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. (See end of Document for details) View outstanding changes

STATUTORY INSTRUMENTS

2005 No. 1094

The Medicines (Advisory Bodies) Regulations 2005

PROSPECTIVE

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- 7.—(1) Schedule 1 to the Act (provisions relating to Medicines Commission and committees) is hereby repealed.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

Status: This version of this provision is prospective.

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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

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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.".

Commencement Information

- II Reg. 7 in force at 31.5.2005 for specified purposes, see reg. 1(2)
- Reg. 7 in force at 30.10.2005 in so far as not already in force, see reg. 1(1)

Status:

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Changes and effects yet to be applied to:

- reg. 1-7 revoked by S.I. 2012/1916 Sch. 35
- 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)