## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make amendments to the Medicines Act 1968 ("the Act"), and related legislation, to make further provision in relation to the statutory bodies which provide advice in relation to medicinal products. The Medicines (Advisory Bodies) Regulations 2005 amend the Act, and related legislation, to establish a new body called the Commission on Human Medicines and introduce new procedures for applications for, and decisions in respect of, licences under the Medicines Act 1968 and marketing authorizations under the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994, which are granted in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use ("the 2001 Directive")(**1**).

Regulation 2 and Schedule 1 further amend the Act to make amendments which are consequential on the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005, which amend the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, which implement the provisions of the 2001 Directive relating to homoeopathic medicinal products and the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, which implement Directive 2004/24/EC, amending, as regards traditional herbal medicinal products, the 2001 Directive(**2**).

Regulation 3 and Schedule 2 make minor amendments to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, in particular to make further provision as to when the procedures in Schedule 2 (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorizations) apply.

Regulation 4 and Schedule 3 make amendments to the Medicines for Human Use (Clinical Trials Regulations) 2004 (which implement the provisions of Directive 2001/20/EC relating to the conduct of clinical trials)(**3**), including the substitution of a new Schedule 5 and amendments to Schedule 8. Schedule 5 sets out the procedural provisions applicable to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorizations and the suspension or termination of clinical trials. Schedule 8 sets out the procedural provisions relating to proposals to grant, vary, suspend or revoke manufacturing authorizations.

Regulation 5 and Schedule 4 make amendments to miscellaneous enactments, which are consequential on the amendments made by the Medicines (Advisory Bodies) Regulations 2005.

Regulation 6 and Schedule 5 make transitional provisions in relation to procedures under the Medicines Act 1968, the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 and the Medicines for Human Use (Clinical Trials Regulations) 2004.

A full regulatory impact assessment has not been produced for this instrument as it has no impact on the costs of business.

(**1**) OJNo. L 311, 28.11.2001, p.67.
(**2**) OJ No. L 136, 30.4.2004, p.85.
(**3**) OJ No. L 121, 1.5.2001, p.34.