SCHEDULE 1

Marketing authorisations

PART 7

Labelling and package leaflets

Labelling with all the information on the immediate packaging

48.—(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters—

(a) the name, strength and pharmaceutical form of the veterinary medicinal product;

(b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;

(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 contents by weight, volume or number of dose units;

(h) the marketing authorisation number;

(i) the name and address of the marketing authorisation holder or, if there is a distributor authorised in the marketing authorisation, that distributor;

(j) a suitably labelled space to record discard date (if relevant);

(k) the target species;

(l) the distribution category;

(m) the words "Keep out of reach of children";

(n) storage instructions;

(o) the in-use shelf-life (if appropriate);

(p) for food-producing species, the withdrawal period for each species or animal product concerned;

(q) any warning specified in the marketing authorisation;

(r) disposal advice;

(s) full indications;

(t) dosage instructions;

(u) contra-indications;

(v) further information required in the marketing authorisation;

(w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.

(2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.