

SCHEDULE 1

Marketing authorisations

PART 7

Labelling and package leaflets

Products with immediate and outer packaging

49.—(1) If it is not reasonably practicable to have all the required information on the immediate packaging then this paragraph applies.

(2) The immediate packaging must have at least the following information—

- (a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;
- (b) the name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”;
- (g) the words “Keep the container in the outer carton”.

(3) In addition, the immediate packaging must have as much of the required information as is reasonably practicable.

(4) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product in accordance with the following paragraph.