EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the principal Regulations"). The principal Regulations implement certain provisions of Directive 2001/83/EC of the European Parliament and of the Council on the community code for medicinal products for human use ("the 2001 Directive")(**1**). In particular, the principal Regulations implement the provisions of the 2001 Directive which relate to marketing authorisations. Schedule 1 of the principal Regulations, which this instrument amends, exercises the derogation in article 5 of the 2001 Directive.

Regulation 2 inserts a definition of "supplementary prescriber" into the principal Regulations.

Regulation 3 amends paragraphs 1 and 2 of Schedule 1 to the principal Regulations. Schedule 1 contains exceptions to the requirement that no relevant medicinal product may be placed on the market or distributed by way of wholesale dealing unless a marketing authorisation for that product has been granted. The exemption in paragraphs 1 and 2 provide that no marketing authorisation is required in respect of the sale or supply of a relevant medicinal product in response to a bona fide unsolicited order formulated in accordance with the specification of a doctor or dentist and for use by his individual patients on his personal responsibility. This amendment provides that a relevant medicinal product may also be sold or supplied in such circumstances where the medicinal product is formulated in accordance with the order of a supplementary prescriber.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**1**) OJNo. L311, 28.11.2001, p.34.