SCHEDULE 8

Regulation 44(2)

AMENDMENTS TO THE MEDICINES ACTS ETC.

PART 1

Consequential amendments to the Medicines Acts 1968 and 1971

The Medicines Act 1968

- 1. The Medicines Act 1968(1) shall be amended as follows.
- 2. In section 1 (Ministers responsible for administration of the Act)(2)—
 - (a) in subsection (1)—
 - (i) in paragraph (a), for "the Health Ministers", in both places those words appear, substitute "the Ministers" and omit "concerned with health in England", and
 - (ii) omit paragraph (b) and the words following that paragraph; and
 - (b) omit subsection (2).
- **3.** In section 3 (functions of the Commission)(**3**), in subsection (1), for "any one or more of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act" substitute "either or both of the Ministers".
 - **4.** In section 4 (establishment of committees)(**4**)—
 - (a) in subsection (1), omit ", the Health Ministers or the Agriculture Ministers";
 - (b) in subsection (5), omit "by whom a committee is established under this section"; and
 - (c) omit subsection (5A).
 - **5.** In section 5 (supplementary provisions as to Commission and committees)—
 - (a) in subsection (2), omit "specified in paragraphs (a) and (b) of section 1(1) of this Act"; and
 - (b) in subsection (3), omit "specified in paragraphs (a) and (b) of section 1(1) of this Act".
 - **6.** In section 6 (the licensing authority)—
 - (a) in subsection (1), for the words from "a body of Ministers" to the end substitute "a body consisting of the Ministers";
 - (b) in subsection (2), for the words from "by any one" to the end substitute "by either of the Ministers acting alone or both of them acting jointly"; and
 - (c) in subsection (3), for "any one or more of those", in both places those words appear, substitute "either or both of the".
 - 7. In section 7 (general provisions as to dealing with medicinal products)(5)—
 - (a) in subsection (1), omit paragraph (b);

^{(1) 1968} c. 67. The Act does not apply in relation to veterinary medicinal products—see regulation 44(1) of S.I.2005/2745.

⁽²⁾ Section 1 was amended by Schedule 1 to S.I. 1969/388, the Schedule to S.I. 1999/3142 and paragraph 15 of Schedule 1 to S.I. 2002/794.

⁽³⁾ Section 3 was substituted by regulation 4 of S.I. 2005/1094 and amended by paragraph 1 of Schedule 1 to S.I. 2005/2754.

⁽⁴⁾ Section 4 was amended by paragraph 2 of Part 1 of Schedule 10 to S.I. 2004/1031, regulation 5 of S.I. 2005/1094 and paragraph 2 of Schedule 1 to S.I. 2005/2754.

⁽⁵⁾ Section 7 was amended by regulation 2(2) of S.I. 1977/1050, regulation 2 of S.I. 1983/1724, regulation 2 of S.I. 1992/604, regulation 3 of S.I. 1994/276, paragraph 3 of Part 1 of Schedule 10 to S.I. 2004/1031, regulation 25(1)(a) of S.I. 2005/50 and paragraph 1 of the Schedule to S.I. 2005/2753.

- (b) in subsection (5)(b), omit ", a ready-made veterinary drug" and "other than a veterinary drug";
- (c) in subsection (6A), omit the words from "Where the product" to "veterinary drug,";
- (d) omit subsection (6B); and
- (e) in subsection (7)—
 - (i) at the end of the definition of "radiopharmaceutical", omit "and", and
 - (ii) omit the definition of "ready-made veterinary drug".
- 8. In section 8 (provisions as to manufacture and wholesale dealing)(6)—
 - (a) in subsection (1), for "(a) to (c)" substitute "(a) and (c)";
 - (b) in subsection (3)(b), omit ", ready-made veterinary drug" and "other than a veterinary drug";
 - (c) in subsection (4), omit the words from "Where the product" to "veterinary drug,";
 - (d) omit subsection (5); and
 - (e) in subsection (6), for the words from "'homoeopathic" to "veterinary drug"" substitute "'proprietary medicinal product" and "radiopharmaceutical"".
- **9.** In section 9 (exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners)(7)—
 - (a) omit subsections (2) and (3); and
 - (b) the heading of section 9 accordingly becomes "Exemptions for doctors and dentists".
 - 10. In section 10 (exemptions for pharmacists)(8)—
 - (a) in subsection (1), omit "Subject to the next following subsection,";
 - (b) omit subsection (2);
 - (c) in subsection (3), omit paragraph (b) and the word "or" before it;
 - (d) omit subsection (6A);
 - (e) in subsection (7A), omit "Health".
 - 11. In section 15 (provision for extending or modifying exemptions)—
 - (a) in subsection (1), omit "appropriate"; and
 - (b) in subsection (3), omit "appropriate".
 - 12. In section 18 (application for licence), omit subsection (3)(9).
 - 13. In section 23 (special provisions as to effect of manufacturer's licence)(10)—
 - (a) in subsection (1), omit "the provisions of this Part of this Act relating to medicinal tests on animals and to";
 - (b) in subsection (2)—
 - (i) omit "Subject to the next following subsection,", and
 - (ii) omit paragraph (b) and the word "or" before it; and

⁽⁶⁾ Section 8 was amended by regulation 3 of S.I. 1977/1050, regulation 3(3) of S.I. 1992/604, regulation 2 of S.I. 1993/834, regulation 4 of S.I. 1994/276, regulation 2(a)(i) of S.I. 2002/236, paragraph 4 of Part 1 of Schedule 10 to S.I. 2004/1031, regulation 25(1)(b) of S.I. 2005/50 and paragraph 1 of Part 1 of Schedule 5 to S.I. 2005/2789.

⁽⁷⁾ Section 9 was amended by regulation 10 of S.I. 1994/2987.

⁽⁸⁾ Section 10 was amended by paragraph 5 of Schedule 3 to the Regulation of Care (Scotland) Act 2001 (asp 8)), article 3 of S.I. 1971/1445, regulation 3 of S.I. 1993/384, regulation 11 of S.I. 1994/2987 and section 26(1) of the Health Act 2006 (c. 28).

⁽⁹⁾ Section 18(3) was substituted by regulation 4 of S.I. 1983/1724 and amended by regulation 2(b) of S.I. 2002/236.

⁽¹⁰⁾ Section 23 was amended by paragraph 5 of Part 1 of Schedule 10 to S.I. 2004/1031.

- (c) omit subsection (3).
- 14. In section 28 (general power to suspend, revoke or vary licences), omit subsection (3)(i)(11).
- 15. Sections 32 to 36 and 38 to 40 shall be omitted.
- **16.** In section 44 (provision of information to the licensing authority)(12)—
 - (a) in subsection (1), omit "or for an animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act)";
 - (b) in subsection (2), omit ", or of an animal test certificate,";
 - (c) in subsection (3), omit "or certificate"; and
 - (d) in subsection (4)—
 - (i) omit ", or of a certificate issued in pursuance of section 37(4) of this Act,",
 - (ii) omit "or certificate", in each place those words appear,
 - (iii) in paragraph (a), for "sections 25 and 37(4)" substitute "section 25", and
 - (iv) in paragraph (b), omit "or issue".
- 17. In section 45 (offences under Part II)(13)—
 - (a) in subsection (1)—
 - (i) for ", section 8, section 32, section 34 or section 40" substitute "or section 8",
 - (ii) omit "or animal feeding stuff", and
 - (iii) for "any of those sections" substitute "either of those sections";
 - (b) in subsection (2)—
 - (i) omit "or animal feeding stuff",
 - (ii) omit ", section 32 or section 40", and
 - (iii) omit "or feeding stuff";
 - (c) in subsection (3)—
 - (i) omit "or of an animal test certificate", and
 - (ii) omit "or certificate", in both places those words appear; and
 - (d) omit subsections (4) and (5).
- **18.** In section 46 (special defences under s45)(14)—
 - (a) in subsection (1)—
 - (i) omit "or of an animal test certificate", and
 - (ii) omit "or certificate"; and
 - (b) in subsection (2)—
 - (i) omit "or of an animal test certificate" in the first place those words appear,
 - (ii) in paragraph (a), omit "or of an animal test certificate applicable to them",
 - (iii) in paragraph (b), omit "or certificate".

⁽¹¹⁾ Section 28(3)(i) was inserted by regulation 2(2) of S.I. 1975/1169 and amended by Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40).

⁽¹²⁾ Section 44 was amended by paragraph 12 of Part 1 of Schedule 10 to S.I. 2004/1031 and paragraph 9 of Schedule 1 to S.I. 2005/1094.

⁽¹³⁾ The relevant amendments to section 45 were made by paragraph 13 of Part 1 of Schedule 10 of S.I. 2004/1031.

⁽¹⁴⁾ Section 46 was amended by paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40) and by paragraph 14 of Part 1 of Schedule 10 to S.I. 2004/1031.

- 19. In section 47 (standard provisions for licences or certificates)(15)—
 - (a) in subsection (2), omit "or any animal test certificate" and "or issued";
 - (b) in subsection (4)—
 - (i) omit ", or any animal test certificate,", and
 - (ii) omit "or certificate", in both places those words appear;
 - (c) in subsection (5)—
 - (i) omit ", or in any certificate issued in pursuance of section 37(4) of this Act,", and
 - (ii) omit "or certificate", in both places those words appear;
 - (d) in subsection (6), omit "or certificate", in both places those words appear;
 - (e) in subsection (8), omit "or certificate"; and
 - (f) in subsection (9), omit "or certificate", in both places those words appear.

The heading accordingly becomes "Standard provisions for licences".

- **20.** In section 48 (postponement of restrictions in relation to exports), in subsection (1), for "sections 49 and 49A" substitute "section 49".
 - 21. In section 49 (special provisions in respect of exporting certain products)—
 - (a) in subsection (1), for "the Health Ministers or the Agriculture Ministers" substitute "the Ministers"; and
 - (b) in subsection (2)—
 - (i) for "the Health Ministers or the Agriculture Ministers" substitute "the Ministers", and
 - (ii) for "the Ministers making the order" substitute "them".
 - 22. In section 51 (general sale lists)—
 - (a) in subsection (1), omit "appropriate"; and
 - (b) in subsection (3), omit "appropriate".
- 23. In section 52 (sale or supply of medicinal products not on general sale list), in subsection (2)(16), omit "Health".
 - 24. In section 53 (sale or supply of medicinal products on general sale list), in subsection (2)—
 - (a) omit "either"; and
 - (b) omit paragraph (b) and the word "or" before it.
- **25.** In section 54 (sale of medicinal products from automatic machines), in subsection (2), omit "appropriate".
- **26.** In section 55 (exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners)(17)—
 - (a) in subsection (2)—
 - (i) in paragraph (a), omit "Health", and
 - (ii) in paragraph (b), for "Health Ministers" substitute "Ministers"; and
 - (b) omit subsection (3).

⁽¹⁵⁾ Section 47 was amended by paragraph 15 of Part 1 of Schedule 10 to S.I. 2004/1031.

⁽¹⁶⁾ Subsection (2) was inserted by section 26(2) of the Health Act 2006 (c. 28).

⁽¹⁷⁾ Section 55 was amended by paragraph 128(1) of Schedule 4 to the National Health Service Reorganisation Act 1973 (c. 32) and paragraph 10(b) of Part 1 of the Schedule to S.I. 2004/1771.

Status: This is the original version (as it was originally made).

The heading of section 55 accordingly becomes "Exemptions for doctors and dentists etc".

- **27.** In section 56 (exemptions in respect of herbal remedies), in subsection (3), omit "appropriate".
 - 28. In section 57 (power to extend or modify exemptions)(18)—
 - (a) in subsection (1), omit "appropriate";
 - (b) omit subsections (2A) to (2D); and
 - (c) in subsection (3), omit "appropriate".
 - 29. In section 58 (medicinal products on prescription only)(19)—
 - (a) in subsection (1), for "appropriate Ministers" substitute "Ministers";
 - (b) in subsection (1A), in paragraph (h), for "appropriate Ministers", in both places those words appear, substitute "Ministers";
 - (c) omit subsection (1B);
 - (d) in subsection (3), omit paragraph (b) and the word "or" before it;
 - (e) in subsection (4), for "appropriate Ministers" substitute "Ministers"; and
 - (f) in subsection (6), for "appropriate Ministers" substitute "Ministers".
- **30.** In section 58A (requirement to specify certain products for human use as prescription-only products)(20)—
 - (a) in subsection (1), omit "appropriate";
 - (b) in subsection (3), omit "appropriate";
 - (c) in subsection (4), omit "appropriate"; and
 - (d) in subsection (5), omit "and section 58B of this Act".

The heading of section 58A accordingly becomes "Requirement to specify certain products as prescription-only products".

- **31.** Section 58B (requirement to specify certain products for veterinary use as prescription-only products)(21) shall be omitted.
- **32.** In section 59 (special provisions in relation to new medicinal products), in subsection (2)(b), omit "appropriate".
 - 33. In section 60 (restricted sale, supply and administration of certain medicinal products)(22)—
 - (a) in subsection (1), omit "appropriate", in both places that word appears;
 - (b) in subsection (3), omit "appropriate";
 - (c) in subsection (4), omit "appropriate";
 - (d) in subsection (5)—
 - (i) omit "appropriate", in each place that word appears, and
 - (ii) for "those Ministers" substitute "the Ministers"; and
 - (e) in subsection (7), for "appropriate Ministers" substitute "Ministers".

⁽¹⁸⁾ Section 55 was amended by section 14 of the Animal Health and Welfare Act 1984 (c. 40).

⁽¹⁹⁾ Section 57 was amended by section 1 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 63 of the Health and Social Care Act 2001 (c. 15), paragraph 2 of Schedule 5 to S.I. 2002/253 and paragraph 10 of Schedule 1 to S. I. 2005/1094.

⁽²⁰⁾ Section 58A was inserted by regulation 2 of S.I. 1992/3271 and amended by regulation 2(a)(v) of S.I. 2002/236.

⁽²¹⁾ Section 58B was inserted by regulation 2 of S.I. 1992/3271.

⁽²²⁾ Section 60 was amended by paragraph 11 of Schedule 1 to S.I. 2005/1094.

- **34.** In section 61 (special restrictions on persons to be supplied with medicinal products), omit "appropriate".
- **35.** In section 62 (prohibition of sale or supply, or importation, of medicinal products of specified description, or of animal feeding stuffs incorporating such products)(23)—
 - (a) in the heading, omit ", or of animal feeding stuffs incorporating such products";
 - (b) in subsection (1)—
 - (i) omit "appropriate", and
 - (ii) omit paragraph (b);
 - (c) in subsection (3)—
 - (i) for "appropriate Ministers" substitute "Ministers", and
 - (ii) omit ", whether of human beings or of animals";
 - (d) in subsection (5)—
 - (i) for "appropriate Ministers", in each place those words appear, substitute "Ministers", and
 - (ii) for "those Ministers", in both places those words appear, substitute "the Ministers"; and
 - (e) in subsection (6), omit "appropriate".
 - **36.** In section 65 (compliance with standards specified in monographs in certain publications)—
 - (a) in subsection (4), omit ", the British Veterinary Codex";
 - (b) in subsection (5), in paragraph (c), omit "or the British Veterinary Codex"; and
 - (c) in subsection (7), omit "Health".
- **37.** In section 66 (further powers to regulate dealings with medicinal products), in subsection (1), omit "appropriate".
 - **38.** In section 72A (the responsible pharmacist)(24)—
 - (a) in subsection (2), omit "Health";
 - (b) in subsection (4)(b), omit "Health";
 - (c) in subsection (5)(b), omit "Health"; and
 - (d) in subsection (6), omit "Health".
 - **39.** In section 73 (power to extend or modify conditions)—
 - (a) in subsection (1), omit "Health"; and
 - (b) in subsection (3), omit "Health".
 - **40.** In section 76 (supplementary provisions as to registration of premises), omit subsection (6).
 - **41.** In section 79 (provision for modifying or extending restrictions under section 78)—
 - (a) in subsection (1), omit "Health";
 - (b) in subsection (2), omit "Health"; and
 - (c) in subsection (3), omit "Health".
- **42.** In section 85 (labelling and marking of containers and packages), in subsection (1), omit "appropriate".

⁽²³⁾ Section 62 was amended by paragraph 12 of Schedule 1 to S.I. 2005/1094.

⁽²⁴⁾ Section 72A was inserted by section 30(1) of the Health Act 2006 (c. 28).

- **43.** In section 86 (leaflets)(25), in subsection (1), omit "appropriate".
- **44.** In section 87 (requirements as to containers), in subsection (1)—
 - (a) omit "appropriate"; and
 - (b) for "those Ministers" substitute "the Ministers".
- **45.** In section 88 (distinctive colours, shapes and markings of medicinal products), in subsection (1)—
 - (a) omit "appropriate"; and
 - (b) for "those Ministers" substitute "the Ministers".
- **46.** In section 89 (display of information on automatic machines), in subsection (1), omit "appropriate".
 - 47. Section 90 (provisions as to medicated animal feeding stuffs) shall be omitted.
 - **48.** In section 91 (offences under Part V, and supplementary provisions)(26)—
 - (a) in subsection (1), for ", section 86(3) or (4) or section 90(2)" substitute "or section 86(3) or (4)";
 - (b) in subsection (2), omit "or any of those provisions as applied by section 90(1) of this Act"; and
 - (c) in subsection (3), omit ", and any power to make regulations conferred by those sections as applied by section 90(1) of this Act shall be exercisable in a corresponding way".
 - **49.** In section 95 (powers to regulate advertisements and representations)(27)—
 - (a) in subsection (1), omit "appropriate", in both places that word appears; and
 - (b) in subsection (3), omit "appropriate".
 - 50. In section 99 (new editions of British Pharmacopoeia, and other compendia)(28)—
 - (a) in subsection (4), in paragraph (a), for "veterinary drugs" substitute "veterinary medicinal products";
 - (b) in subsection (6)—
 - (i) for "subsection (3)(a)" substitute "subsection (3)",
 - (ii) omit "Health", and
 - (iii) omit the words from "; and where the appropriate body has prepared" to the end; and
 - (c) in subsection (7)—
 - (i) after "In this Part of this Act" insert "—",
 - (ii) for ", and "relevant" substitute ";

"relevant"; and

(iii) at the end insert

"veterinary medicinal product" has the same meaning as in the Veterinary Medicines Regulations 2006

- **51.** In section 101 (other publications), in subsection (2)—
 - (a) for "the Health Ministers or the Agriculture Ministers" substitute "the Ministers"; and

⁽²⁵⁾ Section 86 was amended by regulation 7(1) of S.I. 1994/276 and regulation 2(a)(vi) of S.I. 2002/236.

⁽²⁶⁾ Section 91 was amended by section 32(2) of the Magistrates' Courts Act 1980 (c. 43) and regulation 8 of S.I. 1994/267.

⁽²⁷⁾ Section 95 was amended by section 32(2) of the Magistrates' Courts Act 1980 (c. 43).

⁽²⁸⁾ Section 99 was amended by Part 17 of Schedule 1 to the Statute Law (Repeals) Act 2004 (c. 14).

- (b) omit "concerned".
- **52.** In section 102 (supplementary provisions)—
 - (a) in subsection (2)—
 - (i) omit "Health", and
 - (ii) for "those Ministers" substitute "the Ministers";
 - (b) in subsection (4), omit "appropriate";
 - (c) in subsection (5), omit "appropriate";
 - (d) in subsection (6), omit "appropriate"; and
 - (e) in subsection (7), omit the words from "the appropriate Ministers" to "to be published, and".
- **53.** In section 103 (construction of references to specified publications)(**29**), in subsection (1), omit paragraph (d).
- **54.** In section 104 (application of Act to certain articles and substances)(**30**), in subsection (1), omit ", the Health Ministers or the Agriculture Ministers".
- 55. In section 105 (application of Act to certain other substances which are not medicinal products)(31), in subsection (1), in paragraph (b), omit ", or of causing danger to the health of animals generally or of one or more species of animals".
 - **56.** In section 108 (enforcement in England and Wales)(32)—
 - (a) in subsection (6), in paragraph (a), omit "40," and "and of any regulations made under section 40 of this Act";
 - (b) omit subsection (8);
 - (c) in subsection (9), for "(2) to (8)" substitute "(2) to (7)";
 - (d) in subsection (10), as amended by section 31(1)(d) of the Health Act 2006(**33**), omit "and (8)"; and
 - (e) in subsection (11)—
 - (i) omit paragraph (a), and
 - (ii) in paragraph (b), omit "in all other respects,".
 - 57. In section 109 (enforcement in Scotland), in subsection (2), omit paragraph (d).
 - **58.** In section 110 (enforcement in Northern Ireland)—
 - (a) in subsection (1), as amended by section 31(3)(a) of the Health Act 2006, for "subsections (3C) and (4)" substitute "subsection (3C)";
 - (b) omit subsection (4); and
 - (c) in subsection (5)—
 - (i) in paragraph (a), for "(2) to (8)" substitute "(2) to (7)", and
 - (ii) in paragraph (b), as amended by section 31(3) (d) of the Health Act 2006, omit "and (8)".

⁽²⁹⁾ Section 103 was amended by section 22 of the Health and Medicines Act 1988 (c. 49).

⁽³⁰⁾ Section 104 was amended by paragraph 17 of Part 1 to Schedule 10 to S.I. 2004/1031.

⁽³¹⁾ Section 105 was amended by paragraph 18 of Part 1 to Schedule 10 to S.I. 2004/1031.

⁽³²⁾ Section 108 was amended by Schedule 30 to the Local Government Act 1972 (c. 70), paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40), paragraph 8 of Schedule 3 to the Food Safety Act 1990 (c. 16), paragraph 33 of Schedule 16 to the Local Government (Wales) Act 1994 (c. 19), article 5(4) of S.I. 1968/1699 and article 2 of S.I. 1988/1955.

^{(33) 2006} c. 28.

- **59.** In section 116 (liability to forfeiture under Customs and Excise Management Act 1979)(**34**), in subsection (3), omit "or are, or normally are, animal feeding stuffs in which medicinal products have been incorporated".
- **60.** Section 117 (special enforcement and sampling provisions relating to animal feeding stuffs) shall be omitted.
- **61.** In section 121 (contravention due to default of other person), in subsection (4), for "85 to 90" substitute "85 to 89".
 - **62.** In section 122 (warranty as defence), in subsection (2), omit "and section 90".
 - **63.** In section 125 (prosecutions), in subsection (4)—
 - (a) omit "or subsection (8)"; and
 - (b) for "either of those subsections" substitute "that subsection".
 - **64.** In section 126 (presumptions)(35)—
 - (a) in subsection (1)—
 - (i) omit paragraph (a),
 - (ii) omit "animal feeding stuff or", in both places those words appear, and
 - (iii) omit "animal feeding stuffs or";
 - (b) in subsection (2)—
 - (i) omit "or animal feeding stuff", in each place those words appear, and
 - (ii) omit "or of animal feeding stuffs in which medicinal products have been incorporated";
 - (c) in subsection (3), omit the words from ", to any of those provisions" to the end; and
 - (d) in subsection (4)—
 - (i) omit", or of so much of subsection (2) of section 90 of this Act as relates to leaflets",
 - (ii) omit "or of animal feeding stuffs in which medicinal products have been incorporated", and
 - (iii) for the words from "in his possession" to the end, substitute "in his possession for the purpose of supplying it with a medicinal product".
 - **65.** In section 129 (orders and regulations)(**36**)—
 - (a) in subsection (2), omit ", paragraph 5";
 - (b) in subsection (3), in paragraph (a), omit ", 35(2)(b)" and ", 117"; and
 - (c) omit subsection (6A).
 - **66.** In section 130 (meaning of "medicinal product" and related expressions)(37)—
 - (a) in subsection (1), omit "or animals", in both places those words appear;
 - (b) omit subsections (3A) to (3C);
 - (c) in subsection (4)—
 - (i) omit "or (3A)",
 - (ii) omit "or animals", and

⁽³⁴⁾ Section 116 was amended by paragraph 12 of Schedule 4 to the Customs and Excise Management Act 1979 (c. 2).

⁽³⁵⁾ Section 126 was amended by paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40).

⁽³⁶⁾ Section 129 was amended by paragraph 15 of Part 3 of Schedule 3 to the Food Standards Act 1999 (c. 28).

⁽³⁷⁾ Section 130 was amended by section 13(2) of, and paragraph 3 of Schedule 1 to, the Animal Health and Welfare Act 1984 (c. 40), by regulation 2 of S.I. 1994/3119 and regulation 25(1)(c) and (d) of S.I. 2005/50.

- (iii) in paragraph (c), omit the words from ", or beneficial to" to the end of the paragraph;
- (d) in subsection (5), in paragraph (c), omit ", the Health Ministers or the Agriculture Ministers";
- (e) in subsection (6)—
 - (i) omit "or (3B)", and
 - (ii) for "the relevant subsection", in both places those words appear, substitute "that subsection"; and
- (f) in subsection (9)—
 - (i) omit "or an animal", and
 - (ii) omit "or feeding", in both places those words appear.
- **67.** In section 132 (general interpretation provisions)—
 - (a) in subsection (1)—
 - (i) omit the definitions of the following expressions—

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"animal".
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"animal feeding stuff" (38),

"animal test certificate",

"the appropriate Ministers",

"the 1981 Directive" (39),

"herd",

"medicinal test on animals",

"poultry", and

"veterinary drug",

- (ii) in the definition of "manufacture", omit "and does not include the incorporation of the product in any animal feeding stuff", and
- (iii) after the definition of "the Marketing Authorisation Regulations" insert the following definition—

""the Ministers" shall be construed in accordance with section 1(1) of this Act;";

- (b) in subsection (2)—
 - (i) in paragraph (a), omit ", or of causing danger to the health of animals generally or of one or more species of animals", and
 - (ii) omit paragraph (b); and
- (c) in subsection (3), omit the words from ", and any reference" to the end.
- **68.** In Schedule 3 (sampling), in paragraph 17—
 - (a) omit paragraph (a); and
 - (b) in paragraph (b), omit "in any other case".
- **69.** In Schedule 4 (provisions relating to Northern Ireland)(40)—
 - (a) omit paragraphs 2 to 5;

⁽³⁸⁾ The definition of "animal feeding stuff" was inserted by section 13(2) of the Animal Health and Welfare Act 1984 (c. 40).

⁽³⁹⁾ The definition of "the 1981 Directive" was inserted by regulation 3 of S.I. 1992/3271.

⁽⁴⁰⁾ Schedule 4 was amended by paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40), paragraph 10 of Schedule 4 to S.I. 1979/1573 and paragraph 8 of Schedule 5 to S.I. 1976/2713.

- (b) in paragraph 6—
 - (i) for "The appropriate Northern Ireland Minister or Ministers" substitute "The appropriate Northern Ireland Minister",
 - (ii) for "appropriate Ministers" substitute "Ministers",
 - (iii) omit ", section 35", and
 - (iv) omit "or their";
- (c) omit paragraph 7;
- (d) in paragraph 8—
 - (i) omit ", or the Minister of Agriculture for Northern Ireland, or both those Ministers,", and
 - (ii) omit ", paragraph 5";
- (e) in paragraph 9—
 - (i) for "the appropriate Northern Ireland Minister or Ministers" substitute "the appropriate Northern Ireland Minister",
 - (ii) in paragraph (a), omit the words from "for the purpose" to "of animals,",
 - (iii) omit paragraphs (b) and (c), and
 - (iv) omit the words after paragraph (c); and
- (f) in paragraph 10—
 - (i) omit "or to the Minister of Agriculture for Northern Ireland",
 - (ii) for "either or both of those Ministers" substitute "that Minister",
 - (iii) omit the words from "or, as the case may require" to the end.

The Medicines Act 1971

70. In section 1 of the Medicines Act 1971 (fees payable for the purposes of Part II of the Medicines Act 1968)(**41**), in subsection (1A), in the definition of "medicinal product", omit paragraph (b) and the word "and" before it.

PART 2

Consequential amendments to secondary legislation

The Medicines (Surgical Materials) Order 1971

1. In the Medicines (Surgical Materials) Order 1971(42), in article 3 (application of specified provisions of the Medicines Act 1968 to surgical materials), omit "Health".

The Medicines (Specified Articles and Substances) Order 1976

2. In the Medicines (Specified Articles and Substances) Order 1976(**43**), in article 2 (application of specified provisions of the Medicines Act 1968 to articles and substances specified in Schedule 1), omit "Health".

^{(41) 1971} c. 69; section 1 was amended by section 21 of the Health and Medicines Act 1988 (c. 49) and paragraph 20 of Part 1 of Schedule 10 to S.I. 2004/1031, and its effect modified by regulation 9(12)(a) of S.I. 1994/3144.

⁽⁴²⁾ S.I. 1971/1267; relevant amending instrument is S.I. 2004/1031.

⁽⁴³⁾ S.I. 1976/968, amended by S.I. 1994/3199 and 2004/1031.

The Medicines (Radioactive Substances) Order 1978

3. In the Medicines (Radioactive Substances) Order 1978(44), in article 2 (application of specified provisions of the Medicines Act 1968 to certain substances or articles consisting of or containing radioactive substances), omit "Health".

The Medicines (Administration of Radioactive Substances) Regulations 1978

4. In the Medicines (Administration of Radioactive Substances) Regulations 1978(**45**), for "the Health Ministers", in each place those words appear, substitute "the Ministers".

The Medicines (Cyanogenetic Substances) Order 1984

5. In the Medicines (Cyanogenetic Substances) Order 1984(**46**), in article 2 (application of specified provisions of the Medicines Act 1968), omit "Health".

The Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986

6. In the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986(**47**), in rule 2 (interpretation), in paragraph (b), in the definition of "relevant Minister", in sub-paragraph (ii), for "the appropriate Ministers as defined in section 1(2)" substitute "the Ministers as defined in section 1(1)".

The Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992

- 7. In the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992(48), in the Schedule—
 - (a) in the entry relating to section 44(1) to (3)—
 - (i) for the first entry in column (2) substitute "as though in subsection (1) "(including a licence of right)" were omitted",
 - (ii) omit the second entry in column (2), and
 - (iii) in the third entry in column (2), omit "and the words "or certificate" were omitted";
 - (b) in the entry relating to section 45(1), (2) and (6) to (9)—
 - (i) for the first entry in column (2) substitute "as though in subsection (1) the words ", section 8" were omitted and for "any of those sections" there were substituted "that section", and
 - (ii) omit the second entry in column (2);
 - (c) in the entry relating to section 46(1), omit
 - ""or of an animal test certificate" and "or certificate" were omitted and";"
 - (d) in the entry relating to section 47, omit the second, third and fourth entries in column (2);
 - (e) in the entry relating to section 91—
 - (i) for the first entry in column (2) substitute "as though in subsection (1) for "section 85(5), section 83(3) or (4) or section 90(2)" there were substituted "section 86(3) or (4)",

⁽⁴⁴⁾ S.I. 1978/1004.

⁽⁴⁵⁾ S.I. 1978/1006, amended by S.I. 1994/2147 and 2005/2754.

⁽⁴⁶⁾ S.I. 1984/187.

⁽⁴⁷⁾ S.I. 1986/1761, amended by S.I. 2005/2745.

⁽⁴⁸⁾ S.I. 1992/605, amended by S.I. 2004/1031 and 2005/2754.

- (ii) in the second entry in column (2) for "section 90(1)" substitute "section 87(2)", and
- (iii) in the third entry in column (2), omit "and the words from "and any power to make regulations conferred by those sections" to the end of the subsection were omitted"; and
- (f) for the entry relating to section 126(4), substitute "as though the words "or subsection (3)" were omitted".

The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

- 8. In the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(49)—
 - (a) in regulation 6 (grant of a certificate), omit "appropriate"; and
 - (b) in Schedule 4 (application of the provisions of the Medicines Act 1968)—
 - (i) omit the entries relating to sections 23, 58A, 121, 122 and 126,
 - (ii) in the entry relating to section 44—
 - (aa) omit "or for an animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act",
 - (bb) omit "and as though ", or of an animal test certificate," were omitted", and
 - (cc) for "as though "licence or" were omitted" substitute "as though for "licence" there were substituted "certificate"",
 - (iii) in the entry relating to section 108, omit the words from "as though in subsection (8)" to the end, and
 - (iv) in the entry relating to section 110, omit "as though subsection (4) were omitted".

The Medicines (Advertising) Regulations 1994

- **9.** In the Medicines (Advertising) Regulations 1994(**50**), in regulation 2 (interpretation), for paragraph (4) substitute the following paragraph—
 - "(4) In these Regulations, "the Health Ministers" means the Ministers specified in section 1(1) of the Act, and the functions of the Health Ministers under these Regulations may be performed by either of them acting alone or both of them acting jointly."

The Medicines (Monitoring of Advertising) Regulations 1994

- **10.** In the Medicines (Monitoring of Advertising) Regulations 1994(**51**), in regulation 2 (interpretation and application), for paragraph (3) substitute the following paragraph—
 - "(3) In these Regulations, "the Health Ministers" means the Ministers specified in section 1 of the Act, and the functions of the Health Ministers under these Regulations may be performed by either of them acting alone or both of them acting jointly."

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

- 11. In the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(52), in Schedule 4 (modifications of enforcement provisions of the Medicines Act 1968)—
 - (a) in paragraph 9, in paragraph (b), for "85 to 90" substitute "85 to 89"; and

⁽⁴⁹⁾ S.I. 1994/105; relevant amending instruments are S.I. 2004/1031 and 2005/2753.

⁽⁵⁰⁾ S.I. 1994/1932; relevant amending instrument is S.I. 1999/267.

⁽⁵¹⁾ S.I. 1994/1933, to which there are amendments not relevant to this instrument.

⁽⁵²⁾ S.I. 1994/3144, to which there are amendments not relevant to this instrument.

Status: This is the original version (as it was originally made).

(b) in paragraph 10, in paragraph (b), for "sections 85 to 88 and section 90" substitute "and sections 85 to 88".

The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

12. In the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(53), in Schedule 1 (funded operations), in paragraph 1, in sub-paragraph (a), omit "the Health Ministers,".

The Herbal Medicines Advisory Committee Order 2005

13. In the Herbal Medicines Advisory Committee Order 2005(**54**), in article 2 (Herbal Medicines Advisory Committee), in paragraph (b), omit "Health".

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

14. In the Medicines (Advisory Bodies) (No. 2) Regulations 2005(**55**), in regulation 1 (citation, commencement and interpretation), in paragraph (3), for the definition of "the appropriate Ministers" substitute the following definition—

""the appropriate Ministers" means the Secretary of State for Health and the Department for Health, Social Services and Public Safety acting jointly;".

⁽⁵³⁾ S.I. 2003/1076 as amended by S.I. 2005/2061.

⁽**54**) S.I. 2005/2791.

⁽⁵⁵⁾ S.I. 2005/2754.