STATUTORY INSTRUMENTS

2005 No. 1094

The Medicines (Advisory Bodies) Regulations 2005

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Advisory Bodies) Regulations 2005 and, subject to paragraph (2), shall come into force on 30th October 2005.

(2) Regulation 7 shall come into force on 31st May 2005 for the purposes of making regulations under paragraph 6 of Schedule 1A to the Act, as inserted by that regulation.

(3) In these Regulations—

"the Act" means the Medicines Act 1968(**1**); and

"the Marketing Authorisation Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**2**).

Abolition of the Medicines Commission

2.—(1) The Medicines Commission is abolished.

(2) Section 2 of the Act (establishment of the Medicines Commission)(**3**) is hereby repealed.

Establishment of the Commission on Human Medicines

3. After section 2 of the Act insert the following section—

"**Establishment of the Commission on Human Medicines**

2A.—(1) There shall be established a body of persons to be called the Commission on Human Medicines (referred to in this Act as "the Commission") to perform the functions assigned to the Commission by or under this Act.

(2) The Ministers shall appoint the members of the Commission.

(3) The Commission shall have at least eight members.

(4) The Ministers shall appoint the chairmen of the Expert Advisory Groups referred to in paragraphs (a) to (c) of paragraph 4(1) of Schedule 1A to this Act as members of the Commission.

(5) The Ministers shall appoint one of the members of the Commission to be chairman of the Commission.".

Functions of the Commission on Human Medicines

4. For section 3 of the Act (general functions of the Commission)(**4**), substitute—

(**1**) 1968 c. 67.
(**2**) S.I. 1994/3144; relevant amending instruments are S.I. 2002/236 and S.I. 2004/3224.
(**3**) Section 2 was amended by section 10 of, and Schedule 3 to, the House of Commons Disqualification Act 1975 (c. 24) and by Part 1 of Schedule 3 to the Northern Ireland Assembly Disqualification Act 1975 (c. 25).
(**4**) Section 3 was amended by paragraph 1 of Schedule 10 to S.I. 2004/1031.

"**Functions of the Commission**

3.—(1) The Commission shall give to any one or more of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act advice on matters—

(a) relating to the execution of this Act,

(b) relating to the exercise of any power conferred by this Act,

(c) relating to the execution of the Marketing Authorisation Regulations or the Clinical Trials Regulations,

(d) relating to the exercise of any power conferred by those regulations, or

(e) otherwise relating to medicinal products,

where either the Commission consider it expedient, or they are requested by the Minister or Ministers in question, to do so.

(2) Without prejudice to the preceding subsection, and to any other duties or powers imposed or conferred on the Commission by or under this Act, the Marketing Authorisation Regulations or the Clinical Trials Regulations, it shall be the duty of the Commission—

(a) to—

(i) give advice with respect to safety, quality or efficacy in relation to medicinal products,

(ii) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given, and

(iii) undertake the functions mentioned in section 4(4) of this Act,

except in so far as those functions are for the time being assigned to a committee established under section 4 of this Act; and

(b) to advise the licensing authority in cases where the authority—

(i) are required by the provisions of Part 2 of this Act, or by the provisions of the Marketing Authorisation Regulations or the Clinical Trial Regulations, to consult the Commission with respect to any matter arising under those provisions, or

(ii) without being required to do so, elect to consult the Commission with respect to any matter arising under any of those provisions.".

Amendment of section 4 of the Act

5.—(1) Section 4 of the Act (establishment of committees)(**5**) shall be amended as follows.

(2) In subsection (1), omit the words from ", having regard to" to "consider appropriate,".

(3) In subsection (2)(a), before "or the Clinical Trials Regulations", insert ", the Marketing Authorisation Regulations".

(4) After subsection (4), insert the following subsection—

"(4A) A committee established under this section shall have at least eight members.".

(5) For subsection (6), substitute—

"(6) In this Act "the appropriate committee", for the purposes of any provision of this Act under which a function falls to be performed, means—

(a) in a case where—

(**5**) Section 4 was amended by paragraph 15 of Part 3 of Schedule 3 to the Food Standards Act 1999 (c. 28) and by paragraph 2 of Part 1 of Schedule 10 to S.I. 2004/1031.

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

(ii) the authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission.".

Amendment of section 5 of the Act

6.—(1) Section 5 of the Act (supplementary provisions as to Commission and committees) shall be amended as follows.

(2) In subsection (1), for "Schedule 1" substitute "Schedule 1A".

(3) For subsection (2) substitute—

"(2) The Commission shall, at such time in each year as the Ministers may direct, send to the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act a report with respect to—

(a) the performance of their functions; and

(b) the performance of functions by any Expert Advisory Group appointed by them under paragraph 3 of Schedule 1A to this Act, including any Expert Advisory Group which is jointly appointed by them and another Advisory Body or Bodies,

and the Secretary of State shall lay before Parliament a copy of every such report.".

(4) For subsection (3) substitute—

"(3) Each committee established under section 4 of this Act shall, at such time in each year as the Ministers may direct, send to the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act a report with respect to—

(a) the performance of their functions; and

(b) the performance of functions by any Expert Advisory Group appointed by them under paragraph 3 of Schedule 1A to this Act, including any Expert Advisory Group which is jointly appointed by them and another Advisory Body or Bodies,

and the Secretary of State shall lay before Parliament a copy of every such report.".

(5) In subsection (4), in paragraph (a), for "Schedule 1" substitute "Schedule 1A".

Provisions relating to Commission on Human Medicines and other committees

7.—(1) Schedule 1 to the Act (provisions relating to Medicines Commission and committees) is hereby repealed.

(2) After Schedule 1 to the Act, insert the following Schedule—

"SCHEDULE 1A Section 5

PROVISIONS RELATING TO COMMISSION AND COMMITTEES

Interpretation

1. In this Act, "Advisory Body" means the Commission or a committee established under section 4 of this Act.

Co-opted members

2.—(1) Subject to the approval of the Secretary of State, at any meeting of an Advisory Body, that Advisory Body may co-opt additional members.

(2) A co-opted member shall hold office only in relation to the meeting for which he is co-opted.

Expert Advisory Groups

3.—(1) Subject to paragraph 4 of this Schedule, an Advisory Body, or any two or more Advisory Bodies acting jointly, may, subject to the approval of the Secretary of State, appoint sub-committees, to be known as Expert Advisory Groups.

(2) The Secretary of State may direct an Advisory Body to appoint an Expert Advisory Group to advise on such matters as may be specified in the direction.

(3) An Expert Advisory Group may include or consist of persons who are not members of the Advisory Body or Bodies which appointed that Expert Advisory Group.

(4) Subject to paragraph 4(2) of this Schedule, the Advisory Body or Bodies which appointed the Expert Advisory Group shall appoint one of the members of the Expert Advisory Group as chairman.

(5) At any meeting of an Expert Advisory Group, the chairman of that Group may, after consulting the chairman or chairmen of the Advisory Body or Bodies which appointed that Group, co-opt additional members of that Group.

(6) Members co-opted in accordance with sub-paragraph (5) of this paragraph shall hold office only in relation to the meeting for which they are co-opted.

Appointment by the Commission of Expert Advisory Groups

4.—(1) The Commission shall establish—

(a) an Expert Advisory Group to be called "the Biologicals Expert Advisory Group", to advise on the safety, quality and efficacy of medicinal products of biological or bio-technological origin, including vaccines;

(b) an Expert Advisory Group to be called "the Chemistry, Pharmacy and Standards Expert Advisory Group", to advise on the quality, and quality in relation to safety and efficacy, of medicinal products which are the subject of an application for a product licence under this Act, a marketing authorization under the Marketing Authorisation Regulations, or a request for authorisation pursuant to regulation 17 of the Clinical Trials Regulations;

(c) an Expert Advisory Group to be called "the Pharmacovigilance Expert Advisory Group", to advise on pharmacovigilance and other issues relating to the safety of medicinal products; and

(d) such other Expert Advisory Groups as it considers appropriate.

(2) The chairmen of the Expert Advisory Groups referred to in paragraphs (a) to (c) of sub-paragraph (1) above shall be appointed by the Ministers.

Delegation of functions by Advisory Bodies

5.—(1) Subject to sub-paragraph (2) of this paragraph, an Advisory Body may delegate to an Expert Advisory Group such of its functions as it thinks fit.

(2) Subject to sub-paragraph (3) of this paragraph, an Advisory Body may not delegate any function which consists of advising the licensing authority in cases where the licensing authority is required to consult that Advisory Body pursuant to the provisions of—

(a) Part 2 of this Act;

(b) the Clinical Trials Regulations;

(c) the Homoeopathic Regulations; or

(d) the Marketing Authorisation Regulations.

(3) An Advisory Body may arrange for an Expert Advisory Group to provide advice or assistance in relation to the performance of any function referred to in sub-paragraph (2) of this paragraph.

Terms of office of members

6. The Ministers may make provision by regulations with respect to one or more of the following matters—

(a) the terms on which members of Advisory Bodies shall hold and vacate office, including the terms on which any person appointed as chairman of such a Body shall hold and vacate office as chairman; and

(b) the terms on which members of Expert Advisory Groups shall hold and vacate office, including the terms on which any person appointed as chairman of such a Group shall hold and vacate office as chairman.

Staff, premises and facilities

7. The Ministers shall provide each Advisory Body and any committee appointed under section 60 of this Act with such staff and such accommodation, services and other facilities as appear to the Ministers to be necessary or expedient for the proper performance of their functions.

Validity of proceedings

8. The validity of any proceedings of an Advisory Body, Expert Advisory Group or any committee appointed under section 60 of this Act shall not be affected by—

(a) a vacancy among the members of that Advisory Body, Expert Advisory Group, or committee, or

(b) a defect in the appointment of any member of that Advisory Body, Expert Advisory Group or committee.

Proceedings

9.—(1) An Advisory Body may, subject to approval by the Secretary of State, make such provision as it thinks fit to regulate its own proceedings.

(2) The Secretary of State may make such provision as he thinks fit to regulate the proceedings of Expert Advisory Groups.

(3) A committee established under section 60 of this Act shall have the power to regulate their procedure.

Remuneration and expenses of members

10. The Ministers may pay to the members of each Advisory Body and Expert Advisory Group and of any committee appointed under section 60 of this Act such remuneration (if any) and such allowances as may be determined by the Ministers with the consent of the Treasury.

Expenses of Advisory Bodies and Expert Advisory Groups

11. The Ministers shall defray any expenses incurred with their approval by each Advisory Body and Expert Advisory Group or by any committee appointed under section 60 of this Act.

Status

12. No Advisory Body, no Expert Advisory Group and no committee appointed under section 60 of this Act shall be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown.".

Consequential and other amendments to the Act

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

Consequential and other amendments to the Marketing Authorisation Regulations

9. The amendments to the Marketing Authorisation Regulations set out in Schedule 2 shall have effect.

Amendments to other enactments

10. The provisions of the enactments specified in Schedule 3 shall be amended as there specified.

Revocations

11. The Medicines Commission and Committees Regulations 1970(**6**) and the Medicines (Committee on Safety of Medicines) Order 1970(**7**) are hereby revoked.

Transfer of properties, rights and liabilities

12. On 30th October 2005, all property, rights and liabilities to which the Medicines Commission was entitled or subject immediately before that date shall transfer to the Secretary of State.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

4th April 2005

(**6**) S.I. 1970/746.
(**7**) S.I. 1970/1257.