

Mr John Fitzgerald  
Director of Policy  
Veterinary Medicine Directorate  
Woodham Lane  
New Haw  
Addlestone  
Surrey  
KT15 3LS

PRACTICE AND QUALITY  
IMPROVEMENT DIRECTORATE  
PRACTICE DIVISION  
Direct telephone: 020 7572 2409  
Facsimile: 020 7572 2501  
e-mail: lorraine.fearon@rpsgb.org

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Dear Mr Fitzgerald

**Re: Review of the distribution category (legal classification) of veterinary medicinal products**

The Royal Pharmaceutical Society of Great Britain is the professional and self-regulatory body for pharmacists in Great Britain. The Society's functions include: maintaining the register of pharmacists and pharmacies; regular inspection of pharmacies to monitor standards of practice and compliance with legal and professional requirements; accrediting undergraduate pharmacy degree courses; ensuring fitness to practise at the point of registration; promoting continuing education; producing clinical audit tools for pharmacy practice and tools to support uni – and multiprofessional clinical governance. The society also produce a Code of Ethics containing standards governing the conduct and practice of pharmacists.

**Response to reclassification of veterinary medicines**

**Introduction**

For some diseases there is clear evidence to demonstrate under treatment or mismanagement which has resulted in unnecessary animal suffering and potential risk to the animal, humans and the environment e.g. treatment of companion animals with flea products, BVD in cattle.

In some cases failure to vaccinate animals has resulted in increased use of antibiotics. For humans there is a drive to use antibiotics more responsibly as there is concern at the increase in resistance of certain organisms. Strategies which reduce the use of antibiotics in animals e.g. increased use of vaccines should be encouraged.

For many products access is restricted to the veterinary surgeon and whilst for some this is entirely appropriate for other products this restriction should be reviewed.

## **Background**

Marsh and Competition commission report recommended that there should be automatic reviews of distribution classification. Unless there was good scientific reason to require additional information, such reviews should be based on the product's existing dossier and accumulated field experience. An early benefit identified in the recommendations was an immediate review of the distribution classifications of ectoparasiticides (for the treatment of fleas) for companion animals.

## **The Human Medicines Market**

On the human side of medicines the number of switches from POM to P medicines has been shown to encourage movement and free up access. This can be consistently applied to veterinary medicines as the regulations will be reviewed annually and a target for the number of reclassifications would ensure that the Marsh and Competitions Commissions report recommendations are imposed.

## **Pharmacists competencies**

### Code of ethics

Pharmacists under their Code of Ethics are only able to operate within their range of competence. All pharmacists must adhere to the RPSGB Code of Ethics and it is enforced through the RPSGB regulatory machinery. The ultimate sanction would be removing the pharmacist's name from the Register. The Society's forthcoming Section 60 Order will also provide the ability to suspend or restrict practice and where necessary prevent a pharmacist prescribing.

Under their Code of Ethics pharmacists must:

- Only accept work where they have the requisite skills and fitness for the tasks to be performed
- Undertake continuing professional development relevant to their professional duties
- Continually review the skills and knowledge required for their field of practice, identify those skills and knowledge in need of development or improvement and audit their performance.

## **Training**

We would expect pharmacists to limit their prescribing to medicines that they have the competence to prescribe and to conditions that they have the competence to treat. Appropriately trained pharmacists should be able to prescribe any appropriate medicine for any condition that they are competent to treat.

The RPSGB runs a post-graduate diploma in veterinary pharmacy (D Vet Pharm) that covers UK agriculture, veterinary farming and livestock health and husbandry. In addition the certificate in Companion animal health care covers pet health, zoonoses and infectious disease. Pharmacists who are interested in veterinary pharmacy have resources available to update their knowledge and gain competence in specific areas. Guidance for pharmacists on specific subjects is also produced for pharmacists e.g. guidance for treating fleas and ticks in cats and dogs. Pharmacists will understand the species variation affecting the use of products as it proposed that the RPSGB will issue guidance for any reclassification.

The RPSGB has worked closely with the MHRA for the recent POM to P switches and produced guidance for the profession at the time of switch. The guidance has both informed the profession and the public and may be viewed on the RPSGB website.

Pharmacists are proficient at managing human medicines and as part of the new pharmacy contract carry out medicine use reviews. Pharmacists are accustomed to dealing with the cold chain when supplying insulins and vaccines. Short shelf life vaccines such as the toxoplasmosis vaccine (Toxovax) have to have a short supply chain whilst maintaining fridge temperature at all times. Failure to have a satisfactory cold chain has serious implications. The pharmacy network is efficient as pharmacists already supply the flu vaccine to individuals at risk.

## **Reclassification**

The RPSGB believes that when considering reclassification it is important to consider the following criteria:

- Efficacy: - is the product effective for the indication in the dose for the relevant species/breed of animal – the licence should cover this.
- Safety – that safety for the animal or administrator is not compromised
- Access – will this increase the availability of the medication for the animal owner. This is an important consideration where there is under treatment of a condition
- Choice – will this provide an additional option for the individual animal owner that would or could be used to access medicines.
- Appropriateness- Is it appropriate that the product is available from a wider range of outlets. There may be additional reasons why certain products are not made available e.g. widening the availability of antibiotics could increase resistance.
- Commercial interests –is the market value such that would justify this, is there the potential to increase the market size

A balanced view needs to be taken of the above. It is important to recognise that the aim is to improve animal health and welfare and still ensure user, animal and environment safety

Products, which would be suitable to be reclassified, are:

- Where a precise diagnosis is not necessary e.g. prophylactics
- A veterinary surgeon does not need to administer the product
- The risk/benefit is not finely balanced
- Improved access has the potential to increase uptake and use of a product, which would lead to significant improvement in animal health and welfare.

## **Livestock Vaccines (see appendix A)**

### **The RPSGB supports the list produced by ADHA**

For optimum animal health and disease prevention many livestock vaccines should be purchased and used by the farmer routinely. Many POM vaccines used for flock/herd disease prevention are used against ubiquitous organisms affecting a great proportion of UK animals. For example BVD is prevalent in 90% of cattle but still only 40% or so are vaccinated with the killed vaccines available. Similar relatively low usage of vaccines for EAE in sheep and leptospira in cattle exist. A reclassification of cattle and sheep vaccines to POM VPS would increase ease of access for farmers and significantly an uptake in vaccination in many cases would decrease the use of antibiotics in food producing animals which lead to cross-resistance

in humans. There is a clear market need and it would encourage competition in the supply chain leading to a far greater uptake. Evidence from Ireland has shown that there has been an increase in costs where vets have both diagnosed and dispensed dry cow tubes. For humans it is considered good practice to separate where possible the prescribing from the dispensing

The vets imply that diagnosis goes with supply. For the use of vaccines prophylactically a diagnosis does not need to be made although it is noted that some farmers would like a diagnosis.

### **Live Vaccines**

The main issues with live vaccines are safety to target animal and operating standards. In the case of respiratory vaccines the freeze-dried live products need to be reconstituted e.g. spirovac, rispoval 4 and pharmacists would be able to advise on this in their pharmacies if they had the necessary competence. The Code of Ethics expects pharmacists to operate within their competencies and pharmacists would not supply any vaccines for food producing animals if they did not have the specialised knowledge and competency to do so.

### **Poultry and Horse Vaccines**

Poultry vaccines were traditionally PML and should be considered for re-classification in the future. The issue for horse vaccines is the competence of the user as horses are owned by non-professionals. The reclassification of horse vaccines should be kept under review and referred back to the industry. A possible solution is if there are competent technicians available to administer.

### **Deccox**

Deccox (currently an in-feed MFS product) should be re-classified as POM –VPS rather than POM –V. The product is very largely used prophylactically and is “standard” in many feeds. As such vets are prescribing Deccox in feed as a matter of course rather than diagnosing coccidiosis. Re- classification to POM- VPS would certainly help feed manufacturers and farmers as they would be able to obtain scripts from pharmacists and SQPs.

### **Orbeseal**

This teat sealant is POM. However it has no active ingredient and is not used in conjunction with antibiotics but as an alternative to antibiotics. There isn't any logic as to why it is POM and should be re-classified to POM-VPS.

### **Small Animals**

Re-classifications here will affect pharmacies in greater numbers. It is noted that any centralised products are exempt from the review. This places restrictions on the reclassification to POM-VPS and the Marsh Report and Competition Commission recommendations are not being met. This needs to be reviewed.

### **Wormers**

All Fenbendazole products for cats/dogs/horses should be classified NFA-VPS. Currently most Fenbendazole products are PML, but Bob Martin(Easy wormer) and Pedigree (Pedigree Care

Wormer tablets) have GSL products. This seems to be an anomaly, particularly with the benzimidazole resistance issue. Wormers should be in the NFA-VPS category and the use of benzimidazoles tightened up so they are consistent and in the same category.

All new wormer products should be reviewed after five years and if they have a good safety record then they should be considered for reclassification to POM –VPS.

The RPSGB supports the list produced by ADHA.

Indication	Product	Company	Recommendation
Anthelmintic	Milbemax (various formulations)	Novartis	NFA-VPS

### Flea Products

Often flea products are asked for by their brand name and they are currently POM. Flea products should be classified as NFA-VPS in order to increase access, usage and competition. The risk/benefit ratio is not finely balanced in this case and the products do not need to be used under veterinary supervision.

Injectable flea products can be classified as NFA-VPS provided there are adequate controls in place. Pharmacists have a code of ethics that requires them to operate within their areas of competence. Pharmacists would exercise their professional judgement and only provide injectables if they had adequate information on administration and this could be passed on to breeders and other people.

All new flea products should be reviewed after five years and if they have a good safety record then they should be considered for reclassification to NFA–VPS. Fleas are a public health risk and ease of access and competitive pricing would encourage pet owners to treat their pets regularly and prophylactically.

The RPSGB supports the list produced by AHDA.

Indication	Product	Company	Recommendation
Fleas	Frontline	Merial	NFA-VPS
Fleas	Program	Novartis	NFA-VPS
Fleas	Advantage	Bayer	NFA-VPS
Fleas	Stonghold	Pfizer	POM-VPS

### Vaccines

It is in the consumer interest and public health that every dog/cat is immunised. This is in parallel to the situation in human medicine where pharmacists supply flu vaccines. Perhaps the vaccines for companion animals should be in a less restrictive category provided the owner/breeder can show competence of use. The professional responsibility for ensuring the owners competence lies with the professional. Pharmacists supplying vaccines can claim their own area of competency.

### NSAIDS

Diclofenac and ibuprofen are available over the counter as a pharmacy medicine for humans. Metacam (meloxicam) and Rimadyl (carprofen) should be considered for reclassification. Pharmacists who are competent in veterinary medicine would be able to prescribe these drugs. Pharmacists work within their Code of Ethics and operate within their competencies,

thus those who have the specialised knowledge and competency would prescribe these NSAIDS.

### **Antihistamines and Anti-nausea**

Pharmacists receive many requests for products to prevent travel sickness in both in humans and companion animals. Whilst at the present time they are able to offer a range of products for humans they are not able to offer any effective product for the animal. This is an anomaly and should be looked at as many people fail to plan ahead as they are unaware that they need to visit a vet prior to a journey. It is known that people do use the products available for humans to prevent travel sickness in animals. There is a clear need to have an appropriate anti-nausea product available from a pharmacy to prevent travel sickness in companion animals.

### **Topical**

Topical corticosteroids are available for purchase in a pharmacy to treat and manage a range of skin conditions in humans; they should also be available to treat animals.

Yours sincerely

Sue Kilby  
**Head of Practice**

## APPENDIX A LIST OF PROPOSED ADDITIONAL POM-VPS PRODUCTS (agreed AHDA list)

### Proposed additional SHEEP vaccine products:-

Indication	Product	Company
Clostridial	Covexin 10	Schering-Plough
Enzootic Abortion	Mydiavac	Novartis
	Enzovax	Intervet
	Cevac Chlamydophila	Ceva
Toxoplasmosis	Toxovax	Intervet

### Proposed additional CATTLE vaccine products:-

BVD	Bovidec	Novartis
	Bovilis BVD	Intervet
	Pregsure BVD	Pfizer
Clostridial	Covexin 10	Schering-Plough
Leptospirosis	Spirovac	Pfizer
	Leptavoid-H ..Hardjo..	Schering-Plough
Ringworm	Bovilis Ringvac	Intervet
Lungworm	Bovilis Huskvac	Intervet

<b>Indication</b>	<b>Product</b>	<b>Company</b>
Rota, Corona virus e. coli	Lactovac Rotavec Corona Trivaction 6	Intervet Schering-Plough Merial
IBR	Bovilis IBR Tracherine	Intervet Pfizer
RSV	Rispoval RS Bovine...	Pfizer
IBR-PI3	Imuresp RP	Pfizer
Pasteurella	Pastobov Rispoval Pasteurella	Merial Pfizer
RSV-PI3-M. haemolytica	Bovipast RSP	Intervet
RSV-PI3-BVD	Rispaval 3	Pfizer
RSV-PI3-IBR-BVD	Rispoval 4	Pfizer

**Proposed additional CATTLE & SHEEP products**

Copper	Coprin	Schering-Plough	Injection
Selenium	Deposel Multidose	Novartis	injection

**Scabivax**

Orf	Scabivax Forte	Schering-Plough
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