

**5.2. Medicines (Amendment) Bill 2020 –  
Clauses considered**

Mr Ashford to move.

**The Speaker:** We turn our attention now to the Medicines (Amendment) Bill 2020, and I call on Mr Ashford.

**Mr Ashford:** Thank you, Mr Speaker.

I am pleased to move consideration of the clauses of the Medicines (Amendment) Bill 2020, a Bill which will, if passed, amend the Medicines Act 2003 to ensure that the regulation of the sale, supply and administering of prescription medication operates as intended to do.

Turning to each clause of the Bill, with your permission, Mr Speaker, I wish to move clauses 1 and 2 together.

**The Speaker:** Okay.

**Mr Ashford:** Clause 1 gives the resulting Act, should the Bill pass, its short title.

Clause 2 provides for the commencement of the resulting Act to be on the announcement of Royal Assent.

Mr Speaker, I beg to move, that clauses 1 and 2 do stand part of the Bill.

**The Speaker:** Mrs Corlett.

**Mrs Corlett:** Thank you, Mr Speaker, I beg to second.

**The Speaker:** I put the question that clauses 1 and 2 stand part of the Bill. Those in favour, please say aye; against, no. The ayes have it. The ayes have it.

Clause 3, Mr Ashford.

**Mr Ashford:** Thank you, Mr Speaker.

Clause 3 of the Bill seeks to amend Part 1, Dealings with Medicinal Products and Part 5 Veterinary Medicinal Products and Animal Feeding Stuffs of the Medicines Act 2003.

Firstly, with regard to clause 3(2) of this Bill, section 2(1) of the Medicines Act 2003 places a statutory duty on the Department of Health and Social Care to make regulations to control, restrict, regulate or prohibit the following activities in relation to medicinal products: (a) selling, supplying or otherwise placing on the market; (b) manufacturing or assembling; (c) distributing; (d) procuring the sale, supply or placing on the market; (e) importing and exporting; and (f) possessing with a view to selling, supplying or otherwise placing on the market.

Clause 3(2) of the Bill amends section 2(1) to provide a greater degree of legal certainty under the Act as to the Department's regulation-making powers and duties with regard to the administration of medicinal products, by amending section 2(1)(f) to include administering and inserting a new paragraph 2(1)(g). By doing so, it is clear that the Department has the *vires* and indeed a duty under the Act to make regulations to control the administering of medicinal products.

Moving on to clause 3(3) of the Bill, section 3 of the Act provides the Department with a regulation-making power to create exemptions from any restrictions, prohibitions or controls that have been imposed by regulations made under the aforementioned section 2(1). Specifically, such exemption would be to allow doctors, dentists, nurses and pharmacists to supply or administer medicinal products other than in accordance with a general rule while the circumstances dictate.

The amendment being proposed by clause 3(3) to section 3 is a consequence of the amendments that follow to section 5, specifically the insertion of rules relating to the sale, supply and administering of prescription-only medicines.

Clause 3(4) seeks to substitute in its entirety subsection (2) of section 5 for the purpose of prohibiting, as a general rule, a person from doing either of the following: firstly, to prohibit a person from selling by retail, offering or exposing for sale by retail, or supplying in circumstances corresponding to retail sale a prescription-only medicine, unless it is sold or supplied in accordance with a prescription given by an appropriate person; and, secondly, to prohibit a person from administering, other than to himself, a prescription-only medicine unless he is an appropriate person or a person acting in accordance with the directions of an appropriate practitioner.

Clause 3(4) will also insert a new subsection (2A) into section 5, so as to exempt from the aforementioned prohibitions doctors and dentists from selling or supplying medicinal products to one of their patients. Hon. Members will note the Department acknowledges that given the changes proposed above to section 2 it would have the power to make provision for such provisions and the exception in (2A) in regulations. However, the Department is proposing to do so on the face of the Act, the purpose being to tie-in to the existing legislation, namely the Prescription Only Medicines (Human Use) Regulations 2005, which applies UK statutory instruments to the Island.

Lastly, clause 3(4) inserts a new subsection (2B) into section 5 to define for the purposes of that section the term 'appropriate practitioner'. As a consequence of the proposed substitution of section 5(2), i.e. inserting into the Act prohibitions regarding the sale, supply and administration of prescription-only medicines, the Department is proposing to insert offences into the Act should a person contravene such prohibitions. Thus, clause 3(5) of the Bill will insert a new section 5A into the Act, the purpose of which is to make it an offence for a person to contravene section 5(2) or have in their possession a prescription-only medicine with the intent of supplying it otherwise than in accordance with a prescription from an appropriate practitioner. A person guilty of such an offence is to be liable on summary conviction to a fine not exceeding level 5 on the standard scale, or if on conviction on information to custody for a term not exceeding two years or to a fine or both.

Clause 3(6) of the Bill seeks to amend subsections (1) and (2) of section 30, presumptions, the purposes of which are as follows: regarding the offence of offering a prescription medicine for sale or for sale by retail in contravention of clause 5(2)(a) where it is proved that the product in question was found on a vehicle from which medicinal products are sold, it shall be presumed unless the contrary is proved that the person in charge of the vehicle offered the product for sale.

Regarding the offence of possessing a prescription medicine with the intent of selling or supplying it in contravention of clause 5(2)(a) where it is proved that the product was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products, it shall be presumed unless the contrary is proved that he has had the medicinal product in his possession for the purposes of sale or supply.

Hon. Members, regarding clause 3(7), in the Island veterinary medicines and animal feeding stuffs are regulated by DEFA under the Veterinary Medicines Regulations 2019, rather than by the Department in accordance with Part 5 of the Act, which is not in operation. Despite Part 5 not being operable, the amendments proposed by this Bill to the Human Prescription Medicines will for completeness carry through to the Veterinary Prescription Medicines under Part 5, until such time as a wide review of the Act has been undertaken. It is anticipated in due course that Part 5 will be revoked.

Lastly, Hon. Members will be pleased to hear, with regard to clause 3, subsection (8) inserts a definition to Schedule 2, Interpretation, for 'administering'.

Mr Speaker, I am sure Hon. Members will be relieved that I beg to move that clause 3 do stand part of the Bill.

**The Speaker:** Mrs Corlett.

**Mrs Corlett:** Thank you, Mr Speaker, I beg to second.

**The Speaker:** It was noted that Mr Perkins clearly had not written that clause speech!  
*(Laughter)*

Mr Hooper.

**Mr Hooper:** Thank you very much, Mr Speaker.

I might have missed it, the Minister was talking at about 100 miles an hour to get all that information on the record. But he had reference to a 2005 set of regulations in the UK that are applied to the Isle of Man. I was under the impression that a lot of those have been repealed by the Human Medicines Regulations 2012 in the UK. The reason I ask this is because he is embedding in law a very specific exemption in respect of doctors and dentists. The UK has a much broader range of exemptions, some of which are probably not appropriate for the Isle of Man, but there are some in respect of retail pharmacies, for example, which may be relevant.

So the question for the Minister is: have we successfully captured all the relevant and appropriate regulations in what he is talking about today?

Thank you.

**The Speaker:** Mover to reply.

**Mr Ashford:** Thank you, Mr Speaker. I will keep it briefer than my moving of that particular clause.

In answer to the Hon. Member for Ramsey, yes, I am satisfied we have captured the exemptions. He is quite correct, Mr Speaker, a lot of the 2005 regulations were repealed by the 2012 in the UK, but there are certain ones still in force that were applied to the Island and are still there, as are of course the 2012 ones as well.

But I am satisfied we have covered all the exemptions.

**The Speaker:** I put the question that clause 3 stand part of the Bill. Those in favour, please say aye; against, no. The ayes have it. The ayes have it.

Clause 4, Mr Ashford.

**Mr Ashford:** Much more briefly and in keeping with Mr Perkins, Mr Speaker, clause 4 of the Bill makes provision that the amendments being made by clause 3 are deemed to have come into operation on 9th December 2005, this being the date that the Prescription Only Medicines (Human Use) Regulations 2005 were made.

Subsections (2) and(3) of this clause make it clear that anything done by a person during the period from 9th December 2005 to the coming into operation of this Bill, in reliance on an exemption in the aforementioned regulations, is to be treated for all purposes as validly done; does not render a person liable to proceedings to which they would otherwise be liable if the prohibitions being introduced were not operative, and had not been brought into operation by virtue of clause 3 of this Bill; and does not render a person liable to proceedings to which they would not otherwise have been liable.

For the purposes of clause 4, subsection (4) defines the relevant period as being the period beginning with the day on which the Prescription Only Medicines (Human Use) Regulations 2005 were made and ending with the day that section 3 of this Bill comes into operation.

Mr Speaker, I beg to move that clause 4 do stand part of the Bill.

**The Speaker:** Mrs Corlett.

**Mrs Corlett:** Thank you, Mr Speaker, I beg to second.

**The Speaker:** I put the question that clause 4 stand part of the Bill. Those in favour, please say aye; against, no. The ayes have it. The ayes have it.