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 1995 ("the 1995 Regulations") and make amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations").

These Regulations make provision for the fees payable under the Medicines Act 1971, and other fees payable in respect of Community 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 following consultation and are based on an assessment of the costs associated with the functions in association with which fees are charged. The fees prescribed in the Regulations are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 17th October 2007. A summary of the consultation responses is published on the MHRA's website (www.mhra.gov.uk). In general, the fee levels are higher than those previously in force, although in some cases they are lower. Some specific increases have been targeted in priority areas. More generally the average rate of increase is 7.3%.

Parts 2 to 9 and 11and 12 and Schedules 1 and 2 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 for inspections. Most of the fees were previously provided for by the 1995 Regulations. But these Regulations add the following new categories of fees—

(a) a new category of fee is introduced in regulation 5 for pre – application meetings held to provide scientific advice in connection with the classification of a medicinal product as one which will available on general sale or without prescription from a pharmacy;

(b) a new category of fee is introduced in regulation 34 for membership of the accreditation scheme operated by the licensing authority in relation to Phase 1 trials and for a certificate of membership of the scheme;

(c) a new category of fee is introduced in regulation 36 for applicants or authorization holders who give notice under paragraph 11 or 16 of Schedule 2 to the Medicines (Products for Human Use) Marketing Authorisations Etc Regulations 1994 of their wish to appear before or be heard by a person appointed by the licensing authority;

(d) by regulation 12(1)(a) and paragraph 3(1) of Part 2 of Schedule 1, an application which includes a reclassification element and is not a major application attracts a lower fee if it is an eCTD format application than if it is not an eCTD format application(**1**);

(e) by regulation 18(1) and paragraph 15 of Part 4 of Schedule 1 applications for the variation of a marketing authorization which is not within the subject matter or scope of Commission Regulation (EC) No. 1084/2003 attract a lower fee than would otherwise apply, if they

(**1**) "eCTD format application" is defined in Part 1 of Schedule 1 of these Regulations.

are "BROMI variations". That is to say if they are submitted using the MHRA portal(**2**), for a change set out in the BROMI variations guidance(**3**) and comply with the conditions and are accompanied by the documents which that guidance specifies apply or should be provided with the variation;

(f) by regulation 18(1) and paragraph 18 of Part 4 of Schedule 1, certain variation applications which include a reclassification element may also attract a lower fee if they are eCTD format applications;

(g) by regulation 22(1) and paragraph 30 of Part 5 of Schedule 1 a lower fee than would otherwise apply, applies in relation to the consideration by the licensing authority of a set of proposed changes to the labelling or package leaflet of a medicinal product if they are of a type described in the BROMI labels and leaflets self – certification guidance (**4**) and comply with the conditions set out in that guidance in relation to the changes;

(h) by regulation 12(1)(a) and paragraph 10 of part 2 of Schedule 1, these Regulations also introduce a new category of medicinal product for the purpose of attracting the lower application fee for clinical trials authorisations which applies to products known to the licensing authority. This new category comprises a product which is or was being tested or used in a clinical trial which has been authorised by the licensing authority in accordance with Directive 2001/20/EC.

These Regulations make changes to the way the fees for inspections are charged. In the 1995 Regulations the amount of the fee charged for an inspection depended on the type of inspection carried out. By regulations 27 and 30 and Schedule 2 to these Regulations the amount of the fee charged for an inspection depends on the time taken to make the inspection.

Schedule 2 to these Regulations also introduces a definition of the term "turnover" for the purpose of the fee prescribed in paragraph 7 of the Schedule for an inspection made in connection with the grant, variation or renewal of a wholesale dealer's licences in cases where the total turnover in respect of sales by way of wholesale dealing does not exceed £35,000.

Part 10 of and Schedule 3 to these Regulations impose periodic fees to be payable in connection with the holding of marketing authorizations, manufacturer's licences, registrations, authorisations and wholesale dealer's licences. The amount of the periodic fess varies according to the type of product and in some cases according to turnover.

Administrative provisions (Part 13, Schedules 4, 5 and 6) deal with time of payment and waiver or refund of both capital and periodic fees in specified circumstances. Special arrangements are provided in relation to the time of payment of capital fees by small companies. Schedule 4 of these Regulations re- enacts the provisions relating to the time for payment of Capital Fees in Schedule 4 of the 1995 Regulations.

Part 14 of these Regulations makes amendments to increase fees specified in regulations 14 and 15 and Schedules 2 and 2A of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994. The average rate of increase is 5.6%.

Part 15 of these Regulations revokes the earlier Regulations relating to fees for medicinal products for human use and also makes saving provisions.

(**2**) "the MHRA portal" is defined in Part 1 of Schedule 1 of these Regulations.

(**3**) The BROMI variations guidance is version 2.1 of the document entitled "BROMI Dossier Requirements For Type IA and Type IB UK national Notifications, published by the licensing authority on its website in February 2008 and dated November 2007. The document may be downloaded from or the licensing authority's website at www.mhra.gov.uk and copies can be obtained by writing to the licensing authority at Market Towers, 1 Nine Elms Lane, London SW8 5NQ, or by sending an e-mail to info@mhra.gsi.gov.uk.

(**4**) The BROMI labels and leaflets self – certification guidance means the document entitled "Guidance on Changes to Labelling and Patient Information Leaflets For Self – Certification" published by the licensing authority on its website on 28th January 2008. A copy of the guidance may be downloaded from the licensing authority's website at www.mhra.gov.uk or obtained by writing to the licensing authority at Market Towers, 1 Nine Elms Lane, London SW8 5NQ or by sending an e-mail to info@mhra.gsi.gov.uk.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the MHRA at Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.