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STATUTORY INSTRUMENTS

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**1988 No. 1009**

**MEDICINES**

The Medicines (Labelling of Medicinal Products  
for Incorporation in Animal Feeding Stuffs and of  
Medicated Animal Feeding Stuffs) Regulations 1988

*Made - - - - 6th June 1988*

*Laid before Parliament 16th June 1988*

*Coming into force*

*Regulations 1 and 12 7th July 1988*

*Remainder 1st November 1988*

**THE MEDICINES (LABELLING OF MEDICINAL PRODUCTS  
FOR INCORPORATION IN ANIMAL FEEDING STUFFS AND OF  
MEDICATED ANIMAL FEEDING STUFFS) REGULATIONS 1988**

1. Citation and commencement
2. Interpretation
3. Application
4. Labelling requirements for containers and packages of medicinal products and excepted medicated feeding stuffs
5. Labelling requirements for containers and packages of medicated feeding stuffs other than excepted medicated feeding stuffs
6. Medicinal tests on animals
7. Special labelling requirements relating to medicinal products exempt from product licences and medicated feeding stuffs in which such products have been incorporated
8. Sale or supply of medicinal products or medicated feeding stuffs not enclosed in a container
9. General provisions
10. Removal etc of labels
11. Exemptions
12. Transitional provisions
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14. Amendment of the Medicines (Labelling) Regulations 1976
15. Revocation

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

Signature

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SCHEDULE 1 — STANDARD WITHDRAWAL PERIODS

SCHEDULE 2 — STANDARD PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS AND EXCEPTED MEDICATED FEEDING STUFFS

1. The name of the medicinal product or excepted medicated feeding...
2. Any product licence number as allocated by the licensing authority...
3. A statement, in a conspicuous position, of the quantity (expressed...
4. Where under paragraph 1 or 3 above a medicinal product,...
5. Where under paragraph 1 or 3 above a medicinal product,...
6. A description of the pharmaceutical form of the medicinal product...
7. The purposes for which the medicinal product or excepted medicated...
8. In the case of a medicinal product or excepted medicated...
9. The quantity of the medicinal product or excepted medicated feeding...
10. (a) Contra-indications, warnings and precautions required to be given by...
11. (a) Where a product licence relating to the medicinal product...
12. (a) In the case of a prescription only medicine, the...
13. The name and address of the holder of any product...
14. Either the expiry date of the medicinal product or excepted...
15. The manufacturer's reference number of the batch to which the...
16. Any other statements or particulars required to be stated on...
17. In any case where particulars from this Schedule are omitted...

SCHEDULE 3 — STANDARD PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICATED FEEDING STUFFS OTHER THAN EXCEPTED MEDICATED FEEDING STUFFS

1. The name of the medicated feeding stuff, or a description...
2. (a) The name of any medicinal product or excepted medicated...
3. The appropriate non-proprietary name and quantity (expressed as mg per...
4. The medicinal purpose for which any medicinal product or excepted...
5. Directions for use, including— (a) instructions for the rate at...
6. (a) Any warnings or instructions relating to safety, storage or...
7. (a) Where the medicated feeding stuff contains a medicinal product...
8. The name and address of the manufacturer of the medicated...
9. If the period during which any active ingredient in the...
10. The manufacturer's reference number of the batch to which the...
11. Any other statements or particulars required to be stated on...
12. In any case where particulars from this Schedule are omitted...

SCHEDULE 4 — PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS OR MEDICATED FEEDING STUFFS FOR MEDICINAL TESTS ON ANIMALS

1. Such designation as will sufficiently identify the animal test.
2. (a) Where more than one medicinal product or excepted medicated...
3. The quantity of the medicinal product or of each active...
4. The purposes for which the medicinal product or medicated feeding...
5. In the case of a medicinal product or intermediate medicated...

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6. Any special requirements for the handling and storage of the...
7. (a) In the case of a medicinal product or excepted...
8. Any other statement or particulars required to be stated on...
9. In any case where particulars from this Schedule are omitted...

SCHEDULE 5 — AMENDMENT OF THE MEDICINES (LABELLING)  
REGULATIONS 1976

1. In regulation 3(1) thereof (interpretation)— (a) there shall be inserted...
2. Regulation 14 thereof and Schedule 4 thereto (medicinal products for...
3. In regulation 18(2)(iv) thereof (exemptions), the words from “, not...
4. In Schedule 3 thereto (particulars required in the labelling of...

Explanatory Note