STATUTORY INSTRUMENTS

1994 No. 104

The Medicines (Labelling and Leaflets) Amendment Regulations 1994

Insertion of Schedule 9 into the Labelling Regulations

4. After Schedule 8 to the Labelling Regulations, there shall be inserted the following Schedule—

"SCHEDULE 9 Regulation 4F(2)

STANDARD LABELLING REQUIREMENTS FOR CONTAINERS ANDPACKAGES OF HOMOEOPATHIC PRODUCTS MARKETED UNDER ACERTIFICATE GRANTED UNDER THE MEDICINES (HOMOEOPATHICMEDICINAL PRODUCTS FOR HUMAN USE) REGULATIONS 1993

1. The scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homoeopathic manufacturing procedure described therein for that stock or stocks.

2. The name and address of the holder of the certificate of registration and, where different, the name and address of the manufacturer.

3. The method of administration and, if necessary, route.

4. The expiry date of the product in clear terms, stating the month and year.

5. The pharmaceutical form.

6. The contents of the sales presentation.

7. Any special storage precautions.

8. Any special warning necessary for the product concerned.

9. The manufacturer's batch number.

10. The registration number allocated by the licensing authority preceded by the letters "HR" in capital letters.

11. The words "homoeopathic medicinal product without approved therapeutic indications".

12. A warning advising the user to consult a doctor if the symptoms persist during the use of the product.".