STATUTORY INSTRUMENTS

1999 No. 4

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1999

Amendment of regulation 2(1) of the principal Regulations

2. Paragraph (1) of regulation 2 of the principal Regulations (interpretation) shall be amended as follows–

(a) after the definition of "the Act" there shall be inserted the following definition–

> ""the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**1**);";

(b) after the definition of "clinical trial certificate of right" and "animal test certificate of right" there shall be inserted the following definition–

> ""exempt imported product" means a medicinal product as defined in article 1(2) of Council Directive 65/65/EEC(**2**) to which paragraph 1 of Schedule 1 to the 1994 Regulations applies, which was not manufactured in the United Kingdom and in relation to which no marketing authorisation has been granted;"; and

(c) after the definition of "licence holder" and "certificate holder" there shall be inserted the following definition–

> ""marketing authorisation" means
>
> (a) a United Kingdom marketing authorisation granted by the licensing authority under the 1994 Regulations; or
>
> (b) a Community marketing authorisation granted by the European Commission under Council Regulation (EEC) No. 2309/93(**3**); or
>
> (c) a product licence which has effect as a United Kingdom marketing authorisation in accordance with paragraph 1 of Schedule 6 to the 1994 Regulations;".

(**1**) S.I. 1994/3144; there are no amendments affecting the definition.
(**2**) OJ No. 22, 9.2.65, p. 369; there are no amendments affecting the definition.
(**3**) OJ No. L214, 24.8.93, p. 1.