STATUTORY INSTRUMENTS

2006 No. 2407

MEDICINES

The Veterinary Medicines Regulations 2006

Made - - - - 5th September 2006

Laid before Parliament 8th September 2006

Coming into force 1st October 2006

THE VETERINARY MEDICINES REGULATIONS 2006

PART 1

Introduction

- 1. Title and commencement
- 2. Definition of "veterinary medicinal product", interpretation and scope
- 3. Products to which these Regulations do not apply

PART 2

Authorised veterinary medicinal products

- 4. Placing a veterinary medicinal product on the market
- 5. Manufacture of veterinary medicinal products
- 6. The finished product
- 7. Classification, supply and possession of the product
- 8. Administration of the product
- 9. Importation of authorised veterinary medicinal products
- 10. Advertising the product
- 11. Advertising of prescription products and products containing psychotropic drugs or narcotics
- 12. Defence of publication in the course of business
- 13. Wholesale dealing
- 14. Feedingstuffs
- 15. Exemptions
- 16. Fees

PART 3

Records

- 17. Food-producing animals: proof of purchase of veterinary medicinal products
- 18. Food-producing animals: records of administration by a veterinary surgeon
- 19. Food-producing animals: records of acquisition and administration
- 20. Food-producing animals: retention of records
- 21. Records by a holder of a manufacturing authorisation
- 22. Records by a holder of a wholesale dealer's authorisation
- 23. Records of the receipt or supply of prescription products
- 24. Records of products administered to a food-producing animal under the cascade

PART 4

Unauthorised veterinary medicinal products

- 25. Importation of an unauthorised veterinary medicinal product
- 26. Possession of an unauthorised veterinary medicinal product
- 27. Supply of an unauthorised veterinary medicinal product

PART 5

Miscellaneous provisions, enforcement and offences

- 28. The Veterinary Products Committee
- 29. Procedure for suspending, etc. a marketing authorisation or animal test certificate
- 30. Duties on the Secretary of State relating to exports
- 31. Time limits
- 32. Appointment of inspectors
- 33. Powers of entry
- 34. Powers of an inspector
- 35. Inspection of pharmacies
- 36. Obstruction
- 37. Improvement notices
- 38. Appeals against improvement notices
- 39. Powers of a court on appeal
- 40. Seizure notices
- 41. Publication of notices
- 42. Penalties
- 43. Northern Ireland
- 44. Revocations and amendments Signature

SCHEDULE 1 — MARKETING AUTHORISATIONS

PART 1 — Application for a marketing authorisation

- 1. Application for a marketing authorisation
- 2. Information with the application
- 3. Summary of product characteristics
- 4. Supply of a copy of the summary of product characteristics

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

- 5. Time limits for applications for products for use in food-producing animals PART 2 Derogations from some of the requirements in Part 1
- 6. Scope
- 7. Bibliographic application
- 8. Application for a product using a new combination of active substances
- 9. Application using existing data
- 10. Application for a pharmacologically equivalent medicinal product
- 11. Time limits for marketing authorisations granted under the procedure for a pharmacologically equivalent product
- 12. Extension of time limits
- 13. Parallel imports
- 14. Specific batch control scheme
- 15. Similar immunological products
- 16. Marketing in exceptional circumstances
 - PART 3 Grant of a marketing authorisation
- 17. Time limits
- 18. Place of establishment of applicant
- 19. Procedure
- 20. Products authorised in another member State
- 21. Assessment reports
- 22. Grant of a marketing authorisation
- 23. Marketing authorisations for food-producing species
- 24. Refusal of a marketing authorisation
- 25. Publication following the grant of a marketing authorisation
- 26. Provisional marketing authorisation
- 27. Provisions of samples and expertise
- 28. Supply of information
- 29. Duties on the holder of a marketing authorisation relating to an immunological product
- 30. Control tests
- 31. Placing on the market
- 32. Duration and validity of a marketing authorisation
 - PART 4 Variations of marketing authorisations on the application of the holder
- 33. Variation of a marketing authorisation for a mutually recognised veterinary medicinal product
- 34. Variation of a marketing authorisation not authorised in another member State
- 35. Administrative variations
- 36. Changes after a marketing authorisation has been issued
- 37. Compulsory variation
 - PART 5 Suspension, etc. of a marketing authorisation
- 38. Suspension, etc. of a marketing authorisation
- 39. Suspension, etc. of a marketing authorisation of a product authorised in more than one member State
- 40. Prohibiting the supply of veterinary medicinal products
 - PART 6 Mutual recognition and multiple applications
- 41. Application for a marketing authorisation where one already exists in another member State
- 42. Application in another member State
- 43. Application for a marketing authorisation in multiple member States where a marketing authorisation does not exist in any member State
 - PART 7 Labelling and package leaflets

- 44. Approval by the Secretary of State
- 45. Reference to being authorised
- 46. Language
- 47. Labelling with all the information on the immediate packaging
- 48. Products with immediate and outer packaging
- 49. Package leaflets
- 50. Ampoules
- 51. Small containers other than ampoules
- 52. Homeopathic remedies
- 53. Variations

PART 8 — Pharmacovigilance

- 54. Qualified persons responsible for pharmacovigilance
- 55. Duties relating to the qualified person
- 56. Adverse reactions to a veterinary medicinal product administered in the United Kingdom
- 57. Adverse reactions to a veterinary medicinal product administered in a third country
- 58. Periodic safety update reports
- 59. Release of information by the marketing authorisation holder
- 60. Action taken on account of pharmacovigilance

PART 9 — Homeopathic remedies

- 61. Meaning of "homeopathic remedy"
- 62. Placing a homeopathic remedy on the market in accordance with a registration
- 63. Application for registration
- 64. Procedure for registration
- 65. Products on the market before 1994
- 66. Classification

SCHEDULE 2 — THE MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS

PART 1 — Manufacturing authorisation

- 1. Application
- 2. Time limits
- 3. Granting the authorisation
- 4. The authorisation
- 5. Suspension or revocation of the authorisation
- 6. Representation to the Secretary of State
- 7. Inspection of premises
- 8. Report following inspection
- 9. Duties on the holder of a manufacturing authorisation
- 10. Qualified persons for manufacture
- 11. Refusal or revocation of appointment
- 12. Duties on a qualified person
- 13. Register
- 14. Test sites

PART 2 — Authorisation of manufacturers of autogenous vaccines

- 15. Authorisation to manufacture autogenous vaccines
- 16. Types of authorisation
- 17. Labelling
- 18. Records
- 19. Adverse reactions
- 20. Inspection of premises

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

PART 3 — Authorisation of blood banks

- 21. Authorisation of blood banks
- 22. Supply and administration of blood from a blood bank
- 23. Labelling
- 24. Records
- 25. Inspection of blood banks

PART 4 — Authorisation of manufacturers of products for administration under the cascade

- 26. Authorisation to manufacture products for administration under the cascade
- 27. Labelling
- 28. Records
- 29. Adverse reaction
- 30. Inspection of premises

SCHEDULE 3 — CLASSIFICATION AND SUPPLY, WHOLESALE DEALERS AND SHEEP DIP

PART 1 — Classification and supply of authorised veterinary medicinal products

- 1. Classification of veterinary medicinal products
- 2. Wholesale supply of veterinary medicinal products
- 3. Retail supply of veterinary medicinal products
- 4. Prescriptions by a veterinary surgeon
- 5. Prescriptions
- 6. Written prescriptions
- 7. Duties when a product is prescribed or supplied
- 8. Supply by a pharmacist
- 9. Supply by a veterinary surgeon when he is not present
- 10. Supply of products for incorporation into feedingstuffs
- 11. Labelling at the time of retail supply
- 12. Supply of veterinary medicinal products for use under the cascade
- 13. Supply by a suitably qualified person
- 14. Annual audit

PART 2 — Requirements for a wholesale dealer's authorisation

- 15. Application
- 16. Time limits
- 17. Granting the authorisation
- 18. The authorisation
- 19. Suspension or revocation of the authorisation
- 20. Representations
- 21. Duties on the holder of a wholesale dealer's authorisation

PART 3 — Sheep dip

- 22. Supply of sheep dip
- 23. Use of sheep dip

SCHEDULE 4 — ADMINISTRATION OF A VETERINARY MEDICINAL PRODUCT OUTSIDE THE TERMS OF A MARKETING AUTHORISATION

- 1. Administration under the cascade
- 2. Withdrawal periods
- 3. Immunological products for serious epizootic disease
- 4. Immunological products for an imported or exported animal
- 5. Administration by veterinary surgeons from other member States
- 6. Treatment in exceptional circumstances

7. Administration of a homeopathic remedy

SCHEDULE 5 — MEDICATED FEEDINGSTUFFS AND SPECIFIED FEED ADDITIVES

- 1. Scope and interpretation
- 2. Enforcement of Regulation (EC) No. 178/2002
- 3. Enforcement of Regulation (EC) No. 1831/2003
- 4. Enforcement of Regulation (EC) No. 882/2004
- 5. Enforcement of Regulation (EC) No. 183/2005
- 6. Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products
- 7. Incorporation of a veterinary medicinal product into a premixture
- 8. Incorporation of a veterinary medicinal product into feedingstuffs
- 9. Additional record keeping requirements relating to veterinary medicinal products
- 10. Labelling a premixture containing a veterinary medicinal product
- 11. Labelling of feedingstuffs containing a specified feed additive
- 12. Labelling of feedingstuffs containing a veterinary medicinal product
- 13. Supply of specified feed additives
- 14. Supply of premixture
- 15. Supply of feedingstuffs containing a veterinary medicinal product
- 16. Possession
- 17. Sampling and analysis
- 18. Storage
- 19. Packages and other containers
- 20. Transport
- 21. Possession, placing on the market and use of feedingstuffs
- 22. Prescriptions for feedingstuffs containing a veterinary medicinal product
- 23. Imports from third countries
- 24. Trade between member States

SCHEDULE 6 — EXEMPTIONS FOR SMALL PET ANIMALS

- 1. Animals to which this Schedule applies
- 2. Placing on the market, importing and administering the product
- 3. Manufacture
- 4. Approval of the active substance
- 5. The product
- 6. Labelling
- 7. Administration
- 8. Pack size
- 9. Adverse reactions

SCHEDULE 7 — FEES

PART 1 — Introduction

- 1. Interpretation of Schedule 7
- 2. Payment of fees
- 3. Time of payment
- 4. Multiple inspections
- 5. Translation

PART 2 — Fees relating to marketing authorisations

- 6. Fees for specified pharmaceutical applications
- Decentralised pharmaceutical application where the United Kingdom is the reference member State

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

- 8. Application for a marketing authorisation for an immunological product
- 9. Decentralised immunological application where the United Kingdom is the reference member State
- 10. Application for a marketing authorisation using identical data
- 11. Application for a provisional marketing authorisation
- 12. Application for a marketing authorisation relating to a parallel import
- 13. Application for a variation
- 14. Application for a variation to a marketing authorisation that has been issued in other member States
- 15. Application for an extension to a marketing authorisation
- 16. Decentralised application for an extension where the United Kingdom is the reference member State
- 17. Provision of information relating to the recognition of a United Kingdom marketing authorisation
- 18. Application for the renewal of a national marketing authorisation
- 19. Application for the renewal of a marketing authorisation granted in more than one member State
- 20. Registration of a homeopathic remedy
- 21. Annual fees for marketing authorisations
- 22. Auditor's certificate
- 23. Late payment of annual fees
 - PART 3 Fees payable by manufacturers
- 24. Application for a manufacturing authorisation
- 25. Application for a variation of a manufacturing authorisation
- 26. Application for an authorisation to manufacture an autogenous vaccine or a product for administration under the cascade
- 27. Annual fees
- 28. Site inspections—type of site
- 29. Inspection of a site where immunological veterinary medicinal products are manufactured
- 30. Inspection of a site where sterile veterinary medicinal products are manufactured
- 31. Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured
- 32. Inspection of a site where veterinary medicinal products are assembled
- 33. Test sites
- 34. Animal blood bank authorisations
- 35. Expenses
 - PART 4 Fees relating to a wholesale dealer's authorisation
- 36. Application for a wholesale dealer's authorisation
- 37. Variation of a wholesale dealer's authorisation
- 38. Annual fee for a wholesale dealer's authorisation
 - PART 5 Fees relating to feedingstuffs
- 39. Fees relating to feedingstuffs
- 40. Fees relating to distributors
 - PART 6 General
- 41. Testing samples
- 42. Animal test certificates
- 43. Treatment under the cascade
- 44. Treatment in exceptional circumstances
- 45. Specific batch control
- 46. Submission of control tests of an immunological product
- 47. Export certificates

- 48. Fees relating to premises for supply by suitably qualified persons
- 49. Application to the Veterinary Products Committee
- 50. Non-payment of fees
- 51. Waiver or reduction of fees
- 52. Reduction of application fee

SCHEDULE 8 — AMENDMENTS TO THE MEDICINES ACTS ETC.

PART 1 — Consequential amendments to the Medicines Acts 1968 and 1971

- 1. The Medicines Act 1968
- 2. In section 1 (Ministers responsible for administration of the Act)—...
- 3. In section 3 (functions of the Commission), in subsection (1),...
- 4. In section 4 (establishment of committees)— (a) in subsection (1),...
- 5. In section 5 (supplementary provisions as to Commission and committees)
- 6. In section 6 (the licensing authority)—(a) in subsection (1),...
- 7. In section 7 (general provisions as to dealing with medicinal...
- 8. In section 8 (provisions as to manufacture and wholesale dealing)—...
- 9. In section 9 (exemptions for doctors, dentists, veterinary surgeons and...
- 10. In section 10 (exemptions for pharmacists)— (a) in subsection (1),...
- 11. In section 15 (provision for extending or modifying exemptions)—
- 12. In section 18 (application for licence), omit subsection (3).
- 13. In section 23 (special provisions as to effect of manufacturer's...
- 14. In section 28 (general power to suspend, revoke or vary...
- 15. Sections 32 to 36 and 38 to 40 shall be...
- 16. In section 44 (provision of information to the licensing authority)—...
- 17. In section 45 (offences under Part II)—
- 18. In section 46 (special defences under s45)—
- 19. In section 47 (standard provisions for licences or certificates)—
- 20. In section 48 (postponement of restrictions in relation to exports)....
- 21. In section 49 (special provisions in respect of exporting certain...
- 22. In section 51 (general sale lists)— (a) in subsection (1),...
- 23. In section 52 (sale or supply of medicinal products not...
- 24. In section 53 (sale or supply of medicinal products on...
- 25. In section 54 (sale of medicinal products from automatic machines),...
- 26. In section 55 (exemptions for doctors, dentists, veterinary surgeons and...
- 27. In section 56 (exemptions in respect of herbal remedies), in...
- 28. In section 57 (power to extend or modify exemptions)—
- 29. In section 58 (medicinal products on prescription only)—
- 30. In section 58A (requirement to specify certain products for human...
- 31. Section 58B (requirement to specify certain products for veterinary use...
- 32. In section 59 (special provisions in relation to new medicinal...
- 33. In section 60 (restricted sale, supply and administration of certain...
- 34. In section 61 (special restrictions on persons to be supplied...
- 35. In section 62 (prohibition of sale or supply, or importation,...
- 36. In section 65 (compliance with standards specified in monographs in...
- 37. In section 66 (further powers to regulate dealings with medicinal...
- 38. In section 72A (the responsible pharmacist)— (a) in subsection (2),...
- 39. In section 73 (power to extend or modify conditions)—
- 40. In section 76 (supplementary provisions as to registration of premises),...
- 41. In section 79 (provision for modifying or extending restrictions under...
- 42. In section 85 (labelling and marking of containers and packages),...
- 43. In section 86 (leaflets), in subsection (1), omit "appropriate".
- 44. In section 87 (requirements as to containers), in subsection (1)—...

- 45. In section 88 (distinctive colours, shapes and markings of medicinal...
- 46. In section 89 (display of information on automatic machines), in...
- 47. Section 90 (provisions as to medicated animal feeding stuffs) shall...
- 48. In section 91 (offences under Part V, and supplementary provisions)—...
- 49. In section 95 (powers to regulate advertisements and representations)—
- 50. In section 99 (new editions of British Pharmacopoeia, and other...
- 51. In section 101 (other publications), in subsection (2)—
- 52. In section 102 (supplementary provisions)—(a) in subsection (2)—
- 53. In section 103 (construction of references to specified publications), in...
- 54. In section 104 (application of Act to certain articles and...
- 55. In section 105 (application of Act to certain other substances...
- 56. In section 108 (enforcement in England and Wales)—
- 57. In section 109 (enforcement in Scotland), in subsection (2), omit...
- 58. In section 110 (enforcement in Northern Ireland)—
- 59. In section 116 (liability to forfeiture under Customs and Excise...
- 60. Section 117 (special enforcement and sampling provisions relating to animal...
- 61. In section 121 (contravention due to default of other person)....
- 62. In section 122 (warranty as defence), in subsection (2), omit...
- 63. In section 125 (prosecutions), in subsection (4)—
- 64. In section 126 (presumptions)—(a) in subsection (1)—
- 65. In section 129 (orders and regulations)— (a) in subsection (2),...
- 66. In section 130 (meaning of "medicinal product" and related expressions)
- 67. In section 132 (general interpretation provisions)— (a) in subsection (1)
- 68. In Schedule 3 (sampling), in paragraph 17—
- 69. In Schedule 4 (provisions relating to Northern Ireland)—
- 70. The Medicines Act 1971
 - PART 2 Consequential amendments to secondary legislation
- 1. The Medicines (Surgical Materials) Order 1971
- 2. The Medicines (Specified Articles and Substances) Order 1976
- 3. The Medicines (Radioactive Substances) Order 1978
- 4. The Medicines (Administration of Radioactive Substances) Regulations 1978
- 5. The Medicines (Cyanogenetic Substances) Order 1984
- 6. The Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986
- 7. The Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992
- 8. The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994
- 9. The Medicines (Advertising) Regulations 1994
- 10. The Medicines (Monitoring of Advertising) Regulations 1994
- 11. The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994
- 12. The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003
- 13. The Herbal Medicines Advisory Committee Order 2005
- 14. The Medicines (Advisory Bodies) (No. 2) Regulations 2005

SCHEDULE 9 — OTHER CONSEQUENTIAL AMENDMENTS

PART 1 — Consequential amendments to primary legislation

1. The Pharmacy Act 1954

- 2. The Trade Descriptions Act 1968
- 3. The Poisons Act 1972
- 4. The City of London (Various Powers) Act 1977
- 5. The Sporting Events (Control of Alcohol etc.) Act 1985
- 6. The Animals (Scientific Procedures) Act 1986
- 7. The Consumer Protection Act 1987
- 8. The Environmental Protection Act 1990
- 9. The Sunday Trading Act 1994
- 10. The Value Added Tax Act 1994
- 11. The Criminal Law (Consolidation) (Scotland) Act 1995
- 12. The Food Standards Act 1999
- 13. The Licensing Act 2003

PART 2 — Consequential revocations of and amendments to secondary legislation

- 1. Revocations
- 2. Importation of Animal Pathogens Order 1980
- 3. The Warble Fly (England and Wales) Order 1982
- 4. The Environmental Protection (Prescribed Processes and Substances) Regulations 1991
- 5. The Products of Animal Origin (Import and Export) Regulations 1996

Explanatory Note