

## DISTRIBUTION CATEGORY REVIEW PROJECT

### Background

Distribution categories provide controls on the sale and supply of veterinary medicines to ensure that appropriate advice is given at the point of sale so that products can be used safely and effectively. The distribution category of a veterinary medicinal product is decided by scientific assessors at the VMD following evaluation of the application dossier for granting a marketing authorisation. It may be changed following assessment of an application by the marketing authorisation holder, who submits safety and efficacy and pharmacovigilance data in support of this change.

### The current legal distribution categories for veterinary medicines are:

- POM-V (prescription only medicine – veterinarians): prescribed by a veterinary surgeon and supplied by a veterinary surgeon or a pharmacist against a veterinary surgeon's prescription;
- POM-VPS (prescription only medicine – veterinary surgeons, pharmacists and Suitably Qualified Persons (SQP)): prescribed by a veterinary surgeon, a pharmacist or a SQP and supplied by these professionals;
- NFA-VPS (non-food animal - veterinary surgeons, pharmacists and SQPs): no prescription required - supplied by a veterinary surgeon, a pharmacist or a SQP;
- AVM-GSL (authorised veterinary medicine - general sales list): no prescription required – can be supplied by any retailer.

The Government accepted recommendations from both the Report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines (Marsh Report) and the Competition Commission's Report on the Distribution of Prescription Only Veterinary Medicines in the UK to carry out a general review of distribution categories of currently authorised veterinary medicinal products.

The Marsh Inquiry and the Competition Commission both heard evidence that for some products the distribution category had been set too cautiously and some products were, therefore, unnecessarily restricted in their availability. This led to reduced competition and allowed higher than necessary prices to be charged. Their reports recommended a review of distribution categories in the hope that it would make some products more freely available and thereby increase competition.

Following a public consultation in 2005 we were able to start the review in August 2006. To carry out this review the VMD:

- invited proposals to change the distribution category of products or product groups in a public consultation;
- published on the VMD's website the list of products included in the review and the list of product groups to be excluded along with the reasons for excluding them (e.g. antibiotics which were to remain under veterinary control);
- separated the products in the review into groups by their species and therapeutic group and asked the Veterinary Products Committee (VPC) to set up a Sub-Group to review the groups of products against a set of published

criteria and make recommendations as to whether or not their distribution category should change;

- arranged for the VPC to discuss the Sub-Group's recommended changes;
- invited interested parties to comment on the proposed recommendations;
- arranged for the Sub-Group to review their recommendations in light of the consultation responses;
- reviewed the VPC's recommendations in the light of regulatory implications;
- wrote to relevant Marketing Authorisation Holders (MAH) confirming the VPC's final recommendation, requesting confirmation on whether the MAH will accept the recommendation or would wish to put a case together as to why this would not be acceptable.

As well as consulting stakeholders we have kept them informed of the progress on the review through a dedicated page on our web site and at meetings.

### Results of the review

The VPC reviewed 848 products and recommended 55 products for re-classification to a less restrictive distribution category while maintaining appropriate controls on the safe use of these medicines.

Of these 55 products, there were 5 products where the VMD and MAH could not support the VPC's recommendations to reclassification from NFA-VPS to AVM-GSL. These products treat worm infestations (including lungworm and/or giardia) where professional advice is needed for the safe use of the product and the VPC had recommended a category that did not require any professional advice. These are the products in question:

Granofen Wormer 222.2 mg Granules for Dogs and Cats	Vm 11188/4003
Panacur Small Animal 10% Oral Suspension	Vm 01708/4436
Panacur Small Animal 2.5% Oral Suspension	Vm 01708/4428
Panacur Granules 22.2% w/w	Vm 01708/4427
Panacur 18.75 % Oral Paste	Vm 01708/4448

The table below lists the products that were recommended for reclassification. Please note that not all products will be reclassified as in some cases (all relating to dog and cat products) the MAH declined to accept this opportunity.

Product	Vm No.	Current	Recommended
Advantage 100 Spot-on Solution for Dogs	00010/4167	POM-V	NFA-VPS
Advantage 250 Spot-on Solution for Dogs	00010/4166	POM-V	NFA-VPS
Advantage 40 mg Spot-On Solution for Small Cats, Small Dogs and Pet Rabbits	00010/4117	POM-V	NFA-VPS
Advantage 40 Spot On Solution For Cats	00010/4164	POM-V	NFA-VPS

Advantage 40 Spot-on Solution for Dogs	00010/4168	POM-V	NFA-VPS
Advantage 400 Spot-on Solution for Dogs	00010/4165	POM-V	NFA-VPS
Advantage 80 mg Spot-On Solution for Large Cats & Pet Rabbits	00010/4134	POM-V	NFA-VPS
Advantage 80 Spot On Solution For Cats	00010/4163	POM-V	NFA-VPS
Alpha Ject 2-2	21714/4000	POM-V	POM-VPS
Aquavac FNM Plus Vaccine	00201/4196	POM-V	POM-VPS
Aquavac Furovac	00201/4203	POM-V	POM-VPS
Coprin (expired)	00201/4093	POM-V	POM-VPS
Coprite 2 g	00057/4154	POM-VPS	AVM-GSL
Coprite 24 g	00057/4144	POM-VPS	AVM-GSL
Coprite 4 g	00057/4142	POM-VPS	AVM-GSL
Duowin	05653/4046	POM-V	NFA-VPS
Frontline Spot On Cat (expired)	20860/4004	POM-V	NFA-VPS
Furogen 2	18343/4014	POM-V	POM-VPS
Lactovac	00057/4287	POM-V	POM-VPS
Leptavoid H	00201/4200	POM-V	POM-VPS
Nobilis CAV P4	01708/4322	POM-V	POM-VPS
Paracox	00201/4151	POM-V	POM-VPS
Paracox 5 Oral Suspension	01708/4552	POM-V	POM-VPS
Rearguard	12501/4115	POM-V	AVM-GSL
Rotavec Corona	00201/4147	POM-V	POM-VPS
Scalibor Protectorband 4% w/w (48cm collar) for small and medium sized dogs	01708/4482	POM-V	NFA-VPS
Scalibor Protectorband 4% w/w (65 cm collar) for large sized dogs	01708/4481	POM-V	NFA-VPS
Spirovac	00057/4240	POM-V	POM-VPS
Suvaxyn Ery	01596/4322	POM-V	POM-VPS
Top Drop 40 Spot-on Solution for Small Dogs	00010/4122	POM-V	NFA-VPS
Top Drop 100 Spot-on Solution for Medium Dogs	00020/4123	POM-V	NFA-VPS
Top Drop for 250 Spot-on Solution for Large Dogs	00201/4124	POM-V	NFA-VPS
Top Drop for 400 Spot-on Solution for Extra Large Dogs	00010/4125	POM-V	NFA-VPS
<b><i>The products below are those which the MAH has so far decided not to change distribution category</i></b>			
Advantix Spot-on solution for dogs over 10kg up to 25kg	00010/4138	POM-V	NFA-VPS
Advantix Spot-on solution for dogs over 25kg	00010/4139	POM-V	NFA-VPS
Advantix Spot-on solution for dogs over 4kg up to 10kg	00010/4137	POM-V	NFA-VPS
Advantix Spot-on solution for dogs up	00010/4136	POM-V	NFA-VPS

to 4kg			
Fleegard 10mg for Dogs Spot On Solution	00010/4111	POM-V	NFA-VPS
Fleegard 20mg for Dogs Spot On Solution	00010/4112	POM-V	NFA-VPS
Fleegard 4 for Cats	00010/4108	POM-V	NFA-VPS
Fleegard 4mg for Dogs Spot On Solution	00010/4110	POM-V	NFA-VPS
Fleegard 8 for Cats	00010/4106	POM-V	NFA-VPS
Frontline Combo Spot On Cat	08327/4210	POM-V	NFA-VPS
Frontline Combo Spot on dog L	08327/4213	POM-V	NFA-VPS
Frontline Combo Spot on dog M	08327/4212	POM-V	NFA-VPS
Frontline Combo Spot on dog S	08327/4211	POM-V	NFA-VPS
Frontline Combo Spot on dog XL	08327/4214	POM-V	NFA-VPS
Frontline Spray	08327/4113	POM-V	NFA-VPS
Top Drop for Large Cats	00010/4120	POM-V	NFA-VPS
Top Drop for Small Cats	00010/4121	POM-V	NFA-VPS

### Next steps

We have written to those MAHs who have already indicated that they are content with the recommendations to invite them to submit a variation (type II) to change the distribution category for the products involved.

We will not charge for these variations and will allow the MAH to introduce this change at their next label re-print to avoid adding to their costs. The deadline for submission of the distribution category variations is 30 June 2010.

### Further information

For information on the distribution category review please contact Martha Spagnuolo-Weaver on [m.spagnuolo-weaver@vmd.defra.gsi.gov.uk](mailto:m.spagnuolo-weaver@vmd.defra.gsi.gov.uk) or tel: 01932 338319.

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