SCHEDULES

SCHEDULE 25

Regulation 258

Packaging requirements: specific provisions

PART 1

Medicines on prescription

1. Where the product is to be administered to a particular individual, the name of that individual.

2. The name and address of the person who sells or supplies the product.

3. The date on which the product is sold or supplied.

4. Unless paragraph 5, applies, such of the following particulars as the appropriate practitioner who prescribed the product may specify—

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

5. This paragraph applies if the pharmacist, in the exercise of professional skill and judgement, is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 4 is inappropriate.

6. Where paragraph 5 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 4, as the pharmacist thinks appropriate.

PART 2

Transport, delivery and storage

7. Any special requirements for the storage and handling of the product.

8. The expiry date of the product.

9. The manufacturer's batch number.

PART 3

Pharmacy and prescription only medicines

10. Paragraph 11 applies if a pharmacy medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b), or

(d) distributed by way of wholesale dealing.

11. Where this paragraph applies, the capital letter "P" within a rectangle within which there is to be no other matter of any kind.

12. Paragraph 13 applies if a prescription only medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b); or

(d) distributed by way of wholesale dealing.

13. Where this paragraph applies, the capital letters "POM" within a rectangle within which there is to be no other matter of any kind.

PART 4

Medicines containing paracetamol

14. If the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the outer and immediate packaging, the words "Contains paracetamol".

15. If the product contains paracetamol the words "Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor", which must appear adjacent to either the directions for use or the recommended dosage.

16. If the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Do not take anything else containing paracetamol while taking this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 16 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If the product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Do not give anything else containing paracetamol while giving this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 17 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

18. If the product is required by this Part of this Schedule to show the words set out in paragraphs 14, 16 or 17, those words must appear in a prominent position.