EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement certain provisions of Directive 2004/27/EC of the European Parliament and of the Council ("the 2004 Directive") amending Directive 2001/83/EC on the Community code for medicinal products for human use ("the 2001 Directive"), and make consequential amendments to various enactments following the adoption of Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The 2001 Directive is implemented in part by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the 1994 Regulations"). Regulation 3(2)(a)(i) and (ii) of these Regulations amends the 1994 Regulations so as to implement Article 1(21), (44), (45) and (54) of the 2004 Directive. These provisions amend the 2001 Directive so as to provide, in relation to medicinal products for human use, that–

(a) marketing authorization holders have additional obligations to provide information and data to the competent authority (Article 1(21) of the 2004 Directive),

(b) package leaflets accompanying such products must be drawn up in accordance with new requirements, in particular that the leaflet must reflect the results of consultations with target patient groups (Article 1(44) and (45)), and

(c) where a change of classification of such a product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority may not refer to the results of those tests or trials, when examining a change of classification for the same substance within one year of the initial change (Article 1(54)).

Regulation 3(4) creates new criminal offences for failures by marketing authorization holders to provide information in accordance with the requirements of the new paragraphs inserted by Article 1(21) of the 2004 Directive. Regulation 3(5) amends the 1994 Regulations so as to make transitional provision for the application of the amendments relating to package leaflets made by Article 1(44) and (45) of the 2004 Directive.

These Regulations, except regulation 3(2)(a)(i) and (ii), (4) and (5), make amendments to the Terrorism Act 2000 and to various statutory instruments consequential on the coming into force of Title IV of Regulation (EC) No. 726/2004. This Regulation revokes and replaces Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. Most of Regulation (EC) No. 726/2004 does not apply until 20th November 2005, but Title IV came into force on 20th May 2004. Title IV provides for the establishment and constitution of the European Medicines Agency (which replaces the European Agency for the Evaluation of Medicinal Products), and the constitution of the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use (which replace the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, respectively).

A Regulatory Impact Assessment in relation to these Regulations, and a Transposition Note in relation to the implementation of the 2004 Directive, have been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.