EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (PRESCRIBING BY EEA PRACTITIONERS) (AMENDMENT) REGULATIONS 2010

2010 No. 1673

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 This Order amends the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 (the 2008 regulations) to remove the statutory requirement for certain information to be provided on a prescription written by an EEA or Swiss doctor or dentist for it to be valid for dispensing within the United Kingdom (UK).

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

3.1 None.

4. Legislative Context

4.1 Prior to the 2008 Regulations being implemented, UK pharmacists could only dispense a prescription only medicine (POM) if the prescription was written by a doctor or dentist who was registered in the UK. The effect of the pre-2008 Regulations was therefore 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 they knew that the prescription was genuine and there were no public health concerns.

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 56 of the Treaty on the Functioning of the European Union (previously Article 49 of the Treaty establishing the European Community). In reaching that view the Commission made 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 and instead took the view that pharmacists could exercise professional judgement, for the purposes of ensuring patient and public health and safety, when deciding whether or not it is safe to supply a POM.

4.2 The 2008 Regulations came into force in November 2008. The information requirements for an EEA prescription to be valid for dispensing in the UK were the same as those relating to UK prescriptions and required the patient's name, address and age, if under 12 years, to be provided.

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 In a further Reasoned Opinion, the Commission have asserted that the the statutory requirements contained in the 2008 Regulations (relating to address and age (if under 12 years old)) are contrary to the principle of the freedom to provide services enshrined in Article 56 of the Treaty for the Functioning of the European Union (TFEU). The Commission maintain that these UK requirements are restrictive, unjustified and disproportionate for the purpose of maintaining public health and safety.

7.2 In considering the legislative changes required by the Commission, the UK was mindful of the need to maintain robust systems for ensuring patient safety. At the same time, the UK recognised that the requirement for the age (if under 12 years old) and address of the patient to be provided on a prescription, as required under the 2008 Regulations, may have the effect that some prescriptions from Member States/Switzerland where these details are not required may never be accepted by a UK pharmacist because they do not contain the requisite information and in that sense the UK legislation may be discriminatory and disproportionate.

7.3 The current legislative arrangements, which provide the pharmacist with an age (if the prescription is for a patient aged under 12) and an address, allows the pharmacist to check the dose prescribed, to detect prescribing errors and to ensure that the medicine is dispensed to the correct patient. This is a particular problem where a number of patients have the same or similar sounding name and may be a source of dispensing error. The Commission do not object to these requirements in principle but regard their statutory inclusion for an EEA prescription to be valid for dispensing in the UK to be unjustified and disproportionate. Instead the Commission are of the view that these enquiries can be made by the pharmacist when an EEA prescription is presented to them, through the patient presenting official documentation, such as a passport. If there is any doubt the pharmacists may refuse to dispense a prescription for example, where they cannot verify the authenticity of the prescription or, where in their professional judgment, it would not be safe to do so.

7.4. The UK therefore decided to accept the Commission's Reasoned Opinion and amend the 2008 Regulations to remove the requirement for the age (if under 12 years of age) and address information to be provided on an EEA prescription for it to be valid for dispensing within the UK.

8. Consultation outcome

8.1 As the 2008 Regulations are being amended as a result of the UK's acceptance of the Commission's view that certain requirements were contrary to the principle of the freedom to provide services enshrined in Article 56 of the TFEU, a public consultation on the proposals was not appropriate. Instead a 4-week consultation was undertaken to notify interested parties, primarily pharmacists, their regulatory bodies and professional organisations, of the

forthcoming changes to the 2008 Regulations. This shortened consultation period was required to meet the Commission's deadline for the UK to indicate compliance with its Opinion. The opportunity was also taken to seek views on how existing guidance could be further developed to support pharmacists in their professional practice to implement the new requirements, especially in Northern Ireland with its land border with another Member State.

8.2 There were thirteen (13) replies to the consultation. Several made detailed suggestions on how current guidance could be developed and those suggestions have been made available to the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland.

9. Guidance

9.1 The Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland, who are the relevant regulatory bodies, will put further guidance in place to assist community pharmacists in exercising their professional judgement in the exercise of their pharmacy practice following the implementation of these changes.

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 sector.

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