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[M1] by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 2 of these Regulations makes further amendments to the Homoeopathic Products Regulations: introducing further discounts in respect of the fees payable for multiple identical applications for standard variations of certificates of registration by providing for a reduction of 75% in certain cases; and otherwise increasing the level of the capital fees payable in respect of applications for the grant of certificates of registration and for variations by an average overall of 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[M2] concerning medical devices. Regulation 3 of these Regulations amends regulation 3 of the Consultation Requirements Regulations by increasing the amounts of all the fees specified in those Regulations by an average overall of 5%.

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(1) of these Regulations amends Part III of Schedule 1 to the General Fees Regulations in order to widen the category of applications for variations of marketing authorizations (parallel import) which attract the lower level fee. There is also a package of changes relating to the levels of: the capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; capital 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 site inspections (regulation 4(2) and the Schedule). Fees have been increased by an average overall of 5%.

Regulation 5 revokes two provisions which are spent as a result of the coming into force of these Regulations.

A Regulatory Impact 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.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulations revoked by S.I. 2013/532 Sch. 9
- reg. 2(1)(a)-(e) revoked by S.I. 2000/592 reg. 5
- reg. 2(2) revoked by S.I. 2000/592 reg. 5
- reg. 3 revoked by S.I. 2000/592 reg. 5
- reg. 4(2) revoked by S.I. 2000/592 reg. 5