STATUTORY INSTRUMENTS

2005 No. 1094

MEDICINES

The Medicines (Advisory Bodies) Regulations 2005

Made - - - -	*4th April 2005*
Laid before Parliament	*7th April 2005*
Coming into force	
For the purposes of making regulations under paragraph 6 of Schedule 1A to the Medicines Act 1968, as inserted by regulation 7	*31st May 2005*
For all other purposes	*30th October 2005*

The Secretary of State, being a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to medicinal products, in exercise of the powers conferred by the said section 2(2), and of all other powers enabling him in that behalf, hereby makes the following Regulations:

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(**3**); and

"the Marketing Authorisation Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**4**).

(**1**) S.I. 1972/1811.
(**2**) 1972 c. 68.
(**3**) 1968 c. 67.
(**4**) S.I. 1994/3144; relevant amending instruments are S.I. 2002/236 and S.I. 2004/3224.

Abolition of the Medicines Commission

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

(2) Section 2 of the Act (establishment of the Medicines Commission)(**5**) is hereby repealed.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)(**6**), substitute—

"**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

(**5**) 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).

(**6**) Section 3 was amended by paragraph 1 of Schedule 10 to S.I. 2004/1031.

(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)(**7**) 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—

(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

(**7**) 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.

(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(**8**) and the Medicines (Committee on Safety of Medicines) Order 1970(**9**) 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

(**8**) S.I. 1970/746.
(**9**) S.I. 1970/1257.

SCHEDULE 1

Regulation 8

AMENDMENTS TO THE MEDICINES ACT 1968

1. In section 20 of the Act (grant or refusal of licence)—

(a) in subsection (3), omit "or, if for the time being there is no such committee, with the Commission";

(b) omit subsection (4).

2. For section 21 of the Act (procedure on reference to appropriate committee or Commission), substitute—

"**Procedure on reference to appropriate committee**

21.—(1) Where the appropriate committee are consulted under section 20(3) of this Act and are of the provisional opinion that, on grounds relating to safety, quality or efficacy, they—

(a) may be unable to advise the licensing authority to grant the licence; or

(b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application,

they shall notify the applicant accordingly.

(2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.

(3) The appropriate committee shall give the applicant an opportunity to make such representations in accordance with subsections (4) to (7) of this section.

(4) Subject to subsection (5) of this section, the applicant shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in subsection (2) of this section, or within such shorter period as the appropriate committee may specify in the notification under subsection (1).

(5) If the applicant so requests, the appropriate committee may extend the time limit referred to in subsection (4) of this section, up to a maximum period of twelve months beginning with the date of the notice referred to in subsection (2) of this section.

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in subsections (4) and (5) of this section has expired, except with the permission of the appropriate committee.

(7) If the applicant gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with subsection (4) of this section, arrange for the applicant to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this section; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(9) After receiving the report of the appropriate committee, the licensing authority shall—

(a) decide whether to grant or refuse the application, or to grant it otherwise than in accordance with the application; and

(b) take the report into account when making their decision.

(10) The licensing authority shall notify the applicant of—

(a) the decision made pursuant to subsection (9) of this section; and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

(11) If—

(a) the applicant has made representations in accordance with this section and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application; or

(b) the applicant has not made representations in accordance with this section and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application, on grounds which differ from those relied on in the advice of the appropriate committee,

the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(12) In this Part of the Act, "the time allowed" means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.".

3. For section 22 of the Act (procedure in other cases) substitute the following sections—

"**Procedure in other cases**

22.—(1) This section applies when—

(a) an application is made for the grant of a licence under this Part of this Act; and

(b) the appropriate committee—

(i) is not consulted under subsection (3) of section 20, or

(ii) is consulted under that subsection but does not give a provisional opinion in accordance with section 21(1).

(2) If the licensing authority propose—

(a) to refuse to grant the licence, or

(b) to grant it otherwise than in accordance with the application,

they shall notify the applicant of their proposals and the reasons for them.

(3) If the applicant is so notified, he may, within the time allowed—

(a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the proposal; or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(4) If the applicant makes written representations in accordance with subsection (3)(b) of this section, the licensing authority shall take those representations into account before determining the application.

Hearing before person appointed

22A.—(1) If the applicant gives notice under section 21(11) or section 22(3) of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or

(iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of any Minister of the Crown.

(3) Subject to subsection (4) of this section, the applicant shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in subsection (1) of this section.

(4) If the applicant so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in subsection (3) of this section, up to a maximum period of six months beginning with the date of the notice referred to in subsection (1) of this section.

(5) If the applicant fails to comply with the time limit in subsection (3) of this section, or, where he has been granted an extended time limit under subsection (4) of this section, that time limit—

(a) he may not appear before or be heard by the person appointed, and

(b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.

(6) The applicant may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant and the licensing authority may make representations.

(8) If the applicant so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take the report into account and decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, or to confirm or alter their decision, as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant of their decision;

(b) if the applicant so requests, provide the applicant with a copy of the report of the person appointed.".

4. In section 24 (duration and renewal of licence), in subsection (4), for "21 and 22", substitute "21 to 22A".

5. In section 27 (proceedings on application for licence of right)—

(a) in subsection (1), for "22" substitute "22A"; and

(b) for subsection (8), substitute the following subsection—

"Subsections (2), (8) and (10)(b) of section 22A of this Act shall have effect in relation to a person appointed under subsection (3) of this section and to proceedings before him and his report as they have effect for the purposes of that section."

6. In section 36 (application for, and issue of, certificate), in subsection (3), for "22" substitute "22A".

7. In section 38 (duration and renewal of certificate)—

(a) in subsection (5), for "21 and 22" substitute "21 to 22A"; and

(b) in subsection (6), for "section 21 or section 22" substitute "section 21, 22 or 22A".

8. In section 43 (extension of section 7 to certain special circumstances), in subsection (4), for "22" substitute "22A".

9. In section 44 of the Act (provision of information to licensing authority), in subsection (3), omit "by the Commission or" in both places where it occurs.

10. In section 58 of the Act (medicinal products on prescription only), in subsection (6), omit ", or, if for the time being there is no such committee, shall consult the Commission".

11. In section 60 of the Act (restricted sale, supply and administration of certain medicinal products), in subsection (7), omit ", or, if for the time being there is no such committee, shall consult the Commission".

12.—(1) Section 62 of the Act (prohibition of sale, supply, or importation, of certain medicinal products) shall be amended as follows.

(2) In subsection (3) omit ", or if for the time being there is no such committee, shall consult the Commission".

(3) In subsection (4) omit "or the Commission".

(4) In subsection (5), for "Commission" (at each place where it occurs) substitute "appropriate committee".

(5) For subsection (7) substitute—

"(7) If an order is made under this section and either—

(a) the appropriate committee have not considered the proposal to make the order, or

(b) the order is made contrary to the advice of the appropriate committee,

the order shall include a statement of the fact that it has been so made.".

13. In section 65 of the Act (compliance with standards specified in monographs), in subsection (8), for "Medicines Commission" substitute "Commission".

14. In section 132 of the Act (general interpretation provisions), in subsection (1)—

(a) before the definition of "analysis", insert the following definition—

""Advisory Body" has the meaning given to it by paragraph 1 of Schedule 1A to this Act;",

(b) in the definition of "the Commission", for "Medicines Commission" substitute "Commission for Human Medicines";

(c) after the definition of "enforcement authority", insert the following definition—

""Expert Advisory Group" means an Expert Advisory Group established under paragraph 3 or 4 of Schedule 1A to this Act;";

(d) after the definition of "herd", insert the following definition—

""the Homoeopathic Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**10**)

(e) after the definition of "manufacture", insert the following definition—

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

(f) in the definition of "the time allowed", for "section 21(8)" substitute "section 21(12)".

15. For Schedule 2 to the Act (procedure for suspension, revocation or variation of licence), substitute—

"SCHEDULE 2 Section 29

SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Procedure on consultation with appropriate committee

1. Subject to paragraph 8 below, where the licensing authority propose, in the exercise of their powers under section 28 of this Act—

(a) to suspend, revoke or vary a product licence on the grounds specified in paragraph (a) or paragraph (c) of subsection (3) of that section, in a case where it appears to the licensing authority that the matters or characteristics in question are such as to affect the safety, efficacy or quality of medicinal products to which the licence relates, or

(b) to suspend, revoke or vary a product licence on any of the grounds specified in paragraph (g) or paragraph (h) of that subsection,

the licensing authority shall not suspend, revoke or vary the licence except after consultation with the appropriate committee.

2.—(1) Where the appropriate committee are consulted under the preceding paragraph and are of the provisional opinion that, on such grounds as are mentioned in that paragraph, they may have to advise the licensing authority that the product licence ought to be revoked, varied or suspended, the appropriate committee shall notify the holder of the licence accordingly.

(**10**) S.I. 1994/105.

(2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.

(3) The appropriate committee shall give the holder of the licence an opportunity to make such representations in accordance with sub-paragraphs (4) to (7) of this paragraph.

(4) Subject to sub-paragraph (5) of this paragraph, the holder of the licence shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph, or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1) of this paragraph.

(5) If the holder of the licence so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4) of this paragraph, up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph.

(6) The holder of the licence may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) of this paragraph has expired, except with the permission of the appropriate committee.

(7) If the holder gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4) of this paragraph, arrange for the holder to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this paragraph; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

3.—(1) After receiving the report of the appropriate committee the licensing authority shall—

(a) decide whether to continue with the proposal to revoke, vary or suspend the product licence; and

(b) take the report into account when making their decision.

(2) The licensing authority shall then notify the holder of the licence of—

(a) the decision made pursuant to sub-paragraph (1) of this paragraph; and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

4. If—

(a) the appropriate committee was consulted under paragraph 1 of this Schedule;

(b) the committee did not give a provisional opinion under paragraph 2(1) of this Schedule; and

(c) the licensing authority propose—

(i) to determine the matter in a way which differs from the advice of the committee, or

(ii) to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy,

the authority shall notify the holder of the licence accordingly.

(2) A notification given under sub-paragraph (1) of this paragraph shall state—

(a) the advice of the committee and the reasons stated by the committee for that advice; and

(b) the proposals of the licensing authority and the reasons for them.

5.—(1) Subject to sub-paragraph (4) of this paragraph, a person to whom a notification has been given under paragraph 3(2) of this Schedule may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) A person to whom a notification has been given under paragraph 4(1) of this Schedule may, within the time allowed—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority, or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(3) If the applicant makes written representations in accordance with sub-paragraph (2)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

(4) Sub-paragraph (1) of this paragraph shall not apply where—

(a) the person has not made any representations in accordance with paragraph 2(4) to (7) of this Schedule; and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

Procedure in other cases

6.—(1) This paragraph applies where the licensing authority propose, in the exercise of the powers conferred by section 28 of this Act—

(a) to suspend, revoke or vary a licence under Part 2 of this Act, other than a product licence; or

(b) to suspend, revoke or vary a product licence where the holder of the licence has been given neither—

(i) notice of any provisional opinion or any advice of the appropriate committee which led to that proposal under paragraphs 2 and 3 of this Schedule; nor

(ii) notice of that proposal under paragraph 4 of this Schedule,

and the provisions of paragraph 8 of this Schedule do not apply.

(2) The licensing authority shall notify the holder of the licence of—

(a) their proposals;

(b) the reasons for them; and

(c) the date (not being earlier than twenty-eight days from the date of the notification) on which it is proposed that the suspension, revocation or variation should take effect.

(3) The holder of the licence may, before the date specified in the notification—

(a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(4) If the applicant makes written representations in accordance with sub-paragraph (3)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

Hearing before person appointed

7.—(1) If the holder of the licence gives notice under paragraph 5 or 6 of this Schedule of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or

(iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of any Minister of the Crown.

(3) Subject to sub-paragraph (4) of this paragraph, the holder of the licence shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

(4) If the holder of the licence so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3) of this paragraph, up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

(5) If the holder of the licence fails to comply with the time limit in sub-paragraph (3) of this paragraph, or, where he has been granted an extended time limit under sub-paragraph (4) of this paragraph, that time limit—

(a) he may not appear before or be heard by the person appointed, and

(b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.

(6) The holder of the licence may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the holder of the licence and the licensing authority may make representations.

(8) If the holder of the licence so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to revoke, vary or suspend the licence.

(10) The licensing authority shall then—

(a) notify the holder of the licence of their decision;

(b) if the holder so requests, provide the holder with a copy of the report of the person appointed.

Procedure in cases of urgency

8. Notwithstanding anything in paragraphs 1 to 7 of this Schedule, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under Part 2 of this Act with immediate effect, the licensing authority may do so, for a period not exceeding three months.

9. If the licence is a product licence, the licensing authority shall report the suspension forthwith to the appropriate committee.

10. If, after the suspension has taken effect—

(a) it appears to the licensing authority; or

(b) in the case of a product licence, they are advised by the appropriate committee,

that it is necessary to consider whether the licence ought to be further suspended, or ought to be revoked or varied, the licensing authority (subject to paragraph 11 of this Schedule) shall proceed in accordance with such of the provisions of paragraphs 1 to 7 of this Schedule as are applicable in the circumstances.

11.—(1) This paragraph applies where, in the circumstances specified in paragraph 10 of this Schedule, the licensing authority proceed as mentioned in that paragraph and any proceedings under paragraphs 1 to 7 of this Schedule relating to a further suspension of the licence have not been finally disposed of before the end of the period—

(a) for which the licence was suspended under paragraph 8 of this Schedule; or

(b) for which it has been further suspended under this paragraph.

(2) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each such further suspension) shall not exceed three months.

(3) The provisions of section 27(7) of this Act shall, with the necessary modifications, have effect for the purpose of determining the date on which any proceedings are taken to be finally disposed of.

Interpretation

12. In this Schedule, the "the time allowed" means the period of twenty-eight days from the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.".

SCHEDULE 2 Regulation 9

CONSEQUENTIAL AND OTHER AMENDMENTS TO THE MARKETING AUTHORISATION REGULATIONS

1. In regulation 1 (citation, commencement and interpretation), in paragraph (2), after the definition of "the Act" insert the following definition—

""appropriate committee", for the purposes of any provision of these Regulations under which a function falls to be performed, 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 authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

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

2. In regulation 5 (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization), in paragraph (3), after "marketing authorization" insert ", or after notification of a decision relating to an application to vary such an authorization".

3. In regulation 9 (consequential and other amendments of the Act and the Medicines Act 1971), omit paragraph (1).

4. For Schedule 2, substitute—

"SCHEDULE 2 Regulation 5(3) and 6(7)

PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF UNITED KINGDOM MARKETING AUTHORIZATIONS

PART 1

INTERPRETATION AND APPLICATION

Interpretation

1. In this Schedule—

"authorization" means a United Kingdom marketing authorization;

"the time allowed" means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case; and

"Type II variation application" means an application by the holder of an authorization to vary that authorization, if the variation applied for is a major variation of Type II within the meaning of Article 3(3) of Commission Regulation (EC) No. 1084/2003(**11**).

(**11**) OJ L 159, 27.6.2003, p.1.

Scope and application of this Schedule

2. Subject to paragraphs 5 and 6, Part 2 applies to—

(a) any application for the grant of an authorization for a relevant medicinal product where, throughout the period beginning with the date on which the application is made and ending with the date on which the licensing authority give a decision on the application, there is no other marketing authorization in force in respect of the product anywhere in the Community;

(b) any application to renew an authorization for a relevant medicinal product; and

(c) any proposal to revoke, vary or suspend an authorization for a relevant medicinal product, other than a variation on the application of the holder of that authorization.

3. Subject to paragraphs 5 and 6, Part 3 applies to any application to vary an authorization for a relevant medicinal product which is a Type II variation application.

4. Subject to paragraphs 5 and 6, Part 4 applies where—

(a) an applicant for an authorization for a relevant medicinal product, or for the variation or renewal of such an authorization; or

(b) the holder of an authorization for a relevant medicinal product,

gives notice under paragraph 11 or 16 of his wish to appear before or be heard by a person appointed by the licensing authority.

5. This Schedule shall cease to apply if at any time the relevant matter is, by virtue of any relevant Community provision, referred to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

6. This Schedule does not apply if—

(a) the licensing authority rejects, or declines to assess, an application in accordance with Article 17(2) or 18 of the 2001 Directive(**12**); or

(b) the application or proposal relates to the renewal, revocation, suspension or variation of a marketing authorization—

(i) which has been granted—

(aa) in accordance with the provisions of Title III, Chapter 4 of the 2001 Directive, or

(bb) by Member States in accordance with Article 4 of Council Directive 87/22/EEC(**13**) before 1st January 1995, or

(ii) which has not been so granted, but which has been subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorization.

(**12**) OJ L 311, 28.11.2001, p.67; as amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).
(**13**) OJ L 15, 17.1.1987, p.38.

PART 2

PROCEDURES RELATING TO GRANT, RENEWAL, COMPULSORY VARIATION, REVOCATION OR SUSPENSION OF AUTHORIZATIONS

Requirement to consult the appropriate committee

7. The licensing authority shall not, at any time while this Schedule applies—

(a) refuse to grant or renew the authorization applied for; or

(b) revoke, vary or (subject to paragraph 12 of this Schedule) suspend an authorization,

on grounds relating to safety, quality or efficacy, except after consultation with the appropriate committee.

Provisional opinion against authorization

8.—(1) Where the appropriate committee are consulted under the preceding paragraph and are of the provisional opinion that, on grounds relating to safety, quality or efficacy, they—

(a) may be unable to advise the licensing authority to grant or renew the authorization; or

(b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application; or

(c) may have to advise the licensing authority that the authorization ought to be revoked, varied or suspended,

the appropriate committee shall notify the applicant or holder accordingly.

(2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.

(3) The appropriate committee shall give the applicant or holder an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant or holder shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (2), or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1).

(5) If the applicant or holder so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2).

(6) The applicant or holder may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) has expired, except with the permission of the appropriate committee.

(7) If the applicant or holder gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents

in accordance with sub-paragraph (4), arrange for the applicant or holder to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this paragraph; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority's decision after appropriate committee report

9.—(1) After receiving the report of the appropriate committee pursuant to paragraph 8(8) the licensing authority shall—

(a) decide whether to refuse to grant or renew the authorization, or to grant or renew it otherwise than in accordance with the application, or to proceed further with their proposal to revoke, vary or suspend the authorization; and

(b) take the report into account when making their decision.

(2) The licensing authority shall then notify the applicant or holder of—

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Licensing authority proposals in other cases

10. If—

(a) the appropriate committee was consulted pursuant to paragraph 7;

(b) the committee did not give a provisional opinion under paragraph 8(1); and

(c) the licensing authority propose—

(i) to determine an application in a way which differs from the advice of the committee,

(ii) to revoke, vary or suspend a marketing authorization against such advice, or

(iii) on grounds not relating to safety, quality or efficacy—

(aa) not to grant or renew an authorization,

(bb) to grant or renew an authorization otherwise than in accordance with an application, or

(cc) to revoke, vary or suspend an authorization,

the licensing authority shall notify the applicant or holder accordingly.

(2) If—

(a) the appropriate committee has not been consulted pursuant to paragraph 7; and

(b) the licensing authority propose, on grounds not relating to safety, quality or efficacy—

(i) not to grant or renew an authorization,

(ii) to grant or renew an authorization otherwise than in accordance with an application, or

(iii) to revoke, vary or suspend an authorization,

the licensing authority shall notify the applicant or holder accordingly.

(3) A notification given under sub-paragraph (1) or (2) shall state—

(a) the advice of the appropriate committee, if any, and the reasons stated by the committee for any such advice; and

(b) the proposals of the licensing authority and the reasons for them.

Right to be heard by a person appointed or to make further representations

11.—(1) Subject to sub-paragraph (4), a person to whom a notification has been given under paragraph 9(2) may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) A person to whom a notification has been given under paragraph 10(1) or (2) may, within the time allowed—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority, or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(3) If the applicant makes written representations in accordance with sub-paragraph (2)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

(4) Sub-paragraph (1) shall not apply where—

(a) the person has not made any representations in accordance with paragraph 8(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

Cases where suspension is to have immediate effect

12.—(1) Paragraph 7 shall not apply to the suspension of an authorization (whether or not it applies to any existing proposal to suspend or revoke the authorization) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorization with immediate effect for a period not exceeding three months.

(2) Where the licensing authority so suspend an authorization they shall report the suspension forthwith to the appropriate committee.

13. If, after suspending an authorization with immediate effect by virtue of paragraph 12—

(a) it appears to the licensing authority; or

(b) the appropriate committee advise,

that the authorization ought to be further suspended, or ought to be varied or revoked, the licensing authority shall proceed in accordance with the applicable provisions of this Schedule (including paragraph 12).

PART 3

VARIATION OF AUTHORIZATION ON APPLICATION OF HOLDER

Hearing before appropriate committee relating to Type II variation applications

14.—(1) If the licensing authority decide, on grounds relating to safety, quality or efficacy—

(a) to refuse to grant a Type II variation application; or

(b) to grant it otherwise than in accordance with the application,

they shall notify the applicant accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) may, within the time allowed, give notice to the licensing authority of his wish to make written or oral representations to the appropriate committee.

(3) On receipt of a notice under sub-paragraph (2), the licensing authority shall inform the appropriate committee and the committee shall give the applicant an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(5) If the applicant so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2).

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) has expired, except with the permission of the appropriate committee.

(7) If the applicant gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4), arrange for the applicant to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this section; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

15.—(1) After receiving the report of the appropriate committee, the licensing authority shall—

(a) confirm or alter their decision; and

(b) take the report into account before doing so.

(2) The licensing authority shall notify the applicant of—

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Right to be heard by a person appointed

16.—(1) Subject to sub-paragraph (2), if the licensing authority notify the applicant of the authority's decision—

(a) to refuse the application; or

(b) to grant it otherwise than in accordance with the application,

the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) Sub-paragraph (1) shall not apply where—

(a) the person had not made any representations in accordance with paragraph 14(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

PART 4

HEARING BEFORE PERSON APPOINTED

Hearing before person appointed

17.—(1) If an applicant or holder of an authorization gives notice under paragraph 11 or 16 of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant or holder to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the applicant or holder shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the applicant or holder fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or be heard by the person appointed; and

(b) the licensing authority shall decide whether—

(i) to confirm or alter their decision,

(ii) to grant or renew the authorization,

(iii) to grant or renew the authorization otherwise than in accordance with the application, or

(iv) to revoke, vary or suspend the authorization,

as the case may be.

(6) The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations.

(8) If the applicant or holder so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether—

(i) to confirm or alter their decision,

(ii) to grant or renew the authorization,

(iii) to grant or renew the authorization otherwise than in accordance with the application, or

(iv) to revoke, vary or suspend the authorization,

as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant or holder of their decision;

(b) if the applicant or holder so requests, provide the applicant or holder with a copy of the report of the person appointed.”.

SCHEDULE 3 Regulation 10

AMENDMENTS TO OTHER ENACTMENTS

The House of Commons Disqualification Act 1975

1. In Schedule 1 to the House of Commons Disqualification Act 1975(**14**) (offices disqualifying for membership), in Part 2 (bodies of which all members are disqualified)—

(a) omit the entry relating to the Medicines Commission and any committee established under section 4 of the Medicines Act 1968; and

(b) insert, at the appropriate place, the following entry—

"The Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968".

The Northern Ireland Assembly Disqualification Act 1975

2. In Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975(**15**) (offices disqualifying for membership), in Part 2 (bodies of which all members are disqualified)—

(a) omit the entry relating to the Medicines Commission and any committee established under section 4 of the Medicines Act 1968; and

(b) insert, at the appropriate place, the following entry—

"The Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968".

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(**16**).

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

(**14**) 1975 c. 24.
(**15**) 1975 c. 25.
(**16**) OJ L311, 28.11.2001, p.67.

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 (paragraphs 2 to 6) to take account of these new provisions and amendments to Directive 2001/83/EC made by Directive 2004/27/EC(**17**).

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.

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