STATUTORY INSTRUMENTS

2010 No. 551

MEDICINES FEES AND CHARGES CONSUMER PROTECTION

The Medicines (Products for Human Use) (Fees) Regulations 2010

Made - - - - 26th February 2010

Laid before Parliament 4th March 2010

Coming into force 1st April 2010

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) REGULATIONS 2010

PART 1

- 1. Citation and commencement
- 2. Interpretation

PART 2

- 3. Interpretation of Part 2
- 4. Fee for scientific advice: application for, or variation to, EU marketing authorization
- 5. Fee for scientific advice: classification of a medicinal product
- 6. Fee for advertising advice
- 7. Fee for pharmacovigilance advice
- 8. Fee for advice on labelling or leaflets
- 9. Fee for regulatory advice
- 10. Fee for advice for other purposes
- 11. Time for payment of fees under regulations 4 to 10

PART 3

12. Fees for applications for authorizations, licences or certificates etc.

- 13. Fee for applications for copy certificates of good manufacturing practice
- 14. Fees for applications for certificates and copy certificates by exporters of medicinal products

PART 4

EEA

- 15. Meaning of "set of applications"
- 16. Fees for applications for regulatory assistance under the mutual recognition procedure
- 17. Time for payment of fees under regulation 16

PART 5

- 18. Fees for variations of authorizations, registrations, licences and authorisations
- 19. Fees for amendments to clinical trial authorisations
- 20. Applications for multiple variations

PART 6

- 21. Meaning of "set of proposed changes"
- 22. Fees for assessment of a set of proposed changes to labels and leaflets
- 23. Time for payment of fees under regulation 22

PART 7

- 24. Fees for renewals of certain manufacturer's licences
- 25. Fees for renewals in terms which are not identical to the existing authorization, licence or registration

PART 8

26. Fees for regulatory assistance for certain marketing authorizations

PART 9

- 27. Fees for inspections
- 28. Payer of inspection fee (contract laboratories and API manufacturing sites)
- 29. Inspections in connection with multiple applications
- 30. Fees for inspections relating to good clinical practice in clinical trials
- 31. Amount, and time for payment, of inspection fees in respect of an application for a wholesale dealer's licence
- 32. Adjustment and refund of inspection fees in respect of a wholesale dealer's licence

PART 10

- 33. Periodic fees
- 34. Periodic fees for clinical trial authorisations

PART 11

- 35. Meaning of "good clinical practice accreditation scheme"
- 36. Fees for applications for membership and certificates

PART 12

- 37. Fee for a person appointed hearing
- 38. Time for payment under regulation 37

PART 13

- 39. Payment of fees to Ministers
- 40. Time for payment of capital fees in connection with applications or inspections
- 41. Time for payment of capital fees applications made by small companies
- 42. Payment of fees in respect of a traditional herbal registration
- 43. Time for payment of periodic fees
- 44. Penalty fees for late payment of periodic fees
- 45. Daily penalty fees for late payment of periodic fees
- 46. Refund or waiver of fees under regulation 44 or 45
- 47. Adjustment, waiver, reduction or refund of fees
- 48. Suspension of licences and authorisations
- 49. Civil proceedings to recover unpaid fees

PART 14

50. Amendment of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

PART 15

51. Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

PART 16

52. Revocations and savings Signature

SCHEDULE 1 — CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, MARKETING AUTHORIZATIONS, LICENCES, AUTHORISATIONS, REGISTRATIONS AND CERTIFICATES

PART 1 — General: interpretation and categories of applications and variations

- 1. Interpretation
- 2. General: categories of Applications and Variations
- 3. Administrative variation application
- 4. Extension application
- 5. Complex application
- 6. Complex registration application

- 7. Complex variation application
- 8. Decentralised procedure application
- 9. Extended Type II Complex Variation Application
- 10. Major application
- 11. Mutual recognition procedure incoming application
- 12. New excipient variation application
- 13. New indication variation application
- 14. Parallel Import Licence application
- 15. Reclassification variation application
- 16. Reduced registration application
- 17. Simple application
- 18. Standard application
- 19. Standard registration application
- 20. Standard variation application
- 21. Standard variation application for a homoeopathic medicinal product
- 22. Type IB and Type II Applications
- 23. Type II Complex Variation Application

PART 2 — Capital Fees for Applications for Authorizations, Licences, Registrations and Certificates

- 24. Marketing authorizations
- 25. Fees where application includes reclassification
- 26. Fees where person holds clinical trial certificate
- 27. Joint development
- 28. Application for multiple authorizations
- 29. Authorisation for a national homoeopathic product
- 30. Manufacturer's licences and authorisations
- 31. Wholesale dealer's licences
- 32. Clinical trial authorisations
- 33. Traditional herbal registrations

PART 3 — Capital Fees for Assistance in Obtaining Marketing Authorizations in Other EEA States

34. Outgoing mutual recognition applications

PART 4 — Capital Fees for Applications for Variations of Authorizations, Licences and Registrations

- 35. Marketing authorizations
- 36. Variation of marketing authorizations
- 37. Reclassification of marketing authorizations
- 38. Variation of marketing authorization: national homoeopathic products
- 39. Variation of parallel import licence
- 40. Manufacturer's authorisations and licences
- 41. Variation of manufacturer's authorisations and licences
- 42. Wholesale dealer's licences
- 43. Variation of wholesale dealer's licence
- 44. Clinical trial authorisations
- 45. Traditional herbal registrations
- 46. Identical variations
- 47. Complex Variation Applications
- 48. Multiple reclassification variation applications

PART 5 — Capital Fees for Assessment of Labels and Leaflets

- 49. A set of changes
- 50. More than one set of charges proposed

PART 6 — Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the

Assessment of Applications for the Renewal of Specified Marketing Authorizations

- 51. Regulatory assistance
- 52. Regulatory assistance same manufacturer

SCHEDULE 2 — FEES FOR INSPECTIONS

- 1. General provisions relating to fees for inspections
- 2. Fees: general
- 3. Traditional herbal medicinal products
- 4. Sites concerned with starting materials for traditional herbal medicinal products
- 5. Wholesale dealer's licence: general
- 6. Wholesale dealer's licence: traditional herbal medicinal products
- 7. Wholesale dealer's licences: inspection of short duration
- 8. Office-based inspections

SCHEDULE 3 — PERIODIC FEES FOR LICENCES

PART 1 — Interpretation

1. In this Schedule— "anthroposophic product" means a medicinal product prepared...

PART 2 — Calculation of Turnover

- 2. Calculation of turnover
- 3. Manufacturer's prices
- 4. Evidence of turnover
 - PART 3 Periodic Fees for Marketing Authorizations and Licences
- 5. Marketing authorizations
- 6. Marketing authorization: where Part 2 of the Act applies
- 7. Marketing authorization: derivatives
- 8. Number of fee periods
- 9. Authorisation for two or more kinds of medicinal product
- 10. Reduced fees
- 11. Manufacturer's licences or manufacturing authorisations
- 12. Wholesale dealer's licences
- 13. Wholesale dealer's licences: evidence
- 14. Wholesale dealer's licences: exempt imported products
- 15. Additional amount for manufacturer's licences and wholesale dealer's licences which relate to exempt imported products
- 16. Clinical trial authorisations
- 17. Traditional herbal registrations
 - PART 4 Types of Marketing Authorization for which only One Periodic Fee is Payable
- 18. Specified parallel import licences

SCHEDULE 4 — TIME FOR PAYMENT OF CAPITAL FEES

- 1. Interpretation
- 2. Major application
- 3. Complex application
- 4. Multiple application
- 5. Outgoing mutual recognition application
- 6. Application for traditional herbal registration
- 7. Traditional herbal registration: complex variation
- 8. Application for manufacturer's licence, manufacturing authorisation or wholesale dealer's licence

9. Inspection fees in connection with applications

SCHEDULE 5 — WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

- 1. Interruptions of manufacture, assembly, sale or supply
- 2. Reclassification
- 3. Variation of a traditional herbal registration
- 4. Withdrawal of application in relation to marketing authorization, traditional herbal registration or clinical trial authorisation
- 5. Withdrawal of application in relation to manufacturing authorisation, wholesale dealer's licence or manufacturer's licence
- 6. Refusal of application for grant of marketing authorization, traditional herbal registration or clinical trial authorisation
- 7. Parallel import licence
- 8. Surrender of marketing authorization at same time as a variation application
- 9. Clinical trial authorisation
- 10. Scientific advice: paediatric indications

SCHEDULE 6 — ADJUSTMENT, REDUCTION OR REFUND OF PERIODIC FEES

- 1. Refund on surrender or revocation of authorization, registration or licence
- 2. Adjustment and refund: licences relating to exempt imported products
- 3. Refunds: treated as having been paid on account

SCHEDULE 7 — INTERPRETATION

- 1. Interpretation
- 2. For the purposes of these Regulations, a clinical trial authorisation...
- 3. In these Regulations any reference to an application for the...

Explanatory Note