SCHEDULES

SCHEDULE 34

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 Section 10(1), 10(3) and 10(7A) were amended and 10(2) repealed by Part 1 paragraphs 1 and 10 of Schedule 8 to S.I. 2006/2407, section 10(1), 10(4) were amended and 10(5) to (7) and 10(8) inserted by article 3 of S.I.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.