EXPLANATORY MEMORANDUM TO

THE MEDICINES (TRADITIONAL HERBAL MEDICINAL PRODUCTS FOR HUMAN USE) (CONSEQUENTIAL AMENDMENT) REGULATIONS

2006 No. 395

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health, and is laid before Parliament by Command of Her Majesty.

   This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument amends the Medicines (Retail Sale or Supply of Herbal remedies) Order 1977 (S.I. 1977/2130) ("the 1977 Order"). The instrument corrects an error in an amendment to that Order made by the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750) ("the 2005 Regulations").

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

3.1 This instrument corrects an error in the 2005 Regulations and is therefore being issued free of charge to all known recipients of that instrument.

4. Legislative Background

4.1 The 2005 Regulations implement Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. The 2005 Regulations made a number of consequential amendments, including the insertion in the 1977 Order of article 1A, so as to provide that the Order does not apply to medicinal products to which the 2005 Regulations apply. The amendment came into force on 30 October 2005.

4.2 Another article 1A of the 1977 Order was however also inserted, as of the same day, by the Veterinary Medicines Regulations 2005 (S.I. 2005/2745). This instrument renumbers article 1A of the Order, as inserted by the 2005 Regulations, as article 1B, in order to correct the error.

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 The retail sale or supply of herbal remedies is subject to restrictions contained in the 1977 Regulations. The 2005 Regulations provide for a new scheme under which traditional herbal medicinal products may not be placed on the UK market unless they a "traditional herbal registration", as required by Directive 2004/24/EC. Some such products would, before 30 October 2005, have been subject to the 1977 Regulations. The article renumbered by this instrument was inserted into the 1977 Regulations so as to avoid overlapping and inconsistent requirements applying to the same products.

8. Impact

8.1 A Regulatory Impact Assessment is not required.

9. Contact

9.1 Judith Thompson at the Medicines and Healthcare products Regulatory Agency (tel: 020 7084 2945; or e mail: Judith.m.thompson@mhra.gsi.gov.uk) can answer queries regarding the instrument.