SCHEDULE 3

Classification and supply, wholesale dealers and sheep dip

PART 1

Classification and supply of authorised veterinary medicinal products

Classification of veterinary medicinal products

1.—(1) There shall be the following categories of authorised veterinary medicinal products—

(a) Prescription Only Medicine–Veterinarian (abbreviated to POM-V);

(b) Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);

(c) Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);

(d) Authorised Veterinary Medicine–General Sales List (abbreviated to AVM-GSL).

(2) The Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation.

(3) The Secretary of State may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).

(4) When granting the marketing authorisation the Secretary of State must classify the following as POM-V—

(a) products containing narcotic or psychotropic substances;

(b) products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon.

(5) When granting the marketing authorisation the Secretary of State must classify the following as POM-V or POM-VPS—

(a) products for food-producing animals;

(b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—

(i) the target species;

(ii) the person administering the products to the animal; and

(iii) the environment;

(c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; and

(d) new veterinary medicinal products containing an active substance that has not been included in an authorised veterinary medicinal product for five years.

(6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met—

(a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;

(e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.