EXPLANATORY MEMORANDUM TO THE THE MEDICINES FOR HUMAN USE (MARKETING AUTHORISATIONS ETC.) AMENDMENT REGULATIONS 2005

2005 No. 768

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 for Human Use (Marketing Authorisations Etc.) Regulations 1994 to allow the supply of an unlicensed medicinal product under supplementary prescribing arrangements.

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

3.1 None.

4. **Legislative Background**

4.1 These Regulations amend the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 ("the principal Regulations") which, amongst other matters, implement European Community provisions relating to marketing authorisations for medicinal products. In particular, the principal Regulations require all medicinal products which are placed on the market to hold a marketing authorisation granted by the MHRA. There are exemptions from this requirement for medicinal products supplied in response to a bona fide unsolicited order formulated in accordance with the specification of a doctor or dentist for use of their individual patients.

4.2 Supplementary prescribing is an arrangement whereby after a diagnosis by a doctor or dentist (the independent prescriber), the supplementary prescriber can prescribe medicines as part of a Clinical Management Plan agreed with the independent prescriber for an individual patient. Currently, only registered nurses, midwives and pharmacists can act as supplementary prescribers. However, legislation which is due to be implemented at the same time as these amending Regulations will extend the definition of supplementary prescriber to include podiatrists, physiotherapists and radiographers.

4.3 The amending Regulations will permit the supply of an unlicensed medicine in response to an order by a supplementary prescriber on the same lines as the existing arrangements for doctors and dentists.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. **European Convention on Human Rights**

6.1 Not applicable.

7. **Policy Background**

7.1 The proposals recognised that supplementary prescribing would not work to best effect if unlicensed medicines were excluded from the arrangements. This was particularly the case in certain specialised areas such as paediatrics or where parenteral nutrition formed part of a patient's care.

7.2 The proposed amendments were subject to public consultation and advice to Ministers by the Committee on Safety of Medicines. An analysis of the outcome of the public consultation has been published on the MHRA website: www.mhra.gov.uk However, the vast majority of responses (154 out of 157) supported the proposals in principle.

8. **Impact**

8.1 A Regulatory Impact Assessment for the proposals is attached.

8.2 The impact on the public health sector is principally to benefit patient care.

9. **Contact**

9.2 Anne Ryan at the MHRA tel: 0207 084 2392 or e-mail: anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.