STATUTORY INSTRUMENTS

2012 No. 1916

MEDICINES

The Human Medicines Regulations 2012

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THE HUMAN MEDICINES REGULATIONS 2012

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15. (1) The qualified person is responsible for ensuring, in relation...

SCHEDULE 7A — Information to be provided for registration as an importer, manufacturer or distributor of active substances

1. The name and address of the applicant.
2. The name and address of the person (if any) making...
3. The address of each of the premises where any operations...
4. The address of any premises not mentioned by virtue of...
5. The address of each of the premises where active substances...
6. The address of each of the premises where any testing...
7. The name, address, qualifications and experience of the person whose...
8. The name, address, qualifications and experience of the person who...
9. The name, address, qualifications and experience of the person whose...
10. The name, address and qualifications of the person to be...
11. The name, address and qualifications of the person to be...
12. For each active substance to be manufactured, imported, or distributed—...
13. Details of the operations to which the registration relates, including...
14. A statement of the facilities and equipment available at each...
15. A statement as to whether the particular active substances are...
16. A separate statement in respect of each of the premises...
17. A statement of the authority conferred on the person responsible...
18. A description of the arrangements for the identification and storage...
19. A description of the arrangements for the identification and storage...
20. A description of the arrangements at each of the premises...
21. A description of the arrangements for maintaining—
22. A description of the arrangements for keeping reference samples of—...
23. Where the application relates to active substances intended for use...
24. Details of— (a) any manufacturing, importation, storage or distribution operations,...

SCHEDULE 8 — Material to accompany an application for a UK marketing authorisation

PART 1 — General requirements

1. The name or corporate name and permanent address of the...
2. The name of the medicinal product. This may be—
3. Qualitative and quantitative particulars of the constituents of the medicinal...
4. An evaluation of the potential environmental risks posed by the...
5. A description of the methods of manufacturing the medicinal product....
6. The therapeutic indications and contra-indications for the medicinal product and...
7. The posology and pharmaceutical form of the medicinal product, its...
8. The reasons for any precautionary and safety measures to be...
9. A description of the control methods employed by the manufacturer....

9A A written confirmation that the manufacturer of the medicinal product...

10. The results of the following in relation to the medicinal...
11. A detailed summary of those results prepared and signed by...
12. A summary of the applicant's pharmacovigilance system which shall include...
13. The risk management plan, together with a summary, that—

14. Where any clinical trials have been carried out outside the...
15. A summary of the product characteristics for the medicinal product...
16. A mock-up, in accordance with Part 13 (packaging and leaflets)...
17. A document showing that the manufacturer of the medicinal product...
18. Where— (a) in the case of a UKMA(NI) or a...
19. Where an authorisation for the medicinal product to be placed...
20. Where , in the case of a medicinal product for...
21. Where an authorisation for the medicinal product to be placed...
22. In the case of a medicinal product for sale or...

PART 2 — Summary of the product characteristics

23. For medicinal products included on the list referred to—
24. The name of the medicinal product followed by its strength...
25. The qualitative and quantitative composition, using the usual common name...

25A In the case of an advanced therapy medicinal product for...

26. The pharmaceutical form of the medicinal product.
27. Clinical particulars in relation to the medicinal product, covering—
28. The pharmacological properties of the medicinal product, covering—
29. Pharmaceutical particulars in relation to the medicinal product, covering—
30. The holder of the UK marketing authorisation.
31. The number of the UK marketing authorisation.
32. The date of the first UK marketing authorisation or, where...
33. The date of any revisions of the text of the...
34. For radiopharmaceuticals, full details of internal radiation dosimetry.
35. For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality...
36. In the case of an advanced therapy medicinal product for...

SCHEDULE 8A — Material to accompany an application for a parallel import licence

1. The name or corporate name and permanent address of the...
2. The name of the medicinal product. This may be—
3. Details of the product to be imported if requested by...
4. Details of the UK reference product.
5. If requested by the licensing authority, an evaluation of the...
6. If requested by the licensing authority, a summary of the...
7. If requested by the licensing authority, the risk management plan,...
8. If requested by the licensing authority, a summary of the...
9. A mock-up, in accordance with Part 13 (packaging and leaflets)...

SCHEDULE 8B — Modifications of Annex I to the 2001 Directive

SCHEDULE 8C — Material to accompany an application for a UK marketing authorisation under the unfettered access route

1. A copy of the application submitted in connection with the...
2. A copy of all material submitted in support of the...
3. A copy of the EU marketing authorisation or UKMA(NI) which...

SCHEDULE 9 — Undertakings by non- United Kingdom manufacturers

1. The manufacturer must provide and maintain such staff, premises and...
2. The manufacturer must provide and maintain such staff, premises, equipment...
3. The manufacturer must provide and maintain a designated quality control...

SCHEDULE 11 — Advice and representations

PART 1 — General procedures

Application of this Part

1. (1) This Part of this Schedule applies to—

Requirement to consult the appropriate committee

2. (1) The licensing authority must consult the appropriate committee if...

Exceptions to requirement to consult

3. (1) Paragraph 2 does not apply to a proposal to...
4. (1) Paragraph 2 does not apply to a proposal to...

Provisional opinion against authorisation

5. (1) If the appropriate committee is consulted under paragraph 2(1)...

Opportunity to make representations

6. (1) An applicant or holder notified under paragraph 5 may,...

Written representations

7. (1) If the applicant or holder requests the opportunity to...

Oral representations

8. (1) If the applicant or holder requests the opportunity to...

Other decisions of the appropriate committee

9. (1) This paragraph applies if the applicant or holder—

Decision of licensing authority

10. (1) After receiving the appropriate committee's report under paragraph 7...

Right to review after paragraph 10 notification

11. (1) A person to whom a notification is given under...

Licensing authority decisions in other cases

12. (1) This paragraph applies if the appropriate committee has not...

Right to review or representations after paragraph 12 notification

13. (1) A person to whom a notification is given under...

PART 1A — Paediatric Decisions

13A Application of this Part
13B Opportunity to make representations
13C Written representations
13D Oral representations
13E Other decisions of the appropriate committee
13F Decision of licensing authority
13G Right to review after paragraph 13F notification

PART 2 — Type II variation applications, complex variation applications and new excipient variation applications

Application of this Part

14. This Part applies— (a) to an application (a "Type II...
15. (1) In paragraph 14(b)(i) "complex variation application" means an application...
16. (1) In paragraph 14(b)(ii) "new excipient variation application" means an...
17. In relation to an application for a UKMA(NI) or THR(NI),...

Opportunity to make representations

18. (1) This paragraph applies if the licensing authority notifies the...

Written representations

19. (1) If the applicant requests the opportunity to make written...

Oral representations

20. (1) If the applicant requests the opportunity to make oral...

Other decisions of the appropriate committee

21. (1) This paragraph applies if the applicant—

Decision of licensing authority following report

22. (1) After receiving the appropriate committee's report under paragraph 19...

Right to review after paragraph 22 notification

23. (1) This paragraph applies if the licensing authority notifies the...

PART 3 — Referral to the appropriate committee for traditional herbal registrations

Application of this Part

24. (1) This Part applies if the licensing authority proposes to...

Opportunity to make representations

25. (1) The licensing authority must notify the applicant of the...

Written representations

26. (1) If the applicant requests the opportunity to make written...

Oral representations

27. (1) If the applicant requests the opportunity to make oral...

Other decisions of the appropriate committee

28. (1) This paragraph applies if the applicant—

Decision of licensing authority following report

29. (1) After receiving the appropriate committee's report under paragraph 26...

Right to review after paragraph 29 notification

30. (1) This paragraph applies if the licensing authority notifies the...

PART 4 — Exceptions to Schedule

31. This Schedule does not apply to an application for the...
32. This Schedule does not apply to an application for the...
33. This Schedule ceases to apply if at any time the...
34. This Schedule does not apply to an application for a...
35. This Schedule does not apply to an application for a...
36. This Schedule does not apply if the application or proposal...
37. This Schedule does not apply if the application or proposal...
38. This Schedule does not apply if the application or proposal...
39. This Schedule does not apply if— (a) the licensing authority...

SCHEDULE 12 — Material to accompany an application for a traditional herbal registration

PART 1 — General requirements

1. The name or corporate name and permanent address of the...
2. The name of the medicinal product. This may be—
3. Qualitative and quantitative particulars of the constituents of the medicinal...
4. An evaluation of the potential environmental risks posed by the...
5. A description of the methods of manufacturing the medicinal product....
6. The therapeutic indications and contra-indications for the medicinal product and...
7. The posology and pharmaceutical form of the medicinal product, its...
8. The reasons for any precautionary and safety measures to be...
9. A description of the control methods employed by the manufacturer....
10. Results of pre-clinical (toxicological and pharmacological) tests in relation to...
11. A detailed summary of those results prepared and signed by...
12. A summary of the product characteristics for the medicinal product...
13. A mock-up, in accordance with Part 13 (packaging and leaflets)...
14. A document showing that the manufacturer of the medicinal product...
15. Where the medicinal product consists of a combination of one...
16. Details of any authorisation or registration obtained by the applicant...
17. Details of any decision in a country other than the...
18. Bibliographical or expert evidence of the traditional use of the...
19. A bibliographic review of safety data.
20. An expert report on safety.

PART 2 — Summary of the product characteristics

21. For medicinal products included on the list referred to in...
22. The name of the medicinal product followed by its strength...
23. The qualitative and quantitative composition, using the usual common name...
24. The pharmaceutical form of the medicinal product.
25. The pharmacological properties of the medicinal product, covering—
26. Pharmaceutical particulars of the medicinal product, covering—
27. The holder of the traditional herbal registration.
28. The number of the traditional herbal registration.

SCHEDULE 24 — Packaging information requirements

PART 1 — Outer and immediate packaging

1. The name of the medicinal product.
2. The strength and pharmaceutical form of the product.
3. Where appropriate, whether the product is intended for babies, children...
4. Where the product contains up to three active substances, the...
5. A statement of the active substances in the product, expressed...
6. The pharmaceutical form and the contents by weight, by volume...
7. A list of— (a) where the product is injectable or...
8. The method of administration of the product and if necessary...
9. Where appropriate, space for the prescribed dose to be indicated....
10. A warning that the product must be stored out of...
11. Any special warning applicable to the product.
12. The product's expiry date (month and year), in clear terms....
13. Any special storage precautions relating to the product.
14. Any special precautions relating to the disposal of an unused...
15. The name and address of the holder of the UK...
16. The number of the UK marketing authorisation, EU marketing authorisation...
17. The manufacturer's batch number.
18. In the case of a product that is not a...

18A In the case of a medicinal product, other than a...

PART 2 — Immediate packaging: blister packs

19. The name of the medicinal product.
20. The strength and pharmaceutical form of the product.
21. Where appropriate, whether the product is intended for babies, children...
22. Where the product contains up to three active substances, the...
23. The name of the holder of the UK marketing authorisation,...
24. The product's expiry date (month and year), in clear terms....
25. The manufacturer's batch number.

PART 3 — Immediate packaging: small packages

26. The name of the medicinal product.
27. The strength and pharmaceutical form of the product.
28. Where appropriate, whether the product is intended for babies, children...
29. Where the product contains up to three active substances, the...
30. The method of administration of the product and if necessary...
31. The product's expiry date (month and year), in clear terms....
32. The manufacturer's batch number.
33. The contents of the packaging by weight, by volume or...

PART 4 — Outer and immediate packaging: advanced therapy medicinal products for sale or supply in Great Britain only

34. The name of the advanced therapy medicinal product which is...
35. Where appropriate, whether the product is intended for babies, children...
36. The expiry date in clear terms including the year and...
37. A description of the active substance, expressed qualitatively and quantitatively....
38. Where the product contains tissues and cells of human or...
39. The pharmaceutical form and the contents by weight, volume or...
40. A list of excipients, including preservative systems.
41. The method of use, application, administration or implantation and, if...
42. A special warning that the product is to be stored...
43. Any special warning necessary for the particular product.
44. Any special storage precautions.

1. The name of the medicinal product.
2. The strength and pharmaceutical form of the product.
3. Where appropriate, whether the product is intended for babies, children...
4. Where the product contains up to three active substances, the...
5. The pharmaco-therapeutic group, or type of activity, of the product,...
6. The product's therapeutic indications.
7. A list of— (a) contra-indications; (b) appropriate precautions for use;...
8. The list mentioned in paragraph 7 must—
9. Instructions for proper use of the product including in particular—...
10. A description of the adverse reactions which may occur in...
11. A reference to the expiry date printed on the packaging...
12. Where the product is authorised for sale or supply in...
13. For medicinal products included in the list referred to in...
14. A standardised text relating to adverse event reporting in accordance...
15. The date on which the package leaflet was last revised....

PART 2 — Paracetamol

16. If a medicinal product contains paracetamol, unless the product is...
17. If a medicinal product contains paracetamol and is wholly or...

Part 3 — Advanced therapy medicinal products for sale or supply in Great Britain only

18. The name of the advanced therapy medicinal product.
19. Where appropriate, whether the product is intended for babies, children...
20. The common name of the advanced therapy medicinal product.
21. The therapeutic group, or type of activity, of the product,...
22. Where the product contains cells or tissues, a description of...
23. Where the product contains medical devices or active implantable medical...
24. The product's therapeutic indications.
25. A list of information which is necessary before the medicinal...
26. The list mentioned in paragraph 25 must—
27. Instructions for proper use of the product including in particular—...
28. A description of the adverse reactions which may occur in...
29. A reference to the expiry date printed on the packaging...
30. The date on which the package leaflet was last revised....

SCHEDULE 28 — Labelling requirements for registrable homoeopathic medicinal products

PART 1 — Outer and immediate packaging

1. The scientific name of the stock or stocks (which may...
2. The name and address of the holder of the certificate...
3. The method and, if necessary, route of administration.
4. The product's expiry date (month and year), in clear terms....
5. The product's pharmaceutical form.
6. The contents of the presentation, specified by weight, volume or...
7. Special storage precautions, if any.
8. A special warning, if necessary in relation to the product....
9. The manufacturer's batch number.
10. The number of the certificate of registration.
11. The words “homoeopathic medicinal product without therapeutic indications”.
12. A warning advising the user to consult a doctor if...

PART 2 — Blister packs etc contained in outer packaging

13. The scientific name of the stock or stocks (which may...

14. The name and address of the holder of the certificate...
15. The product's expiry date (month and year), in clear terms....
16. The manufacturer's batch number.
17. The words “homoeopathic medicinal product without therapeutic indications”.

PART 3 — Small immediate packaging

18. The scientific name of the stock or stocks (which may...
19. The name and address of the holder of the certificate...
20. The method and, if necessary, route of administration.
21. The product's expiry date (month and year), in clear terms....
22. The contents of the presentation, specified by weight, volume or...
23. The manufacturer's batch number.
24. The words “homoeopathic medicinal product without therapeutic indications”.

SCHEDULE 29 — Labelling of traditional herbal medicinal products

PART 1 — Traditional herbal medicinal products: general

1. A statement to the effect that the product is a...
2. A statement that the user should consult a doctor or...

PART 2 — Traditional herbal medicinal products not subject to general sale

3. Subject to the provisions of regulation 265(2), paragraph 4 applies...
4. Where this paragraph applies, the outer packaging and the immediate...

SCHEDULE 30 — Particulars for advertisements to persons qualified to prescribe or supply

1. The number of the UK marketing authorisation, EU marketing authorisation,...
2. The name and address of the holder of the temporary...

2A In relation to an advertisement in Great Britain (other than...

3. The classification of the medicinal product as—
4. The name of the medicinal product.
5. A list of the active ingredients of the medicinal product...
6. One or more of the indications for the medicinal product...
7. The entries or a succinct statement of the entries (if...
8. The cost excluding value added tax of—
9. (1) The particulars specified in paragraph 7 must be printed...

SCHEDULE 31 — Sampling

— Introductory

1. (1) This Schedule has effect where a person authorised by...

— Division of sample

2. The sampling officer must as soon as practicable—
3. If the sample was purchased by the sampling officer otherwise...
4. If the sampling officer obtained the sample from a vending...
5. If the sample is a sample of goods consigned from...
6. If, in a case not falling within any of paragraphs...
7. If, in a case not falling within any of paragraphs...
8. In any case not falling within any of paragraphs 3...
9. In every case falling within any of paragraphs 3 to...
10. Unless the sampling officer decides not to submit the sample...
11. If a sample consists of substances or articles in unopened...
12. Regulation 343(1)(a) to (d) has effect in relation to supplying...
13. If after reasonable inquiry the sampling officer is unable to...

2. For the text of section 1 (Ministers responsible for the...
3. In section 10 (exemptions for pharmacists)— (a) in subsection (1)...
4. In section 15 (provision for extending or modifying exemptions)—
5. In section 58 (medicinal products on prescription only)—
6. In section 58A(1) (requirement to specify certain products as prescription-only...
7. In section 62 (prohibition of sale or supply, or importation,...
8. In section 64(5) (protection for purchasers of medicinal products) for...
9. (1) Section 67 (offences under Part III) is amended as...
10. In section 72 (representative of pharmacist in case of death...
11. In section 82(4) (pharmacies: procedure relating to disqualification) for "Pharmaceutical...
12. In section 87 (requirements as to containers)—
13. In section 88(1) (distinctive colours, shapes and markings of medicinal...
14. In section 91 (offences under Part V, and supplementary provisions)—...
15. In section 104 (application of Act to certain articles and...
16. In section 105 (application of Act to certain other substances...
17. In section 107 (validity of decisions and proceedings relating thereto)—...
18. (1) Section 108 (enforcement in England and Wales) is amended...
19. In section 109 (enforcement in Scotland)— (a) in subsection (2)—...
20. In section 110 (enforcement in Northern Ireland)—
21. In section 111 (rights of entry)— (a) in subsection (1)...
22. In section 113(1) (application of sampling procedure to substance or...
23. In section 114(1) (supplementary provisions as to rights of entry...
24. In section 121(4) (contravention due to default of other person),...
25. In section 122(2) (warranty as defence), for the words "section...
26. In section 123(1)(b) (offences in relation to warranties and certificates...
27. In section 125 (prosecutions)— (a) in subsection (4)—
28. In section 126 (presumptions)— (a) in subsection (1), omit paragraph...
29. In section 128 (financial provisions)— (a) in subsection (1), for...
30. In section 129 (orders and regulations)— (a) in subsection (2),...
31. In section 130 (meaning of medicinal product and related expressions)—...
32. In section 131(5) (meaning of "wholesale dealing", "retail sale" and...
33. In section 132 (general interpretation provisions)— (a) for subsection (1)...
34. In Schedule 3 (sampling)— (a) omit paragraphs 5 to 7;...
35. In Schedule 4 (provisions relating to Northern Ireland)—

Medicines Act 1971

36. (1) The Medicines Act 1971 shall have effect as follows....
PART 2 — Other primary legislation

Trade Descriptions Act 1968

37. In section 2(5)(b) (trade descriptions) of the Trade Descriptions Act...

House of Commons Disqualification Act 1975

38. In Part II (bodies of which all members are disqualified)...

Northern Ireland Assembly Disqualification Act 1975

39. In Part II (bodies of which all members are disqualified)...

Consumer Protection Act 1987

40. Section 19(1) (interpretation of Part II) of the Consumer Protection...

Environmental Protection Act 1990

41. In section 142(7) (powers to obtain information about potentially hazardous...

Value Added Tax Act 1994

42. In Part II of Schedule 8 (zero-rating) to the Value...

Health Act 1999

43. In section 60(2A)(c) (regulation of health care and associated professions)...

Communications Act 2003

44. In section 368R(1) (interpretation of Part 4A) of the Communications...

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

45. In section 7 (interpretation) of the Christmas Day and New...

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...

Pharmacy (Northern Ireland) Order 1976

47. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976...

Poisons (Northern Ireland) Order 1976

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

Diseases of Animals (Northern Ireland) Order 1981

49. In article 38 of the Diseases of Animals (Northern Ireland)...

Waste and Contaminated Land (Northern Ireland) Order 1997

50. In article 33(6) of the Waste and Contaminated Land (Northern...

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

51. In article 4(3) of the Shops (Sunday Trading &c.) (Northern...

PART 4 — The Medicines for Human Use (Clinical Trials) Regulations 2004

52. The Medicines for Human Use (Clinical Trials) Regulations 2004 are...
53. In regulation 2(1) (interpretation)— (a) before the definition “the Act”...
54. In regulation 4(3) (responsibility for functions under the Directive) for...
55. In regulation 19(10) (authorisation procedure for clinical trials involving medicinal...
56. In regulation 46(2)(c) (labelling) for words from “Schedule 5” to...
57. In regulation 47 (application of enforcement provisions of the Act)—...
58. In regulation 48(5) (infringement notices) for “sections 108 to 110...
59. In regulation 49(5) (offences) for “the Act” substitute “ the...

60. In regulation 53(3) (construction of references to specified publications) for...
61. In paragraph 4(2) of Schedule 5 (procedural provisions relating to...
62. In Schedule 7 (standard provisions for manufacturing authorisations)—
63. In paragraph 5(2) of Schedule 8 (procedural provisions relating to...
64. For Schedule 9 substitute the following Schedule— SCHEDULE 9 MODIFICATIONS OF...

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)...

Importation of Animal Products and Poultry Products Order 1980

66. In the Schedule to the Importation of Animal Products and...

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

67. In rule 2 of The Medicines Act (Hearings by Persons...

Medicines Act (Hearings by Persons Appointed) Rules 1986

68. In rule 2 of The Medicines Act (Hearings by Persons...

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

69. (1) The Medicines (Fixing of Fees Relating to Medicinal Products...

Medical Devices (Consultation Requirements) (Fees) Regulations 1995

70. In regulation 1(2) of the Medical Devices (Consultation Requirements) (Fees)...

Prescription Only Medicines (Human Use) Order 1997

71. (1) The Prescription Only Medicines (Human Use) Order 1997 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...

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

73. The National Health Service (Charges for Drugs and Appliances) Regulations...

Biocidal Products Regulations 2001

74. In Schedule 2 to the Biocidal Products Regulations 2001 —...

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

75. In article 4(4) of the Medicines (Aristolochia and Mu Tong...

Misuse of Drugs Regulations 2001

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

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

77. In paragraph (d) of article 3 of the Medicines for...

Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

78. In article 1(3) of the Medicines and Healthcare Products Regulatory...

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

79. In the column "specified UK laws" of the Schedule to...

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...

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

81. In article 6 of the Health Professions (Parts of and...

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

82. (1) The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform...

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

83. (1) The National Health Service (General Medical Services Contracts) (Scotland)...

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

84. (1) The National Health Service (Primary Medical Services Section 17C...

National Health Service (General Medical Services Contracts) Regulations 2004

85. (1) The National Health Service (General Medical Services Contracts) Regulations...

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

86. (1) The National Health Service (General Medical Services Contracts) (Wales)...

National Health Service (Personal Medical Services Agreements) Regulations 2004

87. (1) The National Health Service (Personal Medical Services Agreements) 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...

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...

General Optical Council (Registration Rules) Order of Council 2005

90. In the Table in rule 10 of the Schedule to...

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...

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

92. In regulation 2(3) of the Human Tissue (Quality and Safety...

Legislative and Regulatory Reform (Regulatory Functions) Order 2007

93. (1) The Schedule to the Legislative and Regulatory Reform (Regulatory...

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

94. In paragraph (d) of article 3 of the Medicines for...

Specified Animal Pathogens Order 2008

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

Specified Animal Pathogens (Wales) Order 2008

96. In article 5(2) of the Specified Animal Pathogens (Wales) Order...

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...

Specified Animal Pathogens (Scotland) Order 2009

98. In article 5(2) of the Specified Animal Pathogens (Scotland) Order...

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

99. (1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009...

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...

Single Use Carrier Bags Charge (Wales) Regulations 2010

101. In Schedule 1(3) to the Single Use Carrier Bags Charge...

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...

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

103. In rule 4 of the Prison and Young Offenders Centre...

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

104. In the Schedule to the Diseases of Animals (Importation of...

Pharmaceutical Services Regulations (Northern Ireland) 1997

105. In Part 2 of Schedule 2 to the Pharmaceutical Services...

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

106. In Schedule 1, Chapter 4, Section 4.8, Part C of...

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

107. The Products of Animal Origin (Import and Export) Regulations (Northern...

Importation of Animal Pathogens Order (Northern Ireland) 1999

108. In article 5(a) of the Importation of Animal Pathogens Order...

Biocidal Products Regulations (Northern Ireland) 2001

109. In Schedule 2 to the Biocidal Products Regulations (Northern Ireland)...

Misuse of Drugs Regulations (Northern Ireland) 2002

110. (1) The Misuse of Drugs Regulations (Northern Ireland) 2002 are...

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

111. In regulation 5(2)(c) of the Control of Substances Hazardous to...

Waste Management Licensing Regulations (Northern Ireland) 2003

112. In paragraph 2 of Schedule 1 to the Waste Management...

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

113. (1) The Health and Personal Social Services (General Medical Services...

Nursing Homes Regulations (Northern Ireland) 2005

114. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland)...

Residential Care Homes Regulations (Northern Ireland) 2005

115. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland)...

Children's Homes Regulations (Northern Ireland) 2005

116. In regulation 20(4)(b) of the Children's Homes Regulations (Northern Ireland)...

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

117. In regulation 3(1) of the Healthy Start Scheme and Day...

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...

Day Care Setting Regulations (Northern Ireland) 2007

119. In regulation 13(6)(b) of the Day Care Setting Regulations (Northern...

Residential Family Centres Regulations (Northern Ireland) 2007

120. In regulation 13(4)(b) of the Residential Family Centres Regulations (Northern...

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...

Specified Animal Pathogens Order (Northern Ireland) 2008

122. In article 5(2)(b) of the Specified Animal Pathogens Order (Northern...

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

123. In regulation 2(2) of the Controlled Drugs (Supervision of Management...

Private Water Supplies Regulations (Northern Ireland) 2009

124. In regulation 4(b) of the Private Water Supplies Regulations (Northern...

SCHEDULE 35 — Repeals and revocations

Explanatory Note

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012.