STATUTORY INSTRUMENTS

1996 No. 683

The Medicines (Products for Human Use —Fees) Amendment Regulations 1996

Amendment of regulation 2 of the principal Regulations

2. In regulation 2(1) (interpretation) of the principal Regulations, for the definition of change of ownership application substitute—

""change of ownership application" means an application—

- (a) for—
 - (i) a marketing authorization for a medicinal product in respect of which another person holds a marketing authorization;
 - (ii) a manufacturer's licence for activities in respect of which another person holds a manufacturer's licence; or
 - (iii) a wholesale dealer's licence for activities in respect of which another person holds a wholesale dealer's licence;
- (b) which refers to particulars which are in all material respects identical to the particulars of the marketing authorization, manufacturer's licence, or wholesale dealer's licence which is held by that other person; and
- (c) which includes a statement to the effect that that other person intends to cease the activities to which his marketing authorization or licence relates and has consented in writing to the making of the application.

and in this definition particulars do not include particulars relating to the name and address of the applicant, the labelling of any medicinal product or the content of any leaflet relating to such a product;".