STATUTORY INSTRUMENTS

# 1997 No. 322

## **MEDICINES**

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

Made	-	-	-	-	
Laid bef	fore I	Parli	amei	nt	
Coming	into	force	e		

12th February 1997 18th February 1997 31st March 1997

## THE REGISTRATION OF HOMOEOPATHIC VETERINARY MEDICINAL PRODUCTS REGULATIONS 1997

### PART I

### GENERAL

1. Title and commencement

### 2. Interpretation

3. Homoeopathic veterinary medicinal products to which these Regulations apply

### PART II

### **REGISTRATION OF PRODUCTS**

- 4. Applications for registration
- 5. Examination of registration applications
- 6. Registration of products
- 7. Renewal of registrations
- 8. Alteration of Article 8 dossiers relating to registered products
- 9. Suspension and revocation of registrations
- 10. Prohibition and withdrawal notices
- 11. Procedure where the Ministers propose to take certain action on grounds relating to safety or quality
- 12. Procedure where the Ministers propose to take certain action on grounds other than grounds relating to safety or quality

#### PART III

## **ARTICLE 24 AUTHORISATIONS**

- 13. Applications for Article 24 authorisations
- 14. Issue of Article 24 authorisations
- 15. Change of Article 25 particulars
- 16. Suspension and revocation of Article 24 authorisations
- 17. Procedure where the Ministers propose to refuse Article 24 authorisations or to suspend or revoke such authorisations

#### PART IV

#### CONTROLS

- 18. Restrictions on the marketing of products
- 19. Duties on persons responsible for marketing registered products
- 20. Prohibition on supply and withdrawal from the market
- 21. Labelling and package inserts
- 22. Restrictions on the manufacture of products
- 23. Restrictions on imports of products from third countries
- 24. Restrictions on exports of certain products to EEA States
- 25. Duties on holders of Article 24 authorisations
- 26. Duties on qualified persons
- 27. Suspension of persons acting as qualified persons

#### PART V

#### MISCELLANEOUS AND SUPPLEMENTAL PROVISIONS

- 28. Confidentiality
- 29. Issue of certificates
- 30. Article 34 duties
- 31. Enforcement
- 32. Offence and penalties
- 33. Defence
- 34. Application of various sections of the Act
- 35. Partial disapplication of various enactments
- 36. Disapplication of various statutory instruments
- 37. Amendment Signature

SCHEDULE 1 — INTERPRETATION

- PART I Expressions having the same meaning as in the Homoeopathics Directive
- PART II Expressions having the same meaning as in Directive 81/851

SCHEDULE 2 — PROCEDURE WHERE THE MINISTERS PROPOSE TO TAKE CERTAIN ACTION ON GROUNDS RELATING TO SAFETY OR QUALITY

- 1. Subject to paragraph 8(1), where the Ministers propose to act...
- 2. Where the Board is consulted pursuant to paragraph 1, the...
- 3. After the Board has reported to the Ministers pursuant to...

- 4. Where the Ministers provisionally determine to take the proposed regulation...
- 5. (1) Where the Commission is consulted pursuant to paragraph 4,...
- 6. Where the Commission is consulted pursuant to paragraph 4, the...
- 7. After the Commission has reported to the Ministers pursuant to...
- 8. (1) The provisions of paragraph 1 shall not apply where...

### SCHEDULE 3 — PROCEDURE WHERE THE MINISTERS PROPOSE TO TAKE CERTAIN ACTION ON GROUNDS OTHER THAN GROUNDS RELATING TO SAFETY OR QUALITY

1. (1) Where the Ministers propose to act in a manner...

## SCHEDULE 4 — PROCEDURE WHERE THE MINISTERS PROPOSE TO REFUSE ARTICLE 24 AUTHORISATIONS OR TO SUSPEND OR REVOKE SUCH AUTHORISATIONS

- 1. (1) Where the Ministers propose to act in a manner...
- 2. Where a person on whom such notice is served under...

SCHEDULE 5 — APPLICATION OF VARIOUS SECTIONS OF THE ACT

#### SCHEDULE 6 — AMENDMENT

Explanatory Note