SCHEDULES

SCHEDULE 34

Amendments to existing law

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(**1**)—

(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".

Importation of Animal Products and Poultry Products Order 1980

66. In the Schedule to the Importation of Animal Products and Poultry Products Order 1980(**2**), 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(**3**)—

(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".

(**1**) S.I. 1978/1006, as amended by S.I. 1995/2147 and S.I. 2006/2407. There are other amendments, but none is relevant.
(**2**) S.I. 1980/14, as amended by S.I. 1994/2920, S.I. 1994/3142 and S.I. 1994/3144.
(**3**) S.I. 1986/1700. There are amendments, but none is relevant.

Medicines Act (Hearings by Persons Appointed) Rules 1986

68. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986(**4**)—

(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(**5**) 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;".

(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—

(**4**) S.I. 1986/1761, as amended by S.I. 2006/2407. There are other amendments, but none is relevant.
(**5**) 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.

(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(**6**)—

(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(**7**) is amended as follows.

(2) In article 1—

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

(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(**8**), 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.

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

(**7**) 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.

(**8**) S.I. 1999/3267, as amended by S.I. 2005/1476. There are other amendments, but none is relevant.

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

73. The National Health Service (Charges for Drugs and Appliances) Regulations 2000(**9**) 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(**10**)—

(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(**11**), 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."

Misuse of Drugs Regulations 2001

76. In regulation 2(1) of the Misuse of Drugs Regulations 2001(**12**)—

(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 (**13**), 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.".

(**9**) S.I. 2000/620, as amended by S.I. 2000/3189 and S.I. 2009/1166. There are other amendments, but none is relevant.
(**10**) S.I. 2001/880, as amended by S.I. 2010/745. There are other amendments, but none is relevant.
(**11**) S.I. 2001/1841, as amended by S.I. 2005/2750 and S.I. 2008/548.
(**12**) 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.
(**13**) S.I. 2002/3170, as amended by S.I. 2005/2750 and S.I. 2008/548.

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(**14**) 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(**15**) 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(**16**)—

(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.

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(**17**)—

(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".

(**14**) S.I. 2003/1076, as amended by S.I. 2005/2061. There are other amendments, but none is relevant.
(**15**) S.I. 2003/1374. There are amendments, but none is relevant.
(**16**) S.I. 2003/1376. There are amendments, but none is relevant.
(**17**) S.I. 2003/1571, as amended by S.I. 2006/1996. There are other amendments, but none is relevant.

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 (**18**) (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;";

(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;".

(**18**) S.I. 2003/1680, as amended by S.I. 2004/3224, S.I. 2005/2750 and S.I. 2005/2754.

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

83.—(1) The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(**19**) 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(**20**) 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

(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(**21**) 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".

(**19**) S.S.I. 2004/115, as amended by S.S.I. 2005/337. There are other amendments, but none is relevant.
(**20**) S.S.I. 2004/116, as amended by S.S.I. 2005/336. There are other amendments, but none is relevant.
(**21**) S.I. 2004/291, as amended by S.I. 2005/893. There are other amendments, but none is relevant.

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

86.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**22**) 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(**23**) 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 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(**24**) 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".

(**22**) S.I. 2004/478, as amended by S.I. 2006/358 and S.I. 2010/1647. There are other amendments, but none is relevant.
(**23**) S.I. 2004/627, as amended by S.I 2005/893. There are other amendments, but none is relevant.
(**24**) S.I. 2004/1022, as amended by S.I 2005/366 and S.I. 2009/1977. There are other amendments, but none is relevant.

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(**25**) 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".

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(**26**)—

(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".

(**25**) S.I. 2004/1975.
(**26**) S.I. 2005/1478, as amended by S.I. 2008/1940. There are other amendments, but none is relevant.

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(**27**) 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(**28**)—

(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(**29**) 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",

"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

(**27**) S.I. 2007/121, as amended by S.I. 2009/1175 and S.I. 2010/1647. There are other amendments, but none is relevant.
(**28**) S.I. 2007/1523.
(**29**) S.I. 2007/3544, as amended by S.I. 2009/2981. There are other amendments, but none is relevant.

(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 (**30**), 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.".

Specified Animal Pathogens Order 2008

95. In article 5(2) of the Specified Animal Pathogens Order 2008(**31**)—

(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(**32**)—

(**30**) S.I. 2008/548.
(**31**) S.I. 2008/944. There are amendments, but none is relevant.
(**32**) S.I. 2008/1270. There are amendments, but none is relevant.

(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(**33**) 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(**34**)—

(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(**35**) 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";

(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

(**33**) S.I. 2008/3258. There are amendments, but none is relevant.
(**34**) S.S.I. 2009/45. There are amendments, but none is relevant.
(**35**) S.S.I. 2009/183.

(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(**36**) 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—

"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(**37**)—

(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";

(**36**) S.I. 2009/669. There are amendments, but none is relevant.
(**37**) S.I. 2010/2880. There are amendments, but none is relevant.

(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".