EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and re-enact in consolidated form, with some amendments, the Medicines (Products for Human Use) (Fees) Regulations 2010 ("the 2010 Regulations"). They make amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Regulations") and the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations").

These Regulations make provision for the fees payable under the Medicines Act 1971 and other fees payable in respect of EU obligations relating to marketing authorizations, licences and certificates in respect of medicinal products for human use.

The fees prescribed in the Regulations are revised on an annual basis and based on an assessment of the costs associated with a range of licensing requirements and functions. The fee amounts specified in these Regulations are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 21st December 2011. A summary of the consultation responses is published on the MHRA's website (www.mhra.gov.uk).

In general these Regulations provide for fee reductions in some areas, simplification measures and amendments to facilitate better administrative practice.

Parts 2 to 9 and 11 and 12 and Schedules 2 and 3 provide for capital fees to be payable in connection with pre-application meetings; applications for, or variations to, marketing authorizations, manufacturer's licences, wholesale dealer's licences, clinical trial authorisations, traditional herbal registrations and certificates permitting the export of medicinal products; assistance in obtaining or renewing marketing authorizations in other EEA States; the assessment of labels and leaflets; renewals of certain manufacturer's licences; and inspections. Most of the fees were previously provided for by the 2010 Regulations (as amended).

However, these Regulations also—

(a) provide a 10% reduction in fees for applications under decentralised procedure where the UK is the Reference Member State;

(b) simplify the fee structure for capital fees payable for authorizations, licenses, registrations and certificates so that there is no price differential between applications made electronically and others.

Part 10 and Schedule 4 provide for periodic fees in connection with authorizations, registrations and licenses. Schedule 4 includes amendments to—

(a) clarify how the total value of products sold or supplied is to be determined;

(b) introduce a "lower fee" in respect of periodic fees for prescription only medicines;

(c) replace the 3 types of periodic fees previously payable in connection with pharmacy or general sale medicines with a single fee set at the same level as the lower fee for prescription only medicines;

(d) replace the 3 types of periodic fees for parallel import licenses with a single fee; and

(e) provide a single fee rate for herbal, homoeopathic and traditional herbal medicinal products licenses.

Part 13 and Schedule 5 provides for fees in relation to homoeopathic medicinal products. In particular, the fee provisions from the Homoeopathic Regulations have been consolidated into these Regulations.

Part 14 and Schedule 6, 7 and 8 deal with the time for payment and waiver or refund of both capital and periodic fees in specified circumstances. These Regulations make provision for payments to be made in advance of any application or the fee becoming due to the licensing authority.

Part 15 of these Regulations make consequential amendments to—

(a) the Clinical Trials Regulations to update cross-references to these Regulations; and

(b) the Homoeopathic Regulations to remove some obsolete definitions from those regulations.

Part 16 of these Regulations revokes and makes savings provisions in relation to—

(a) earlier Regulations relating to fees for medicinal products for human use; and

(b) parts of the Homoeopathic Regulations.

An impact assessment of the effect that this instrument will have on the costs of business is available from the MHRA at 151 Buckingham Palace Road, London SW1W 9SZ and is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk