EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (PRESCRIBING BY EEA PRACTITIONERS) (AMENDMENT) (No. 2) REGULATIONS 2010

2010 No. 2785

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. Purpose of the Instrument

2.1 These Regulations amend the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 ("the 2008 Regulations") to allow prescriptions for Schedule 4 and 5 controlled drugs written by EEA and Swiss practitioners to be valid for dispensing in the United Kingdom.

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

3.1 None.

4. Legislative Context

4.1 Until the implementation of the 2008 Regulations, UK pharmacists could dispense a prescription only medicine (POM) only if the doctor or dentist writing the prescription was registered in the UK. The effect of the pre-2008 provisions was that a UK pharmacist could not supply a POM against a prescription written in another Member State or Switzerland by a non-UK registered practitioner (an EEA prescription) even if the pharmacist knew the prescription was genuine and there were no public health concerns.

4.2 Against this background, the European Commission asserted that the provisions of the relevant UK legislation were contrary to the principle of the freedom to provide services enshrined in Article 49 of the EC Treaty (now article 56 of the Treaty on the Functioning of the European Union). In reaching that view, the Commission made it clear that it did not consider that UK pharmacists must always dispense against a prescription written by a doctor or dentist practising in another Member State. The Commission accepted that pharmacists were free to exercise their professional judgement, for the purposes of ensuring patient and public health and safety when deciding whether or not it was safe to supply a POM.

4.3 The 2008 Regulations came into force in November 2008 and, subject to certain conditions being met, they made provision for prescriptions from EEA Member States and Switzerland to be dispensed by pharmacists in the UK. The Regulations exclude all EEA prescriptions for controlled drugs.

5. Territorial Extent and Application

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 procedures and does not amend primary legislation, no statement is required.

7. Policy Background

7.1 In an Additional Reasoned Opinion of November 2009, the Commission have asserted that in order to maintain the restriction on dispensing of EEA prescriptions for controlled drugs the UK should clarify which medicines should be "subject to special medical prescription" (SSMP) requirements. The UK and the Commission agree that Schedule 1 to 3 controlled drugs could come within the SSMP requirements.

7.2 The Commission maintain that a continued refusal to recognise EEA prescriptions which are not subject to the SSMP requirements is contrary to the principle of freedom to provide services enshrined in Article 56 of the Treaty on the Functioning of the European Union. The Commission maintain that the practice is restrictive, unjustified and disproportionate.

7.3 In considering the changes required by the Commission, the UK took account of recommendations from the Advisory Council on the Misuse of Drugs (ACMD) (the Government's statutory advisory body on the risk of diversion or misuse of drugs) that Schedule 4 and 5 controlled drugs should not be designated as SSMP. In view of these recommendations, the UK has decided to make provision for prescriptions for Schedule 4 and 5 controlled drugs written by EEA registered practitioners to be dispensed by UK pharmacists. A related change has also been made to the regulation on the emergency sale or supply of such drugs to an EEA or Swiss national.

This change has no practical effect on how controlled drugs are regulated and the dispensing of such controlled drugs will continue to be subject to the professional judgement of the pharmacist.

8. Consultation Outcome

8.1 The 2008 Regulations are being amended in order to ensure that UK domestic legislation is compliant with its obligations under European law. A four week consultation was undertaken to notify interested parties, primarily pharmacies, their regulatory bodies and professional organisations of the forthcoming changes to the 2008 Regulations and to seek views on how existing guidance could be further developed to support pharmacists in their professional practice to implement the new requirements.

8.2 There were five replies to the consultation. Several made suggestions on how the current guidance could be developed.

9. Guidance

9.1 The Royal Pharmaceutical Society and the Pharmaceutical Society of Northern Ireland, who are the relevant regulatory bodies, will put further guidance into place to assist community pharmacists in exercising their professional judgement when the revised arrangements are implemented.

10. Impact

10.1 An impact assessment has not been prepared for these proposals as they do not impose a significant cost compliance on business, charities or the voluntary sectors.

10.2 The impact on the public sector is principally to benefit patient care by enabling EEA/Swiss nationals to have their EEA prescriptions dispensed in the UK.

11. Regulating Small Business

11.1 There are no adverse implications for small business.

12. Monitoring and Review

12.1 The changes in this instrument are aimed at benefiting patient care. In line with the Better Regulation Agenda, the instrument will be reviewed in three years time to assess whether it is still fit for purpose.

13. Contact

13.1 Anne Ryan at the MHRA (tel 0203 080 6392, e-mail anne.ryan@mhra.gsi.gov.uk) can answer any queries regarding the instrument.