EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations"), the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the Devices Regulations") and the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations").

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971, and other fees payable in respect of Community obligations, relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulation 2 and the Schedule to these Regulations provide for a number of the fees payable by virtue of the General Fees Regulations to be increased. The increases are of amounts between 4% and 42.8%, Most capital fees have been increased by amounts between 10% and 19%, periodic fees have been increased by 17% and all but two of the inspection fees have been increased by 42.8% (the remaining two inspection fees have both been increased by 4%).

Regulation 2 also provides for certain provisions of the General Fees Regulations to be revoked. Those provisions provided for particular fees to be payable in respect of manufacturer's licences where those licences related solely to import of medicines from third countries. The revocation of those provisions means that the fees payable in respect of such licences will be the same as for other manufacturers' licences (i.e for manufacturer's licences which do not relate solely to import of medicines from third countries).

[M1][M2]The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC (now replaced by Directive 2001/83/EC) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 3 of these Regulations amends the Homoeopathic Products Regulations so as to increase the amounts of the fees payable for applications for, and variations of, certificates of registration and the fees payable by holders of certificates of registration. The increases average overall 10%.

[M3]The Devices Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC concerning medical devices. Regulation 4 of these Regulations amends the Devices Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations. The increases average overall 10%.

A full Regulatory Impact Assessment of the effect that this instrument will have on the costs of business has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2006.