EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Annexes II and III to that Directive require the manufacturer of a medical device which incorporates a medicinal substance, or his authorised representative, to lodge an application with one of the notified bodies designated by the member States. The notified body with which an application is lodged is required to consult the competent body of a member State in order to verify the safety, quality and usefulness of the medicinal substance. A competent body which is so consulted is required to express views about the safety, quality and usefulness of the medicinal substance.

Regulation 1 contains definitions of terms used in these Regulations. Regulation 2 prescribes the circumstances in which fees are payable under these Regulations. Regulation 3 prescribes the amounts of those fees. Regulation 4 makes provision for the payment of fees and the recovery of unpaid fees.

An assessment of the cost to business of complying with these Regulations has been made, coies 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.