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The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC(**1**) (now repealed and re-enacted in Directive 2001/83/EC(**2**)) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for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. These increases average overall 8 per cent.

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(**3**) concerning medical devices. Regulation 3 of these Regulations amends the Devices Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations by an average overall of 8 per cent.

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971 relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulation 4 of these Regulations amend those Regulations as follows. Regulation 4(3) inserts a new Part IA of those Regulations, to make provision for fees in respect of meetings at which the licensing authority provides scientific advice to potential applicants for marketing authorizations; regulation 4(2) makes a consequential amendment. Regulation 4(4) and 4(6) insert new Part IIIA of, and new Part IIIA of Schedule 1 to, those Regulations, to make provision for fees for proposed changes to the labels and package leaflets of medicinal products submitted to the licensing authority by marketing authorization holders. Regulation 4(5) makes a consequential amendment. Regulation 4(7) amends Schedule 2 to those Regulations (fees for inspections) so as to make provision for fees for "non-routine inspections", inspections in connection with wholesale dealer's licences under which certain medicinal products which do not have marketing authorizations are imported ("exempt imported products") and inspections in connection with the pharmacovigilance obligations of marketing authorization holders. Regulation 4(8) provides for the circumstances in which the fees for some of those inspections may be refunded or waived.

There is also a package of changes to the General Fees Regulations relating to the levels of capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; capital fees payable for variations and renewals of such authorizations, licences and certificates; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 4(9) and the Schedule to these Regulations). Fees have been increased by 3 to 8 per cent.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**1**) OJNo. L 297, 13.10.1992, p. 8.
(**2**) See articles 1(5), 13 to 16, 53, 68, 69, 85, 100, 119 and 124.
(**3**) OJ No. L 169, 12.7.1993, p.1; amended by Directive 98/79/EC (OJ No. L 331, 7.12.1998, p. 1).