
STATUTORY INSTRUMENTS

2012 No. 1916

MEDICINES

The Human Medicines Regulations 2012

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THE HUMAN MEDICINES REGULATIONS 2012

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Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

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Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

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4. The licence holder must provide such information as may be...
5. The licence holder must inform the licensing authority of any...
6. The licence holder must— (a) keep readily available for inspection...
7. The licence holder must keep readily available for examination by...
8. Where the licence holder has been informed by the licensing...
9. The licence holder must ensure that tests for determining conformity...
10. Where the manufacturer's licence relates to the assembly of a...
11. Where— (a) the manufacturer's licence relates to the assembly of...
12. The licence holder must keep readily available for examination by...
13. Where— (a) animals are used in the production of medicinal...
14. The licence holder must take all reasonable precautions and exercise...

- 14A A licence holder— (a) in Great Britain may only supply...
- 14B A licence holder may only manufacture or assemble EAMS medicinal...
- PART 2 — Manufacturer's licence relating to the import of medicinal products from a state other than an EEA State / Country other than an Approved Country for Import
15. The provisions of this Part are standard provisions of a...
- 15A The provisions of this Part are standard provisions of a...
16. The licence holder must place the quality control system referred...
17. The licence holder may use a contract laboratory pursuant to...
18. The licence holder must provide such information as may be...
19. The licence holder must— (a) keep readily available for inspection...
20. Where the licence holder has been informed by the licensing...
21. The licence holder must ensure that any tests for determining...
22. (1) Where and in so far as the licence relates...
23. The licence holder must take all reasonable precautions and exercise...
- 23ZA The licence holder in Great Britain must take all reasonable...
- 23A A licence holder— (a) in Great Britain may only supply...
- 23B A licence holder may only import EAMS medicinal products if...
- PART 3 — Manufacturer's licence relating to exempt advanced therapy medicinal products
24. The provisions of paragraphs 25 to 27 are incorporated as...
25. The licence holder must ensure that the immediate packaging of...
26. The licence holder must ensure that the package leaflet of...
27. The licence holder must keep the data referred to in...
- PART 4 — Wholesale dealer's licence

All wholesale dealer's licences

28. The provisions of this Part are standard provisions of a...
29. The licence holder must not use any premises for the...
30. The licence holder must provide such information as may be...
31. The licence holder must take all reasonable precautions and exercise...

Wholesale dealer's licence relating to special medicinal products

32. The provisions of paragraphs 33 to 42 are incorporated as...
33. Where and in so far as the licence relates to...
- 33A A licence holder may only import EAMS medicinal products if...
34. No later than 28 days prior to each importation of...
35. The licence holder may not import the special medicinal product...
36. The licence holder may import the special medicinal product referred...
37. Where the licence holder sells or supplies special medicinal products...
38. The licence holder must not, on any one occasion, import...
39. The licence holder must inform the licensing authority immediately of...
40. The licence holder must not publish any advertisement, catalogue, or...
41. The licence holder must cease importing or supplying a special...
- 41A A licence holder— (a) in Great Britain may only supply...
42. In this Part— “British approved name” means the name which...

Wholesale dealer's licence relating to exempt advanced therapy medicinal products

43. The provisions of paragraph 44 are incorporated as additional standard...
44. The licence holder shall keep the data referred to in...

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

SCHEDULE 5 — Review upon oral representations

— Application of this Schedule

1. (1) This Schedule applies if a person (“the applicant”) mentioned...
— Appointment of reviewers
2. (1) The licensing authority must— (a) appoint a panel of...
— Procedure before hearing
3. (1) The applicant must supply the reviewers with a written...
— Procedure at hearing
4. (1) Both the applicant and the licensing authority may make...
— Procedure following hearing
5. (1) After the hearing the reviewers must provide a report...

SCHEDULE 6 — Manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products

PART 1 — Manufacturer's licences

1. The requirements in paragraphs 2 to 12 apply to a...
2. The licence holder must inform the licensing authority of any...
3. The licence holder must ensure, if using human cells or...
4. The licence holder must ensure that any human tissue or...
5. The licence holder must ensure that any blood or blood...
6. Where the holder of a manufacturer's licence distributes by way...
7. The licence holder must, at the written request of the...
8. The licence holder must establish and maintain a system ensuring...
9. The licence holder must, subject to paragraph 27 of Schedule...
10. The licence holder must secure that the data referred to...
11. The licence holder must, where an exempt advanced therapy medicinal...
12. The licence holder must not import or export any exempt...

PART 2 — Wholesale dealer's licences

13. The requirements in paragraphs 14 to 20 apply to a...
14. The licence holder must obtain supplies of exempt advanced therapy...
15. The licence holder must distribute an exempt advanced therapy medicinal...
16. The licence holder must establish and maintain a system ensuring...
17. The licence holder must inform the licensing authority of any...
18. The licence holder must, subject to paragraph 44 of Schedule...
19. The licence holder must secure that the data referred to...
20. The licence holder must not import or export any exempt...

SCHEDULE 7 — Qualified persons

PART 1 — Qualification requirements for qualified person

1. A person must satisfy the requirements in paragraphs 2 and...
2. The person must have a degree, diploma or other formal...
3. A qualification satisfies the requirements of this Part if it...
4. (1) A course should include at least the following core...
5. If the course referred to in paragraph 3 is followed...
6. If two university courses, or courses recognised as of university...
7. If the person's formal qualifications do not satisfy the requirements...
8. (1) The person must (subject to sub-paragraph (2)) have at...

PART 2 — Qualified persons with long experience

9. (1) This paragraph applies to a person who has acted...
10. (1) This paragraph applies to a person who—
11. If a person to whom paragraph 10 applies acquired the...

PART 3 — Obligations of qualified person

12. (1) In Great Britain, the qualified person is responsible for...

- 12A (1) In Northern Ireland, the qualified person is responsible for...
- 13. (1) This paragraph applies in Northern Ireland where—
- 14. (1) This paragraph applies where— (a) medicinal products are imported...
- 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—

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

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...

4. The manufacturer must conduct all manufacture and assembly operations in...
5. The manufacturer must maintain an effective pharmaceutical quality assurance system...
6. Where animals are used in the production of any medicinal...
7. The manufacturer must make such adequate and suitable arrangements as...
8. The manufacturer must inform the holder of the UK marketing...
9. (1) The manufacturer shall keep readily available for inspection by...
10. The manufacturer must keep readily available for examination by a...
11. (1) The manufacturer must implement a system for recording and...
12. The manufacturer must inform the holder of the UK marketing...

SCHEDULE 9A — Meaning of terms used in the orphan criteria and in regulation 58D

1. Prevalence of a condition in Great Britain
2. Potential for return on investment
3. Existence of other methods of diagnosis, prevention or treatment
4. Increased safety or effectiveness and clinical superiority
5. (1) This paragraph applies for the purposes of the definition...
6. (1) This paragraph applies for the purposes of the definition...
7. (1) This paragraph applies for the purposes of the definition...
8. (1) This paragraph applies for the purposes of the definition...

SCHEDULE 10 — National homoeopathic products

— Meaning of “national homoeopathic product”

1. (1) In this Schedule “national homoeopathic product” means a homoeopathic...
— General requirements for application
2. (1) An application for the grant of a UK marketing...
— Requirement to submit safety data
3. (1) The applicant must submit data as to the safety...
— Exceptions to requirement to submit safety data
4. (1) The applicant does not need to submit data as...
— Requirement to submit efficacy data
5. (1) The applicant must submit data as to the efficacy...

SCHEDULE 10A — Variations to a UK marketing authorisation

1. Interpretation
2. Classification of variations
3. Licensing authority recommendation on unclassified variations
4. Variations leading to the revision of product information
5. Grouping of variations
6. Notification procedure for minor variations of type IA
7. Notification procedure for minor variations of type IB
8. Prior approval procedure for major variations of type II
9. Elements to be submitted
10. Measures to close the procedures specified in paragraphs 6 to 8
11. Extensions of marketing authorisations
12. Human influenza vaccines
13. Pandemic situation with respect to human influenza
14. Urgent safety restrictions
15. Amendments to the decision granting the marketing authorisation
16. Implementation of variations
17. Continuous monitoring

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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.

29. The date of the first traditional herbal registration or, where...
30. The date of any revisions of the text of the...

SCHEDULE 12A — Further provision as to the performance of pharmacovigilance activities

PART 1 — Pharmacovigilance system master file

1. Structure of the pharmacovigilance system master file
 2. Content of the pharmacovigilance system master file
 3. Content of the Annex to the pharmacovigilance system master file
 4. Maintenance of the pharmacovigilance system master file
 5. Form of the documents contained in the pharmacovigilance system master file
 6. Subcontracting
 7. Availability and location of the pharmacovigilance system master file
- PART 2 — Minimum requirements for the quality systems for the performance of pharmacovigilance activities by the licensing authority and holders
8. Quality system
 9. Performance indicators
- PART 3 — Minimum requirements for the quality systems for the performance of pharmacovigilance activities by holders
10. Management of human resources
 11. Compliance management
 12. Record management and data retention
 13. Audit
- PART 4 — Minimum requirements for the quality systems for the performance of pharmacovigilance activities by the licensing authority
14. Management of human resources
 15. Compliance management
 16. Record management and data retention
 17. Audit
- PART 5 — Use of terminology, formats and standards
18. Use of internationally agreed terminology, formats and standards
- PART 6 — Transmission of reports of suspected adverse reactions
19. Individual case safety reports
 20. Content of the individual case safety report
 21. Format of electronic transmission of suspected adverse reactions
- PART 7 — Risk management plans
22. Content of the risk management plan
 23. Summary of the risk management plan
 24. Updates of the risk management plan
 25. Format of the risk management plan
- PART 8 — Periodic safety update reports
26. Content of periodic safety update reports
 27. Format of periodic safety update reports
- PART 9 — Post-authorisation safety studies
28. Scope and interpretation
 29. Obligations as to post-authorisation safety studies
 30. Format of the study protocol
 31. Format of the abstract of the final study report
 32. Format of the final study report

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

SCHEDULE 13 — Prescription only medicines for which community practitioner nurse prescribers are appropriate practitioners
Co-danthramer Capsules NPF Co-danthramer Capsules Strong NPF Co-danthramer Oral Suspension...

SCHEDULE 14 — Prescription etc by supplementary prescribers: particulars of clinical management plan
A clinical management plan must contain the following particulars—

SCHEDULE 15 — Requirements for specific products subject to general sale

1. A medicinal product that contains aloxiprin, aspirin or paracetamol (or,...
2. A medicinal product that contains ibuprofen and that is in...

SCHEDULE 16 — Patient group directions

PART 1 — Particulars to be included in a patient group direction

1. The period during which the direction is to have effect...
 2. The description or class of medicinal product to which the...
 3. The clinical situations which medicinal products of that description or...
 4. Whether there are any restrictions on the quantity of medicinal...
 5. The clinical criteria under which a person is to be...
 6. Whether any class of person is excluded from treatment under...
 7. Whether there are circumstances in which further advice should be...
 8. The pharmaceutical form or forms in which medicinal products of...
 9. The strength, or maximum strength, at which medicinal products of...
 10. The applicable dosage or maximum dosage.
 11. The route of administration.
 12. The frequency of administration.
 13. Any minimum or maximum period of administration applicable to medicinal...
 14. Whether there are any relevant warnings to note and, if...
 15. Whether there is any follow up action to be taken...
 16. Arrangements for referral for medical advice.
 17. Details of the records to be kept of the supply,...
- PART 2 — Persons on whose behalf a patient group Direction must be signed
- PART 3 — Persons by whom or on whose behalf a patient group direction used as described in regulation 234 must be signed
- PART 4 — Classes of individuals by whom supplies may be made
Pharmacists. Registered chiropodists and podiatrists. Registered dental hygienist. Registered dental...

SCHEDULE 17 — Exemption for sale, supply or administration by certain persons

PART 1 — Exemption from restrictions on sale and supply of prescription only medicines

PART 2 — Exemption from the restriction on supply of prescription only medicines

PART 3 — Exemptions from the restriction on administration of prescription only medicines

PART 4 — Exemptions from the restrictions in regulations 220 and 221 for certain persons who sell, supply, or offer for sale or supply certain medicinal products

PART 5 — Exemptions from the restrictions in regulations 220 and 221 for certain persons who supply certain medicinal products

SCHEDULE 18 — Substances that may not be sold or supplied by a pharmacist without a prescription in reliance on regulation 225

Ammonium bromide Calcium bromide Calcium bromidolactobionate
Embutramide Fencamfamin hydrochloride Fluanisone...

SCHEDULE 19 — Medicinal products for parenteral administration in an emergency
Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis...

SCHEDULE 20 — Herbal medicinal products specified for the purposes of regulation 241

PART 1

PART 2

SCHEDULE 21 — Medicinal products at high dilutions

PART 1 — Dilutions of unit preparations diluted to at least one part in a thousand (3x)

PART 2 — Dilutions of unit preparations diluted to at least one part in a million (6x)

PART 3 — Dilutions of unit preparations diluted to at least one part in ten (1x)

PART 4 — Dilutions of unit preparations diluted to at least one part in ten (1x) for external use

SCHEDULE 22 — Classes of person for the purposes of regulation 249

Doctors

Dentists

Persons lawfully conducting a retail pharmacy business within the meaning...

Authorities or persons carrying on the business of—

Holders of wholesale dealer's licences or persons to whom the...

Ministers of the Crown and Government departments.

Scottish Ministers.

Welsh Ministers.

A Northern Ireland Minister.

An NHS trust.

An NHS foundation trust.

The Common Services Agency.

A health authority or a special health authority.

.....

A person other than an excepted person who carries on...

A person other than an excepted person who carries on...

In this Schedule “excepted person” means— (a) a doctor or...

SCHEDULE 23 — Particulars in pharmacy records

1. Paragraph 2 applies, subject to paragraph 3, where the sale...
2. In such a case, the particulars referred to in regulation...
3. Where the sale or supply is in pursuance of a...
4. Where the sale or supply of a prescription only medicine...
5. Paragraph 6 applies where— (a) the sale or supply of...
6. In such a case, the particulars referred to in regulation...

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.

45. Specific precautions relating to the disposal of the unused product...
46. The name and address of the holder of the UK...
47. The UK marketing authorisation number.
48. The manufacturer's batch number.
49. The unique donation code assigned by a tissue establishment pursuant...
50. Where the exempt advanced therapy medicinal product is for autologous...
PART 5 — Immediate packaging: blister packs and small packaging (advanced therapy medicinal products for sale or supply in Great Britain only)
51. The information specified in Part 2.
52. The unique donation code assigned by a tissue establishment pursuant...
53. Where the exempt advanced therapy medicinal product is for autologous...

SCHEDULE 25 — Packaging requirements: specific provisions

PART 1 — Medicines on prescription

1. Where the product is to be administered to a particular...
2. The name and address of the person who sells or...
3. The date on which the product is sold or supplied...
4. Unless paragraph 5, applies, such of the following particulars as...
5. This paragraph applies if the pharmacist, in the exercise of...
6. Where paragraph 5 applies, the pharmacist may include such particulars,...

PART 2 — Transport, delivery and storage

7. Any special requirements for the storage and handling of the...
8. The expiry date of the product.
9. The manufacturer's batch number.

PART 3 — Pharmacy and prescription only medicines

10. Paragraph 11 applies if a pharmacy medicine is—
11. Where this paragraph applies, the capital letter “P” within a...
12. Paragraph 13 applies if a prescription only medicine is—
13. Where this paragraph applies, the capital letters “POM” within a...

PART 4 — Medicines containing paracetamol

14. If the product contains paracetamol, except where the name of...
15. If the product contains paracetamol the words “Do not take...
16. If the product contains paracetamol, unless the product is wholly...
17. If the product contains paracetamol and is wholly or mainly...
18. If the product is required by this Part of this...

SCHEDULE 26 — Packaging requirements: special provisions

PART 1 — Supply by doctors, dentists, nurses and midwives

1. Where the product is to be administered to a particular...
2. The name and address of the person who sells or...
3. The date on which the product is sold or supplied...
4. Such of the following particulars as the person under whose...

PART 2 — Pharmacy exceptions

5. Where the product is to be administered to a particular...
6. The name and address of the person who sells or...
7. The date on which the product is sold or supplied...
8. Where the product is prescribed by an appropriate practitioner, such...
9. This paragraph applies if a pharmacist, in the exercise of...
10. Where paragraph 9 applies, the pharmacist may include such particulars,...
11. Where the product is not prescribed by an appropriate practitioner,...

SCHEDULE 27 — Package leaflets

PART 1 — General requirements

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

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...

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

- Notice to person named on container
- 14. (1) This paragraph applies where the sampling officer has obtained...
 - Analysis or other examination
- 15. Where the enforcing authority that authorises the sampling officer is...
- 16. Where any other enforcing authority authorises the sampling officer, if...
- 17. (1) Arrangements of the kind mentioned in paragraphs 15(b) and...
- 18. A laboratory to which a sample is submitted under paragraph...
- 19. A laboratory that has analysed or examined a sample submitted...
- 20. A person to whom a part of the sample is...
 - Provisions as to evidence
- 21. (1) In proceedings for an offence under these Regulations, a...
- 22. In proceedings for an offence under these Regulations, a document...
- 23. (1) If, in proceedings before a magistrates' court for an...
 - Analysis under direction of court
- 24. (1) This paragraph applies where proceedings for an offence under...
- 25. The costs of analysis or examination under paragraph 24 are...
 - Proof by written statement
- 26. (1) In relation to England and Wales section 9 of...
 - Payment for sample taken under compulsory powers
- 27. (1) Where a sampling officer takes a sample in the...

SCHEDULE 32 — Transitional provisions and savings

- Continuity of the law
- 1. (1) This paragraph applies where any provision of these Regulations...
 - Product licences
- 2. (1) This paragraph applies to a marketing authorisation that—
 - Product licences of right
- 3. (1) This paragraph applies to a product licence of right...
 - Classification of UK marketing authorisation and certificate of registration
- 4. (1) Sub-paragraph (3) applies to a UK marketing authorisation granted...
 - Advanced therapy medicinal products
- 5. No provision of these Regulations that applies only to advanced...
 - Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882)
- 6. Regulation 9 (amendment of the Medicines for Human Use (Clinical...
 - Section 60 of the Medicines Act 1968 etc
- 7. (1) Section 60 of the Medicines Act 1968 (“the Act”)...

SCHEDULE 33 — Transitional arrangements: pharmacovigilance

1. Pharmacovigilance system master file
2. Regulation 210(3)(b) (offences relating to pharmacovigilance obligations under Regulation (...))
3. Post-authorisation safety studies
4. Regulation 210(3)(g) (offences relating to pharmacovigilance obligations under Regulation (EC)...)
 - Reporting obligations
5. Reporting obligations
6. The references to “the Eudravigilance database” in regulation 188(1)(a) and...
7. The licensing authority must ensure that all reports and updated...
8. Regulations 186(1)(e) (reporting obligations on licensing authority in relation to...)
9. Periodic safety update reports

10. The reference to “the EMA” in regulations 191(1) (obligation on...

SCHEDULE 33A — Transitional provision in relation to EU Exit

PART 1 — Interpretation

1. In this Schedule— “ the COMP ” means the Committee...

PART 2 — Manufacturing, wholesale dealing and brokering

2. Wholesale dealer's licence used to distribute a medicinal product imported from an EEA State before IP completion day
3. Approved country for import list on IP completion day (regulation 18A)
4. Qualified persons and approved country for batch testing list on IP completion day (Schedule 7)
5. List of countries with equivalent regulatory standards as to the manufacturing of active substances on IP completion day (regulation 45O(6) to (9))

PART 3 — Transitional provision in respect of conversion of EU marketing authorisations in force immediately before IP completion day

6. Conversion of EU marketing authorisations in force before IP completion day
 7. Classification of converted EU marketing authorisations
 8. Obligations of licensing authority in connection with converted EU marketing authorisations
 9. Obligations of holders of converted EU marketing authorisations
 10. Powers of licensing authority in connection with provision of information
 11. Variations of converted EU marketing authorisations notified or applied for before IP completion day
 12. Variations of converted EU marketing authorisations submitted to EMA after IP completion day but before the data submission date
 13. Variations of converted EU marketing authorisations sought in advance of the data submission date
 14. Applications for renewals of converted EU marketing authorisations made before IP completion day
 15. Applications for renewals of conditional marketing authorisations made before IP completion day
 16. Applications for renewals of converted EU marketing authorisations made after IP completion day
 17. Applications for renewals of conditional marketing authorisations made after IP completion day
 18. Renewals of converted EU marketing authorisations sought in advance of the data submission date
 19. Article 61(3) notifications made before IP completion day in relation to converted EU marketing authorisations
 20. Article 61(3) notifications made in relation to converted EU marketing authorisations after IP completion day but before the data submission date
 21. Article 61(3) notifications sought in advance of the data submission date
 22. Place of establishment for converted EU marketing authorisation holder established in EEA state before IP completion day
 23. Temporary exemption as to packaging requirements for converted EU marketing authorisations
 24. Referrals made under Article 20 of Regulation (EC) No 726/2004 that have not concluded or been implemented before IP completion day
 25. Enforcement
- PART 4 — Transitional provision in respect of UK marketing authorisations, parallel import licences and parallel distribution notices

- 26ZA Status of certain UK marketing authorisations granted before IP completion day
 - 26. Place of establishment for UK marketing authorisation holder or parallel import licence holder established in an EEA State before IP completion day
 - 27. Temporary exemption as to packaging requirements: change of place of establishment
- 27A Status of parallel import licences granted before IP completion day
 - 28. Conversion of parallel distribution notices in to parallel import licences
 - 29. Inclusion of the batch testing condition in relevant UK marketing authorisations, and batch testing of biological medicinal products in the EEA before IP completion day (regulation 60A)
- 29A Application of the batch testing requirement to relevant EU marketing authorisations, and batch testing of biological medicinal products in the EEA before IP completion day (regulation 60B)
 - 30. Existing data and marketing exclusivity and global marketing authorisations
 - 31. Applications for EU marketing authorisations made before IP completion day
 - 32. Place of establishment for UK marketing authorisation holder established in EEA state before IP completion day (pre-exit EU marketing authorisation applications)
 - 33. Packaging in relation to UK marketing authorisations granted in response to application for EU marketing authorisation made before IP completion day
 - 34. Applications made for a UK marketing authorisation before IP completion day to which Chapter 4 of Title III of the 2001 Directive applied
 - 35. Transitional provision in respect of Plasma Master Files
 - 36. Suspensions of UK marketing authorisations that have effect immediately before IP completion day that were imposed under Chapter 4 of Title III of the 2001 Directive or Regulation (EC) No 726/2004
 - 37. Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of an EU marketing authorisation or a UK marketing authorisation that have not concluded before IP completion day
 - PART 5 — Transitional provision in relation to variations of marketing authorisations other than converted EU marketing authorisations
- 38. Application or notification made before IP completion day in respect of a variation under Chapter IIa of Regulation (EC) No 1234/2008 (variations to purely national marketing authorisations)
- 39. Application or notification made before IP completion day in respect of a variation under Chapter II of Regulation (EC) No 1234/2008 (variations to marketing authorisations granted in accordance with Chapter 4 of the 2001 Directive)
- 40. Application or notification in respect of a variations made before IP completion day under Article 20 of Regulation (EC) No 1234/2008 (work-sharing procedure)
 - PART 6 — Transitional provision in relation to the Paediatric Regulation
- 41. Transitional provision in relation to applications made to EMA before IP completion day under the Paediatric Regulation
- 41A Transitional provision in relation to global marketing authorisations under the 2001 Directive
 - PART 8 — Transitional provision in respect of homoeopathic medicinal products

43. List of countries for the purposes of the definition of “homoeopathic medicinal product” on IP completion day
44. Place of establishment for holders of certificates of registration established in EEA before IP completion day
45. Temporary exemption as to packaging requirements: change of place of establishment
46. Applications made for a certificate of registration for a registrable homoeopathic product before IP completion day to which Chapter 4 of Title III of the 2001 Directive applied
47. Suspensions of certificates of registration that have effect immediately before IP completion day that were imposed under Chapter 4 of Title III of the 2001 Directive
48. Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of a certificate of registration that have not concluded before IP completion day
PART 9 — Transitional provision in respect of traditional herbal registrations
49. Place of establishment for holders of traditional herbal registrations established in EEA before IP completion day
50. Temporary exemption as to packaging requirements: change of place of establishment
51. List of approved countries for traditional use of a herbal medicinal product on IP completion day
52. Applications made for a traditional herbal registration before IP completion day to which Chapter 4 of Title III of the 2001 Directive applied
53. Suspensions of traditional herbal registrations that have effect immediately before IP completion day that were imposed under Chapter 4 of Title III of the 2001 Directive
54. Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of a traditional herbal registration that have not concluded before IP completion day
55. Proposals to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products and the procedure in Part 3 of Schedule 11 that were on-going at IP completion day
PART 10 — Transitional provision in respect of pharmacovigilance
58. Referrals made under Article 107i of the 2001 Directive concerning the evaluation of data from pharmacovigilance activities which are not concluded before IP completion day
59. Matters on-going at IP completion day in respect of periodic safety update reports
60. Matters on-going at IP completion day in relation to draft study protocols under Article 107n and 107o of the 2001 Directive (submission of, and amendment to, draft study protocols for required studies)
61. Matters on-going at IP completion day in respect of the follow up of final study reports
PART 11 — Transitional provision in respect of Part 12
62. Approved country health professional list on IP completion day (regulation 214(6A))
PART 12 — General provision in relation to transitional provisions
63. Licensing authority power to require information

SCHEDULE 34 — Amendments to existing law

PART 1 — The Medicines Acts 1968 and 1971

1. The Medicines Act 1968 is amended as follows.

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

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...

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012. (See end of Document for details)

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...

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*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)...

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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.