SCHEDULES

SCHEDULE 24

Regulation 257

Packaging information requirements

PART 1

Outer and immediate packaging

1. The name of the medicinal product.

2. The strength and pharmaceutical form of the product.

3. Where appropriate, whether the product is intended for babies, children or adults.

4. Where the product contains up to three active substances, the common name of each active substance.

5. A statement of the active substances in the product, expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names.

6. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.

7. A list of—

(a) where the product is injectable or is a topical or eye preparation, all excipients; or

(b) in any other case, those excipients known to have a recognized action or effect and included in the guidance published pursuant to Article 65 of the 2001 Directive.

8. The method of administration of the product and if necessary the route of administration.

9. Where appropriate, space for the prescribed dose to be indicated.

10. A warning that the product must be stored out of the reach and sight of children.

11. Any special warning applicable to the product.

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

13. Any special storage precautions relating to the product.

14. Any special precautions relating to the disposal of an unused product or part of a product, or waste derived from the product, and reference to any appropriate collection system in place.

15. The name and address of the holder of the marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product and, where applicable, the name of the holder's representative.

16. The number of the marketing authorisation, Article 126a authorisation or traditional herbal registration for placing the medicinal product on the market.

17. The manufacturer's batch number.

18. In the case of a product that is not a prescription only medicine, instructions for use.

PART 2

Immediate packaging: blister packs

19. The name of the medicinal product.

20. The strength and pharmaceutical form of the product.

21. Where appropriate, whether the product is intended for babies, children or adults.

22. Where the product contains up to three active substances, the common name of each active substance.

23. The name of the holder of the marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product.

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

25. The manufacturer's batch number.

PART 3

Immediate packaging: small packages

26. The name of the medicinal product.

27. The strength and pharmaceutical form of the product.

28. Where appropriate, whether the product is intended for babies, children or adults.

29. Where the product contains up to three active substances, the common name of each active substance.

30. The method of administration of the product and if necessary the route of administration.

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

32. The manufacturer's batch number.

33. The contents of the packaging by weight, by volume or by unit.