
MEDICINES (AMENDMENT) BILL 2020

Explanatory Memorandum

1. This Bill is promoted by Mr Ashford.
2. *Clause 1* of the Bill provides for the short title of the resulting Act.
3. *Clause 2* provides for the commencement of the resulting Act.
4. *Clause 3* amends the Medicines Act 2003 (“the 2003 Act”).
 - 4.1 Subsection (2) amends section 2 of the 2003 Act. Section 2 of the 2003 Act imposes a duty on the Department of Health and Social Care to make provision in regulations controlling, restricting, regulating or prohibiting certain activities in relation to any medicinal product. By virtue of subsection (2) that duty is extended to apply to the activity of administering any medicinal product.
 - 4.2 Subsection (3) amends section 3 of the Act to insert a reference to section 5 which is consequential on the amendment to section 5 itself (see below).
 - 4.3 Subsection (4) amends section 5 of the 2003 Act to —
 - (a) prohibit any person from —
 - (i) selling or supplying or offering to do so, any medicinal product unless that product is sold or supplied in accordance with a prescription given by an appropriate practitioner;
 - (ii) administering any medicinal product (otherwise than to himself) unless that person is an appropriate practitioner or acts under the direction of an appropriate practitioner;
 - (b) provide that exemptions to the prohibitions referred to in (a) may be made by regulations under sections 2, 3 or 52 of the 2003 Act;
 - (c) provide that the prohibitions referred to in (a) do not apply to the sale or supply of a medicinal product by a doctor or dentist (who is an appropriate practitioner) to his patient, and to define “appropriate practitioner” for that purpose.
 - 4.4 Subsection (5) inserts a new section (5A) into the 2003 Act. New section 5A makes it an offence for a person to contravene section 5 (as amended) or to have in his possession a medicinal product to which section 5 applies which he intends to supply otherwise than in accordance with a prescription. The offence is punishable by a fine not exceeding level 5 (summary) or by custody or a fine or both (on information).

- 4.5 Subsection (6) amends section 30 of the 2003 Act to include a consequential reference to section 5(2)(a).
- 4.6 Subsection (7) amends section 32 of the 2003 Act to —
- (a) apply, suitably modified, the new section 5(2A) and (2B) to the sale, supply or administration of veterinary medicinal product by an appropriate practitioner to an animal or herd in his care; and
 - (b) to provide a definition of “appropriate practitioner” for that purpose.
- 4.7 Subsection (8) amends Schedule 2 to the 2003 Act (interpretation) to include a definition of “administering”.
5. *Clause 4* provides —
- (a) in subsection (1), that the amendments to the 2003 Act made in clause 3 are deemed to have been in operation at the date the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (“the 2005 Regulations”) were made;
 - (b) in subsection (2), the circumstances in which the deeming referred to in (a) has effect - namely where a person has done anything in reliance on an exemption in the 2005 Regulations to the prohibitions dealt with in clause 3;
 - (c) in subsection (3), that in the circumstances referred to in (b) anything done by a person during the relevant period , —
 - (i) is to be treated as validly done for all purposes;
 - (ii) does not render a person liable to proceedings to which that person would otherwise have been so liable if the deeming provision and clause 3 had not been operative; and
 - (iii) does not render a person liable to proceedings to which that person would not otherwise have been so liable;
 - (d) in subsection (4), for a definition of the relevant period (a period that begins with the day on which the Prescription Only Medicines (Human Use) Regulations 2005 were made and ends on the day clause 3 comes into operation).
6. In the opinion of the member moving the Bill its provisions are compatible with the Convention rights within the meaning of the Human Rights Act 2001.



Ellan Vannin

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Ellan Vannin

MEDICINES (AMENDMENT) BILL 2020

- 1 **A BILL** to regulate the administration, sale and supply of medicinal products;
2 and for connected purposes.

BE IT ENACTED by the Queen's Most Excellent Majesty, by and with the advice and consent of the Council and Keys in Tynwald assembled, and by the authority of the same, as follows:—

3 **1 Short title**

4 The short title of this Act is the Medicines (Amendment) Act 2020.

5 **2 Commencement**

6 This Act commences on its announcement day.

7 **3 Amendment of the Medicines Act 2003**

8 (1) The Medicines Act 2003 is amended as follows.

9 (2) In section 2 (restrictions on dealing with medicinal products) —

10 (a) in subsection (1)(f), after “view to” insert “administering,”;

11 (b) after subsection (1)(f), insert —

12 | “(g) administering any medicinal product.”

13 (3) In section 3 (exemptions), in subsection (1) after “section 2(1)” insert “or
14 section 5”.

15 (4) In section 5 (medicinal products on prescription only), for subsection (2)
16 substitute —

17 | “(2) No person shall —

18 | (a) sell by retail, offer or expose for sale by retail or supply in
19 | circumstances corresponding to retail sale, a medicinal
20 | product to which this section applies unless it is sold or
21 | supplied in accordance with a prescription given by an
22 | appropriate practitioner; or

23 | (b) administer (otherwise than to himself) any medicinal
24 | product to which this section applies unless he is an

appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner.

This is subject to regulations made under section 2, 3 or 52.

(2A) Subsection (2)(a) does not apply to the sale or supply of a medicinal product to a patient of his by a doctor or dentist who is an appropriate practitioner.

(2B) For the purposes of this section, “appropriate practitioner” means a practitioner referred to in paragraph (a) of the definition of “practitioner” in Schedule 2.”

(5) After section 5, insert —

“5A Offences

Any person who—

- (a) contravenes section 5(2); or
- (b) has in his possession a medicinal product to which section 5 applies and which he intends to supply otherwise than in accordance with a prescription of an appropriate practitioner,

shall be guilty of an offence and liable—

- (i) on summary conviction, to a fine not exceeding level 5 on the standard scale;
- (ii) on conviction on information, to custody for a term not exceeding 2 years or to a fine, or to both.”.

(6) In section 30 (presumptions), in subsection (1) and (2), before “7(b)” insert “5(2)(a) or”.

(7) In section 32 (application of Parts 1 to 4 to veterinary medical products), after subsection (3) insert —

“(3A) In section 5, for subsections (2A) and (2B) substitute —

“(2A) Subsection (2)(a) does not apply to the sale or supply of a veterinary medicinal product for administration to an animal or herd under his care, by a veterinary surgeon or veterinary practitioner who is an appropriate practitioner.

(2B) For the purposes of this section, “appropriate practitioner” means a practitioner referred to in paragraph (b) of the definition of “practitioner” in Schedule 2.”

(8) In Schedule 2 (interpretation)—

- (a) in the column headed “Expression”, insert at the appropriate place “administering”;
- (b) in the corresponding place in the column headed “Meaning”, insert —

- 1 “means administering to a human being, or as the case may be, an
2 animal—
- 3 (a) orally, by injection, or by introduction into the body in any
4 other way, or
- 5 (b) by external application whether or not by direct application to
6 the body,
- 7 and, save where expressly provided, any reference in this Act to
8 administering anything is to administering it in its existing state
9 or after it has been dissolved or dispersed in, or diluted or mixed
10 with, a substance used as a vehicle”.

11 **4 Exemptions relied on before this Act**

- 12 (1) The amendments to the Medicines Act 2003 made by this Act are deemed
13 to have been in operation when the Prescription Only Medicines (Human
14 Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only
15 Medicines (Human Use) Order 1997 (of Parliament) to the Island), were
16 made.
- 17 (2) The following subsections apply to anything done by a person (P) during
18 the relevant period in reliance on an exemption in the Prescription Only
19 Medicines (Human Use) Regulations 2005 to the prohibitions set out in
20 the amended sections 5 and 32 of the Medicines Act 2003 (see section 3 of
21 this Act) .
- 22 (3) Anything done by P in the circumstances referred to in subsection (2) —
- 23 (a) is to be treated for all purposes as validly done;
- 24 (b) does not render P liable to any proceedings to which P would
25 otherwise be liable if the prohibitions set out in the amended
26 sections 5 and 32 of the Medicines Act 2003 were not operative
27 and had not been brought into operation by virtue of section 3 of
28 this Act;
- 29 (c) does not render P liable to any proceedings to which P would not
30 otherwise be liable.
- 31 (4) “The relevant period” means the period beginning with the day the
32 Prescription Only Medicines (Human Use) Regulations 2005 were made
33 and ending with the day section 3 of this Act comes into operation.

IN THE KEYS

MEDICINES (AMENDMENT) BILL 2020

A **BILL** to regulate the administration of medicinal products; and for connected purposes.

Leave to introduce given by the Council on 18 June 2020.

MR ASHFORD

JUNE 2020