Isle of Man Government

Reiltys Ellan Vannin

MEDICINES (AMENDMENT) BILL 2020

EXPLANATORY NOTES

These Notes have been produced for the assistance of Members with the approval of the Member in charge of the Bill, Mr David Ashford MHK.

INTRODUCTION

1. These explanatory notes relate to the Medicines (Amendment) Bill 2020 ("the Bill"). They have been prepared by the Department of Health and Social Care ("the Department") in order to assist readers of the Bill. They do not form a part of the Bill and have not been endorsed by the House of Keys.

2. The notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill.

BACKGROUND

3. The Medicines Act 2003 ("the Act") regulates the trade in human medicinal products from the licensing of the product itself through to manufacturing, wholesale dealing, importing, exporting and the retail sale or supply of the product to the end user.

4. To regulate the trade in human medicinal products Part 1 of the Act is largely enabling (rather than prescriptive) as it provides the Department with a statutory duty to make regulations to control, restrict, regulate or prohibit the following activities:

a) selling, supplying or otherwise placing on the market;

b) manufacturing or assembling;

c) distributing (wholesale dealing);

d) procuring the sale, supply or placing on the market otherwise than by sale or supply, manufacture, assembly or distribution;

e) importing and exporting; and

f) possessing with a view to selling or supplying or otherwise placing on the market.

5. With regard to a specific category of human medicines – i.e. those available only on prescription – further provisions are made as to their regulation under section 5 of the Act.

6. Section 5 places a duty on the Department, when making regulations to control the sale or supply of medicines, to prohibit a person from selling or supplying a prescription only medicine other than in accordance with a prescription given by an appropriately qualified person. Such regulations, as well as setting out who is an appropriately qualified person could prescribe exceptions to the general rule (for example to allow a pharmacist to supply a prescription medicine without being in receipt of a prescription in an emergency).

7. Regarding the sale/supply of prescription medicines, the Department's intended position under the Act/regulations made under it is:

a) as a general rule, to prohibit a person from selling or supplying by retail a prescription only medicine except in accordance with a prescription issued by a person qualified to do so;

b) the Act/regulations would set out who is qualified to issue a prescription and in respect of which medicines (for example doctors, dentists and nurses); and

c) the general rule would be subject to exceptions prescribed in regulations.

8. Similarly, with regard to the administering of human prescription medicines, the Department's intended position under the Act/regulations made under it is:

   a) as a general rule, to prohibit a person from administering (other than to himself) a prescription only medicine unless he or she is appropriately qualified or acting in accordance with the directions of such a person;

   b) the Act/regulations would set out who is qualified to administer a prescription only medicine to another person; and

   c) the general rule would be subject to exceptions prescribed in regulations (for example the administration of adrenaline to save a person's life).

9. With regard to the trade in veterinary medicinal products, Part 5 of the Act seeks to apply the preceding Parts 1 to 4 and the subsequent Schedule 1 – which legislate(s) for human medicinal products – to veterinary medicinal products. This application is subject to the modifications set out in section 32.

10. To date, Part 5 (veterinary medicinal products and animal feeding stuffs) of the Act has not been brought into operation. Instead, under the auspices of DEFA the Veterinary Medicines Regulations 2019 regulate the sale and supply of veterinary prescription medicines and their administration in the Island.

11. Despite Part 5 not being operable, the amendments being made by the Bill to the Act regarding human prescription medicines will for completeness carry through to Part 5 until such time as a wider review of the Act has been undertaken. The Department acknowledges that wider reforms are needed to the Act and the legislation sitting underneath it. It is anticipated that in due course Part 5 will be revoked.

12. Given that there are no policy changes which might affect the public directly, the Bill has not been the subject of a consultation.

13. 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.

FINANCIAL EFFECTS OF THE BILL

14. There are no known likely financial effects of the amendments proposed by this Bill.

15. An Impact Assessment of the Bill has been prepared by the Department; this is attached at Appendix 1.

CLAUSE BY CLAUSE NOTES

Clause 1

16. This clause gives the short title to the Act which will, if enacted, result from the Bill.

Clause 2

17. This clause provides for the resulting Act to come into operation on the day on which Royal Assent is announced to Tynwald.

Clause 3

18. This clause amends the Act.

19. Section 2(1) of the Act imposes a statutory obligation on the Department to make provision, by regulations, for controlling, restricting, regulating or prohibiting certain trade related activities (for example manufacturing) in medicinal products. Section 2(1) is being amended to extend the Department's duty so that it is required by regulations to make provision for controlling (etc.) the administering of medicinal products. Consequentially, a definition for "administering" is inserted into Schedule 2 (interpretation) to the Act.

20. Section 3 of the Act imposes a statutory obligation on the Department to provide, by regulations, for exemptions to controls, restrictions or prohibitions that have been imposed by the Department under the aforementioned section 2(1) for:

    a. prescribed activities in the course of a practitioners profession; and

b. prescribed activities in a registered pharmacy, hospital or health centre undertaken by a pharmacist or under the supervision of one.

Section 3 is amended as a consequence of the amendments made to section 5: amendments that insert prohibitions into the Act with regard to the sale/supply and administering of prescription only medicines.

21. Section 5(2) of the Act is amended to prohibit:

a. a person from selling or supplying a prescription medicine otherwise than in accordance with a prescription given by an appropriate practitioner; or

b. a person from administering a prescription medicine unless he is an appropriate practitioner or acting in accordance with the directions of an appropriate practitioner.

The prohibitions described at a. and b. above are to be subject to such exemptions that are provided for in regulations made under sections 2, 3 or 52 of the Act. Further, the prohibition described at a. will not apply where a doctor or a dentist is supplying a prescription only medicine to his or her patient.

22. As a consequence of the amendments made to section 5(2) (as described above), new section 5A (offences) is being inserted into the Act. Section 5A will make it an offence for a person to contravene section 5(2) or have in his possession a prescription medicine intending to supply it otherwise than in accordance with a prescription.

23. Subsection (6) of this clause makes amendments to section 30 of the Act. By doing so:

a. regarding the offence of offering a prescription medicine for sale in contravention of the newly inserted section 5(2)(a), where it is proved that the product 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 that product for sale;

b. regarding the offence of possessing a prescription medicine with the intent of selling or supplying it, in contravention of the newly inserted section 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 had the medicinal product in his or her possession for the purpose of sale or supply.

Clause 4

24. This clause provides that the amendments made by this Bill are deemed to have been in operation from the 9 December 2005, being the date the Prescription Only Medicines (Human Use) Regulations 2005[1] ("the Regulations") were made.

25. However, anything done during the period from the 9 December 2005 up until the date clause 3 of the Bill comes into operation by a person in reliance on an exemption set out in the Regulations:

    a. is to be treated as validly done;

    b. does not render them liable to proceedings that they would otherwise have been liable to if the prohibitions set out in the amended sections 5 and 32 were not operative; and

    c. does not render them liable to proceedings they would otherwise to which they would not otherwise be liable.

[1] SD 11/05

Appendix 1

DEPARTMENT: **Health and Social Care**		
IMPACT ASSESSMENT **FOR A MEDICINES (AMENDMENT) BILL 2020**		
Stage: 12 – Council approval to introduce legislation into Branches	**Version:** 3	**Date:01/06/2020**
Related Publications: Medicines (Amendment) Bill 2020 (VO4), Explanatory Memorandum.		
Responsible Officer: Maria Bell **Email Address:** Maria.Bell@gov.im		**Telephone:** 642647

SUMMARY: INTERVENTION AND OPTIONS
Briefly summarise the proposal's purpose and the intended effects 1. The Medicines Act 2003 (**Act**) exists to regulate the import, manufacture, sale, supply, and other dealings with human and veterinary medicinal products. *Human medicinal products* 2. Regarding dealings with human medicinal products, Part 1 of the Act regulates their trade: from the licensing of a medicinal product (so that it can be placed on the

market), though to the manufacturing, assembling, dealing and distributing (including importation and exportation) and the sale or supply of such product to the end user.

3. For the purposes of regulating the trade in human medicinal products, Part 1 is largely enabling rather than prescriptive. It provides the Department of Health and Social Care (**Department**) with the vires to make regulations to control, restrict, regulate or prohibit activities that relate to the trade in human medicines.

4. As to the making of such regulations, the Department under Part 1, must under the Act have regard to the systems of control operating in the U.K.; further the Department has the vires under section 52 (regulations) to apply UK human medicines legislation to the Island.

5. To date, with regard to:

   a) regulating the retail sale, or supply in circumstances corresponding to retail sale of prescription only medicines; and

   b) regulating the administering of such medicines,

   the Department has looked to mirror the position in the UK. Thus, the intention was to achieve the following.

The retail sale or supply of prescription only medicines

6. With regard to the retail sale, or supply in circumstances corresponding to retail sale, of prescription only medicines the general rule would be that a person could not, by retail, sell or supply a prescription only medicine except in accordance with a prescription issued by an appropriate practitioner (e.g. a doctor).

7. For the purposes of the general rule, as to what constituted a "prescription" and as to whom an "appropriate practitioner" is each term would be defined and the exceptions to the general rule (i.e. the circumstances in which a prescription only medicine could be sold or supplied otherwise than in accordance with a prescription issued by an appropriate practitioner) would be set out in secondary legislation sitting underneath

the Act.

(An example of such an exception would be to allow for the emergency sale or supply of a prescription only medicine by a pharmacist in specified circumstances.)

Administering a prescription only medicine to another person

8. Regarding the administering of prescription only medicines, the general rule would be that a person could not administer (otherwise than to himself) any such medicine unless he were an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner. "Administering" and "appropriate practitioner" would for the purposes of the general rule be defined.

9. Again, the general rule would then be subject to exceptions – i.e. the Department's medicines legislation would set out the circumstances in which a person, not being an appropriate practitioner or acting in accordance with the directions of one, could administer a prescription only medicine to someone else.

   (For example, to allow adrenaline to be administered for the purpose of saving a person's life.)

The Prescription Only Medicines (Human Use) Regulations 2005

10. To seemingly achieve the above, the Department – in addition to relying on the provisions of the Act – on 9 December 2005 made the Prescription Only Medicines (Human Use) Regulations 2005[2] (**Regulations**).

11. The Regulations, made under the powers conferred on the Department under sections 2 (restrictions on dealing with medicinal products) and 52 (regulations) of the Act and of all other enabling powers, applied the following UK statutory instruments to the Island:

    a) the Prescription Only Medicines (Human Use) Order 1997[3] (**UK principle order)**;

[2] S.D. 11/05
[3] S.I. 1997/1830

b) a further set of U.K. orders, detailed in Schedule 1 (amending orders applied to the Isle of Man) to the Regulations, that amended the UK principle order;

c) any U.K. order made after the making of the Regulations and amending the UK principle order,

being orders made under the provisions of the Medicines Act 1968 (of Parliament), corresponding to section 2 of the Act.

12. Schedule 2 (modifications subject to which the orders apply to the Island) to the Regulations sets out the modifications made to the applied legislation to ensure that the legislation applied would be fit for purpose in the Island.

Veterinary medicinal products

13. Part 5 (veterinary medicinal products and animal feeding stuffs) of the Act legislates for veterinary medicinal products and animal feeding stuffs.

14. With regard to veterinary medicinal products, section 31 of the Act defines what a veterinary medicinal product is.

15. Regarding dealings with veterinary medicinal products, section 32 applies with modifications Part 1 of the Act and, in doing so, provides the Department with the vires to make regulations to control (etc) trade related activities in veterinary medicinal products.

16. Regarding dealings with animal feeding stuffs, section 33 confers a regulation making power on the Department to control, restrict, regulate or prohibit the following:

a) the incorporation of a veterinary medicinal product into an animal feeding stuff; and

b) the importation, sale, supply or otherwise placing on the market of animal feeding stuff containing a veterinary medicinal product.

17. Section 34 confers a further regulation making power on the Department to apply sections 20 to 30 of the Act.[4]

18. To date, Part 5 of the Act has not been brought into operation. Instead, presently the Veterinary Medicines Regulations 2019 – made under section 2B of the European Communities (Isle of Man) Act 1973 – regulate amongst other things:

    a) the retail sale or supply in circumstances corresponding to retail sale of veterinary medicinal products on prescription and medicated animal feeding stuffs; and

    b) the administration of such medicines.

The purpose of the Medicines (Amendment) Bill 2020

19. This Bill will amend the Medicines Act 2003. The purpose of the amendments being made is to ensure the regulation in the Island of:

    a) the retail sale and supply in circumstances corresponding to retail sale of human prescription only medicines; and

    b) the administering of such medicines,

    operates in the manner described above and as intended by the Department.

20. To achieve this amendments are required to the Act in the manner proposed by the provisions of this Bill and, in due course, to the Regulations.

What are the options that have been considered

Option One – Maintain the status quo

1. The first option considered by the Department was to maintain the status quo. In doing so the regulation of the retail sale and supply and administering of prescription medicines would not operate, as it is intended to do so, in the Island.

[4] These sections of the Act provide the Department with powers of enforcement. For example, section 20 provides the Department with a power to inspect and take samples for the purpose of ascertaining whether there has been a contravention of the Act.

2. Specifically, the Department's medicines legislation in its current form does not prohibit:

   a) a person from selling by retail or supplying in circumstances corresponding to retail sale a prescription only medicine except in accordance with a prescription issued by an appropriate practitioner; or

   b) a person administering (otherwise than to himself) a prescription only medicine without being an appropriate practitioner or acting in accordance with the directions of an appropriate practitioner.

3. Maintaining the status quo has been discounted as a viable option by the Department. Regulating the retail sale and supply and administering of prescription only medicines is necessary to ensure the Island has in place sufficient safeguards to protect public health.

4. Potentially, failure to put in place sufficient controls carries a risk to public health for the following reasons:

   a) even if a prescription only medicine is used correctly, if it is done so without the proper medical supervision it increases (directly or indirectly) any danger associated with the product;

   b) there is potential for an increase in the frequency and the extent to which prescription only medicines are used incorrectly presenting a danger to health;

   c) adverse reactions to prescription only medicines may not receive the further investigation required;

   d) it is highly likely to increase the substantial risk of medicinal abuse, addiction or misuse for illegal purposes.

Option Two – Address the issues identified as a part of the wider amendments

required to the Department's medicines legislation

1. A Medicines (Amendment) Bill is on the Government's legislative programme. The aim of this Bill is to reform the Island's medicines legislation. In particular, consideration will be given to:

   a) the manufacture and distribution of medicinal products and active substances;

   b) dealings in medicinal products;

   c) the licensing of medicinal products;

   d) the regulation of homoeopathic and traditional herbal medicinal products;

   e) 'borderline' products;

   f) pharmacovigilance;

   g) the sale of medicines to the public at a distance;

   h) packaging and leafleting;

   i) advertising; and

   j) the conduct of retail pharmacies.

2. The amendments to the Department's medicines legislation regarding the retail sale and supply and administering of prescription only medicines could potentially have formed a part of the larger package of reforms required to the Medicines Act 2003.

3. Whilst the Department remains fully committed to updating the provisions of the Medicines Act 2003, the essential legislative work required in anticipation of the United Kingdom's withdrawal from the European Union, the legislative issues picked up by the Independent Health and Social Care Review Final Report by Sir Jonathan Michael and the emergency health and social care legislation required in response to the

coronavirus pandemic, have impacted upon the timetable of the delivery of this Bill.

4. The Department considered that the revisions required to the legislative provisions concerning the sale, supply and administering of prescription medicines were urgent, warranted immediate attention and must be brought forward without further delay.

Option Three – Address the issues identified as a matter of priority

1. The third option considered by the Department was to regularize the controls on the retail sale and supply and administering of prescription only medicines as an urgent priority.

2. Whilst there is some level of statutory control regarding the retail sale and supply of prescription medicines afforded by:
   a) the Island's misuse of drugs legislation, where that prescription medicine is also a controlled drug; and

   b) the Island's National Health Service legislation in that a pharmacist must provide pharmaceutical services in accordance with the terms of services set out in the National Health Service (Pharmaceutical Services) Regulations 2005,

   the omissions identified must be dealt with, for the reasons identified above, as a matter of urgency.

Link to Government Strategic Plan

The Programme for Government 2016 – 2021 includes two outcomes in the theme of 'A Healthy and Safe Island': one that "we live longer, healthier lives"; and the other that "we live our lives safe from crime and danger".

Link to Department Aims and Objectives

To protect vulnerable people, providing safeguards for people who cannot protect themselves.

Responsible Departmental Member

Ann Corlett, MHK.
Ministerial sign off I have read the Impact Assessment and I am satisfied that the balance between the benefit and any costs is the right one in the circumstances. Signed by the Minister Date:

SUMMARY: ANALYSIS AND EVIDENCE
IMPACT OF PROPOSAL
Resource Issues - Financial (including manpower)
Statement The Medicines (Amendment) Bill 2020 makes technical amendments to the Medicines Act 2003 to ensure that the regulation of the sale, supply and administering of prescription only medicines operates in the Island as it is intended to. It does not introduce new

Department policy.

Thus, the Medicines (Amendment) Bill 2020 will not result in any requirement for additional financing including manpower.

Likely Financial Costs

The amendments, for the reasons described above, will not result in any financial costs being incurred.

Likely Financial Benefits

n/a.

If the proposal introduces provisions that will require another Department, Board, Office or Body to take on additional work or responsibility please ensure that they have been consulted with early on in your considerations. Please provide a brief statement as to who they are and the consultation that has taken place.

The amendments to the Medicines Act 2003 will not place a requirement on any other Department, Board, Office or Body to take on additional work or responsibility.

Are there any costs or benefits that are not financial i.e. social

Regulating the retail sale, supply and administering of prescription only medicines is necessary to ensure the Island has in place sufficient safeguards to protect public health.

The omission from the Department's medicines legislation of sufficient controls and restrictions carries a high risk to public health for the following reasons:

a) even if the product is used correctly, if it is done so without the proper medical supervision it is likely to increase the danger associated with the use of the product either directly or indirectly;

b) it is likely to increase the frequency and the extent to which prescription medicines are used incorrectly and as a result present a danger to human health;

c) adverse reactions to prescription medicines may not receive the further

investigation required; and

d) it is highly likely to increase the substantial risk of medicinal abuse, addiction or misuse for illegal purposes.

Which Business sectors/organisations will be impacted, if any, and has any direct consultation taken place?

No sector or organisation of the Island's business community will be impacted by this Bill.

Does the proposal comply with privacy law? Please provide a brief statement as to any issue of privacy or security of personal information.

The amendments proposed by this Bill have no affect or impact on the privacy or security of personal information.

Has Treasury Concurrence been given for the preferred option

The preferred option does not carry cost implications. Thus the Department, in accordance with financial services regulations, has not sought Treasury's concurrence for the Bill to be submitted to the Council of Ministers for the introduction of the Bill into the Branches.

Key Assumptions / Sensitivities / Risks

To address the anomalies that have been identified regarding the existing legislative framework for the sale, supply and administration of prescription medicines the Department's intention is that the Bill be introduced into the Branches in June 2020.

Approximate date for legislation to be implemented if known

On the assumption that the Bill is introduced into the Branches in June 2020 and that it progresses the House of Keys and the Legislative Council as anticipated, the approximate date for the coming into operation of the Bill would be January 2021.

SUMMARY: CONSULTATION

Consultation in line with Government standard consultation process

Given the purpose of the Bill, what it achieves and that it does not introduce any new Departmental policy, no public consultation was undertaken.
Date n/a.
Summary of Responses: n/a.
EVIDENCE BASE • Medicines Act 2003; • Prescription Only Medicines (Human Use) Regulations 2005; • Medicines Act 1968 (of Parliament); • Prescription Only Medicines (Human Use) Order 1997, as amended (of Parliament); and • Human Medicines Regulations 2012 (of Parliament).