EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations"), the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the Consultation Requirements 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**) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. These Regulations introduce a new category of permissible variation of certificates of registration, allowing for certificates to be varied in some circumstances where medical, scientific or pharmaceutical assessment is required (regulation 2(1) and (2)). The fee payable in respect of variations is £75 (for administrative) or £150 (for standard), reduced by half in respect of certain applications for identical variations (regulation 2(3)). The periodic fee payable by holders of certificates of registration is reduced from £15 to £10 (regulation 2(4)), and the capital fees for applications for the grant of certificates of registration are reduced by an average overall of 10% (regulation 2(5)).

The Consultation Requirements 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(**2**). Regulation 3 of these Regulations amends regulation 3 of the Consultation Requirements Regulations by reducing the amounts of all the fees specified in those Regulations by an average overall of 10%. As a consequence, the Medical Devices (Consultation Requirements) (Fees) Amendment Regulations 1996 are revoked (regulation 6).

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. These Regulations change the turnover threshold for reductions on certain of the fees for small businesses from £30,000 to £35,000 (regulation 4(1)). They also change the definition relating to major complex variation applications which applies for the purposes of Part III of Schedule 1 to the General Fees Regulations so that the higher major complex variation application fee is now generally payable in respect of applications which must include evidence relating to certain studies, tests or trials and which require substantial assessment resources on the part of the licensing authority (regulation 4(2) to (4)). Dates relating to the calculation of turnover for periodic fees' purposes are made consistent with the dates relating to other calculations under Schedule 3 (regulation 4(5)), and a periodic fee will no longer be charged for homoeopathic product licences of right or for anthroposophic products (regulation 4(6)). There is also a package of changes relating to the levels of certain capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; fees for variations and renewals of such authorizations, licences and certificates; periodic fees payable in connection with the holding of certain authorizations and licences; and fees payable in connection with certain site inspections (regulation 5 and the Schedule). No fees have been increased. Most of the capital fees have been reduced, by amounts varying between 0.5% and 65%; periodic fees have been reduced by an average overall of 14%; and just under half of the fees for site inspections have been reduced, by amounts varying between 0.5% and 26%.

(**1**) OJNo. L 297, 13.10.92, p. 8.
(**2**) OJ No. L 169, 12.7.93, p. 1.

A Regulatory Appraisal 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 2102, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.