose it is not genuine or has taken reasonably sufficient steps to satisfy himself that it is genuine;

(d) the date of supply shall not be before the date specified in the prescription; and

(e) the date of supply shall not be later than 13 weeks after the date specified in the prescription, or of a direction that the prescription may be repeated.

Provided that where a practitioner urgently requires such a medicinal product, the supplier may, if he is reasonably satisfied that the practitioner so requires the product and is, by some reason of emergency, unable to furnish a prescription before the product is supplied, supply the product on an undertaking by the practitioner to furnish such a prescription within the seventy-two hours next following.

(2) The person dispensing the prescription shall comply with the following requirements –

(a) he shall supply all the items included in the prescription provided that he has available the materials necessary for such prescription;

(b) he shall not, to the prejudice to the person for whom the product has been prescribed, supply any medicinal product which is not of the nature or quality specified in the prescription;

(c) the prescription must not be dispensed more than once unless the prescriber has directed thereon either that it may be dispensed a stated number of times or that it may be dispensed at stated intervals;

(d) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the direction;

(e) a prescription which contains a direction that it may be dispensed a stated number of times but no direction as to the intervals at which it may be dispensed shall not be dispensed more often than once in three days, and a prescription which contains a direction that it is to be dispensed at stated intervals

but no directions as to the number of times that it may be dispensed shall not be dispensed more often than three times;

(f) a prescription which contains a direction that it is to be repeated shall not be repeated more than once and a prescription which contains a direction that it is to be dispensed indefinitely shall not be dispensed for more than six months;

(g) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed;

(h) except in the case of a health prescription or of a prescription which may be repeated and which should, in that case, be kept by the patient, the prescription must, for a period of two years, be retained and kept on the premises on which it was dispensed in such manner as to be readily available for inspection.

Provided that the Chief Executive under the advice of the Director of Public Health may, in his direction, vary the requirements of paragraph (b) to (h) of this subregulation, in case of a health prescription.

Register of Prescriptions.

6. (1) The particulars that are required by Section 50 of the Act to be entered in a register of prescriptions shall be as follows:

(a) every entry required to be made in such register shall be made on the day on which the prescription was dispensed;

(b) no cancellation, obliteration or alteration of any such entry shall be made, and a correction of such an entry shall be made only by way of a marginal note or footnote which shall specify the date on which the correction is made;

(c) every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible;

(d) such a register shall not be used for any purpose other than the purposes of these regulations.

(2) The requirements of this regulation do not apply to a health prescription.

Exemptions for Emergency Sale of Supplies.

7.(1) The restrictions imposed by regulation 3 shall not apply to the sale or supply of a prescription only medicine by a pharmacist if and so long as the conditions specified in subregulation (2) are fulfilled.

(2) The conditions referred to in sub-regulation (1) are –

(a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor who by reason of an emergency is unable to furnish a prescription immediately;

(b) that that doctor has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours;

(c) that the prescription only medicine is sold or supplied in accordance with the directions of the doctor requesting it;

(d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1 to the Drugs (Misuse) Act;

(e) that an entry is made in the register kept under regulation 6.

(3) The restrictions imposed by regulation 3 also shall not apply to the sale or supply of prescription only medicine by a pharmacist if and so long as the conditions specified in subregulation (4) are fulfilled.

(4) The conditions referred to in sub-regulation (3) are –

(a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting a prescription only medicine and has satisfied himself–

(i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay,

(ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor for the person requesting it, and

(iii) as to the dose which in the circumstances it would be appropriate for that person to take;

(b) that no greater quantity of the prescription only medicine than will provide 5 days' treatment is sold or supplied except that there may be sold or supplied where the prescription only medicine –

(i) is an aerosol for the relief of asthma, an ointment or a cream, and has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply,

(ii) is an oral contraceptive, sufficient for a full cycle,

(iii) is an antibiotic for oral administration in liquid form, the smallest quantity that will provide a full course of treatment;

(c) subject to paragraph (5), that the prescription only medicine and is not a controlled drug specified in Schedule 1 to the Drugs (Misuse) Act;

(d) that an entry is made in the register kept under regulation 6;

(e) that the container or package of the prescription only medicine is labelled so as to show –

(i) the date on which the prescription only medicine is sold or supplied,

(ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,

(iii) the name of the person requesting the prescription only medicine,

(iv) the name and address of the registered pharmacy from which the prescription only medicine was sold or supplied, and

(v) the words "Emergency Supply".

(5) The conditions specified in subregulations (2) (d) and (4)(c) shall not apply where the prescription only medicine consists of or contains Phenobarbitone or Phenobarbitone Sodium (but no other substance specified in Schedule 4 to the 1997 Order or Schedule 1 to the Drugs (Misuse) Act) and is sold or supplied for use in the treatment of epilepsy.

Offences and penalty.

8. Any person who is in breach of any of the provisions of these regulations shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 4 on the standard scale.

PART 2

Patient Group Direction.

9. In these Regulations "Patient Group Direction" means, in connection with the supply or administration of a prescription only medicine, a written direction relating to the supply and administration, or administration only, of a description or class of prescription only medicines to persons generally (subject to any exclusions which are stated in the direction).

Exemptions for the supply and administration of prescription only medicines.

10.(1) The restrictions imposed under Part 1 of these Regulations shall not apply to the supply of a prescription only medicine where the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in subregulation (2) are satisfied.

(2) The conditions referred to are that–

(a) the Patient Group Direction relates to the supply or, as the case may be, the administration, by the person who supplies or administers the medicine, of a description or class of prescription only medicine, and the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;

(b) the Patient Group Direction contains the particulars specified in Part I of the Schedule 2 to these Regulations (but with the omission of paragraph (c) of that Part in the case of a Patient Group Direction which relates to administration only);

(c) the Patient Group Direction is signed by the person authorised to do so under regulation 11; and

(d) the individual who supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part II of the Schedule 2 to these Regulations (other than medical practitioners), and is designated in writing, on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction.

Persons authorised to sign Patient Group Direction.

11. A Patient Group Direction issued under this Part shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.

PART 3
Exemptions for Midwives

Exemption.

12. The restrictions imposed under Part 1 of these Regulations shall not apply to a medicinal product administered by a midwife in the course of the midwife's professional practice and–

(a) the medicinal product is listed in the corresponding paragraph in column 1 of Part IV of Schedule 3; and

(b) the condition specified in the corresponding paragraph in column 2 is met.

SCHEDULE 1

Regulation 3(4)(b)

Substances which if included in medicinal products make those products prescription only medicines.

List

Sildenafil.

The hormonal preparation known as the "morning after pill" consisting of the chemical product known as levornogestrel alone or in combination with the chemical product known as ethinylestradiol (ethinyloestradiol) and sold under the brand name "Schering PC4", "Levonelle–2" or any other product to like effect.

SCHEDULE 2

Regulation 10

PART I

PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION

(a) the period during which the Patient Group Direction shall have effect;

(b) the description or class of prescription only medicine to which the Patient Group Direction relates;

(c) whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;

(d) the clinical situations which prescription only medicines of that description or class may be used to treat;

(e) the clinical criteria under which a person shall be eligible for treatment;

(f) whether any class of person is excluded from treatment under the Patient Group Direction and, if so, what class of person;

(g) whether there are circumstances in which further advice should be sought from a doctor and, if so, what circumstances;

(h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;

(i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;

(j) the applicable dosage or maximum dosage;

(k) the route of administration;

(l) the frequency of administration;

(m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;

(n) whether there are any relevant warnings to note, and, if so, what warnings;

(o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;

(p) arrangements for referral for medical advice;

(q) details of the records to be kept of the supply, or the administration, of medicines under the Patient Group Direction.

PART II

(a) dentists registered under Part II of register maintained pursuant to section 7 of the Medical and Health Act, 1997;

(b) pharmacists registered under Part III of register maintained pursuant to section 7 of the Medical and Health Act, 1997;

(c) dispensers registered under Part IIIA of register maintained pursuant to section 7 of the Medical and Health Act, 1997;

(d) nurses registered in the register maintained pursuant to section 28 of the Medical and Health Act, 1997;

(e) midwives registered in the register maintained pursuant to section 28 of the Medical and Health Act, 1997;

(f) health visitors registered in the register maintained pursuant to section 28 of the Medical and Health Act, 1997.

SCHEDULE 3

Regulation 3

PART I
Deleted

PART II

Level 1

Cyclopentolate hydrochloride

Tropicamide

Chloramphenicol 1% ointment

Fusidic acid

Proxymetacaine*

Lidocaine Hydrochloride*

Oxybuprocaine hydrochloride*

Tetracaine Hydrochloride*

*Topical anaesthetic for administration only

Level 2

Atropine sulphate

Homatropine hydrobromide

Pilocarpine hydrochloride

Pilocarpine nitrate

Emedastine

Lodoxomide 10ml

Nedocromil Sodium

Sodium Cromoglicate

Azelastine Hydrochloride

Ketotifen

Olopatadine

Diclofenac Sodium

Polymyxin B / Bacitracin

Polymyxin B / Trimethoprim

Acetylcysteine

Level 3

Ocular therapeutics prescribed as per the Consultant Ophthalmologist's protocol for the following ocular conditions:

Glaucoma

Ocular Hypertension

Allergic Conjunctivitis

Keratitis

Microbial Conjunctivitis

Episcleritis

Dry Eye / Keratoconjunctivitis sicca

Corneal Decompensation

Uveitis

Post surgical cystoid macula oedema

Age Related Macula Degeneration

Blepharitis

Repeat prescriptions for Chronic Ocular Disease where the original therapy has been initiated and followed by a Consultant Ophthalmologist, with the guidance issued by the Consultant Ophthalmologist of the Gibraltar Health Authority.

PART III

EMERGENCY MEDICINAL PARAMEDIC PRODUCTS

Medicines specified in the GHA Paramedics Formulary from the Gibraltar National Formulary as the same may be amended from time to time.

PART IV

Exemptions from the restriction on administration of prescription only medicines

Column 1	Column 2
Prescription only medicines for parenteral administration containing any of the following substances but no other substance that is classified as a product available on prescription only— (a) Adrenaline, (b) Anti-D immunoglobulin, (c) Carboprost, (d) Cyclizine lactate, (e) Diamorphine, (f) Ergometrine maleate, (g) Gelofusine, (h) Hartmann's solution, (i) Hepatitis B vaccine, (j) Hepatitis immunoglobulin, (k) Lidocaine hydrochloride, (l) Morphine, (m) Naloxone hydrochloride, (n) Oxytocins, natural and synthetic, (o) Pethidine hydrochloride, (p) Phytomenadione, (q) Prochloperazine, (r) Sodium chloride 0.9%.	The medicine shall— (a) in the case of Lidocaine and Lidocaine hydrochloride, be administered only while attending on a woman in childbirth, and (b) where administration is— (i) by a midwife, be administered in the course of their professional practice; (ii) by a pupil— (aa) be administered under the direct supervision of a midwife; and (bb) not include Diamorphine, Morphine or Pethidine hydrochloride.
Prescription Only Medicines containing any of the following substances– Diclofenac Hydrocortizone acetate Miconazole Nystatin Phytomenadione.	