EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement for the United Kingdom, and in so far as they are concerned with medicinal products for human use, the Council Directives mentioned in regulation 1(2) in the definition of "relevant Community provisions". They also contain provisions supplementing the provisions of Council Regulation (EEC) No. 2309/93. Both the Directives and the Regulation are concerned with the marketing of medicinal products.

The Regulations provide that the functions of a member state or the competent authority of a member State under the relevant Community provisions are, except as otherwise provided, to be performed in the United Kingdom by the licensing authority (ie the Ministers in the United Kingdom concerned with health and agriculture— *see* sections 1 and 6 of the Medicines Act 1968) (regulation 2). They also provide that no medicinal product for human use which is subject to the relevant Community provisions may be placed on the market in the United Kingdom or be dealt with by way of wholesale dealing unless there is in force in respect of it a marketing authorization granted either by the European Commission or by the licensing authority (regulation 3).

Regulations 4 to 7 and Schedules 2 and 3 provide for the manner of making applications for the grant, renewal or variation of a United Kingdom marketing authorization, the procedure for the consideration of such an application, the revocation and suspension of a marketing authorization and the suspension of the use or marketing of medicinal products and the obligations of applicants for and holders of marketing authorizations. In particular regulation 7(4) and Schedule 3 create certain offences in connection with those obligations.

Regulation 8 is about the control of retail sale or supply of relevant medicinal products. Regulation 9 makes consequential and other amendments to the Medicines Acts 1968 and 1971.

Schedule 1 makes certain exceptions and exemptions from the requirement to hold a marketing authorization. Schedule 4 contains provisions applying with modifications the provisions of the Medicines Act 1968 about enforcement. Schedule 5 contains provisions about the labelling of medicinal products, Schedule 6 contains transitional provisions and Schedule 7 makes consequential amendments to other regulations.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.