EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (PRESCRIBING BY EEA PRACTITIONERS) REGULATIONS 2008

2008 No. 1692

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 provide that subject to the fulfilment of certain conditions, doctors and dentists who give a prescription for a medicinal product (other than one which is a controlled drug) in an EEA State other than the UK or in Switzerland are appropriate practitioners within the meaning of section 58(2) (a) of the Medicines Act 1968 ("the Act"). The effect of this is to enable the sale or supply in circumstances corresponding to retail sale, of such a medicinal product in accordance with a prescription given by such a doctor or dentist, provided the conditions in relation to the prescription are complied with.

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

3.1 None.

4. Legislative Background

4.1 Pursuant to section 58 of the Medicines Act 1968 and the Prescription Only Medicines (Human Use) Order 1997 (the POM Order), a UK pharmacist is prohibited from supplying a prescription only medicine against a prescription that has not been issued by an "appropriate practitioner". An appropriate practitioner for the purposes of section 58 of the Medicines Act 1968 will usually be a doctor, but dentists, veterinary surgeons and practitioners and some nurses and pharmacists are also appropriate practitioners able to issue prescriptions which may be honoured by a UK pharmacist. In order to be an appropriate practitioner the relevant health professional must be on a specified register within the UK.

4.2 By reason of these definitions a medicinal product within the meaning of these Regulations is one which is specified in article 3 of the POM Order 1997, other than those that are products or substances for the time being specified in Schedule 2 of the Misuse of Drugs Act 1971, known as "controlled drugs".

5. **Territorial Extent and Application**

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy

7.1 In March 2007 the Commission issued a Reasoned Opinion (infraction 2002/4199) arguing that the UK's statutory provisions (paragraph 4.1) were contrary to the freedom to provide services under Article 49 EC. The UK has responded to this Reasoned Opinion to the effect that it will amend section 58 of the Medicines Act to ensure that prescriptions issued to a patient in an EEA State, other than the UK, or in Switzerland by doctors and dentists can be recognised in the UK without the need for registration provided that the practitioner is lawfully established in a medical or dental practice in that EEA State.

7.2 The MHRA consulted on the proposals in October 2007. Responses varied in the level of support for the changes but all welcomed the undertaking that pharmacists would not be compelled to dispense prescriptions issued by doctors and dentists in an EEA State, other than the UK, or in Switzerland and would instead make a case by case decision based on their professional judgment. Respondees also raised questions as to whether certain other provisions of existing medicines legislation should apply. In the light of the responses the policy decision has been taken to also impose conditions with which a prescription must comply in order for it to be lawfully dispensed and to provide a due diligence type defence for pharmacists who in good faith dispense against a prescription which is not given by an EEA doctor or dentist.

7.3 The legislative changes will not change the restrictions against the supply of unauthorised medicines in the Medicines for Human Use (Marketing Authorisation etc) Regulations 1994, nor will they apply to any products or substances for the time being specified in Parts I – III of the Misuse of Drugs Act 1971.

7.4 The Commission on Human Medicines (CHM) have been consulted on and have noted the final proposals to amend legislation to make it clear that pharmacists will be able to dispense prescriptions written by a doctor or dentist that lawfully practises medicine or dentistry in another Member State or Switzerland; to enable similar arrangements to be put in place if nurses, midwives and pharmacists are in the future enabled to write prescriptions by their Member State; to provide protection for individual pharmacists against another's default or forgery - subject to the due diligence requirement existing in medicines legislation - and to enable pharmacists to supply a prescription only medicine in an emergency where that drug has been previously prescribed by a doctor that lawfully practises medicine in another Member State or Switzerland.

8. Impact

An Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies.

9. **Contact**

Anne Thyer at the MHRA (tel: 020 7084 2642, or e-mail: anne.thyer@mhra.gsi.gov.uk) can answer any queries regarding the instrument.