

To the Hon. Noel Q. Cringle, President of Tynwald, and
the Hon Council and Keys in Tynwald assembled

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

The Prescription Only Medicines (Human Use)
Regulations 2005

Explanatory Memorandum

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1. Title of measure

The Prescription Only Medicines (Human Use) Regulations 2005.

2. Changes in policy

These Regulations, which are made under section 2 of the Medicines Act 2003, revise and restate legislation made under the Medicines Act 1976.

However, the opportunity has been taken to apply additional regulations in the same series making the following changes:-

- Introducing "Patient Group Directions" (i.e. a written direction providing for the supply and administration, or administration, of certain prescription only medicines to specified types of patients without the requirement for a prescription and in the absence of a prescriber);
- Allowing the supply of medicines containing levonorgestrel, by pharmacists, to allow them to provide Emergency Hormonal Contraception, to women over the age of 16 years;
- Allowing prescriptions to be created, signed and transferred by electronic means, provided certain conditions are met;
- Introducing the definition of an independent nurse prescriber which allows suitably qualified nurses to prescribe specified medicinal products;
- Making provision for nurses and pharmacists to be supplementary prescribers who are able to prescribe medicinal products in accordance with Clinical Management Plans.

3. Effects of the measure

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

The Regulations specify 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.

4. Reasons for the measure

The Medicines Act 1976 was revised and updated by the Medicines Act 2003. These Regulations, made under section 2 of the 2003 Act, will revise and update the associated subordinate legislation and will introduce the new policies described above.

5. Financial implications

There are no financial implications associated with these Regulations.