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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**MEDICINES**

**The Human Medicines Regulations 2012**

*Made* - - - - *19th July 2012*  
*Laid before Parliament* *24th July 2012*  
*Coming into force* *14th August 2012*

**THE HUMAN MEDICINES REGULATIONS 2012**

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*Status: This is the original version (as it was originally made).*

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*Status: This is the original version (as it was originally made).*

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*Status: This is the original version (as it was originally made).*

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*Status: This is the original version (as it was originally made).*

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*Status: This is the original version (as it was originally made).*

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*Status*

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*Status: This is the original version (as it was originally made).*

*Manufacturers' licence relating to import*

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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...
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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...
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23. The licence holder must take all reasonable precautions and exercise...

PART 3 — Manufacturer's licence relating to exempt advanced therapy medicinal products

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PART 4 — Wholesale dealer's licence

*All wholesale dealer's licences*

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30. The licence holder must provide such information as may be...
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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...
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*Wholesale dealer's licence relating to exempt advanced therapy medicinal products*

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*Procedure at hearing*

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PART 1 — Manufacturer's licences

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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...

*Status: This is the original version (as it was originally made).*

PART 2 — Wholesale dealer's licences

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16. The licence holder must establish and maintain a system ensuring...
17. The licence holder must inform the licensing authority of any...
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20. The licence holder must not import or export any exempt...

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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...

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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

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14. (1) This paragraph applies where— (a) medicinal products are imported...
15. (1) The qualified person is responsible for ensuring, in relation...

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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. 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 an application for authorisation for the medicinal product to...
19. Where an authorisation for the medicinal product to be placed...
20. Where an authorisation for the medicinal product to be placed...
21. Where an authorisation for the medicinal product to be placed...
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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 marketing authorisation...
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 marketing authorisation...

SCHEDULE 10 — National homoeopathic products

*Meaning of “national homoeopathic product”*

1. (1) In this Schedule “national homoeopathic product” means a homoeopathic...

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*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 11 — Advice and representations

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*Application of this Part*

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

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*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 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. This Part is subject to Part 4 of this Schedule....

*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 Committee for Herbal Medicinal Products

*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...

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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 another member State or a...
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

SCHEDULE 13 — Prescription only medicines for which community practitioner nurse prescribers are appropriate practitioners

SCHEDULE 14 — Prescription etc by supplementary prescribers: particulars of clinical management plan

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
- 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
- SCHEDULE 19 — Medicinal products for parenteral administration in an emergency
- 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
- 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...

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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 marketing...
16. The number of the marketing authorisation, Article 126a authorisation or...
17. The manufacturer's batch number.
18. In the case of a product that is not 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 marketing authorisation, Article...
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...

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

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 under different names in different...
13. For medicinal products included in the list referred to in...
14. The statement: “Also you can help to make sure that...”
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...

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.

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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 marketing authorisation, certificate of registration, traditional...
2. The name and address of the holder of the marketing...
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. A succinct statement of the entries (if any) in the...
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...

*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—

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*Product licences of right*

- (1) This paragraph applies to a product licence of right....

*Classification of UK marketing authorisation and certificate of registration*

- (1) Sub-paragraph (3) applies to a UK marketing authorisation granted...

*Advanced therapy medicinal products*

- 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)*

- Regulation 9 (amendment of the Medicines for Human Use (Clinical...

*Section 60 of the Medicines Act 1968 etc*

- (1) Section 60 of the Medicines Act 1968 (“the Act”)...

SCHEDULE 33 — Transitional arrangements: pharmacovigilance

- Pharmacovigilance system master file
- Regulation 210(3)(b) (offences relating to pharmacovigilance obligations under Regulation (EC)...
- Post-authorisation safety studies
- Regulation 210(3)(g) (offences relating to pharmacovigilance obligations under Regulation (EC)...
- Reporting obligations
- The references to “the Eudravigilance database” in regulation 188(1)(a) and...
- The licensing authority must ensure that all reports and updated...
- Regulations 186(1)(e) (reporting obligations on licensing authority in relation to...
- Periodic safety update reports
- The reference to “the EMA” in regulations 191(1) (obligation on...

SCHEDULE 34 — Amendments to existing law

PART 1 — The Medicines Acts 1968 and 1971

- The Medicines Act 1968 is amended as follows.
- For the text of section 1 (Ministers responsible for the...
- In section 10 (exemptions for pharmacists)— (a) in subsection (1)...
- In section 15 (provision for extending or modifying exemptions)—
- In section 58 (medicinal products on prescription only)—
- In section 58A(1) (requirement to specify certain products as prescription-only...
- In section 62 (prohibition of sale or supply, or importation,...
- In section 64(5) (protection for purchasers of medicinal products) for...
- (1) Section 67 (offences under Part III) is amended as...
- In section 72 (representative of pharmacist in case of death...
- In section 82(4) (pharmacies: procedure relating to disqualification) for “Pharmaceutical...
- In section 87 (requirements as to containers)—
- In section 88(1) (distinctive colours, shapes and markings of medicinal...
- 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)...

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*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 2012...

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— SCHEDULE9  
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...

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*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...

*Status:* This is the original version (as it was originally made).

*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