SCHEDULES

SCHEDULE 34

Regulation 348

Amendments to existing law

PART 1

The Medicines Acts 1968 and 1971

1. The Medicines Act 1968 is amended as follows.

2. For the text of section 1 (Ministers responsible for the administration of Act) substitute—

"**1.** In this Act, "the Ministers" has the meaning given by regulation 6(6) to (8) of the 2012 Regulations (but as if references in that regulation to those Regulations were references to this Act). ".

3. In section 10(**1**) (exemptions for pharmacists)—

(a) in subsection (1) for "a practitioner" substitute "an appropriate practitioner";

(b) in subsections (1) and (4) for "sections 7 and 8 of this Act" substitute "regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of the 2012 Regulations";

(c) in subsection (5) for "section 7 of this Act" substitute "regulation 46 of the 2012 Regulations";

(d) in subsection (6) for "section 8(2) of this Act" substitute "regulation 17(1) of the 2012 Regulations";

(e) omit subsection (7); and

(f) in subsection (8) for the words from "section 92" to the end of the subsection substitute "regulation 7 (advertisements relating to medicinal products) of the 2012 Regulations".

4. In section 15 (provision for extending or modifying exemptions)—

(a) omit subsections (1) and (2); and

(b) in subsection (3)(**2**) for "sections 9 to 14" substitute "section 10".

5. In section 58(**3**) (medicinal products on prescription only)—

(a) in subsection (1) for the words from the first occurrence of "for the purposes" to the end of the subsection substitute "as prescription only medicines";

(b) omit subsections (1A), (2) and (3);

(**1**) 1968, c.67. Section 10(1), 10(3) and 10(7A) were amended and 10(2) repealed by Part 1 paragraphs 1 and 10 of Schedule 8 to S.I. 2006/2407, section 10(1), 10(4) were amended and 10(5) to (7) and 10(8) inserted by article 3 of S.I. 1971/1445, section 10(1) was amended and section 10(9) inserted by paragraph 5 Schedule 1 to the Regulations of Care (Scotland) Act 2001, and section 10(7A) to (7C) were inserted by section 26(1) of the Health Act 2006.

(**2**) Section 15(3) was amended by paragraphs 1 and 11(b) of Part 1 of Schedule 8 to S.I. 2006/2407.

(**3**) Section 58((1), (4) and (6) was amended by paragraph 29 of Part 1 of Schedule 8 to S.I. 2006/2407. Section 58(4) was amended by paragraph 2(b) of Schedule 5 to S.I. 2002/53. Section 58(4) was amended by section 63(1 and (4) of, and section 58(4A) and (4C) inserted by section 63(1) and (5) of, the Health and Social Care Act 2001.

(c) in the opening words of subsection (4) for "the last preceding subsection" substitute "regulation 223(1) of the 2012 Regulations";

(d) in subsection (4)(a)—

(i) for "paragraph (a) or paragraph (b) of subsection (2) of this section, or both those paragraphs," substitute "regulation 214(1) or (2) of the 2012 Regulations", and

(ii) for the words from "or, where" to "of this section" substitute "or, in the case of an appropriate practitioner, other than a doctor or dentist,";

(e) in subsection (4)(b) for "paragraph (a) of that subsection" substitute "regulation 214(1) of the 2012 Regulations";

(f) in subsection (4A) for "a person who is an appropriate practitioner by virtue of subsection (1)(d) or (e)" substitute "an appropriate practitioner, other than a doctor or dentist";

(g) in subsection (4C) for "subsection (2)(a) or (b) of this section" substitute "regulation 214(1) or (2) of the 2012 Regulations"; and

(h) after subsection (6) insert—

"(7) In subsection (6) "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.".

6. In section 58A(1)(**4**) (requirement to specify certain products as prescription-only products)—

(a) omit paragraphs (a) and (b) and the word "and" following paragraph (b); and

(b) for the words following paragraph (c) to the end of the subsection substitute "is specified as a prescription only medicine".

7. In section 62(**5**) (prohibition of sale or supply, or importation, of medicinal products of specified description), after subsection (7) add—

"(8) In this section "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.".

8. In section 64(5) (protection for purchasers of medicinal products) for "a practitioner" substitute "an appropriate practitioner".

9.—(1) Section 67(**6**) (offences under Part III) is amended as follows.

(2) In subsection (1B)(a) for "by virtue of provision made under section 58(1) of this Act" substitute "within the meaning of regulation 214 of the 2012 Regulations";

(3) in subsection (2)—

(a) for "52, 58, 63, 64 and 65", substitute "63 and 64"; and

(b) omit "any regulations made under section 60 or section 61 or".

(4) Omit subsection (3A).

(**4**) Section 58A was inserted by regulation 2 of S.I. 1992/3271, and the heading substituted by and subsection (1) amended by paragraph 30 Part 1 of Schedule 8 to S.I. 2006/2407.

(**5**) Section 62(7) was substituted by paragraph 12(5) of Schedule 1 to S.I. 2005/1094.

(**6**) Section 67(1B) was inserted by section 63(7) of the Health and Social Care Act 2001, and section 67(3A) inserted and section 67(4) amended by paragraph 8 of Schedule 5 to S.I. 2005/2789

(5) In subsection (4) for "subsection (1A), (1B), (2), (3) or (3A)" substitute "subsection (1A), (1B), (2) or (3)".

(6) Omit subsections (5) and (6).

10. In section 72 (representative of pharmacist in case of death or disability)—

(a) in paragraph (1)(c)(**7**), for the words from "a committee" to the end of paragraph (c) substitute "a controller is appointed in his case under the Mental Health (Northern Ireland) Order 1986(**8**)"; and

(b) in paragraph (4)(c) for "committee" substitute "controller".

11. In section 82(4) (pharmacies: procedure relating to disqualification) for "Pharmaceutical Society" substitute—

(a) in the first place it appears, "General Pharmaceutical Council or, in Northern Ireland, the Pharmaceutical Society of Northern Ireland"; and

(b) in the second place it appears, "Council or the Society".

12. In section 87(**9**) (requirements as to containers)—

(a) in subsection (1) for "section 85(2) of this Act" substitute "subsection (3)"; and

(b) after subsection (2) insert—

"(3) The purposes mentioned in subsection (1) are—

(a) securing that medicinal products are correctly described and readily identifiable;

(b) securing that any appropriate warning or other appropriate instruction or information is given, and that false or misleading information is not given, with respect to medicinal products;

(c) promoting safety in relation to medicinal products."

13. In section 88(1)(**10**) (distinctive colours, shapes and markings of medicinal products) for "section 85(2)" substitute "section 87(3)".

14. In section 91(**11**) (offences under Part V, and supplementary provisions)—

(a) omit subsection (1);

(b) in subsection (2) omit "section 85(3), section 86(2) or"; and

(c) in subsection (3) for "sections 85 to" substitute "section".

15. In section 104 (application of Act to certain articles and substances)—

(a) in the heading to the section for "Act" substitute "the 2012 Regulations"; and

(b) in paragraph (1) for "this Act" substitute "the 2012 Regulations".

16. In section 105 (application of Act to certain other substances which are not medicinal products)—

(a) in the heading to the section for "Act" substitute "the 2012 Regulations"; and

(b) in paragraph (1) for "this Act" substitute "the 2012 Regulations".

17. In section 107 (validity of decisions and proceedings relating thereto)—

(**7**) Section 72(1)(c) was amended by paragraph 12(a) of Schedule 5 to the Adults with Incapacity (Scotland) Act 2000 and paragraph 14(a) of Schedule 6 to the Mental Capacity Act 2005, and section 72(4)(c) by paragraph 14(d) of Schedule 6 to the Mental Capacity Act 2005.

(**8**) S.I. 1986/594 (N.I. 4).

(**9**) Section 87(1) was amended by paragraph 44 of Part 1 of Schedule 8 to S.I. 2006/2407.

(**10**) Section 88(1) was amended by paragraph 45 of Part 1 of Schedule 8 to S.I. 2006/2407.

(**11**) Section 91(2) and (3) was amended by paragraph 48(b) and (c) of Part 1 of Schedule 8 to S.I. 2006/2407, and section 91(2) was amended by section 32(2) of the Magistrates' Courts Act 1980.

(a) in subsection (1)—

(i) omit "of the licensing authority under Part II of this Act or", and

(ii) for "licence or certificate granted or issued" substitute "certificate issued";

(b) in subsection (4)—

(i) for "grant a licence or certificate" substitute "issue a certificate",

(ii) for "licence or certificate granted" substitute "certificate issued", and

(iii) for "grant of the licence or" substitute "issue of the";

(c) in subsection (6) omit "of Justice".

18.—(1) Section 108(**12**) (enforcement in England and Wales) is amended as follows.

(2) In subsection (2)—

(a) in paragraph (a) for the words from "sections 64" to "and 89(2)" substitute "section 64 and sections 87(2) and 88(3)";

(b) omit paragraphs (b) and (c); and

(c) in the words following those paragraphs—

(i) for "the Pharmaceutical Society" substitute "the General Pharmaceutical Council",

(ii) for "the Society" substitute "the Council",

(iii) for "that Society" substitute "that Council"

(iv) for "paragraphs (a) and (b)" substitute "paragraph (a)",

(v) for "those paragraphs" substitute "that paragraph", and

(vi) omit the words from ", and the provisions" to the end of the subsection.

(3) Omit subsections (3) to (5).

(4) In subsection (6)—

(a) for "the Pharmaceutical Society" substitute "the General Pharmaceutical Council";

(b) omit paragraph (a); and

(c) in paragraph (b) omit "or section 61".

(5) In subsections (6A) and (6B) for "the Pharmaceutical Society" substitute "the General Pharmaceutical Council".

(6) Omit subsection (7).

(7) In subsection (9) for "(7)" substitute " (6D)".

(8) In subsection (10)—

(i) for "the Pharmaceutical Society" substitute "the General Pharmaceutical Council", and

(ii) for the words from "or any" to "that duty" substitute "has in relation to any matter failed to perform a duty imposed on it by subsections (6A) or (6B) to enforce any provisions mentioned in those subsections".

(9) In subsection (12) for paragraphs (a) and (b) substitute—

"(a) in relation to an area in England other than the City of London, the council of a non-metropolitan county, metropolitan district or London borough;

(**12**) Section 108(2) was amended and 108(12) inserted by paragraph 8 of Schedule 3 to the Food Safety Act 1990, section 108(6A) to (6D) was inserted and section 108(9) and (10) amended by section 31(1) of the Health Act 2006, section 108(9) was amended by paragraph 56(c), section 108(10) by paragraph 56(d) and section 108(11) by paragraph 56(e) of Part 1 of Schedule 8 to S.I. 2006/2407, and section . 108(12) was amended by paragraph 33 of Schedule 16 to the Local Government (Wales) Act 1994.

(b) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London; and

(c) in relation to an area in Wales, the council of a county or county borough.".

19. In section 109 (**13**) (enforcement in Scotland)—

(a) in subsection (2)—

(i) for the words from "(2)" to "(10)" substitute "(2), (6) to (6D), (9) and (10)", and

(ii) in paragraph (a) omit the words from "or" to "jointly"; and

(b) omit subsection (3).

20. In section 110(**14**) (enforcement in Northern Ireland)—

(a) in subsection (1), for "Minister of Health and Social Services for Northern Ireland" substitute "Minister for Health, Social Services and Public Safety";

(b) in subsection (2)—

(i) for "paragraphs (a) and (b)" substitute "paragraph (a)" in both places where it occurs,

(ii) for the words from "those paragraphs" to "subsection" substitute "that paragraph ",

(iii) for "area" substitute "district"(**15**),

(iv) for "health authority" in both places where it occurs substitute "district council",

(v) omit the words "and the provisions and regulations specified in the said paragraph (c)";

(c) omit subsection (3);

(d) in subsections (3A) and (3B), after "the Pharmaceutical Society" insert "of Northern Ireland";

(e) in subsection (5)—

(i) for "Subsections (9) and (10)" substitute "Subsection (9)",

(ii) in paragraph (a) for "(2) to (7)" substitute "(2) to (6D)", and

(iii) omit paragraph (b) and the word "and" preceding that paragraph;

(f) omit subsections (6) and (7); and

(g) for subsection (8) substitute—

"(8) In this section "district council" means a council established under the Local Government Act (Northern Ireland) 1972(**16**).".

21. In section 111(**17**) (rights of entry)—

(a) in subsection (1) omit paragraph (aa) except for the word "or";

(b) in subsection (2) omit paragraph (a);

(c) omit subsection (3);

(d) in subsection (6) omit—

(i) "aircraft," in both places where it occurs, and

(**13**) Section 109(2)(c) was repealed by paragraph 9(a) of Schedule 3 to the Food Safety Act 1990, and section 109(2)(d) was repealed by paragraph 57 of Part 1 of Schedule 8 to S.I. 2006/2407.

(**14**) Section 110(1) was amended by paragraph 58(a) and section 110(5)(a) was amended by paragraph 58(c)(i) of Part 1 of Schedule 8 to S.I. 2006/2407, and section 110(3A) and (3B) were inserted by section 31(3)(b) and section 110(5)(a) amended by section 31(3)(c) of the Health Act 2006. In relation to Northern Ireland,

(**15**) The amendments in paragraph 19(b)(iii) and (iv), (f) and (g) reproduce amendments already made with effect in Northern Ireland by article 2 and the Schedule to S.R. (NI) 1973 No 211.

(**16**) 1972 c. 9 (N.I.).

(**17**) Section 111(1)(aa) was inserted by paragraph 9 of Schedule 5 to S.I. 2005/2789.

(ii) ", commander"; and

(e) for subsection (9) substitute—

"(9) References in this section to a justice of the peace—

(a) in relation to England, include a reference to a district judge (magistrates' courts);

(b) in relation to Scotland, are to be read as references to a sheriff, stipendiary magistrate or justice of the peace, and

(c) in relation to Northern Ireland, are to be read as references to a lay magistrate or a district judge (magistrates' courts).".

22. In section 113(1) (application of sampling procedure to substance or article seized under section 112), omit the words from "(including" to the end of the subsection.

23. In section 114(1) (supplementary provisions as to rights of entry and related rights), omit—

(a) "aircraft," in both places where it occurs; and

(b) ", commander".

24. In section 121(4)(**18**) (contravention due to default of other person), for the words from "63" to "96" substitute "63, 64, 87 and 88".

25. In section 122(2)(**19**) (warranty as defence), for the words "section 63(b), sections 64 and 65, sections 85 to 88" substitute "sections 63(b), 64, 87 and 88".

26. In section 123(1)(b) (offences in relation to warranties and certificates of analysis), omit "section 115 of this Act, or under".

27. In section 125(**20**) (prosecutions)—

(a) in subsection (4)—

(i) for "the Pharmaceutical Society" substitute "the General Pharmaceutical Council", and

(ii) for "that Society" substitute "the Council";

(b) in subsections (6) and (7) for "Minister of Health and Social Services for Northern Ireland" substitute "Minister for Health, Social Services and Public Safety".

28. In section 126(**21**) (presumptions)—

(a) in subsection (1), omit paragraph (b) and the word "or" following it;

(b) in subsection (3), omit "subsections (3) and (5) of section 85,"; and

(c) omit subsection (4).

29. In section 128 (financial provisions)—

(a) in subsection (1), for the words from "any of" to "section 1(1) of this Act" substitute "either of the Ministers";

(b) in subsections (4) and (5), for "the Pharmaceutical Society" substitute "the General Pharmaceutical Council or (as the case may be) the Pharmaceutical Society of Northern Ireland";

(c) in subsection (5), for "a Minister" substitute "either of the Ministers"; and

(**18**) Section 121(4) was amended by paragraph 61 of Part 1 of Schedule 8 to S.I. 2006/2407.
(**19**) Section 122(2) was amended by paragraph 62 of Part 1 of Schedule 8 to S.I. 2006/2407.
(**20**) Section 125(4) was amended by paragraph 63 of Part 1 of Schedule 8 to S.I. 2006/2407.
(**21**) Section 126(3) was amended by paragraph 64(c) of Part 1 of Schedule 8 to S.I. 2006/2407.

(d) in subsection (6), for the words from "any of the Ministers" to "Ireland" substitute "the Secretary of State".

30. In section 129(**22**) (orders and regulations)—

(a) in subsection (2), omit the words from "or any regulations" to "section 120 of this Act";

(b) in subsection (3)—

(i) in paragraph (a), for the words from "13" to "and 130(5)(c)" substitute "58, 62, 79 and 106", and

(ii) omit paragraph (b);

(c) in subsection (4) omit the words from ", other" to "69(3),", and

(d) in subsection (7)—

(i) omit "Part V or Part VI", and

(ii) for the words "a committee established under section 4 of this Act" substitute "an expert committee appointed by themselves, or by one of them acting alone".

31. In section 130(**23**) (meaning of medicinal product and related expressions)—

(a) for subsection (1) substitute—

"(1) In this Act, "medicinal product" has the meaning given by regulation 2 of the 2012 Regulations."; and

(b) omit subsections (2) to (8) and (10).

32. In section 131(5)(**24**) (meaning of "wholesale dealing", "retail sale" and related expressions) for "or the Health and Personal Social Services (Northern Ireland) Order1972" substitute ", the Health and Personal Social Services (Northern Ireland) Order 1972 or the Health and Social Care (Reform) Act (Northern Ireland) 2009".

33. In section 132 (general interpretation provisions)—

(a) for subsection (1) substitute—

"(1) In this Act—

(a) unless the context otherwise requires, any expression defined by any provision of the 2012 Regulations, and not defined in this Act, has the same meaning as it has for the purposes of those Regulations; and

(b) "the 2012 Regulations" means the Human Medicines Regulations 2012.";

(b) omit subsections (2) and (3);

(c) in subsection (4) omit "licence or" in each place it appears; and

(d) omit subsection (5).

34. In Schedule 3(**25**) (sampling)—

(a) omit paragraphs 5 to 7;

(b) in paragraph 8 for "3 to 7" substitute "3 or 4";

(c) in paragraph 9 for "3 to 8" substitute "3, 4, or 8"; and

(d) in paragraph 17, in the words following paragraph (c)—

(**22**) Section 129(2) was amended by paragraph 65(a) of and section 129(3) was amended by paragraph 65(b) of Part 1 of Schedule 8 to S.I. 2006/2407.

(**23**) Section 130(1) was amended by paragraph 66(a) of Part 1 of Schedule 8 to S.I. 2006/2407.

(**24**) Section 131(5) was amended by paragraphs 43 and 44 of Schedule 1 to the National Health Service (Consequential Provisions) Act 2006, paragraph 30 of Schedule 16 to the National Health Service (Scotland) Act 1978 and paragraph 128(2) of Schedule 4 to the National Health Service Reorganisation Act 1973.

(**25**) Paragraph 17 of Schedule 3 was amended by paragraph 66 of Part 1 of Schedule 8 to S.I. 2006/2407.

(i) for the words "a health authority" substitute "the Pharmaceutical Society of Northern Ireland", and

(ii) for "the Minister of Health and Social Services for Northern Ireland" substitute "the Minister for Health, Social Services and Public Safety".

35. In Schedule 4(**26**) (provisions relating to Northern Ireland)—

(a) for every reference to "the Minister of Health and Social Services for Northern Ireland" substitute "the Minister for Health, Social Services and Public Safety";

(b) in paragraph 6 omit the words from "(except" to "Act)";

(c) in paragraph 8 omit the words from ", and every regulation made solely" to "this Act,"; and

(d) in paragraph 10 for "the Ministry of Health and Social Services for Northern Ireland" substitute "the Department of Health, Social Services and Public Safety".

Medicines Act 1971

36.—(1) The Medicines Act 1971(**27**) shall have effect as follows.

(2) In section 1 (fees)—

(a) in subsection (1), the reference to any application in pursuance of the Medicines Act 1968 for a licence or certificate under Part II of that Act, or for the variation or renewal of such a licence or certificate, shall have effect as a reference to any application under Parts 3 to 8 of these Regulations for the grant, variation or renewal of—

(i) a manufacturer's licence,

(ii) a wholesale dealer's licence,

(iii) a marketing authorisation,

(iv) a certificate of registration,

(v) a traditional herbal registration, or

(vi) an Article 126a authorisation; and

(b) in subsection (2)(b), the reference to any licence or certificate under the Medicines Act 1968 shall have effect as a reference to a manufacturer's licence, a wholesale dealer's licence, a marketing authorisation, a certificate of registration, a traditional herbal registration, or an Article 126a authorisation under these Regulations.

(3) Paragraph (2) has effect in relation to references of the kind mentioned in that paragraph in regulations made under section 1.

(**26**) Paragraphs 2 to 5, 7 and 9(b) and (c) and following words of Schedule 4 were omitted by paragraphs 69(a), (c) and (e)(iii) and (iv) of Part 1 of Schedule 8 to S.I. 2006/2407. Paragraph 6 was amended by paragraph 69(b), paragraph 8 by paragraph 69(d), paragraph 9 by paragraph 69(e) and paragraph 10 by paragraph 69(f) of that Part.

(**27**) 1971 c.69.

PART 2

Other primary legislation

Trade Descriptions Act 1968

37. In section 2(5)(b) (trade descriptions) of the Trade Descriptions Act 1968(**28**) for the words from "made under Part V" to "that Act)" substitute "of Chapter 1 of Part 13 of the Human Medicines Regulations 2012".

House of Commons Disqualification Act 1975

38. In Part II (bodies of which all members are disqualified) of Schedule 1 to the House of Commons Disqualification Act 1975(**29**) for the entry for the Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968 substitute—

"The Commission on Human Medicines.".

Northern Ireland Assembly Disqualification Act 1975

39. In Part II (bodies of which all members are disqualified) of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975(**30**) for the entry for the Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968 substitute—

"The Commission on Human Medicines.".

Consumer Protection Act 1987

40. Section 19(1) (interpretation of Part II) of the Consumer Protection Act 1987(**31**) shall have effect as if, in the definition "licensed medicinal product", the reference to any medicinal product within the meaning of the Medicines Act 1968, in respect of which a product licence within the meaning of that Act is for the time being in force, included a reference to a medicinal product, in respect of which a marketing authorisation or a traditional herbal registration within the meaning of these Regulations is for the time being in force.

Environmental Protection Act 1990

41. In section 142(7) (powers to obtain information about potentially hazardous substances) of the Environmental Protection Act 1990(**32**), for the entry relating to the Medicines Act 1968 substitute "Parts 3 to 8 and 16 of the Human Medicines Regulations 2012".

Value Added Tax Act 1994

42. In Part II of Schedule 8 (zero-rating) to the Value Added Tax Act 1994(**33**)—

(**28**) 1968 c.29. Paragraph (b) of section 2(5) was inserted by paragraph 16 of Schedule 5 to the Medicines Act 1968.
(**29**) 1975 c.24.
(**30**) 1975 c.25.
(**31**) 1987 c.43. Section 19(1) was amended by paragraph 7 of Part 1 of Schedule 9 to S.I. 2006/2407; there are other amendments to that subsection, but none is relevant.
(**32**) 1990 c.43. Section 142(7) was amended by paragraph 8 of Schedule 4 to the Radioactive Substances Act 1993 (1993 c.12), in relation to England and Wales by paragraph 5(1) and (12) of Part 1 of Schedule 26 to S.I. 2010/675, and by paragraph 8 of Part 1 of Schedule 9 to S.I. 2006/2407.
(**33**) 1994 c.23. In Part II of Schedule 8, note (2B) to Group 12 was inserted by S.I. 2009/2972, and note (11)(a) to Group 15 was amended by paragraph 10(a), and (11)(d) inserted by paragraph 10(b), of Schedule 9 to S.I. 2006/2407.

(a) in note (2B) to Group 12 (drugs, medicines, aids for the handicapped etc) for the words "article 1(2) of the Prescription Only Medicines (Human Use) Order 1997" substitute "regulation 8(1) of the Human Medicines Regulations 2012"; and

(b) in note (11) to Group 15 (charities etc)—

(i) for paragraph (a) substitute—

"(a) "medicinal product" has the meaning assigned to it by regulation 2(1) of the Human Medicines Regulations 2012;", and

(ii) omit paragraphs (b) and (c).

Health Act 1999

43. In section 60(2A)(c) (regulation of health care and associated professions) of the Health Act 1999(**34**), after "that Act" insert "or the Human Medicines Regulations 2012".

Communications Act 2003

44. In section 368R(1) (interpretation of Part 4A) of the Communications Act 2003(**35**), for the definition "prescription-only medicine" substitute the following definition—

""prescription-only medicine" means a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012;".

Christmas Day and New Year's Day Trading (Scotland) Act 2007

45. In section 7 (interpretation) of the Christmas Day and New Year's Day Trading (Scotland) Act 2007(**36**)—

(a) omit the definition "appropriate person"; and

(b) for the definition "on prescription" substitute the following definition—

""on prescription" means in accordance with a prescription given by an appropriate practitioner, within the meaning of regulation 214(1) and (3) to (6) (sale or supply of prescription only medicines) of the Human Medicines Regulations 2012;".

PART 3

Northern Ireland Orders in Council

Health and Personal Social Services (Northern Ireland) Order 1972

46. The Health and Personal Social Services (Northern Ireland) Order 1972(**37**) is amended as follows—

(a) in article 2(2), in the definition "pharmacist" for "Medicines Act 1968" substitute "Human Medicines Regulations 2012"; and

(b) in article 57D—

(i) in paragraphs (3) and (5) for "Community" substitute "EU", and

(**34**) 1999 c.8. Subsection (2A) was inserted by paragraph 1 of Schedule 8 to the Health and Social Care Act 2008 (2008 c.14).
(**35**) 2003 c.21. Section 368R was inserted by regulation 2 of S.I. 2009/2979.
(**36**) 2007 asp 13.
(**37**) S.I. 1972/1265 (N.I. 14). Article 57D was inserted by article 4 of the Primary Medical Services (Northern Ireland) Order 2004 (S.I. 2004/311 (N.I. 2))

(ii) in paragraph (5) for "regulation 1 of the Medicines for Human Use (Marketing Authorisations etc Regulations 1997" substitute "regulation 8(1) of the Human Medicines Regulations 2012".

Pharmacy (Northern Ireland) Order 1976

47. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976(**38**), in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute "regulation 8(1) of the Human Medicines Regulations 2012".

Poisons (Northern Ireland) Order 1976

48. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976(**39**)—

(a) in the definition "pharmacist" after "Medicines Act" insert "or the Human Medicines Regulations 2012"; and

(b) in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute "regulation 8(1) of the Human Medicines Regulations 2012".

Diseases of Animals (Northern Ireland) Order 1981

49. In article 38 of the Diseases of Animals (Northern Ireland) Order 1981(**40**) in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute "regulation 8(1) of the Human Medicines Regulations 2012".

Waste and Contaminated Land (Northern Ireland) Order 1997

50. In article 33(6) of the Waste and Contaminated Land (Northern Ireland) Order 1997(**41**) for the entry relating to the Medicines Act 1968 substitute "Parts 3 to 8, 12 and 16 of the Human Medicines Regulations 2012".

Shops (Sunday Trading &c.) (Northern Ireland) Order 1997

51. In article 4(3) of the Shops (Sunday Trading &c.) (Northern Ireland) Order 1997(**42**) for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

PART 4

The Medicines for Human Use (Clinical Trials) Regulations 2004

52. The Medicines for Human Use (Clinical Trials) Regulations 2004(**43**) are amended as follows.

53. In regulation 2(1) (interpretation)—

(a) before the definition "the Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;";

(**38**) S.I. 1976/1213 (N.I. 22).
(**39**) S.I. 1976/1214 (N.I. 23).
(**40**) S.I. 1981/1115 (N.I. 22).
(**41**) S.I. 1997/2778 (N.I. 19). Article 33(6) was amended by S.R. (NI) 2006 No 45.
(**42**) S.I. 1997/2779 (N.I. 20).
(**43**) S.I. 2004/1031, as amended by S.I. 2005/2754. There are other amendments, but none is relevant.

(b) for the definition "appropriate committee" substitute—

""appropriate committee" for the purposes of any provision of these Regulations under which a function falls to be performed means whichever the licensing authority considers to be appropriate of—

(a) the Commission on Human Medicines; or

(b) an expert committee appointed by the licensing authority;";

(c) insert in the appropriate position in alphabetical order the following definition—

""the Commission on Human Medicines" means the Commission on Human Medicines within the meaning of regulation 9 of the 2012 Regulations;";

(d) in the definition "licensing authority" for "section 6 of the Act" substitute "regulation 6 of the 2012 Regulations";

(e) for sub-paragraph (a) of the definition "marketing authorisation" substitute—

"(a) a UK marketing authorisation granted by the licensing authority under the 2012 Regulations,"; and

(f) for the definition "medicinal product" substitute—

""medicinal product" means a medicinal product within the meaning of regulation 2(1) of the 2012 Regulations."

54. In regulation 4(3) (responsibility for functions under the Directive) for "the Act" substitute "the 2012 Regulations".

55. In regulation 19(10) (authorisation procedure for clinical trials involving medicinal products for gene therapy etc) omit "established by section 2A of the Act".

56. In regulation 46(2)(c) (labelling) for words from "Schedule 5" to the end of the sub-paragraph substitute "Part 13 of the 2012 Regulations that apply in relation to medicinal products sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner within the meaning of regulation 214(3) to (6) of those Regulations".

57. In regulation 47 (application of enforcement provisions of the Act)—

(a) for "the Act" in the heading substitute "the 2012 Regulations"; and

(b) for paragraph (1) substitute—

"(1) Regulations 2, 8(1), 322, 323(1), 324(1), 325 to 330, 332 to 339, 343 and Schedule 31 of the 2012 Regulations ("those provisions") shall apply for the purposes of these Regulations as they apply for the purposes of the 2012 Regulations, but with the modifications specified in Schedule 9, and any reference in those provisions to the 2012 Regulations includes a reference to these Regulations."; and

(c) after paragraph (2) insert the following paragraph—

"(3) In those provisions as applying by virtue of paragraph (1), any reference to, or relating to, a requirement, a power, a function, a right, a duty, an entitlement, or a protection shall be read as a reference to, or relating to, that requirement, power, function, right, duty, entitlement, or protection as applied by this regulation.".

58. In regulation 48(5) (infringement notices) for "sections 108 to 110 of the Act" substitute "regulation 323(1) or 324(1) of the 2012 Regulations".

59. In regulation 49(5) (offences) for "the Act" substitute "the 2012 Regulations".

60. In regulation 53(3) (construction of references to specified publications) for "section 103(1) of the Act" substitute "regulation 321(1) of the 2012 Regulations".

61. In paragraph 4(2) of Schedule 5 (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

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

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert ", the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister".

62. In Schedule 7 (standard provisions for manufacturing authorisations)—

(a) in Part 2—

(i) in paragraph 5 for "the Act" substitute "the 2012 Regulations",

(ii) in paragraph 9 for "the Act or any regulations under the Act" substitute "or the 2012 Regulations", and

(iii) in paragraph 13—

(aa) for "Part II of the Act" substitute "Parts 3 to 8 of the 2012 Regulations", and

(bb) for "the Act" in the second place where it occurs substitute "the 2012 Regulations"; and

(b) in Part 3—

(i) in paragraph 6 for "the Act" in the first place where it occurs substitute "the 2012 Regulations", and

(ii) in paragraph 8—

(aa) for "Part II of the Act" substitute "Parts 3 to 8 of the 2012 Regulations", and

(bb) for "the Act" in the second place where it occurs substitute "the 2012 Regulations".

63. In paragraph 5(2) of Schedule 8 (procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

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

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert ", the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister".

64. For Schedule 9 substitute the following Schedule—

"SCHEDULE 9 Regulation 47(1)

MODIFICATIONS OF THE ENFORCEMENT PROVISIONS OF THE 2012 REGULATIONS SUBJECT TO WHICH THOSE PROVISIONS ARE APPLIED FOR THE PURPOSES OF THESE REGULATIONS

1. The modifications of the 2012 Regulations mentioned in regulation 47 are as follows.

2. In regulation 2 (medicinal products)—

(a) at the beginning of paragraph (1) insert "Subject to paragraph (3),"; and

(b) after paragraph (2) insert the following paragraph—

"(3) "Medicinal product" includes any investigational medicinal product.".

2. In regulation 8(1) (interpretation)—

(a) the definition "assemble" is substituted by the definition of that expression in regulation 2(1) of these Regulations; and

(b) there is inserted in the appropriate position in alphabetical order a definition "container" in the same terms as the definition of that expression in regulation 2(1) of these Regulations; and

(c) the definition "qualified person" is substituted by the definition of that expression in regulation 2(1) of these Regulations.

3. In regulation 322(1) (validity of decisions and proceedings) omit "or" and insert a comma before "8 (Article 126a authorisations)", and after those words insert "or the Clinical Trials Regulations".

4. In regulation 325(1) (rights of entry) insert after sub-paragraph (b) the following sub-paragraph—

"(ba) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations;".

5.—(1) Regulation 327 (powers of inspection, sampling and seizure) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (b) omit "; or";

(b) after sub-paragraph (c) insert "; or" and the following sub-paragraph—

"(d) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations.".

(3) After paragraph (2)(g) insert the following sub-paragraph—

"(h) information and documents relating to clinical trials".

(4) In paragraph (3)—

(a) omit "or" following sub-paragraph (a); and

(b) following paragraph (b) insert "; or" and the following sub-paragraph—

"(c) a medicinal product used, or intended to be used, in a clinical trial".

(5) In paragraph (4)—

(a) after "require" insert "— (a)"; and

(b) after "control" insert "; or" and the following sub-paragraph—

"(b) a person associated with a clinical trial to produce information or documents relating to the clinical trial which are in the person's possession or under the person's control".

(6) In paragraph (5)(a) for "(2)(f) or (g)" substitute "(2)(f), (g) or (h)".

(7) After paragraph (9) insert the following paragraph—

"(10) In this regulation, "a person associated with a clinical trial means any of the following—

(a) the sponsor of a clinical trial (within the meaning of regulation 3 of the Clinical Trials Regulations);

(b) any person who, under arrangements made with the sponsor of a clinical trial, carries out functions of the sponsor of the trial;

(c) in investigator for a clinical trial (within the meaning of regulation 2(1) of the Clinical Trials Regulations);

(d) any person, other than an investigator, who conducts a clinical trial;

(e) any person occupying premises at which a clinical trial is being conducted; or

(f) any person who, in the course of employment with a person listed in any of sub-paragraphs (a) to (e), undertakes activities in connection with a clinical trial.".

(8) In regulation 335(6) (contravention due to fault of another person) omit "and" after sub-paragraph (e) and after sub-paragraph (f) insert "; and" and the following sub-paragraph—

"(g) any obligation or prohibition under the Clinical Trials Regulations".

(9) In regulation 336(3) (warranty as defence) omit "and" after sub-paragraph (c) and after sub-paragraph (d) insert "; and" and the following sub-paragraph—

"(e) regulation 46 of the Clinical Trials Regulations (labelling)"."

PART 5

Other United Kingdom, Scotland and Wales Secondary legislation

Medicines (Administration of Radioactive Substances) Regulations 1978

65. In regulation 8(1) of the Medicines (Administration of Radioactive Substances) Regulations 1978(**44**)—

(a) for "Section 6(2) of the Act" substitute "Regulation 6(3) of the Human Medicines Regulations 2012 ("the 2012 Regulations"); and

(b) for "by or under the Act" substitute "by the 2012 Regulations".

(**44**) S.I. 1978/1006, as amended by S.I. 1995/2147 and S.I. 2006/2407. There are other amendments, but none is relevant.

Importation of Animal Products and Poultry Products Order 1980

66. In the Schedule to the Importation of Animal Products and Poultry Products Order 1980(**45**), for "or the Medicines for Human Use (Marketing Authorisations Etc. Regulations) 1994" substitute "or the Human Medicines Regulations 2012".

Medicines Act (Hearings by Persons Appointed) (Scotland) Rules 1986

67. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986(**46**)—

(a) in the definition "applicant" omit the words "a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or";

(b) in the definition "person appointed" omit—

(i) sub-paragraphs (i), (ii), (iii), (v) and (vi), and

(ii) the words following sub-paragraph (vii), from "including" until the end of the definition; and

(c) in the definition "relevant Minister"—

(i) omit sub-paragraph (i), and

(ii) in sub-paragraph (ii) for "the appropriate Ministers as defined in section 1(2)" substitute "the Ministers as defined in regulation 6(6) and (7) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012".

Medicines Act (Hearings by Persons Appointed) Rules 1986

68. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986(**47**)—

(a) in the definition "applicant" omit the words "a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or";

(b) in the definition "person appointed" omit—

(i) sub-paragraphs (i), (ii), (iii), (v) and (vi), and

(ii) the words following sub-paragraph (vii), from "including" until the end of the definition; and

(c) in the definition "relevant Minister"—

(i) omit sub-paragraph (i), and

(ii) in sub-paragraph (ii) for "section 1(1)" substitute "regulation 6(6) and (7) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012".

Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989

69.—(1) The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989(**48**) is amended as follows.

(2) In article 1(2) insert after the definition "the 1987 Act" the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(**45**) S.I. 1980/14, as amended by S.I. 1994/2920, S.I. 1994/3142 and S.I. 1994/3144.
(**46**) S.I. 1986/1700. There are amendments, but none is relevant.
(**47**) S.I. 1986/1761, as amended by S.I. 2006/2407. There are other amendments, but none is relevant.
(**48**) S.I. 1989/684, as amended by S.I. 1995/871, S.I. 2004/1031 and S.I. 2005/2754. There are other amendments, but none is relevant.

(3) In Schedule 1—

(a) in paragraph 1 omit ", II" and ", VI";

(b) after paragraph 1 insert the following paragraph—

"**1A.** Functions of the Ministers under the 2012 Regulations (except those under Part 15 (British Pharmacopeia) of those Regulations), subject to paragraph 11 below.".

(c) in paragraph 2 for "Part II of the 1968 Act " substitute "Parts 3 to 8 of the 2012 Regulations";

(d) for paragraph 3 substitute—

"**3.** Functions of the Commission on Human Medicines, whose continuation is provided for in regulation 9 of the 2012 Regulations (except those under Part 15 (British Pharmacopoeia) of those Regulations).";

(e) for paragraph 4 substitute—

"**4.** Functions of any expert committee appointed by the licensing authority under the 2012 Regulations.".

(f) for paragraph 8 substitute—

"**8.** Functions of reviewers appointed under the 2012 Regulations.".

(g) omit paragraphs 9A, 9C and 9D;

(h) in paragraph 10(c) for "and of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute "and of the 2012 Regulations" and

(i) in paragraph 11—

(i) after "Paragraphs 1" insert ", 1A", and

(ii) after "under it" insert "or under the 2012 Regulations".

Medical Devices (Consultation Requirements) (Fees) Regulations 1995

70. In regulation 1(2) of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**49**)—

(a) in the definition "authorised medicinal product"—

(i) in sub-paragraph (b) before "under" insert "the Human Medicines Regulations 2012 or", and

(ii) in sub-paragraph (c) for "those" substitute "the latter"; and

(b) in the definition "product licence of right" for "section 25(4) of that Act" substitute "paragraph 3(2) of Schedule 32 to the Human Medicines Regulations 2012".

Prescription Only Medicines (Human Use) Order 1997

71.—(1) The Prescription Only Medicines (Human Use) Order 1997(**50**) is amended as follows.

(2) In article 1—

(a) in paragraph (2) omit all the defined expressions except "inhaler" and "maximum strength";

(**49**) S.I. 1995/449

(**50**) S.I. 1997/1830, as amended by S.I. 1997/2044, S.I. 1998/108, S.I. 1998/1178, S.I. 1998/2081, S.I. 1999/1044, S.I. 1999/3463, S.I. 2000/1917, S.I. 2000/2899, S.I. 2000/3231, S.I. 2001/2777, S.I. 2001/3942, S.I. 2003/696, and S.I. 2006/915. There are other amendments, but none is relevant.

(b) for paragraph (2A) substitute—

"(2A) In this Order, unless the context otherwise requires, any expression defined by any provision of the Human Medicines Regulations 2012 has the same meaning as it has for the purposes of those Regulations.";

(c) in paragraph (5) for "Schedules 1, 2, 3A and 5" substitute "Schedules 1 and 2"; and

(d) omit paragraphs (6) to (9).

(3) In article 5(1) for the words from the beginning of the paragraph until sub-paragraph (a) substitute "A medicinal product that is not the subject of a marketing authorisation is a prescription only medicine for the purposes of the Human Medicines Regulations 2012 if it, or a substance in it, is listed in column 1 of Schedule 1, unless there".

(4) In paragraphs (1) and (2) of article 10 for the words "The restrictions" to "administration of" substitute "A medicinal product is not a prescription only medicine for the purposes of the Human Medicines Regulations 2012 by virtue of Article 5(1) if it is ".

General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999

72. In rule 7B(b) of the Schedule to the General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999(**51**), for the words from "article" to the end of the paragraph substitute "regulation 215 (prescribing and administration by supplementary prescribers)" of the Human Medicines Regulations 2012.

National Health Service (Charges for Drugs and Appliances) Regulations 2000

73. The National Health Service (Charges for Drugs and Appliances) Regulations 2000(**52**) are amended as follows—

(a) in regulation 5(3B)(b) for the words from "article 12F" to the end of the paragraph substitute "regulation 247 (exemption for supply in the event or anticipation of pandemic disease) of the Human Medicines Regulations 2012"; and

(b) in regulation 6A(6) for the words from "the Medicines" to the end of the paragraph substitute "the Human Medicines Regulations 2012".

Biocidal Products Regulations 2001

74. In Schedule 2 to the Biocidal Products Regulations 2001(**53**)—

(a) omit entry (f); and

(b) for entry (i) substitute—

"(i) the Human Medicines Regulations 2012;".

Medicines (Aristolochia and Mu Tong etc) (Prohibition Order) 2001

75. In article 4(4) of the Medicines (Aristolochia and Mu Tong etc) (Prohibition Order) 2001(**54**), for the words following "marketing authorisation" to the end of the paragraph substitute ", certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012."

(**51**) S.I. 1999/3267, as amended by S.I. 2005/1476. There are other amendments, but none is relevant.
(**52**) S.I. 2000/620, as amended by S.I. 2000/3189 and S.I. 2009/1166. There are other amendments, but none is relevant.
(**53**) S.I. 2001/880, as amended by S.I. 2010/745. There are other amendments, but none is relevant.
(**54**) S.I. 2001/1841, as amended by S.I. 2005/2750 and S.I. 2008/548.

Misuse of Drugs Regulations 2001

76. In regulation 2(1) of the Misuse of Drugs Regulations 2001(**55**)—

(a) in the definitions "clinical management plan", "nurse independent prescriber", "patient group direction", "pharmacist independent prescriber", "registered chiropodist", "registered midwife", "registered nurse", "registered occupational therapist", "registered optometrist", "registered orthoptist", "registered orthotist and prosthetist", "registered paramedic", "registered physiotherapist", "registered radiographer" and "supplementary prescriber", for "the Prescription Only Medicines (Human Use) Order 1997" substitute "the Human Medicines Regulations 2012"; and

(b) in the definitions "pharmacist" and "registered pharmacy" for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

Medicines for Human Use (Kava-kava) (Prohibition Order) 2002

77. In paragraph (d) of article 3 of the Medicines for Human Use (Kava-kava) (Prohibition Order) 2002 (**56**), for the words following "subject" to the end of the article substitute "of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012.".

Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

78. In article 1(3) of the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**57**) for "the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994" substitute "the Human Medicines Regulations 2012".

Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003

79. In the column "specified UK laws" of the Schedule to the Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003(**58**) for "the Medicines (Advertising) Regulations 1994" substitute "Chapters 1 and 2 of Part 14 (advertising) of the Human Medicines Regulations 2012".

Enterprise Act 2002 (Part 8 Notice to OFT of Intended Prosecution Specified Enactments, Revocation and Transitional Provision) Order 2003

80. In the Schedule to the Enterprise Act 2002 (Part 8 Notice to OFT of Intended Prosecution Specified Enactments, Revocation and Transitional Provision) Order 2003(**59**)—

(a) in the first column, insert in the appropriate position in alphabetical order "Human Medicines Regulations 2012";

(b) in the second column, insert adjacent to the entry "Human Medicines Regulations 2012" in the first column "regulation 303 (advertising offences)"; and

(c) omit "Medicines (Advertising) Regulations 1994" in the first column and the adjacent entry "regulation 23 (offences)" in the second column.

(**55**) S.I. 2001/3998, as amended by S.I. 2003/2429, S.I. 2005/271, S.I. 2006/986, S.I. 2006/1450, S.I. 2007/2154 and 2012/973. There are other amendments, but none is relevant.
(**56**) S.I. 2002/3170, as amended by S.I. 2005/2750 and S.I. 2008/548.
(**57**) S.I. 2003/1076, as amended by S.I. 2005/2061. There are other amendments, but none is relevant.
(**58**) S.I. 2003/1374. There are amendments, but none is relevant.
(**59**) S.I. 2003/1376. There are amendments, but none is relevant.

Health Professions (Parts of and Entries in the Register) Order of Council 2003

81. In article 6 of the Health Professions (Parts of and Entries in the Register) Order of Council 2003(**60**)—

(a) for sub-paragraph (b) of paragraph (2), up to and including the word "analgesics", substitute—

"(b) referred to in the following provisions of Schedule 17 (exemption for sale, supply or administration by certain persons) to the Human Medicines Regulations 2012 —

(i) in Part 1 (exemption from restrictions on sale or supply of prescription only medicines), paragraph 11 (certificate of competence in the use of specified medicines), or

(ii) in Part 3 (exemptions from the restriction on administration of prescription only medicines), paragraph 1 (certificate in the use of analgesics),"; and

(b) in paragraph (3) for "the Prescription Only Medicines (Human Use) Order 1997" substitute "the Human Medicines Regulations 2012".

Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

82.—(1) The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 (**61**) (interpretation) are amended as follows.

(2) In regulation 1(2)—

(a) omit the following definitions—

(i) "the 1994 Regulations", and

(ii) "herbal remedy";

(b) before the definition of "the appropriate committee" insert—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(c) for the definition of "the appropriate committee" substitute—

""the appropriate committee" means whichever the appropriate Minister considers to be the appropriate body of the following—

(a) the Commission; or

(b) an expert committee appointed by the appropriate Minister, or by the appropriate Ministers for Great Britain and for Northern Ireland acting jointly;";

(d) after the definition of "the appropriate Minister" insert—

""the Commission" means the Commission on Human Medicines continued in existence by regulation 9 of the 2012 Regulations;";

(e) for the definition of "excluded medicine" substitute—

""excluded medicine" means a medicinal product to which the restrictions in regulation 46 (requirement for authorisation) of the 2012 Regulations do not apply by virtue of regulation 3(6) (scope of these Regulations: special provisions) or 4(1) (special provisions for pharmacies etc) of those Regulations;";

(**60**) S.I. 2003/1571, as amended by S.I. 2006/1996. There are other amendments, but none is relevant.
(**61**) S.I. 2003/1680, as amended by S.I. 2004/3224, S.I. 2005/2750 and S.I. 2005/2754.

(f) in the definition of "market" for the words from "have the same meaning" to the end substitute "are to be construed in accordance with the 2012 Regulations;";

(g) for the definition of "medicinal product" substitute—

""medicinal product" has the meaning given by regulation 2 of the 2012 Regulations;"; and

(h) in the definition of "unlicensed product"—

(i) in paragraph (a)(i), for "the 1994 Regulations" substitute "the 2012 Regulations",

(ii) omit paragraph (b) and the word "or" following it,

(iii) for paragraph (c) substitute—

"(c) no traditional herbal registration has been granted by the licensing authority under the 2012 Regulations;", and

(iv) after that paragraph insert the word "or" and the following paragraph —

"(d) no Article 126a authorisation has been granted by the licensing authority under those regulations;".

National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004

83.—(1) The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(**62**) are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute "regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012".

(3) In paragraph 41(2)(a) of Schedule 5—

(a) for "article 3B(3) of the POM Order" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(b) for "that Order" substitute "those Regulations".

National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004

84.—(1) The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004(**63**) are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute "regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012".

(3) In paragraph 13(2)(a) of Schedule 1—

(a) for "article 3B(3) of the POM Order" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(**62**) S.S.I. 2004/115, as amended by S.S.I. 2005/337. There are other amendments, but none is relevant.
(**63**) S.S.I. 2004/116, as amended by S.S.I. 2005/336. There are other amendments, but none is relevant.

(b) for "that Order" substitute "those Regulations".

National Health Service (General Medical Services Contracts) Regulations 2004

85.—(1) The National Health Service (General Medical Services Contracts) Regulations 2004(**64**) are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute "regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012".

(3) In paragraph 43(2)(a) of Schedule 6—

(a) for "article 3B(3) of the POM Order" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(b) for "that Order" substitute "those Regulations".

National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

86.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**65**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition "the POM Order"; and

(ii) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute "regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012"; and

(b) in paragraph (3) for "the POM Order" substitute "the Human Medicines Regulations 2012".

(3) In paragraph 43(2)(a) of Schedule 6—

(a) for "article 3B(3) of the POM Order" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(b) for "that Order" substitute "those Regulations".

National Health Service (Personal Medical Services Agreements) Regulations 2004

87.—(1) The National Health Service (Personal Medical Services Agreements) Regulations 2004(**66**) are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute "regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012".

(**64**) S.I. 2004/291, as amended by S.I. 2005/893. There are other amendments, but none is relevant.
(**65**) S.I. 2004/478, as amended by S.I. 2006/358 and S.I. 2010/1647. There are other amendments, but none is relevant.
(**66**) S.I. 2004/627, as amended by S.I 2005/893. There are other amendments, but none is relevant.

(3) In paragraph 42(2)(a) of Schedule 5—

(a) for "article 3B(3) of the POM Order" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(b) for "that Order" substitute "those Regulations".

National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004

88. In Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004(**67**) for "article 12F of the Prescription Only Medicines (Human Use) Order 1997 or article 8 of the Medicines (Pharmacy and General Sale-Exemptions) Order 1980", in both places where those words occur, substitute "regulation 247 (exemption for supply in the event or anticipation of pandemic disease) of the Human Medicines Regulations 2012".

Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004

89.—(1) The Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004(**68**) is amended as follows.

(2) In article 2(1)—

(a) omit the definition "the 1994 Regulations"; and

(b) after the definition "the 2003 Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(3) In article 7—

(a) in paragraph (1) for "the 1994 Regulations" substitute "Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations"; and

(b) in paragraph (2)—

(i) for "the 1994 Regulations" substitute "the 2012 Regulations", and

(ii) for the words from "the following" to the end of the paragraph substitute "regulation 314 of the 2012 Regulations".

(4) In article 8(3)(d) for "the 1994 Regulations" substitute "Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations".

(5) In article 11—

(a) in paragraph (2) for "the 1994 Regulations" substitute "the 2012 Regulations"; and

(b) in paragraph (3)—

(i) for "section 1(1)(a) of the Medicines Act 1968" substitute "regulation 6(6) of the 2012 Regulations", and

(ii) for "the 1994 Regulations" substitute "Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations".

(**67**) S.I. 2004/1022, as amended by S.I 2005/366 and S.I. 2009/1977. There are other amendments, but none is relevant.
(**68**) S.I. 2004/1975.

General Optical Council (Registration Rules) Order of Council 2005

90. In the Table in rule 10 of the Schedule to the General Optical Council (Registration Rules) Order of Council 2005(**69**)—

(a) in entry B column 3—

(i) in paragraph (a) for "paragraph 6A of Schedule 5 to the Prescription Only Medicines (Human Use) Order 1997" substitute "paragraph 8 of Part 1 of Schedule 17 of the Human Medicines Regulations 2012", and

(ii) in paragraph (b) for "6B" substitute "9";

(b) in entry C column 3 for "article 3B of the Prescription Only Medicines (Human Use) Order 1997" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(c) in entry D column 3 for "article 3 of the Prescription Only Medicines (Human Use) Order 1997" substitute "regulation 5(3) of the Human Medicines Regulations 2012".

National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

91.—(1) The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(**70**) are amended as follows.

(2) In regulation 2(1) omit the definition of "the POM Order".

(3) In regulation 2(2A) for "the POM Order" substitute "the Human Medicines Regulations 2012".

(4) In regulation 7(2) for the words from "the Medicines" to the end of the regulation substitute "the Human Medicines Regulations 2012".

(5) In regulation 7A(1)(b) for the words from "article 12F" to the end of the regulation substitute "regulation 247 of the Human Medicines Regulations 2012".

Human Tissue (Quality and Safety for Human Application) Regulations 2007

92. In regulation 2(3) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**71**)—

(a) omit sub-paragraph (a); and

(b) for sub-paragraph (b) substitute—

"(b) the Human Medicines Regulations 2012;".

Legislative and Regulatory Reform (Regulatory Functions) Order 2007

93.—(1) The Schedule to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007(**72**) is amended as follows.

(2) In Part 2 under the heading "Medicines"—

(a) omit the entries—

"Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994",

"Medicines (Advertising) Regulations 1994",

(**69**) S.I. 2005/1478, as amended by S.I. 2008/1940. There are other amendments, but none is relevant.
(**70**) S.I. 2007/121, as amended by S.I. 2009/1175 and S.I. 2010/1647. There are other amendments, but none is relevant.
(**71**) S.I. 2007/1523.
(**72**) S.I. 2007/3544, as amended by S.I. 2009/2981. There are other amendments, but none is relevant.

"Medicines (Monitoring of Advertising) Regulations 1994",

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

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005", and

"Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012".

(3) In Part 3 under the heading "Public health and safety"—

(a) omit the entries—

"Medicines (Advertising) Amendment Regulations 2004", and

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(4) In Part 6—

(a) omit the entry—

"Medicines (Advertising) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Chapters 1 and 2 of Part 14 (advertising) of those Regulations".

(5) In Part 8—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(6) In Part 13—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008

94. In paragraph (d) of article 3 of the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 (**73**), for the words following "subject" to the end of the article substitute "of a marketing authorisation, certificate of registration, traditional herbal

(**73**) S.I. 2008/548.

registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012.".

Specified Animal Pathogens Order 2008

95. In article 5(2) of the Specified Animal Pathogens Order 2008(**74**)—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute "the Human Medicines Regulations 2012"; and

(b) omit sub-paragraph (c).

Specified Animal Pathogens (Wales) Order 2008

96. In article 5(2) of the Specified Animal Pathogens (Wales) Order 2008(**75**)—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute "the Human Medicines Regulations 2012"; and

(b) omit sub-paragraph (c).

Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008

97. In regulation 1(2) of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008(**76**) in the definition "prescription only medicine", for "the Prescription Only Medicines (Human Use) Order 1997" substitute "the Human Medicines Regulations 2012".

Specified Animal Pathogens (Scotland) Order 2009

98. In article 5(2) of the Specified Animal Pathogens (Scotland) Order 2009(**77**)—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;" substitute "the Human Medicines Regulations 2012."; and

(b) omit sub-paragraph (c).

National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

99.—(1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(**78**) are amended as follows.

(2) In regulation 2(1)—

(a) in the definition "clinical management plan" for the words from "article" to the end of the definition substitute "regulation 8(1) of the Human Medicines Regulations 2012";

(b) in the definition "non-proprietary name"—

(i) for "section 103(5) of the 1968 Act" in both places where it occurs substitute "regulation 321(3) of the Human Medicines Regulations 2012, and

(ii) for "section 100 of that Act" substitute "regulation 318 of those Regulations";

(**74**) S.I. 2008/944. There are amendments, but none is relevant.
(**75**) S.I. 2008/1270. There are amendments, but none is relevant.
(**76**) S.I. 2008/3258. There are amendments, but none is relevant.
(**77**) S.S.I. 2009/45. There are amendments, but none is relevant.
(**78**) S.S.I. 2009/183.

(c) in the definition "Patient Group Direction" for the words from "Article" to the end of the definition substitute "regulation 213 of the Human Medicines Regulations 2012"; and

(d) in the definition "supply form" for the words from "Article" to the end of the definition substitute "regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012".

(3) In Schedule 1—

(a) in paragraph 4—

(i) in sub-paragraph (23) for "Article 12C of the Prescription Only Medicines (Human Use) Order 1997 (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)" substitute "regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012"; and

(ii) in sub-paragraph (29) for "paragraph (4) of article 8 of the Prescription Only Medicines (Human Use) Order 1997" substitute "regulation 225 (emergency sale etc by pharmacist: at patient's request) of the Human Medicines Regulations 2012"; and

(b) in paragraph 10(8) for "article 12C of the Prescription Only Medicines (Human Use) Order 1997, (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)" substitute "regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012,".

Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009

100.—(1) The Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009(**79**) is amended as follows.

(2) In Part 1 of Schedule 1, to the entry "Medicines Act 1968 (section 109)" add "or Human Medicines Regulations 2012 (regulation 323)".

(3) In Part 2 of Schedule 1—

(a) omit the entry—

"Medicines (Advertising) Regulations 1994"; and

(b) add in the appropriate place the entry—

"Human Medicines Regulations 2012, in relation to Chapters 1 and 2 of Part 14 (advertising) of those Regulations".

(4) In Part 4 of Schedule 1—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for human use) Regulations 2005"; and

(b) add in the appropriate place the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(5) In Part 2 of Schedule 2—

(a) omit the entry—

(**79**) S.I. 2009/669. There are amendments, but none is relevant.

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

Single Use Carrier Bags Charge (Wales) Regulations 2010

101. In Schedule 1(3) to the Single Use Carrier Bags Charge (Wales) Regulations 2010(**80**)—

(a) in the definition "EEA health professional" for the words from "1(2)" to the end of the definition substitute "213(1) of the Human Medicines Regulations 2012";

(b) in the definition "pharmacy medicine" for the words from "means" to the end of the definition substitute "has the meaning given in regulation 5(5) of the Human Medicines Regulations 2012";

(c) in the definition "prescription only medicine" for the words from "means" to the end of the definition substitute "has the meaning given in regulation 5(3) of the Human Medicines Regulations 2012"; and

(d) in the definition beginning "supplementary prescriber" for "article 1(2) of the Prescription Only Medicines (Human Use) Order 1997" substitute "regulation 8(1) of the Human Medicines Regulations 2012".

PART 6

Northern Ireland statutory rules

Control of Pesticides Regulations (Northern Ireland) 1987

102. For regulation 3(2)(b)(i) of the Control of Pesticides Regulations (Northern Ireland) 1987(**81**) substitute—

"(i) the Human Medicines Regulations 2012;".

Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995

103. In rule 4 of the Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995(**82**)—

(a) omit the definition "the 1997 Order";

(b) in the definitions "nurse independent prescriber" and "pharmacist independent prescriber" for "article 1(2) of the 1997 Order" substitute "regulation 8(1) of the Human Medicines Regulations 2012"; and

(c) in the definition "prescription only medicine" for "article 1(2) of the 1997 Order" substitute "regulation 5(3) of the Human Medicines Regulations 2012".

(**80**) S.I. 2010/2880. There are amendments, but none is relevant.
(**81**) S.R. (NI) 1987 No 414, as amended by S.R. (NI) 1997 No 469.
(**82**) S.R. (NI) 1995 No 8, as amended by S.R. (NI) 2009 No 429. There are other amendments, but none is relevant.

Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996

104. In the Schedule to the Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996(**83**) for "Medicines Act 1968" substitute "Human Medicines Regulations 2012".

Pharmaceutical Services Regulations (Northern Ireland) 1997

105. In Part 2 of Schedule 2 to the Pharmaceutical Services Regulations (Northern Ireland) 1997(**84**), in paragraph 2(12) for the words from "Articles" to the end of the paragraph substitute regulation 224 of the Human Medicines Regulations 2012".

Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998

106. In Schedule 1, Chapter 4, Section 4.8, Part C of the Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998(**85**), for the words from "means" to the end of the Part substitute "has the meaning given in regulation 2 of the Human Medicines Regulations 2012".

Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998

107. The Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998(**86**) are amended as follows—

(a) in regulation 10(1)(a) for "section 8 of the Medicines Act 1968" substitute "regulation 17 of the Human Medicines Regulations 2012"; and

(b) in regulation 11(1) for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

Importation of Animal Pathogens Order (Northern Ireland) 1999

108. In article 5(a) of the Importation of Animal Pathogens Order (Northern Ireland) 1999(**87**) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute "the Human Medicines Regulations 2012".

Biocidal Products Regulations (Northern Ireland) 2001

109. In Schedule 2 to the Biocidal Products Regulations (Northern Ireland) 2001(**88**)—

(a) omit entry (f); and

(b) for entry (i) substitute—

"(i) the Human Medicines Regulations 2012;".

Misuse of Drugs Regulations (Northern Ireland) 2002

110.—(1) The Misuse of Drugs Regulations (Northern Ireland) 2002(**89**) are amended as follows.

(**83**) S.R. (NI) 1996 No 81.
(**84**) S.R. (NI) 1997 No 381, as amended by S.R. (NI) 1999 No 405. There are other amendments, but none is relevant.
(**85**) S.R. (NI) 1998 No 28.
(**86**) S.R. (NI) 1998 No 45, as amended by S.R. (NI) 2011 No 124.
(**87**) S.R. (NI) 1999 No 433.
(**88**) S.R. (NI) 2001 No 422.
(**89**) S.R. (NI) 2002 No 1, as amended by S.R. (NI) 2003 No 324, S.R. (NI) 2003 No 420, S.R. (NI) 2005 No 119, S.R. (NI) 2005 No 564, S.R. (NI) 2006 No 214, S.R. (NI) 2006 No 264, and S.R. (NI) 2007 No 348.

(2) In regulation 2(2)—

(a) in the definitions "clinical management plan", "nurse independent prescriber", "patient group direction", "registered chiropodist", "registered midwife", "registered nurse", "registered occupational therapist", "registered optometrist", "registered orthoptist", "registered orthotist and prosthetist", "registered paramedic", "registered physiotherapist", "registered radiographer" and "supplementary prescriber", for "the Prescription Only Medicines (Human Use) Order 1997" substitute "the Human Medicines Regulations 2012"; and

(b) in the definition "medicinal product" for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012"

(3) In regulation 6A(1)(e) for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

(4) In regulation 8(2)—

(a) in sub-paragraph (h) after the first occurrence of "the Medicines Act 1968" insert "or of Schedule 31 to the Human Medicines Regulations 2012"; and

(b) in sub-paragraph (j) after "the Medicines Act 1968" insert "or of regulation 324 of the Human Medicines Regulations 2012".

(5) In regulation 9(2)—

(a) in sub-paragraph (f) after "the Medicines Act 1968" insert "or of Schedule 31 to the Human Medicines Regulations 2012"; and

(b) in sub-paragraph (h) after "the Medicines Act 1968" insert "or of regulation 324 of the Human Medicines Regulations 2012".

(6) In regulation 11(1) for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

(7) In regulation 17—

(a) after "the Medicines Act 1968" insert "or of the Human Medicines Regulations 2012"; and

(b) after "that Act" insert "or of those Regulations".

(8) In regulation 18 for paragraph (3) substitute—

"(3) In this regulation, "clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004.".

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003

111. In regulation 5(2)(c) of the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003(**90**) for "section 58 of the Medicines Act 1968" substitute "regulation 214 of the Human Medicines Regulations 2012".

Waste Management Licensing Regulations (Northern Ireland) 2003

112. In paragraph 2 of Schedule 1 to the Waste Management Licensing Regulations (Northern Ireland) 2003(**91**), in the definition "hazardous waste" for the words following ""medicinal product" means" to the end of the definition substitute "a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012".

(**90**) S.R. (NI) 2003 No 34.
(**91**) S.R. (NI) 2003 No 493.

Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004

113.—(1) The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004(**92**) are amended as follows.

(2) In regulation 2—

(a) in the definition "licensing authority" for "section 6(3) of the Medicines Act 1968" substitute "regulation 6 of the Human Medicines Regulations 2012";

(b) omit the definition "the POM Order" and

(c) in the definition "prescription only medicine" for the words from "referred" to the end of the definition substitute "within the meaning of regulation 5(3) of the Human Medicines Regulations 2012".

(3) In regulation 47(2) for the words from "Part 3" to the end of the regulation substitute "Part 12 of the Human Medicines Regulations 2012".

(4) In Schedule 5—

(a) in paragraph 11A(1) in the definition "Patient Group Direction" for "the Prescription Only Medicines (Human Use) Order 1997" substitute "the Human Medicines Regulations 2012"; and

(b) in paragraph 41(2)(a)—

(i) for "article 3B(3) of the POM Order" substitute "regulation 215 of the Human Medicines Regulations 2012"; and

(ii) for "that Order" substitute "those Regulations".

Nursing Homes Regulations (Northern Ireland) 2005

114. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005(**93**) for "section 58 of the Medicines Act 1968" substitute "regulation 214 or 215 of the Human Medicines Regulations 2012".

Residential Care Homes Regulations (Northern Ireland) 2005

115. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005(**94**) for "section 58 of the Medicines Act 1968" substitute "regulation 214 or 215 of the Human Medicines Regulations 2012".

Children's Homes Regulations (Northern Ireland) 2005

116. In regulation 20(4)(b) of the Children's Homes Regulations (Northern Ireland) 2005(**95**), for "section 58 of the Medicines Act 1968" substitute "regulations 214 or 215 of the Human Medicines Regulations 2012".

(**92**) S.R. (NI) 2004 No 140, as amended by S.R. (NI) 2005 No 368.
(**93**) S.R. (NI) 2005 No 160.
(**94**) S.R. (NI) 2005 No 161.
(**95**) S.R. (NI) 2005 No 176.

Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006

117. In regulation 3(1) of the Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006(**96**) in the definition "Pharmacist" for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007

118. In regulation 71(3)(a) of the Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007(**97**), for "section 8(2) of the Medicines Act 1968" substitute "regulation 17 of the Human Medicines Regulations 2012".

Day Care Setting Regulations (Northern Ireland) 2007

119. In regulation 13(6)(b) of the Day Care Setting Regulations (Northern Ireland) 2007(**98**) for "section 58 of the Medicines Act 1968" substitute "regulations 214 or 215 of the Human Medicines Regulations 2012".

Residential Family Centres Regulations (Northern Ireland) 2007

120. In regulation 13(4)(b) of the Residential Family Centres Regulations (Northern Ireland) 2007(**99**) for "section 58 of the Medicines Act 1968" substitute "regulations 214 or 215 of the Human Medicines Regulations 2012".

Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007

121. In regulation 3(1)(a) of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007(**100**) for "the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994" substitute "the Human Medicines Regulations 2012".

Specified Animal Pathogens Order (Northern Ireland) 2008

122. In article 5(2)(b) of the Specified Animal Pathogens Order (Northern Ireland) 2008(**101**) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute "the Human Medicines Regulations 2012".

Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

123. In regulation 2(2) of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009(**102**), in the definition "retail pharmacy business" for "section 132 of the Medicines Act 1968" substitute "regulation 8(1) of the Human Medicines Regulations 2012".

(**96**) S.R. (NI) 2006 No 478.
(**97**) S.R. (NI) 2007 No 68.
(**98**) S.R. (NI) 2007 No 234.
(**99**) S.R. (NI) 2007 No 236.
(**100**) S.R. (NI) 2007 No 420.
(**101**) S.R. (NI) 2008 No 336.
(**102**) S.R. (NI) 2009 No 225.

Private Water Supplies Regulations (Northern Ireland) 2009

124. In regulation 4(b) of the Private Water Supplies Regulations (Northern Ireland) 2009(**103**) for "the Medicines Act 1968" substitute "the Human Medicines Regulations 2012".

(**103**)S.R. (NI) 2009 No 413.