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The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC(**1**) (now repealed and re-enacted in Directive 2001/83/EC(**2**)) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for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 3.7 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 3.7 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. Regulations 4 to 14 of these Regulations amend those Regulations as follows.

Regulations 4(a) and (b), 6 to 10 and 13 make provision for fees for inspections of contract laboratories. Regulations 6 to 10 amend the provisions for fees for inspections so as to provide that when an inspection is made of a contract laboratory the fee for that inspection is payable by the operator of the laboratory. Regulation 13 introduces the new fee for inspections of contract laboratories.

Regulations 4(c) and 11 make provision for new penalty fees for late payment of periodic fees.

Regulation 5 amends regulation 3A of the General Fees Regulations and inserts new regulations to make provision for new fees for meetings at which the licensing authority provide pharmacovigilance, advertising, or regulatory advice, or advice on proposed changes to labelling or package leaflets, to holders of marketing authorizations or to potential applicants for a marketing authorization. Regulation 14 makes provision for the waiver of fees payable in connection with these meetings where the meeting has been held at the request of the licensing authority.

Regulation 12 amends the definition of a complex application in Part I of Schedule 1 to the General Fees Regulations to add a new category of complex application as a consequence of the adoption of Commission Directive 2003/63/EC(**4**), which amends Directive 2001/83/EC(**5**) by substituting a new Annex I setting out standards and protocols in respect of the testing of medicinal products for which applications for marketing authorization are made.

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

(**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).
(**4**) OJ No. L 159, 27.6.2003, p. 46.
(**5**) OJ No. L 311, 28.11.2001, p. 67.

and renewals of such authorizations, licences and certificates; capital fees payable for pre-application meetings; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 15 and the Schedule to these Regulations). There have been adjustments to specific capital fees, some increases and three reductions, plus a general 1.2 per cent increase, which together represent an overall 3.7 per cent increase in capital fees. Periodic fees have been increased by 3.7 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 and Healthcare products Regulatory Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.