STATUTORY INSTRUMENTS

1992 No. 3274

The Medicines (Leaflets) Amendment Regulations 1992

Amendment of regulation 5 of the principal Regulations

6.—(1) In paragraph (1) of regulation 5 of the principal Regulations (approval of contents of leaflets), after the words "a proprietary medicinal product" there shall be inserted the words "other than a relevant medicinal product".

(2) After paragraph (2) of regulation 5 of the principal Regulations (approval of contents of leaflets) there shall be inserted the following paragraph—

> "(2A) Where the holder of a product licence for a relevant medicinal product proposes to alter the leaflet relating to it in any respect as to which regulation 4 of these regulations imposes a requirement (not being an alteration made in connection with the grant or variation of a product licence) he shall notify the licensing authority in writing of such proposed alteration, and, unless the licensing authority has earlier notified him that it does not approve the altered leaflet, he may after the expiry of a period of 90 days from the date of the notification by him, supply that altered leaflet, or cause it to be supplied, with that product."