



**Isle of Man**

*Ellan Vannin*

**AT 4 of 2021**

**MEDICINES (AMENDMENT) ACT 2021**





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## MEDICINES (AMENDMENT) ACT 2021

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## MEDICINES (AMENDMENT) ACT 2021

*Signed in Tynwald:* 20 April 2021  
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**AN ACT** to regulate the administration, sale and supply of medicinal products; 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:—

### 1 Short title

The short title of this Act is the Medicines (Amendment) Act 2021.

### 2 Commencement

This Act commences on its announcement day.

### 3 Amendment of the Medicines Act 2003

- (1) The Medicines Act 2003 is amended as follows.
- (2) In section 2 (restrictions on dealing with medicinal products) —
  - (a) in subsection (1)(f), after “view to” insert **63** administering, **62**;
  - (b) after subsection (1)(f), insert —
    - 63** (g) administering any medicinal product. **62**
- (3) In section 3 (exemptions), in subsection (1) after “section 2(1)” insert **63** or section 5”.
- (4) In section 5 (medicinal products on prescription only), for subsection (2) substitute —
  - 63** (2) No person shall —
    - (a) sell by retail, offer or expose for sale by retail or supply in circumstances corresponding to retail sale, a medicinal product to which this section applies unless it is sold or

supplied in accordance with a prescription given by an appropriate practitioner; or

- (b) administer (otherwise than to himself) any medicinal 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. **22**

- (5) After section 5, insert —

#### **23 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 sell, supply or administer in contravention of that section,

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. **22**

- (6) In section 30 (presumptions), in subsection (1) and (2), before “7(b)” insert **24** 5(2)(a) or **22**.

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

**25** (3A) In section 5, for subsections (2A) and (2B) substitute —

**26** (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 —
  - “** means administering to a human being, or as the case may be, an animal —
    - (a) orally, by injection, or by introduction into the body in any other way, or
    - (b) by external application whether or not by direct application to the body,
 and, save where expressly provided, any reference in this Act to administering anything is to administering it in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, a substance used as a vehicle **”**.

#### 4 Exemptions relied on before this Act

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

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