STATUTORY INSTRUMENTS

2005 No. 2754

The Medicines (Advisory Bodies) (No. 2) Regulations 2005

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Advisory Bodies) (No. 2) Regulations 2005.

(2) These Regulations shall come into force—

(a) for the purpose of Schedules 1 and 2, immediately after the coming into force of the Medicines (Advisory Bodies) Regulations 2005(**1**); and

(b) for all other purposes, 30th October 2005.

(3) In these Regulations—

"the Act" means the Medicines Act 1968(**2**);

"appropriate committee" means—

(a) in a case where—

(i) a committee has been established under section 4 of the Act for purposes which consist of or include any of those specified in subsection (3) of that section, and

(ii) the relevant authority considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission.

"the appropriate Ministers" has the meaning given by section 1(2) of the Act;

"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004(**3**);

"the Commission" means the Commission on Human Medicines established under section 2A of the Act(**4**);

"licence" means a licence granted under Part II of the Act;

"licensing authority" has the meaning given by section 6 of the Act;

"the Marketing Authorization Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**5**);

"marketing authorization" means—

(a) a marketing authorization granted by the licensing authority under the Marketing Authorization Regulations;

(b) a product licence granted under Part II of the Act that has effect as a marketing authorization by virtue of paragraph 1 of Schedule 7 to those Regulations;

(**1**) S.I.2005/1094.
(**2**) 1968 c. 67.
(**3**) S.I. 2004/1031.
(**4**) Section 2A is inserted by S.I. 2005/1094.
(**5**) S.I. 1994/3144, amended by S.I. 2005/1094; there are other amending instruments but none is relevant.

"relevant authority" means—

(a) in relation to Part 2 of Schedule 5, the appropriate Ministers, and

(b) in relation to any other provision of these Regulations, the licensing authority;

"the time allowed" means the period of 28 days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.

Amendments to the Act

2. The amendments to the Act set out in Schedule 1 shall have effect.

Amendments to the Marketing Authorization Regulations

3. The amendments to the Marketing Authorization Regulations set out in Schedule 2 shall have effect.

Amendments to the Clinical Trials Regulations

4. The amendments to the Clinical Trials Regulations set out in Schedule 3 shall have effect.

Amendments to other enactments

5. The provisions of the enactments specified in Schedule 4 shall be amended as there specified.

Transitional Provisions

6. The transitional provisions set out in Schedule 5 shall have effect.

Signed by authority of the Secretary of State for Health

Warner
Minister of State,
Department of Health

4th October 2005