

Statutory Document No. 2005/0013



Medicines Act 2003

MEDICINES (PHARMACY AND GENERAL SALE - EXEMPTION) REGULATIONS 2005¹

Approved by Tynwald: 17 January 2006
Coming into Operation: 1 February 2006

In exercise of the powers conferred on the Department of Health and Social Security by sections 3 and 52 of the Medicines Act 2003¹ and of all other enabling powers the following Regulations are hereby made:-

1 Citation, commencement and interpretation

- (1) These Regulations may be cited as the Medicines (Pharmacy and General Sale - Exemption) Regulations 2005 and shall come into operation on 1st February 2006.

2 Application of UK exemption orders

The provisions of —

- (a) the Medicines (Pharmacy and General Sale List-Exemption) Order 1980²
- (b) the Orders amending that Order specified in Schedule 1; and,
- (c) any Order made after the making of these Regulations and amending the Orders specified in Schedule 1,

being orders made under the provisions of the Medicines Act 1968 (An Act of Parliament)³ corresponding to section 2 of the Medicines Act 2003, shall apply to the Island subject to the modifications specified in Schedule 2.

¹ 2003 c.4

² SI 1980/1924

³ 1968 c.67

3 Revocations

The Medicines (Pharmacy and General Sale - Exemption) Order 1996⁴ and the Medicines (Pharmacy and General Sale - Exemption) (Application) Order 1998⁵ are revoked.

MADE 9 DECEMBER 2005

⁴ SD 677/96

⁵ SD 112/98

SCHEDULE 1

ORDERS APPLIED TO THE ISLE OF MAN

[Regulation 2]

<i>Reference</i>	<i>Title</i>
SI 1982/27	Medicines (Pharmacy and General Sale List - Exemption) Amendment Order 1982
SI 1994/2409	Medicines (Pharmacy and General Sale List-Exemption) Amendment Order 1994
SI 1998/107	Medicines (Pharmacy and General Sale List-Exemption) Amendment Order 1998
SI 1998/2368	Medicines (Pharmacy and General Sale List-Exemption) Amendment (No.2) Order 1998
SI 2000/1919	Medicines (Pharmacy and General Sale List - Exemption) Amendment Order2000
SI 2003/697	Medicines (Pharmacy and General Sale List - Exemption) Amendment Order 2003
SI 2004/1	Medicines (Pharmacy and General Sale List - Exemption) Amendment Order2004
SI 2004/1190	Medicines (Pharmacy and General Sale List - Exemption) Amendment (No.2) Order 2004
SI 2005/766	Medicines (Pharmacy and General Sale List - Exemption) Amendment Order 2005

SCHEDULE 2

MODIFICATIONS SUBJECT TO WHICH THE ORDERS APPLY TO THE ISLAND

[Regulation 2]

PART 1 - GENERAL MODIFICATIONS

For any reference to a matter specified in column 1 of the following table substitute a reference to the corresponding matter specified in column 2 of the table:

the Medicines Act 1968 (an Act of Parliament)	the Medicines Act 2003
any provision of the said Act of 1968	the corresponding provision of the Medicines Act 2003
any order or regulations made under the said Act of 1968 (including the orders applied by this Order).	the corresponding order or regulations made under the Medicines Act 2003 or, as the case may be, the said order or regulations as they have effect in the Island.
the Misuse of Drugs Act 1971 (an Act of Parliament)	the Misuse of Drugs Act 1976 ⁶
any provisions of the said Act of 1971	the corresponding provision of the Misuse of Drugs Act 1976
any order or regulations made under the said Act of 1971	the corresponding order or regulations made under the Misuse of Drugs Act 1976 or, as the case may be, the said order or regulations as they have effect in the Island.

PART 2

SPECIFIC MODIFICATIONS OF SI 1980/1924

1. In article 1(2)(a) —
 - (a) omit the definition of “enrolled nurse”;
 - (b) for the definition of “offshore installation” (inserted by SI 1989/1852) substitute —

“offshore installation” means an offshore installation within the meaning of the Mineral Workings (Offshore Installations)(Isle of Man) Act 1974 (an Act of Tynwald)⁷ which is within tidal waters

⁶ 1976 c.21

⁷ 1974 c.23

and parts of the sea adjacent to the Isle of Man up to the seaward limit of territorial waters;²;

(c) in the definition of “health authority”, for paragraphs (i), (ii) and (iii) substitute **43** means the Department of Health and Social Security **44**;

(d) in the definition of “registered ophthalmic optician”, for “1958” substitute **45** 1989 **46**;

(da) at the appropriate place insert —

47 “coronavirus” means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

“health care professional” means —

(a) a health professional regulated by the Health Care Professionals Act 2014;

(b) a dentist;

(c) a registered dental care professional, as defined in section 11 of the Dental Act 1985; or

(d) a pharmacist;

“occupational health vaccinator” means a health care professional who is employed or engaged by a person operating an occupation health scheme who is —

(a) a nurse or a midwife;

(b) an operating department practitioner, a paramedic or a physiotherapist;

(c) a pharmacist;

“temporary authorisation” means an authorisation granted by the UK licensing authority on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc) of the Human Medicines Regulations 2012 (of Parliament)⁸;

“UK licensing authority” means either or both of the United Kingdom Secretary of State and the Minister for Health, Social Services and Public Safety responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under the Human Medicines Regulations 2012 (of Parliament); **48**.²

1B⁹ In article 4B(2)(f), after “supplied,” insert **49** a temporary authorisation, **50**.³

⁸ SI 2012/1916

⁹ Paragraphs 1B to 1F are inserted into Part 2 of Schedule 2 to the Medicines (Pharmacy and General Sale – Exemption) Regulations 2005 (SD 13/05) after paragraph 1. Paragraph 1A is inserted by SD 2019/0102, which has not yet come into operation.

1C In article 4C(2)(e) after “is sold or supplied,” insert **63** “a temporary authorisation, **62**.⁴

1D After article 5(3) insert —

63 (4) Entry 9A in the table in Part II of Schedule 1 will cease to have effect on 1 April 2022. **62**.⁵

1E In article 7A(b)(ii)(aa)¹⁰ for “symptoms of, and” substitute **63** how the medicinal product is to be used for the prevention of, or **62**.⁶

1F After article 8¹¹ insert —

63 8A Protocols relating to coronavirus and influenza vaccinations and immunisations

- (1) The restrictions imposed by sections 52 and 53 shall not apply to the supply or administration of a medicinal product —
- (a) for parenteral administration; and
 - (b) used for vaccination or immunisation against coronavirus or influenza virus (of any type),
- that meets the following conditions.
- (2) Condition A is that the supply is made, or the medicinal product is administered, while a disease (which may be neither coronavirus nor influenza) is, or in anticipation of a disease being imminently —
- (a) pandemic; and
 - (b) a serious risk or potentially serious risk to human health.
- (3) Condition B is that the supply or administration is in accordance with the requirements of a protocol that is approved by the Department.
- (4) Condition C is that the protocol specifies (amongst other matters) —
- (a) the classes of persons permitted to administer medicinal products under the protocol;
 - (b) the process by which a person of the specified class is designated, and by whom, as a person authorised to administer medicinal products under the protocol; and

¹⁰ Duplicate article 8 was added to SI 1980/1924 by SI 2009/1165 (possibly a drafting error). The reference in the inserted paragraphs 1E and 1F is to that duplicate article 8 (exemption for the supply of medicines in the event, or anticipation, of pandemic disease).

¹¹ See footnote 10.

- (c) requirements as to the recording of the name of a person who, on any particular occasion, administers a medicinal product under the protocol.
 - (5) Condition D is that when the medicine is supplied, there is in force in relation to it —
 - (a) a temporary authorisation;
 - (b) a Community authorisation; or
 - (c) a UK authorisation.
 - (6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol issued under this article has effect, the Department must —
 - (a) review the operation of this article with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this article;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report. ~~22~~.⁷
2. (1) In Part I of Schedule 1 —
- (a) in column 1 of head 5 —
 - (i) for paragraphs (1) and (2) substitute —
 - ~~22~~(1) a public analyst within the meaning of the Interpretation Act 1976 (an Act of Tynwald)¹²;
 - (2) an agricultural analyst appointed for the purposes of the Fertilisers and Feeding Stuffs Act 1975 (an Act of Tynwald)¹³; ~~22~~;
 - (ii) for paragraph (4) substitute —
 - ~~22~~(4) an authorised officer within the meaning of the Food Act 1996 (an Act of Tynwald)¹⁴; ~~22~~;
 - (b) omit heads 6 and 10.
 - (2) In Part II of Schedule 1, in column 1 of head 6, omit the words from “or regulation 5” to “1974”.
- 3 In Part II of Schedule 1, after item 9 insert —

22 9A. The Department operating an occupational health scheme and occupational health	9A. A prescription only medicine used for vaccination or immunisation against coronavirus or	9A The supply of the medicine is in the course of an occupational health scheme and the individual
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¹² 1976 c.20

¹³ 1975 c.31

¹⁴ 1996 c.8

vaccinators employed or engaged by it	influenza virus (of any type) sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or an occupational health scheme vaccinator	supplying the medicine is, if not a doctor, an occupational health scheme vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used. ⁸
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SPECIFIC MODIFICATIONS OF SI 2003/697

In article 2 —

- (1) for the definition of “nursing home” substitute —
 | ¹⁵ “nursing home” has the meaning given to it by section 1(1)(c) of the
 | Nursing and Residential Homes Act 1988¹⁵ ¹⁵;
- (2) for the definition of “prison service” substitute —
 | ¹⁶ “prison service” means the exercising of functions in relation to
 | prisoners by the Department of Home Affairs within the meaning
 | of the Custody Act 1995¹⁶ ¹⁶.

¹⁵ 1998 c.9

¹⁶ 1995 c.1

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.

² Para (da) inserted by SD2020/0469.

³ Para 1B inserted by SD2020/0469.

⁴ Para 1C inserted by SD2020/0469.

⁵ Para 1D inserted by SD2020/0469.

⁶ Para 1E inserted by SD2020/0469.

⁷ Para 1F inserted by SD2020/0469.

⁸ Para 3 inserted by SD2020/0469.