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 principal Regulations"). The principal Regulations implemented in part Council Directive 92/73/EEC (OJ L297 13.10.92, p. 8) by introducing a simplified registration procedure for the marketing of certain homoeopathic medicinal products for human use.

Regulation 3 makes new provision for the fees payable under Part III of the principal Regulations in respect of applications for certificates of registration. For Schedule 2 to the principal Regulations (which prescribed a fee of £335 where a certificate of registration had previously been granted and a fee of £475 in other cases) there is substituted a new Schedule. The fees prescribed in the new Schedule (which range from £100 to £650) are determined by the number of homoeopathic stocks used in the preparation of homoeopathic medicinal products and by criteria relating to whether the licensing authority has previously assessed stocks and formulations identical to those proposed to be used.

Regulation 4 corrects a reference in Schedule 4 to the principal Regulations.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.