S C H E D U L E S

SCHEDULE 28

Regulation 264

Labelling requirements for registrable homoeopathic medicinal products

PART 1

Outer and immediate packaging

1. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

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

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

4. The product's expiry date (month and year), in clear terms.

5. The product's pharmaceutical form.

6. The contents of the presentation, specified by weight, volume or number of doses.

7. Special storage precautions, if any.

8. A special warning, if necessary in relation to the product.

9. The manufacturer's batch number.

10. The number of the certificate of registration.

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

12. A warning advising the user to consult a doctor if symptoms persist.

PART 2

Blister packs etc contained in outer packaging

13. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

14. The name and address of the holder of the certificate of registration.

15. The product's expiry date (month and year), in clear terms.

16. The manufacturer's batch number.

17. The words "homoeopathic medicinal product without therapeutic indications".

PART 3

Small immediate packaging

18. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

19. The name and address of the holder of the certificate of registration.

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

21. The product's expiry date (month and year), in clear terms.

22. The contents of the presentation, specified by weight, volume or number of doses.

23. The manufacturer's batch number.

24. The words "homoeopathic medicinal product without therapeutic indications".