SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 3727 of 30 July, 2009

LEGAL NOTICE NO. 43 OF 2009.

MEDICAL AND HEALTH ACT, 1997

MEDICINES (PRESCRIPTION ONLY) (AMENDMENT) REGULATIONS 2009

In exercise of the powers conferred upon her under sections 36 and 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 Medicines (Prescription Only) (Amendment) Regulations 2009, and come into operation on the day of publication.

Amendment of regulations.

2.(1) The Medicines (Prescription Only) Regulations, 1987 are amended in accordance with the provisions of these Regulations.

(2) After regulation 2 insert the following part heading–

"PART 1".

(3) In regulation 3–

(a) in subregulation (1) for the words "and regulation 6" substitute the words ", regulation 6 and Part 2 of these Regulations";

(b) in subregulation (2) after paragraph (b) insert the following paragraph–

"(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.".

(4) After regulation 8 insert the following Part–

"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 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 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.

SCHEDULE

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.".

Dated 29th July, 2009.

Y DEL AGUA,

Minister for Health.

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