EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the Devices Regulations"), the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations"), the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations") and the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 ("the Marketing Authorisations Regulations").

The Marketing Authorisations Regulations implemented in part the following provisions of the European Community: Council Directives 65/65/EEC(**1**), 75/318/EEC(**2**), 75/319/EEC(**3**) and any Regulation adopted by the Commission under Article 15 of that Directive, 89/342/EEC(**4**), 89/343/EEC(**5**), 89/381/EEC(**6**), 92/26/EEC(**7**), 92/27/EEC(**8**), 92/73/EEC(**9**), Regulation (EEC) No. 2309/93(**10**) and any Regulations adopted by the Commission under Article 15.4 or 22.1 of that Regulation. They provide for the manner of making applications for the grant, renewal or variation of a United Kingdom marketing authorisation and for procedures for consideration, revocation, suspension and related matters. Regulation 2 of these Regulations amends the Marketing Authorisations Regulations by inserting into regulation 1(2) of those Regulations a definition of "EEA State", omitting the definition of "parallel import", inserting a definition of "parallel import licence" and substituting a new definition of "United Kingdom marketing authorisation". Regulations 2(2) and (3) make amendments consequential on those new definitions. These amendments together with the amendments to the Fees Regulations referred to below clarify the status of the parallel import scheme.

The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC(**11**) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. These Regulations amend the Homoeopathic Products Regulations in the following way. Regulation 3(1) of these Regulations adds to the definition of "standard variation", regulation 3(2) increases the amounts of the fees payable for variations of certificates of registration, regulation 3(3) increases the fee payable by holders of certificates of registration and regulation 3(4) increases the amounts of the capital fees payable for applications for certificates of registration. These increases average overall 5%.

The Devices Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC(**12**) concerning medical devices. Regulation 4 of these Regulations amends the Devices Regulations by increasing the amounts of certain of the fees specified in regulation 3 of those Regulations by an average overall of 5%.

(**1**) OJ No. L22, 9.2.1965, p.369.
(**2**) OJ No. L147, 9.6.1975, p.1.
(**3**) OJ No. L147, 9.6.1975, p.13.
(**4**) OJ No. L142, 25.5.1989, p.14.
(**5**) OJ No. L142, 25.5.1989, p.16.
(**6**) OJ No. L181, 28.6.1989, p.44.
(**7**) OJ No. L113, 30.4.1992, p.5.
(**8**) OJ No. L113, 30.4.1992, p.8.
(**9**) OJ No. L297, 13.10.1992, p.8.
(**10**) OJ No. L214, 24.8.1993, p.1.
(**11**) OJ No. L297, 13.10.1993, p.8.
(**12**) OJ No. L169, 12.7.1993, p.1.

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971 relating to marketing authorisations, licences and certificates in respect of medicinal products for human use. These Regualtions amend those Regulations as follows: regulation 5(1) of these Regulations amends regulation 2(1) of those Regulations by inserting a definition of "parallel import licence" and amends the definition of "authorised medicinal product" to take account of this; regulation 5(6), (8), (9), (10) and (13) make amendments consequential on this; these amendments together with those made to the Marketing Authorisations Regulations referred to above clarify the status of the parallel import scheme. Regulation 5(2) renumbers regulations 4A–4C of the General Fees Regulations and regulations 5(4), (7) and (11) make amendments consequential upon this. Regulation 5(3) of these Regulations reduces the number of export certificates comprising a "set". Regulation 5(12) allows for the waiver of any fee payable in connection with a variation application for the purpose of demonstrating compliance with the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products", published by the European Commission.

There is also a package of changes to the General Fees Regulations relating to the levels of capital fees payable for applications for marketing authorisations, manufacturer's licences, wholesale dealer's licences, clinical trial certificates and export certificates; capital fees payable for variations and renewals of such authorisations, licences and certificates; periodic fees payable in connection with the holding of certain authorisations and licences; and the fees payable in connection with site inspections. Fees have been increased by approximately 5% except in the case of the fee for export certificates, which is increased by 30%.

A Regulatory Impact Assessment 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 16107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2001.