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 Medicines (Products for Human Use—Fees) Regulations 1995 ("the Medicines Fees Regulations") and the Medical Devices Regulations 2002. These Regulations revoke and replace the Medicines for Human Use and Medical Devices (Fees Amendment) Regulations 2007 (see regulation 14).

M1M2The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC (now repealed and re-enacted in Directive 2001/83/EC) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 2 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 overall average increase is 4.9%.

The Medicines 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. Regulations 3 to 10 of these Regulations amend the Medicines Fees Regulations so as to: amend the definition of "the 2001 Directive" to reflect the amendment of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products by Regulation (EC) No. 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use (regulation 3(a)); provide that the fee for pharmacovigilance advice meetings is payable in respect of meetings at which the licensing authority give advice on the pharmacovigilance and risk-management systems of marketing authorization holders (regulation 4(2)); provide for a new fee for meetings at which the licensing authority give advice on the development of medicinal products or post authorisation issues (regulation 4(4)); provide that a periodic fee is payable in respect of each clinical trial authorisation held by a clinical trial sponsor (regulation 5); make an amendment consequential on the amendments to the Medicines Act 1968 made by the Veterinary Medicines Regulations 2006 (regulation 6); extend the types of marketing authorization applications for which a "complex application" fee is payable (regulation 7(2)(a)); provide for increased fees for applications for marketing authorizations and variations to marketing authorizations where the application is not submitted electronically via the MHRA portal and using the European Community's electronic Common Technical Document format (regulation 7(2)(b) and (c), (3) and (4)); replace the inspection fees for manufacturers and wholesale dealers who import unlicensed medicinal products with new supplementary periodic fees based on the number of products imported each year (regulations 3(b) and (c) and 8 to 10); and introduce a periodic fee for homoeopathic and anthroposophic medicinal products which have a product licence of right (regulation 9(2)). Regulations 4(3) and 11 and the Schedule to these Regulations provide for increases in the fees payable under the Medicines Fees Regulations. The overall average increases are 88% for capital fees for pre-application meetings, 4.9% for capital fees for applications for marketing authorizations etc, 5.5% for fees for inspections and 7% for periodic fees.

M3The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 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 12 of these Regulations amends the 1995 Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations (overall average increase of 4.9%) and provides for new fees in relation to meetings

at which the Department of Health give advice in relation to medicinal substances incorporated in medical devices.

M4M5The Medical Devices Regulations 2002 contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices, set out in Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices , Council Directive 93/42/EEC concerning medical devices and Council Directive 98/79/EC on *in vitro* diagnostic devices . Regulation 13 of these Regulations amends regulations 54 to 56 of the Medical Devices Regulations 2002, which provide for the fees payable in connection with the designation etc of UK notified bodies and EC conformity assessment bodies and the fees payable in relation to clinical investigation notices. The fees are increased (the overall average increase is 30%) and provision is made for reduced fees where the Secretary of State conducts two or more inspections, for the purposes of deciding whether a body meets the criteria for notified bodies or EC conformity assessment bodies, at the same premises on the same date.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007.