STATUTORY INSTRUMENTS

# 1994 No. 3144

# The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

**Control of retail sale of supply of relevant medicinal products**

**8.**—(1) Paragraphs (2) or (3) applies where a Community marketing authorization for a relevant medicinal product is subject to any condition or restriction which attaches to the authorization under Article 9.3(b) of Council Regulation (EEC) No. 2309/93.

(2) If the condition or restriction is to the effect that the product is to be sold or supplied only in accordance with a prescription given by a person who, in relation to the product, is an appropriate practitioner for the purposes of section 58 of the Act, the appropriate Ministers shall, subject to Article 3.4 of Council Directive 92/26/EEC (power to waive the application of the other provisions of that Article), give effect to the condition or restriction—

(a) by exercising their powers under section 58 or 60 of the Act; or

(b) where it appears to them that such an exercise would not be immediately practicable, by means of a written direction addressed to the holder of the authorization.

(3) If the condition or restriction is not to that effect, the appropriate Ministers shall give effect to it—

(a) by the exercise of any other statutory power available to them for that purpose; or

(b) if there is no such power, by means of a written direction addressed to the holder of the authorization.

(4) Except as provided by paragraph (2), the appropriate Ministers shall not exercise their powers under section 58(1) or, subject to paragraph (5), section 60 of the Act in relation to any relevant medicinal product for which a Community marketing authorization has been granted.

(5) Paragraph (4) does not prevent the appropriate Ministers from exercising their powers under section 60 of the Act for the purposes mentioned in subsection (2) of that section.