EXPLANATORY MEMORANDUM TO

THE MEDICINES (SALE OR SUPPLY) (MISCELLANEOUS PROVISIONS) AMENDMENT REGULATIONS 2007

2007 No. 2179

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. These Regulations amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (the Sale or Supply Regulations). They extend the list of persons who may be sold prescription only medicines (POMs) or pharmacy medicines by wholesale to specified independent healthcare providers in Northern Ireland. The amending Regulations also remove the requirement for pharmacists to retain private prescriptions for prescription only medicines listed as controlled drugs in Schedules 1, 2 and 3 of the Misuse of Drugs Regulations 2001.

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

3.1 None.

4. **Legislative Background**

4.1 The Sale or Supply Regulations impose various restrictions on the sale and supply of medicinal products; in particular on the classes of person who can be sold POMs or pharmacy medicines on a wholesale basis. The amending Regulations will allow sale by wholesale of medicinal products to registered independent hospitals, clinics and medical agencies in Northern Ireland...

4.2 The Sale or Supply Regulations also contain provisions relating to the keeping of records by pharmacists. These include a requirement for pharmacists to keep originals of all private prescriptions for POMs for two years after dispensing. The amending Regulations will remove this requirement for POMs listed as controlled drugs in Schedules 1, 2 and 3 of the Misuse of Drugs Regulations 2001.

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 A related SI, the Medicines for Human Use (Administration and Sale or Supply) Miscellaneous Amendments Order 2007 (the amending Order) will extend the use of patient group directions (PGDs) to independent hospitals, clinics and agencies in Northern Ireland. The amending Regulations allow these establishments to be sold medicines by wholesale on the same basis as the rest of the UK.

7.2 The amending Regulations also allow nursing homes in Northern Ireland to be sold medicines by wholesale. The provisions permitting sale by wholesale were extended to specified private sector healthcare providers by the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2003 Due to a drafting error, nursing homes were not included in the amendments to the Sale or Supply Regulations. The amending Regulations correct this error and fulfil the original intention of the proposals.

7.3 The amendments to the record-keeping requirements for pharmacists arise from changes to the Misuse of Drugs Regulations 2001 which are being taken forward by the Home Office as a result of the Shipman Inquiry. This includes a requirement for pharmacists to send original private prescription forms for Schedules 1, 2 and 3 controlled drugs to the appropriate NHS reimbursement agency. Without any corresponding amendment to the Sale or Supply Regulations, pharmacists would still need to retain originals of these prescriptions in the pharmacy. It would not, therefore, be possible to comply with both sets of legislation. This is an unnecessary administrative burden.

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

7.5 The amending Regulations, together with the amending Order (paragraph 7.1 above refers) are being laid in the parliamentary recess. This is to correspond with the Home Office legislation, the Misuse of Drugs (Amendment) Regulations 2007.

7.6 The amending Order makes changes which are related to these Regulations. Therefore, it is being made now to avoid two sets of amendments to the Sale or Supply Regulations 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.