



THE MEDICINES ACT 2003
**THE PRESCRIPTION ONLY MEDICINES (HUMAN USE)
REGULATIONS 2005**

*Approved by Tynwald
Coming into operation*

*17th January 2006
1st February 2006*

In exercise of the powers conferred on the Department of Health and Social Security by sections 2 and 52 of the Medicines Act 2003¹, and of all other enabling powers, the following Regulations are hereby made: —

1. Citation and commencement

These Regulations may be cited as the Prescription Only Medicines (Human Use) Regulations 2005, and shall come into operation on the 1st February 2006.

2. Application of UK prescription-only orders

The provisions of —

- (a) the Prescription Only Medicines (Human Use) Order 1997²;
- (b) the orders amending that Order specified in Schedule 1; and,
- (c) any order made after the making of these Regulations and amending that Order,

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.

3. Revocations

The Prescription Only Medicines (Human Use) Order 1997⁴ is revoked.

¹ 2003 c.4

² SI 1997/1830

³ 1968 c.67

⁴ SD 486/97

SCHEDULE 1

AMENDING ORDERS APPLIED TO THE ISLE OF MAN

<i>Reference</i>	<i>Title</i>
SI 1997/2044	Prescription Only Medicines (Human Use) Amendment (No.2) Order 1997
SI 1998/108	Prescription Only Medicines (Human Use) Amendment Order 1998
SI 1998/1178	Prescription Only Medicines (Human Use) Amendment (No.2) Order 1998
SI 1998/2081	Prescription Only Medicines (Human Use) Amendment (No.3) Order 1998
SI 1999/1044	Prescription Only Medicines (Human Use) Amendment Order 1999
SI 1999/3463	Prescription Only Medicines (Human Use) Amendment (No.2) Order 1999
SI 2000/1917	Prescription Only Medicines (Human Use) (Amendment) Order 2000
SI 2000/2899	Prescription Only Medicines (Human Use) Amendment (No.2) Order 2000
SI 2000/3231	Prescription Only Medicines (Human Use) Amendment (No.3) Order 2000
SI 2001/2777	Prescription Only Medicines (Human Use) Amendment Order 2001
SI 2001/2889	Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001
SI 2001/3942	Prescription Only Medicines (Human Use) Amendment (No.2) Order 2001
SI 2002/549	Prescription Only Medicines (Human Use) (Amendment) Order 2002
SI 2003/696	Prescription Only Medicines (Human Use) (Amendment) Order 2003
SI 2003/2915	Prescription Only Medicines (Human Use) (Amendment) (No.2) Order 2003
SI 2004/2	Prescription Only Medicines (Human Use) (Amendment) Order 2004
SI 2004/1189	Prescription Only Medicines (Human Use) (Amendment) (No.2) Order 2004
SI 2004/2693	Prescription Only Medicines (Human Use) Amendment (No.3) Order 2004
SI 2005/765	The Medicines for Human Use (Prescribing) Order 2005

Regulation 2

SCHEDULE 2
MODIFICATIONS SUBJECT TO WHICH THE ORDERS APPLY
TO THE ISLAND

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 that 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 in 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
any provision of the said Act of 1971	the corresponding provisions 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.
the National Health Service Act 1977	the National Health Service Act 2001
any provisions of the said Act of 1977	the corresponding provisions of the National Health Service Act 2001

PART 2
SPECIFIC MODIFICATIONS OF SI 1997/1830

1. In article 1(2) –
 - (a) for the definition of “health prescription” substitute –

““health prescription” means a prescription issued by a prescriber under or by virtue of the National Health Service Act 2001;”
 - (b) in the definition of “the Misuse of Drugs Regulations”, omit “, in relation to England, Wales and Scotland,” and the words from “and in relation” onwards;
 - (c) for the definition of “offshore installation” 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)⁵ which is within tidal waters and parts of the sea adjacent to the Isle of Man up to the seaward limits of territorial waters;”.
2. In Part 1 of Schedule 5 –
 - (a) in column 1 for entry 2 substitute –

“2. Persons selling or supplying prescription only medicines to any of the following –

 - (1) a public analyst as defined by section 3 of the Interpretation Act 1976 (an Act of Tynwald)⁶;
 - (2) an authorised officer within the meaning of the Food Act 1996 (an Act of Tynwald)⁷;
 - (3) a person duly authorised by the Department under Part 4 of the Act;
 - (4) a sampling officer within the meaning of Schedule 1 of the Act.”
 - (b) omit entries 3 and 7.

SPECIFIC MODIFICATIONS OF SI 2001/2889

1. In article 2(d) –
 - (a) for the definition of “electronic communication” substitute –

““electronic communication” has the meaning given by section 12 of the Electronic Transactions Act 2000⁸”;
 - (b) for the definition of “electronic signature” substitute –

““electronic signature” has the meaning given by section 5 of the Electronic Transactions Act 2000”.

⁵ 1964 c.33

⁶ 1976 c.20

⁷ 1996 c.8

⁸ 2000 c.8

SPECIFIC MODIFICATIONS OF SI 2003/696

1. In article 2(2) –

(a) for the definition of “health record” substitute –

““health record” has the meaning given by section 62 of the Data Protection Act 2002⁹”;

for the definition of “nursing home” substitute –

““nursing home” has the meaning given by section 1(1)(c) of the Nursing and Residential Homes Act 1988¹⁰”;

(b) for the definition of “prison service” substitute –

““prison service” means the exercising of functions in relation to prisoners by the Department of Home Affairs within the meaning of the Custody Act 1995¹¹”.

MADE 9th December 2005

Aune Crane

Member for Health

⁹ 2002 c.2

¹⁰ 1988 c.9

¹¹ 1995 c.1

EXPLANATORY NOTE
(This note is not part of the Regulations)

These Regulations apply to the Isle of Man the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830) as amended.

That Order specifies the descriptions and classes of prescription only medicines (i.e. medicinal products which, subject to exemptions, may be sold or supplied by retail only in accordance with a prescription given by an authorised prescriber and may only be administered according to the directions of the prescriber).

Many medicinal products are included in a class of such medicines by reason of the substances contained within them, but others are included because of other criteria, such as their method of administration. In many cases the provisions of the Act apply subject to exemptions.

The amendment made by SI 2000/1917 introduces "Patient Group Directions" (i.e. a written direction providing for the supply and administration, or administration, of a description or class of prescription only medicine to patients generally), where certain conditions are satisfied (Schedule 7 of the SI).

The application of SI 2000/3231 allows the supply of a medicinal product containing levonorgestrel by pharmacists in the form of Emergency Hormonal Contraception to women over the age of 16 years.

SI 2001/2889 applied by these Regulations permits NHS prescriptions to be created, signed and transferred by electronic means, provided certain conditions are met.

The definition of an independent nurse prescriber is introduced by SI 2002/549, which allows suitable qualified nurses to prescribe specified medicinal products.

SI 2003/696 extends the use of Patient Group Directions to organisations which operate outside the National Health Service and also makes provision for nurses and pharmacists to be supplementary prescribers who are able to prescribe medicinal products in the Regulations in accordance with Clinical Management Plans.

SI 2005/765 extends the definition of supplementary prescriber to include podiatrists, physiotherapists and radiographers. It also extends electronic prescribing arrangements to medicines controlled under the Misuse of Drugs Act. The list of medicines which can be prescribed by optometrists and nurse prescribers is also extended.

