Statutory Document No. 2020/0246

Emergency Powers Act 1936 and Emergency Powers (Coronavirus) (Sale or Supply of Medicinal Products and Appliances) Regulations 2020

EMERGENCY POWERS (CORONAVIRUS) (SALE OR SUPPLY OF MEDICINAL PRODUCTS AND APPLIANCES) PROTOCOL 2020[1]

Laid before Tynwald: 14 April 2020
Coming into Operation: in accordance with regulation 2

The Department of Health and Social Care makes the following Protocol under section 4 of the Emergency Powers Act 1936 and regulation 5 of the Emergency Powers (Coronavirus) (Sale or Supply of Medicinal Products and Appliances) Regulations 2020[1].

1 Title

This Protocol is the Emergency Powers (Coronavirus) (Sale or Supply of Medicinal Products and Appliances) Protocol 2020.

2 Commencement

This Protocol comes into operation immediately after it is made[2].

3 Interpretation

In this Protocol —

"**the Act**" means the Medicines Act 2003;

"**appliance**" means an appliance which is a prescribed appliance within the meaning of section 8(1) of the National Health Service Act 2001;

"**appropriate date**" means, in the case of a prescription, whichever is the later of —

(a) the date on which it was issued by the appropriate practitioner giving it; or

[1] SD 2020/0184.

[2] By virtue of regulation 5(1) of the Emergency Powers (Coronavirus) (Sale or Supply of Medicinal Products and Appliances) Regulations 2020, this Protocol is required to be laid before Tynwald in accordance with section 34(2) of the Legislation Act 2015.

(b) a date indicated by the appropriate practitioner as the date before which it should not be dispensed;

"**appropriate practitioner**" has the meaning given in article 2 of the Prescription Only Medicines (Human Use) Order 1997[3], as it applies to the Island[4];

"**business hours**" means the period during which the retail pharmacy business is operational on any day;

"**controlling pharmacist**" means the pharmacist exercising personal control at the premises where the retail pharmacy business is carried on;

"**Coronavirus**" means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

"**the Coronavirus Proclamation period**" means the period for which the Proclamation of Emergency dated 16 March 2020[5] is in operation;

"**electronic communication**" has the meaning given by section 12 of the Electronic Transactions Act 2000;

"**electronic signature**" has the meaning given by section 5 of the Electronic Transactions Act 2000;

"**medicinal product**" has the meaning given in the Act;

"**medicinal product on a general sale list**" means a medicinal product of a description or falling within a class specified in article 2 (general sale list) of the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984[6], as it applies to the Island[7];

"**medicines legislation**" means the Misuse of Drugs Act 1976, the National Health Service Act 2001 and the Medicines Act 2003 and any legislation made under those Acts;

"**pharmacist**" has the meaning given in the Act;

"**pharmacy medicine**" means a medicinal product that —

[3] S.I. 1997/1830.

[4] SD 11/05. The Prescription Only Medicines (Human Use) Regulations 2005 applied to the Island the Prescription Only Medicines (Human Use) Order 1997, orders amending that Order as specified in Schedule 1 and any order made after the making of the Regulations and amending that Order being orders made under the provisions of the Medicines Act 1968 (of Parliament) corresponding to section 2 of the Act, subject to the modifications specified in Schedule 2.

[5] SD 2020/0162.

[6] S.I. 1984/769.

[7] SD 10/05. The Medicines (General Sales List) Regulations 2005 applies to the Island the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984, orders amending that Order, as specified in Schedule 1 and any order made after the making of the Regulations and amending that Order being orders made under the provisions of the Medicines Act 1968 (of Parliament) corresponding to section 2 of the Act, subject to the modifications specified in Schedule 2.

(a) is not a prescription only medicine or a medicinal product on a general sale list, but

(b) is covered by an authorisation of which it is a term that the product may only be sold by, or under the supervision of, a pharmacist;

"**pharmacy staff**" means any pharmacist (other than the controlling pharmacist) or any other person who is working at the premises in question in a role connected to the retail pharmacy business;

"**premises**" means the premises from which the retail pharmacy business is carried on;

"**prescription only medicine**" has the meaning given by section 5(1) of the Act;

"**retail pharmacy business**" means a business referred to in section 35 of the Act;

"**retail sale**" has the meaning given by section 53 of the Act; and

"**supply in circumstances corresponding to retail sale**" has the meaning given by section 53 of the Act.

4 Application of the Protocol

This Protocol applies during the Coronavirus Proclamation period.

5 Absence of the controlling pharmacist

(1) The controlling pharmacist must not be absent from the premises unless —

(a) it is reasonably practicable for the controlling pharmacist —

(i) to be contacted by other pharmacy staff throughout the period of absence; and

(ii) to return to the premises with reasonable promptness if, in the opinion of the controlling pharmacist, this is necessary to secure the safe and effective running of the retail pharmacy business; or

(b) if it is not reasonably practicable to put in place the arrangements specified in (a) of this sub-paragraph, the controlling pharmacist has ensured that another pharmacist is both available and contactable to provide advice to other pharmacy staff.

(2) The maximum period for which the controlling pharmacist may be absent from the premises is two hours during the pharmacy's business hours.

(3) If there is more than one controlling pharmacist during the pharmacy's business hours, the maximum period in sub-paragraph (2) relates to the total period of absence for all of them.

(4) During the period of absence of the controlling pharmacist the retail sale, or supply in circumstances corresponding to retail sale, of —

(a) medicinal products on a general sale list; and

(b) prescription only medicines and appliances that have been dispensed by or under the direct supervision of a pharmacist,

may continue.

6 Requirements for prescriptions: general

(1) A prescription only medicine is sold or supplied in accordance with a prescription given by an appropriate practitioner if conditions A to D are met and, in the case of a prescription for a controlled drug listed in Schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001[8] (as they apply to the Island[9]), if condition E is also met.

This is subject to sub-paragraph (7) below.

(2) Condition A is that the prescription —

(a) is written in ink (or otherwise so as to be indelible); or

(b) in the case of a prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001[10] (as they apply to the Island[11]), is written either as described in (a) of this sub-paragraph or by means of carbon paper or similar material.

(3) Condition B is that the prescription contains the following particulars —

(a) the address of the appropriate practitioner giving it;

(b) the appropriate date;

(c) an indication of the type of appropriate practitioner giving it;

(d) the name and address of the person for whose treatment it is given; and

(e) if that person is under 12, that person's age.

(4) Condition C is that the prescription —

(a) is not dispensed after the end of the period of 6 months beginning with the date indicated by the appropriate practitioner as the date on which the prescription was issued; or

(b) in the case of a repeatable prescription, it is not dispensed for the first time after the end of the period referred to in (a) of this sub-paragraph and it is dispensed in accordance with the directions contained in the prescription.

[8] S.I. 2001/3998.

[9] The Misuse of Drugs Regulations 2001 were applied to the Island by the Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013 (S.D. 0310/13), as amended by the Misuse of Drugs (Miscellaneous Enactments) (Application) (Amendment) Order 2016 (S.D. 2016/0254).

[10] S.I. 2001/3998.

[11] The Misuse of Drugs Regulations 2001 were applied to the Island by the Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013 (S.D. 0310/13), as amended by the Misuse of Drugs (Miscellaneous Enactments) (Application) (Amendment) Order 2016 (S.D. 2016/0254).

(5) Condition D is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed —

(a) it is not dispensed on more than two occasions; or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the appropriate date.

(6) Condition E is that the prescription is signed in ink by the appropriate practitioner giving it.

(7) A prescription only medicine is also sold or supplied in accordance with a prescription given by an appropriate practitioner if —

(a) conditions B to D are met;

(b) the prescription is created in electronic form;

(c) where the prescription is for a controlled drug specified in Schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001[12] (as they apply to the Island[13]), the prescription is signed with an electronic signature; and

(d) the prescription is sent to the person by whom it is dispensed as an electronic communication.

7 Saving

For the avoidance of doubt, except as otherwise provided by this Protocol, all other provisions of the medicines legislation continue to apply to the sale or supply by a person of any medicinal product or appliance.

MADE
08/04/2020 AT 16:00

[12] S.I. 2001/3998.

[13] The Misuse of Drugs Regulations 2001 were applied to the Island by the Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013 (S.D. 0310/13), as amended by the Misuse of Drugs (Miscellaneous Enactments) (Application) (Amendment) Order 2016 (S.D. 2016/0254).

ENDNOTES

Table of Endnote References

[1] The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.