EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (ADMINISTRATION AND SALE OR SUPPLY) (MISCELLANEOUS AMENDMENTS) ORDER 2007

2007 No. 2178

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) part of the Department of Health and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1. This Order amends the Prescription Only Medicines (Human Use) Order 1997 and the Medicines (Pharmacy and General Sale – Exemption) Order 1980. It extends the exemption for prescription only medicines (POMs) to include sale in accordance with a Patient Group Direction (PGD) in independent hospitals, clinics and agencies. The Order also extends the use of PGDs in the private sector in Northern Ireland.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None.

4. **Legislative Background**

4.1 This Order amends two Orders relating to the administration and sale and supply of medicines –

- the Prescription Only Medicines (Human Use) Order 1997 (the POM Order) which specifies the description and classes of medicines, which, subject to exemptions in the Order may only be sold or supplied in accordance with the prescription of an appropriate practitioner and may be administered only in accordance with the directions of such a practitioner (see section 58(2) of the Medicines Act 1968);
- the Medicines (Pharmacy and General Sale – Exemption) Order 1980 which provides exemptions from the restrictions on sale and supply of medicines under sections 52 and 53 of the Medicines Act 1968. In particular, it provides exemptions from the requirement that POMs and medicines classed as pharmacy ("P") medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist.

Sale of Medicines under a PGD

4.2 Under existing exemptions contained in the Orders, specified groups of health professional can supply or administer medicines under PGDs. A PGD is a written instruction for the supply or administration of POMs to persons generally. PGDs were initially confined to the NHS but their use was extended to specified non-NHS healthcare settings including independent hospitals, clinics and medical agencies by the Prescription Only Medicines (Human Use) Amendment Order 2003. The amending Order will allow medicines to be sold under a PGD in these settings.

PGDs in Northern Ireland

4.3 The amending Order will extend the use of PGDs in the independent healthcare sector in Northern Ireland to independent hospitals, clinics and medical agencies. Until now the use of PGDs in the private sector in Northern Ireland has been restricted to nursing homes.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. **European Convention on Human Rights**

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. **Policy Background**

7.1 It was intended to allow medicines to be sold, as well as supplied and administered, under PGDs when their use was extended to the private sector in 2003. Due to a drafting error, changes made to legislation at the time did not explicitly permit the sale of medicines. The amending Order corrects this error and fulfils the original intention of the proposals.

7.2 The expansion of PGDs to independent healthcare settings was also intended to apply equally across the UK. In Northern Ireland, however, the use of PGDs in the private sector was originally confined to nursing homes because the necessary legislation regulating a wider range of providers was not in place. Subsequent legislative changes in Northern Ireland (the Health and Personal Social Services (Quality, Improvement and Regulation) Northern Ireland Order 2003) now make provision for registration of independent hospitals, clinics and medicinal agencies. This has provided the opportunity to enable the sale, supply and/or administration of medicines under PGDs in independent hospitals, clinics and agencies in Northern Ireland on the same basis as the rest of the UK.

7.3 The proposals were subject to public consultation and were generally supported. For example, 28 replies were received in response to the proposals for extending PGDs in Northern Ireland. The majority (20) were supportive.

7.4 The amending Order, together with a related SI, (the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2007) (the amending regulations) are being laid in the parliamentary recess. The amending Regulations contain a provision which relates to changes being made by Home Office legislation, the Misuse of Drugs (Amendment) Regulations 2007. The changes arise from the Shipman Inquiry.

7.5 The amending Regulations also make changes which are related to those in this amending Order. Therefore, the amending Order is being made now to avoid two sets of amendments to the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within a short period of time. The changes in both the Regulations and the amending Order are considered to be relatively minor and uncontroversial.

8. **Impact**

8.1 Regulatory Impact Assessments have not been prepared for these proposals because they do not impose a cost compliance on business, charities or voluntary bodies.

8.2 There is no specific impact on the public sector but the proposals relating to Northern Ireland ensure consistency throughout the UK.

9. **Contact**

9.1 Anne Ryan at the MHRA tel: 0207 084 2392 can answer any queries regarding the instrument.