PROSPECTIVE

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines Act 1968, and related legislation, to abolish the Medicines Commission and the Committee on Safety of Medicines and to establish a new body in their place called the Commission on Human Medicines ("the Commission"). The Commission will be responsible, amongst other things, for advising the licensing authority in relation to licences under the Act and marketing authorizations under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the 1994 Regulations"), granted in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use(**1**).

Regulation 2 abolishes the Medicines Commission and repeals section 2 of the Act. Regulation 3 inserts a new section 2A, which provides for establishment of the Commission and regulation 4 substitutes a new section 3 which sets out details of the membership and functions of the Commission. Regulation 5 amends section 4 of the Act as a consequence of the abolition of the Medicines Commission and to require that committees established under that section must have at least 8 members. Regulation 6 amends section 5 of the Act to make provision for the reports by the Commission and committees established under section 4 of the Act.

Regulation 7 repeals Schedule 1 to the Act and inserts a new Schedule 1A, containing detailed provisions relating to the Commission and to committees established under section 4 of the Act, including: arrangements for co-opting members; appointment by the Commission and committees established under section 4 of sub-committees called Expert Advisory Groups; the delegation of functions to those Expert Advisory Groups; and miscellaneous provisions relating to staff, premises, proceedings and funding.

Regulation 8 and Schedule 1 substitute new sections 21 (procedure on reference to appropriate committee) and 22 (procedure in other cases) of the Act, insert a new section 22A (hearing before person appointed by the licensing authority) and substitute a new Schedule 2 (suspension, revocation or variation of licence). These make new provision for the procedures on applications for, and decisions in respect of, licences granted under the Act; in particular for consultation of the Commission or another "appropriate committee". Licences granted under the Act include those licences which constitute UK manufacturing and wholesale distribution authorisations under Articles 40 and 76 of Directive 2001/83/EC. Schedule 1 also makes a number of consequential amendments.

Regulation 9 and Schedule 2 make amendments to the 1994 Regulations (which implement the provisions of Directive 2001/83/EC relating to marketing authorizations), including the substitution of a new Schedule 2, which sets out the procedural provisions applicable to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorizations and includes, in Part 3 of that Schedule, a new procedure applicable to certain applications to vary a marketing authorization. Changes are made to the scope and application of the Schedule

(**1**) OJ L311, 28.11.2001, p.67.

(paragraphs 2 to 6) to take account of these new provisions and amendments to Directive 2001/83/EC made by Directive 2004/27/EC(**2**).

Regulation 10 and Schedule 3 make amendments to other enactments. Regulation 11 revokes the Medicines Commission and Committees Regulations 1970 (which make provision relating to the appointment of members and committees of those bodies) and the Medicines (Committee on Safety of Medicines) Order 1970 (which established the Committee on Safety of Medicines).

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. A copy of that assessment has been placed in the libraries of both Houses of Parliament.

(**2**) OJ L136, 30.4.2004, p.34.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Advisory Bodies) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Sch. 1 para. 1 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 2 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 3 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 4 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 5 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 6 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 7 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 8 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 9 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 10 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 11 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 12 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 13 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 14 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 15 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 1 para. 1-11 revoked by S.I. 2012/1916 Sch. 35
- Sch. 1 para. 12(2)(3) revoked by S.I. 2012/1916 Sch. 35
- Sch. 1 para. 13-15 revoked by S.I. 2012/1916 Sch. 35
- Sch. 2 para. 1 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 2 para. 2 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 2 para. 3 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 2 para. 4 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 23 revoked by S.I. 2012/1916 Sch. 35
- Sch. 3 para. 1 coming into force by S.I. 2005/1094 reg. 1(1)
- Sch. 3 para. 2 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 1 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 1-7 revoked by S.I. 2012/1916 Sch. 35
- reg. 2 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 3 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 4 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 5 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 6 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 7 coming into force by S.I. 2005/1094 reg. 1(2)
- reg. 7 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 8 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 9 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 9-12 revoked by S.I. 2012/1916 Sch. 35
- reg. 10 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 11 coming into force by S.I. 2005/1094 reg. 1(1)
- reg. 12 coming into force by S.I. 2005/1094 reg. 1(1)