

# MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 81 – JANUARY 2012

## ■ CHANGES TO STATUTORY AND NON-STATUTORY SURVEILLANCE INFORMATION FOR RESIDUES

The entries under the Residues section providing details of the results of the statutory and non-statutory surveillance schemes have been changed. The information provides an overall update of the results summarising the main findings together with a link to the Veterinary Residues Committee (VRC) website, where full details of all the results can be accessed.



## ■ VPC NEWS

The Veterinary Medicines Directorate (VMD) and the Veterinary Products Committee (VPC) held their Open Meetings on 23 November 2011.

A report of the meetings is available on the VMD and VPC websites [www.vmd.defra.gov.uk/business/about\\_events.aspx#open](http://www.vmd.defra.gov.uk/business/about_events.aspx#open) and [www.vmd.defra.gov.uk/vpc/meetings/open.aspx](http://www.vmd.defra.gov.uk/vpc/meetings/open.aspx).

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ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

# NEWS

## MEMBERSHIP OF THE VETERINARY PRODUCTS COMMITTEE (VPC)

The appointment of Mr Rory Bell (veterinary surgeon, small animals), Dr Elizabeth Kubiak (medical/clinical microbiologist) and Mr Peter Scott (veterinary surgeon, fish) as members of the VPC for terms of office of four years and Mr John Sherington (statistician) for a term of office of two years was announced in a Defra information bulletin on 5 January.

Mr Bell was appointed Head of the small animal internal medicine service at the University of Glasgow Small Animal Hospital in 2009. He is also Chairperson of the Education Committee of the European College of Veterinary Internal Medicine.

Dr Kubiak has been Consultant Medical Microbiologist and Infection Control Doctor to Aneurin Bevan Local Health Board in Wales since 1994 and has been Lead clinician for Microbiology Services across the county of Gwent for the last 10 years.

Mr Scott is a practising veterinary surgeon and is a Royal College of Veterinary Surgeons Recognised Specialist in Fish Health and Production. He is currently President of the Fish Veterinary Society.

Mr Sherington is an applied statistician with over 35 years experience in applying statistical methods and ideas in biological research in a variety of contexts, using a wide range of statistical techniques.

Dr Anil Adisesh, Dr Robert Jefferson, Professor Andy Peters, and Mr Keith Siddorn have been re-appointed to the VPC and Professor Tim Marrs has been re-appointed to the VPC's sub-committee, the Medical and Scientific Panel, for a further four

years. Following the closure of the VPC's sub-committee the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines, Professor Marrs has also been re-appointed for a further four years to the VPC.

A further exercise to appoint a dermatologist and environmental scientist is expected to begin in April. In the meantime expressions of interest or requests for further information on membership of the VPC should be made to **Colin Bennett** ([c.bennett@vmd.defra.gsi.gov.uk](mailto:c.bennett@vmd.defra.gsi.gov.uk), tel: 01932 338490).

## STAFF CHANGES

- Anna Burrows was promoted and transferred to the New Licensing team on 31 October.
- Trish Logie, Veterinary Assessor in the Pharmaceuticals and Feed Additives team, left the VMD on 25 November.
- Caroline Povey transferred to the Residues team on 14 November.
- Reena Agrawal was promoted and transferred to the SARSS team on 28 November.
- Sam Fletcher was promoted within the Safety team on 1 November.
- Nina Dorian was promoted and transferred to the Committee Support team on 5 December.
- Andrew Hall joined the IT team on transfer from the Defence Science and Technology Laboratory (DSTL) on 3 January.
- James Freer is on a temporary promotion in the Feed Additives, Research and Enforcement (FARE) team.
- Renee Sheehan and Nicole Batey joined the FARE team on transfer from AHVLA on 9 January. Their work will be on antimicrobial resistance.

# LICENSING

## VALIDATION ISSUES

The VMD has noted a number of common problems arising during the validation of applications for new Marketing Authorisations (MAs) and variations. Clarifications on some of these points have been highlighted below and are also included in the frequently asked questions (FAQ) on our website [www.vmd.gov.uk/pharm/applicationFAQ\\_validation.aspx](http://www.vmd.gov.uk/pharm/applicationFAQ_validation.aspx). Applicants are advised to read this FAQ before submitting applications to the VMD to avoid any unnecessary delay at validation.

### Active Substance Master Files (ASMF)

When applicants are intending to use the European ASMF procedure in support of an application, the Marketing Authorisation Holder (MAH) should ensure that the proposed Active Substance Manufacturer (ASM) has lodged with the VMD the latest version of the full ASMF (Open and Restricted parts including Expert Reports or Quality Overall Summary if submitted in CTD format) prior to the submission of the

proposed application. This applies equally whether the active substance is new to UK veterinary medicinal products; the active substance is from an ASM previously not seen by the UK or; an updated file from a manufacturer previously seen by the VMD. If you would like to check the version of the ASMF that the VMD holds, **please contact Howard Stenson (VMD 01932 338311, e-mail: [h.stenson@vmd.defra.gsi.gov.uk](mailto:h.stenson@vmd.defra.gsi.gov.uk)).**

### Fees Reductions for Variations

Under the previous Variations Regulations and variations classification system, the VMD applied a number of reduced fees for certain situations as it was considered that some of the variation types and hence fees were too high for the work that was involved. These situations included identical variations to a number of products and a reduction in fees for Type II variations to informed consent products where the identical change had already been approved for the parent product. With the implementation of the new Variations Regulations, we are no longer applying these reduced fees to variations as in most cases, the implementation of the new Classification Guideline has downgraded the variation type (e.g. from Type II to Type IB) and the grouping of variations results in fees reductions. However, the following are applied and do lead to an overall reduction in the cost of variation applications:

- For variations to informed consent products where the same change has already been assessed for the parent product, the VMD will accept an unforeseen Type IB variation under the relevant category.
- Where the same change is being made to multiple products simultaneously and the supporting data are identical for each product, the VMD will apply a grouped fee (even if the applications are not submitted under a grouped or worksharing procedure).

### Submitting Variations/Renewals for Products with Pending Applications

The VMD has noticed that applicants are increasingly submitting variations when renewals, MRPs and or variations are currently ongoing for the same product. Questions 2.4 and 2.5 of the CMDh questions and answers regarding variations (available on the Heads of Medicines Agencies website [www.hma.eu](http://www.hma.eu)) state that variations should not be submitted during ongoing renewals and mutual recognition procedures. This advice is also followed by the veterinary sector. This is discrepant with the advice given in the Veterinary Medicines Guidance Note (VMGN) 2 paragraph 163 which states:

*“Please note that a renewal application will not be accepted while the MA is subject to on-going variation procedures, which affect the SPC, label or leaflet, and variation applications that affect the SPC, label or leaflet will not be accepted while the MA is subject to a current renewal procedure.”*

The VMD wishes to align its guidance with that given at European level wherever possible and therefore for national marketing authorisations, irrespective of whether the variation affects the SPC, label or leaflet, a renewal will now not be accepted with an on-going variation procedure and *vice versa*.

The VMD apologises for this discrepancy and will update the VMGN when they are next reviewed.

It is permitted to submit a variation for a product when another variation is already ongoing; however, applicants should time the submission of their variations carefully, especially when they involve changes to the SPC and/or product literature. Where the VMD notices that several variations are ongoing simultaneously, we may advise the applicant to withdraw applications at validation in order to avoid multiple versions of the same SPC and/or product literature being assessed at the same time.

### Supporting Documentation for Variations

The VMD has recently received several grouped variations which have involved a number of changes. Due to the presentation of the submitted data package, it has been difficult to locate the corresponding supporting documentation for each variation category type during validation. When an applicant intends to submit a grouped variation which involves a number of changes, please ensure that the location of the supporting data for each variation category type is clearly indicated.

### Lack of documentation for Type IAs

The VMD would like to remind applicants that Type IA variations are not usually subject to a separate validation phase. There is no provision to stop the clock during assessment for Type IA variations and therefore the onus is on the applicant to identify and submit all the necessary supporting data in their application package. If the application is incomplete, it will be refused. Please note, a fee is charged for a Type IA variation regardless of whether it is approved or refused.

For queries relating to the content and format of an application package for pharmaceutical products, MAs, Veterinary Homeopathic Remedies (VHRs) and Animal Test Certificates (ATCs), including queries relating to Active Substance Master Files (ASMF) **please contact Howard Stenson (VMD, 01932 338484, e-mail: [h.stenson@vmd.defra.gsi.gov.uk](mailto:h.stenson@vmd.defra.gsi.gov.uk)).**

For queries relating to the content and format of a variation application package for pharmaceutical products, MAs, VHRs and ATCs **please contact Alison Reynolds (VMD, 01932 8407, e-mail: [a.reynolds@vmd.defra.gsi.gov.uk](mailto:a.reynolds@vmd.defra.gsi.gov.uk)).**

For queries relating to the content and format of an application package for immunological products, MAs and ATCs or relating to the content and format of a variation application package for immunological products, MAs and ATCs **please contact Alison Young (VMD, 01932 8408, email: [a.young@vmd.defra.gsi.gov.uk](mailto:a.young@vmd.defra.gsi.gov.uk)).**

## ■ PUBLIC ASSESSMENT REPORTS

### Information included in Public Assessment Reports

Last year, the VMD conducted a survey on the public assessment reports which are available on the VMD Product Information Database [www.vmd.defra.gov.uk/ProductInformationDatabase/](http://www.vmd.defra.gov.uk/ProductInformationDatabase/). The aim of the survey was to establish the audience base and to determine whether the content and style of Public Assessment Reports (PARs) is appropriate. A common theme of the responses was that the clinical summaries included in the PARs were not sufficiently detailed and in addition 25% of responders said that they find the efficacy section of the PAR most useful. Specific comments included:

- Would like to have more information on studies conducted for a Marketing Authorisation (MA).
- PARs should include more details about the studies e.g. animal numbers.
- Clinical summaries that the VMD provides are too short. For example, they generally do not say how many animals were included in the study and they also do not go into criteria for enrolment, statistical power, monitoring, etc.

In order to address these comments and to provide a greater transparency in the information presented in PARs, the VMD has decided to increase the level of detail included for clinical trials (e.g. field trials and dose confirmation studies). This initiative fits nicely with the general drive to improve the transparency of the regulatory process and information submitted to support an MA and this initiative responds to this.

The VMD considers that the disclosure of additional information on the clinical trials will be relevant for the veterinarian as it will give them more confidence in the products that are authorised. Evidence based medicine is now widely encouraged and veterinarians should have a certain level of information available on the studies that have been conducted so that they can make an informed choice as to treatment for the individual animal under their care. In order to determine if the benefit shown for a particular product in a study could be extrapolated to the animal that they are treating, they need to know the clinical characteristics of the animals on which the product was tested and the clinical outcomes that were observed. At the most basic, this includes details about the study design such as whether the study was randomised, controlled and blinded.

The VMD considers that clinical trials are generally performed to a high standard and it is in the interests of industry as well as the VMD, that the veterinary profession should be made aware of the credibility of the data to support an MA. As per the current practice, the VMD will be giving Marketing Authorisation Holders (MAH) the chance to comment on PARs before they are published.

Further information on the Product Information Database and PARs can be found in our frequently asked questions on our website [www.vmd.defra.gov.uk/ProductInformationDatabase/FAQs.aspx](http://www.vmd.defra.gov.uk/ProductInformationDatabase/FAQs.aspx).

### Copycats

PARs are created for National MA applications and European MA applications where the UK is Reference Member State. To date we have not produced PARs for products authorised via the copycat/informed consent route as these rely on a cross-reference to data for other products. However, following legal advice it is our intention to commence publishing reduced assessment reports for copycat and informed consent applications which will include naming the parent product for the application.

**For further information: Scott Price (VMD, 01932 338311, e-mail: [s.price@vmd.defra.gsi.gov.uk](mailto:s.price@vmd.defra.gsi.gov.uk)).**

## ■ VETERINARY MEDICINES IMPORTS INTO THE UK

In January 2010 the VMD published an article in *MAVIS* concerning the availability of veterinary medicines in the UK. This article contained a tabulated summary of those product types which were regularly being imported at that time in the hope that this might encourage pharmaceutical companies to seek authorisations for relevant products to fill these gaps. An update of the summary of such imports is now presented. This summary is based on an analysis of the requests for import certificates received between 1 August 2011 and 31 October 2011.

Included in this analysis are Special Import Certificates and Special Treatment Certificates. Excluded from this analysis are those products that had to be imported into the UK because the UK distributor experienced temporary supply problems. The VMD would very much welcome hearing from

any company who is considering applying for a UK (Full, Provisional or Limited) Marketing Authorisation that would address any of the scenarios set out below, either using the active substance indicated or an alternate substance with the same or similar activity.

The import certificate schemes operated by the VMD are described in full in the Veterinary Medicines Guidance Note 5 available on the VMD website [www.vmd.defra.gov.uk/pdf/vmgn/vmgn05.pdf](http://www.vmd.defra.gov.uk/pdf/vmgn/vmgn05.pdf).

**Further information: Sam Ward (VMD, 01932 338496, e-mail: [s.ward@vmd.defra.gsi.gov.uk](mailto:s.ward@vmd.defra.gsi.gov.uk)) or should you wish to organise a meeting with assessors to discuss a forthcoming application, please contact Nina Dorian (VMD, 01932 338491, e-mail: [n.dorian@vmd.defra.gsi.gov.uk](mailto:n.dorian@vmd.defra.gsi.gov.uk)).**

Active Ingredient	Species	Route	Indication
Allergens	Horse/Dog/Cat	Injectable Solution	Treatment of atopic dermatitis
Campylobacter Fetus and Jejuni	Sheep	Injectable Solution	For protection against abortion caused by campylobacter fetus and jejuni
Canine Melanoma DNA	Dog	Injectable Solution	To treat malignant melanoma
Vitamin A Cholecalciferol (Vitamin D3) and Alpha-tocopherol	Cattle/Sheep/Pig	Injectable Solution	Prevention and treatment of Vitamin A, D3 and E deficiencies in cattle, sheep and pigs
Cisapride	Dog/Cat/Rabbit/ Guinea Pig	Tablets	To increase lower intestinal motility
Clostridium Botulinum Types C & D	Cattle	Injectable Solution	To aid in the protection against botulism
Dimethyl Sulphoxide, Lidocaine Hydrochloride, Prednisolone Acetate	Horse	Topical Liquid	Musculoskeletal inflammation with a traumatic or infectious aetiology. Arthritis, peri-arthritis, arthrosis, osteitis, synovitis, tendinitis, sprains and strains
Doxycycline	Aviary Birds	Injectable Solution	Treatment of respiratory infections in birds
European Viper Venom Antiserum	Dog	Injectable Solution	Antiserum for viper envenomation (adder)
Ketanserin Tartrate	Horse	Topical Liquid	To encourage wound healing and the prevention of the formation of hyper-granulation
Lomustine	Cat/Dog	Capsule	Treatment of mast cell tumour, lymphoma
Milbemycine Oxime	Dog	Tablets	For the treatment of demodicosis
Miltefosine	Dog	Oral	Control of canine leishmaniasis
Mycobacterium Paratuberculosis	Cattle/Sheep/Goat	Injectable Solution	Prevention of Johnes' disease
Oxolinic Acid	Salmon/Trout/ Ornamental Fish	Powder	Treatment of enteric red mouth
Phytomenadione	Dog	Tablets	Treatment of poisoning by anticoagulant rodenticides
Staphylococcus Aureus	Dog	Injectable Solution	Prevention of staphylococcus aureus allergy
Tacrolimus Monohydrate	Dog	Intra-Ocular	Treatment of keratoconjunctivitis sicca
Virginiamycin	Horse	Oral Granules	Reduction of risk of dietary induced laminitis

## MONTHLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK 2010/2011

The VMD's performance against its published standards for the period 1 April 2010 to 31 December 2011 can be viewed on the VMD website [www.vmd.defra.gov.uk/pdf/PublishedStandards.pdf](http://www.vmd.defra.gov.uk/pdf/PublishedStandards.pdf). The following summary is the performance against the published standards for the third quarter of 2011.

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days <sup>1</sup> )	Average time in days	Box Whisker Plots Key: <span style="color:red">-----</span> = Median <span style="color:blue">-----</span> = Average
<b>National</b>					
<b>MA and MAPIs</b>					
Initial assessment	13	Excellent	90	75	
Sign off, VPC or further questions	24	Excellent	120	79	
Sign off	0	Excellent	180	0	2
Sign off and issue	29	Excellent	210	129	
<b>MAPIS for MR products &amp; copy-cats</b>					
Initial assessment	4	Excellent	75	72	2
Sign off, VPC or further questions	5	Excellent	120	118	
Sign off	5	Excellent	150	127	
<b>Variations</b>					
Type 1A - decision	202	Excellent	14	9	
Type 1A - decision (30 days)	57	Excellent	30	18	
Type 1B admin - issue	55	Excellent	30	11	
Type 1B - initial assessment	187	Excellent	30	18	
Type 1B - sign off	194	Excellent	30	8	
Harmonisation - sign off	1	Excellent	60	13	2
Type II - initial assessment	58	Excellent	60	43	
Type II - sign off	70	Effective	60	37	

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days <sup>1</sup> )	Average time in days	Box Whisker Plots Key: <span style="color:red">-----</span> = Median <span style="color:blue">-----</span> = Average
<b>Renewals</b>					
Initial assessment	18	Excellent	60	49	
Sign off	21	Excellent	60	39	
<b>Batch release (Immunologicals)</b>					
Issue	1846	Excellent	15	4	
<b>AVAS and NFABBA (inc variations)</b>					
Assess	2	Excellent	45	36	
<b>ATCs</b>					
Type A, S and B - validate	14	Excellent	5	3	
Type A and S - sign off	6	Excellent	30	23	
Type B - sign off	7	Excellent	50	41	
Type A, S and B - issue	11	Ineffective	5	4	
<b>Specific Batch Control</b>					
Validation	68	Excellent	3	1	
Initial assessment	68	Excellent	10	1	
Assess response	66	Excellent	10	< 1	
Issue	67	Excellent	3	1	
<b>Validation/Issue</b>					
Validation	327	Excellent	10	5	
Issue	920	Excellent	10	6	
<b>SARs</b>					
Enter human SARs	87	Excellent	2		
Enter serious animal SARs	1288	Excellent	2		
Enter environmental SARs	3	Excellent	2		
Enter non-serious SARs	1470	Excellent	10		
Report to Eudravigilance	1478	Excellent	15		

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days <sup>1</sup> )	Average time in days	Box Whisker Plots Key: <span style="color:red">-----</span> = Median <span style="color:blue">-----</span> = Average
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### SIC/STC

Urgent products not previously imported	1	Excellent	5	5
Routine products not previously imported	27	Excellent	15	3
Urgent products previously imported	178	Excellent	2	<1
Routine products previously imported	3799	Excellent	10	3
On-line instantaneous issue of certificates	8484	Excellent	-	

### Inspections

GMP and GDP inspections performed on a risk-basis within 3 yrs of last inspection	65	Excellent		
Written deficiency reports sent after GMP and GDP inspection	65	Excellent	30	15
Issue GMP Certificate after last day at site	31	Excellent	90	74
Updated documentation for GDP site issued after last day at site	33	Excellent	90	59

### UKPARs

Make publicly available via VMD internet & SPC for New MA	150	Excellent	30	12
Make publicly available via Product Information Database	45	Excellent	120	92
Make publicly available after issue of post-authorisation assessments	379	Excellent	60	16

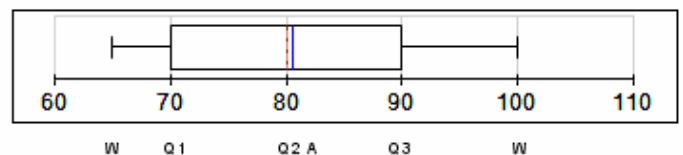
### Box-and-Whisker Plots

Box-and-whisker plots are helpful in interpreting the distribution of days an application may take. The median of a set of data separates the data into two equal parts and data can then be further separated into quartiles.

E.g. Application days for 10 applications: 80, 75, 90, 95, 65, 65, 80, 85, 70, 100  
 First order the data in numerical order: 65, 65, 70, 75, 80, 80, 85, 90, 95, 100

W
Q1
Q2 A
Q3
W

- <sup>Q1</sup> The 1st quartile is the median of the lower part of the data.
- <sup>Q2</sup> The 2nd quartile is the median of the entire set.
- <sup>Q3</sup> The 3rd quartile is the median of the upper part of the data
- <sup>W</sup> The whiskers represent the smallest and largest value.
- <sup>A</sup> The average number of days



Category/application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days <sup>1</sup> )
<b>European</b>			
<b>Centralised</b>			
Rapp - Initial assessment by 70 days	2	Excellent	70
Co-Rapp - Provide comments on assessment report by 85 days	1	Excellent	85
UK as Member only - LOQ by 100 days	5	Excellent	100
<b>Mutual Recognition</b>			
<b>RMS</b>			
Production of Final Assessment Report by 1st 90 days	14	Excellent	90
RMS Circulate the Consolidated List of Questions by Day 57	17	Excellent	57
Assessment of Responses by 2nd 70 days	17	Excellent	70
Procedure completed by 2nd 90 days	18	Excellent	90
<b>CMS</b>			
CMS send any UK comments by Day 54	11	Excellent	54
Procedure completed by 2nd 90 days	8	Excellent	90
<b>Decentralised</b>			
<b>RMS</b>			
Production of Assessment Report within 70 days	27	Excellent	70
Production of Assessment Report within 120 days	44	Excellent	120
RMS Circulate Consolidated List of Questions in Phase 2 by Day 30	32	Excellent	30
Assessment of Responses by 70 days	29	Excellent	70
RMS send confirmation of acceptance/referral by Day 90 (Phase 2)	34	Excellent	90
<b>CMS</b>			
UK comments sent by 100 days	55	Excellent	100
CMS Send any UK Comments in Phase 2 by Day 25	52	Effective	25
UK acceptance/referral sent by 90 days[2nd phase] [210 days]	40	Excellent	90[210]
<b>European Variations</b>			
<b>Type 1B EUCE Rapp</b>			
Initial Assessment Completed according to timetable	7	Excellent	
<b>Type II EUCE Rapp</b>			
Initial Assessment Completed according to timetable	5	Excellent	
<b>Type II - Mutual Recognition RMS</b>			
PAR circulated by 40 days	44	Excellent	40
CLOQ circulated by 59 days	42	Excellent	59
<b>Type IB - Mutual Recognition RMS</b>			
CLOQ circulated by 30 days	65	Effective	30
<b>Type IA - Mutual Recognition RMS</b>			
Determined within 30 days	54	Excellent	30
<b>Type II Mutual Recognition CMS</b>			
UK comments sent by 55 days	41	Excellent	55
UK comments sent by 80 days	38	Excellent	80
<b>Type IB Mutual Recognition CMS</b>			
UK comments sent by 20 days	59	Excellent	20
UK comments sent by 50 days	16	Excellent	50

Category/application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days <sup>1</sup> )
<b>European Renewals</b>			
<b>Mutual Recognition RMS</b>			
PAR circulated by 40 days	15	Excellent	40
CLOQ circulated by 59 days	15	Excellent	59
<b>Mutual Recognition CMS</b>			
UK Comments sent by 55 days	19	Excellent	55
UK Comments sent by 80 days	27	Excellent	80
<b>Others</b>			
UK as Rapporteur - Complete IA according to EMA timetable	1	Excellent	
<b>Customer Relations</b>			
<b>Unreturned authorisation documents</b>			
Right first time (Authorisations)	1257	Effective	

<sup>1</sup> The days are specified as either calendar days or clock days according to the target and as set out in detail in the published standards.

<sup>2</sup> Box whisker plots have been omitted due to low numbers of applications.

# ENFORCEMENT

*A key element in our strategy for assuring the safety, quality and efficacy of veterinary medicines is the action that we take against the illegal marketing and use of unauthorised products and to promote the responsible use of authorised products. This section describes the most significant developments and outcomes in this area.*

## ■ PROSECUTIONS

On 21 October 2011 at Newcastle Crown Court, Mr Kevin Winter was sentenced to 12 months imprisonment suspended for 2 years. Mr Winter pleaded guilty on the 28 July 2011 to 16 offences including the illegal importation, possession and supply of veterinary medicines, including antibiotics, under the Veterinary Medicines Regulations.

- Mr Stewart Gabriel, Shaw, Oldham. A large quantity of different products, including antibiotics, for which the majority were treatment for pigeons, were seized because they were not authorised in the UK and had not been supplied lawfully in accordance with the Regulations.

## ■ SEIZURE NOTICES

Since the last edition of MAVIS two seizure notices have been issued.

- Ms Libby Bell, Carlisle, Cumbria. Nineteen bottles purporting to be Micotil were seized because they were not authorised in the UK and had not been supplied lawfully in accordance with the Regulations.

## ■ IMPROVEMENT NOTICES

Since the last edition of MAVIS no improvement notices have been issued.

# ANTIMICROBIAL RESISTANCE

*Antimicrobial resistance is a serious problem in human and veterinary medicines, resulting in increasing concerns about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. A Government Strategy has been developed to address this issue. The Veterinary Medicines Directorate is responsible for delivering key elements of this Strategy, including the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK and providing a secretariat to the Defra Antimicrobial Resistance Coordination (DARC) Group. The following articles describe the most recent actions that the VMD has taken to progress this strategy.*

## ■ DARC GROUP MEETING

The Defra Antimicrobial Resistance Coordination (DARC) Group next meets on 21 February 2012.

All Summary reports of meetings can be accessed on the VMD website at [www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk) under "General Public/Antimicrobial Related Information/Defra Antimicrobial Resistance Coordination (DARC) Group" tabs or from Gemma Adam at the VMD.

## ■ MRSA SUB-GROUP

The VMD has now taken over chairmanship of the MRSA Sub-Group meetings and the date of the next meeting is 1 February 2012.

All Summary reports of meetings can be accessed on the VMD website [www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk) under "General Public/Antimicrobial Related Information/Meticillin-Resistant Staphylococcus aureus (MRSA)" tabs or from Gemma Adam at the VMD.

## ■ ESBLs SUB-GROUP

The final report prepared by the ESBLs Sub-Group of the DARC and Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infections (ARHAI) is due to be published in January 2012, but at the time of writing the actual publication date had yet to be finalised. The report will be available on the VMD website at [www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk) under “General Public/Antimicrobial Related Information/Extended-Spectrum Beta-Lactamase (ESBL)” tabs or from Gemma Adam at the VMD.

## ■ HMA-VETERINARY ACTION PLAN ON ANTIMICROBIAL ISSUES

The VMD chairs the Heads of Medicines Agencies – Veterinary (HMA-V) group, which is tasked with the finalisation and progression of the HMA Antimicrobial Issues Strategy and Action Plan. The VMD also provides the secretariat for the Group.

On 15 and 16 September, the HMA hosted a meeting with the European Medicines Agency (EMA) on “Progress in the area of Antimicrobial Resistance – Veterinary Medicines”. A report from the meeting and the presentations delivered can be found at [www.vmd.defra.gov.uk/business/about\\_events.aspx#open](http://www.vmd.defra.gov.uk/business/about_events.aspx#open).

One action from the HMA Action Plan was to gain more information from National Competent Authorities (NCA) on their current national activities relating to antimicrobial resistance. This has been done and an overview of Member State and EFTA country Veterinary Regulatory Agency Activities in the area of AMR (as of November 2011), and also a summary of the veterinary antimicrobial resistance surveillance activities performed in each Member State and EFTA country (as of November 2011), can be found at the following link [www.hma.eu/283.html#c2753](http://www.hma.eu/283.html#c2753).

The next teleconference of the Heads of Medicines Agencies – Veterinary (HMA-V) group was held on 19 January 2012.

## ■ SALES DATA REPORT

The VMD published the Antimicrobial Sales Data Report for 2010 on 22 November 2011.

Copies of this and all the published Reports detailing veterinary antimicrobial sales from 1998 to 2010 can be obtained from the VMD website at [www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk) under “General Public/Antimicrobial Related Information/Publications” tabs.

## ■ EUROPEAN SURVEILLANCE OF VETERINARY ANTIMICROBIAL CONSUMPTION (ESVAC)

The European Medicines Agency has developed a harmonised approach for the collection and reporting of antimicrobial sales data on a national basis and the UK participated as part of that working group. A report detailing the results from the pilot study has now been published and can be viewed at [www.ema.europa.eu](http://www.ema.europa.eu) under “Regulatory/Veterinary Medicines/Antimicrobial Resistance/European Surveillance of Veterinary Antimicrobial Consumption/Report of Trends in the sales of veterinary antimicrobial agents in nine European countries” tabs.

The VMD is part of the technical consultancy group for the ESVAC project and we have recently supplied data from 2010 to the project. A virtual meeting of the Technical Consultancy Group was held in January.

## ■ OTHER ANTIMICROBIAL ISSUES

The VMD attended the Responsible Use of Medicines in Agriculture Alliance (RUMA) meeting on 28 October 2011. Agenda items included: Chairman’s report on his activities since the last meeting, Secretary-General’s update, Antimicrobials/EU proposals, Conference on Responsible Antimicrobial Use, Netherlands 14-16 November 2011, Royal Society of Medicine seminar on AMR, 7 December 2011, Antimicrobial use in the dairy sector, Medicines distribution and public relations issues.

The European Commission published its “Action plan against the rising threats from antimicrobial resistance” on 17 November. This has 12 action points to address antimicrobial resistance which are aimed at human medicine as well veterinary medicine. We have yet to hear how the Commission intends to take forward these actions but strengthening the legislation on veterinary medicines is specifically mentioned in action 2. The document can be found on the European Commission’s website at [www.ec.europa.eu](http://www.ec.europa.eu) under “Departments (Directors-General) and services/Health and Consumers (SANCO)/Commission plan to combat antimicrobial resistance-Communication in all EU languages” tabs.

# SUSPECTED ADVERSE REACTION SURVEILLANCE SCHEME

*The definition of a Suspected Adverse Reaction (SAR) is taken from article 1, paragraph 10, of the Directive 2001/82/EC: "adverse reaction means a reaction which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or the modifications of physiological function". The definition of a human adverse reaction is taken from article 1, paragraph 11, of Directive 2001/82/EC "... means a reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine." In addition to this, the UK also include reports of suspected lack of expected efficacy, reports of off-label use of veterinary medicines, reports of environmental incidents and reported violations of approved maximum residue limits arising from the use of a veterinary medicinal product.*

During the period 1 October to 31 December 2011, the VMD received 975 suspected adverse reaction reports involving animals. Of these, 79 reports related to unauthorised use, 35 involved an unauthorised or unidentified product and 41 reports were considered unlikely to be product related. There were no reports involving animal trials under Animal Test Certificates (ATCs) and 124 reports involved suspected lack of efficacy.

The remaining 696 suspected adverse reaction reports were associated with 217 licensed products.

The 696 reports were divided by marketing categories as follows:

- 628 Prescription Only Medicine - Veterinarian (POM-V)
- 37 Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
- 23 Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
- 8 Authorised Veterinary Medicine - General Sales List (AVM-GSL)

During the quarter 23 reports of human suspected adverse reactions were received. All serious human incidents are considered by the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines. The information thus accrued is analysed to identify any trends or signals that need attention.

During the quarter there were no reports of environmental incidents received.

The SARSS Bi-monthly Reports for July and August and, September and October 2011 were presented to the VPC meeting in November 2011. The reports for November and December were presented at the January 2012 meeting.

**Further information: Denise Burge (VMD, 01932 338427, e-mail: [d.burge@vmd.defra.gsi.gov.uk](mailto:d.burge@vmd.defra.gsi.gov.uk)).**

## VETERINARY PRODUCTS COMMITTEE

*The Veterinary Products Committee (VPC) is a statutory committee established to:*

- i) provide the Secretary of State with scientific<sup>1</sup> advice on any aspect of veterinary medicinal products and specified feed additives;*
- ii) hear representations on decisions relating to the granting, refusal, variation, suspension or revocation of a marketing authorisation for a veterinary medicinal product or an animal test certificate;*
- iii) promote the collection of information relating to suspected adverse reactions for the purpose of enabling the advice at i) above to be given.*

*Each year the Veterinary Products Committee will publish a report of its activities and those of its Sub-Committees.*

*<sup>1</sup>Scientific advice means all aspects, including risk/benefit analysis, of the safety, quality and efficacy of a veterinary medicinal product apart from regulatory issues.*

### ■ MINUTES OF VPC MEETINGS

The VPC met in November and January. Summary minutes of the November meeting and all meetings held since 2007 are available on its website [www.vmd.defra.gov.uk/vpc/meetings/summary.aspx](http://www.vmd.defra.gov.uk/vpc/meetings/summary.aspx). The minutes of the January meeting will be published on the website on 24 February.

**Comments on the website or requests for further information on the summary minutes should be sent to Colin Bennett (VMD, 01932 338490, e-mail: [c.bennett@vmd.defra.gsi.gov.uk](mailto:c.bennett@vmd.defra.gsi.gov.uk)).**

# VETERINARY RESIDUES COMMITTEE

*The Veterinary Residues Committee (VRC) is an expert committee of Defra. It gives advice to the chief executives of the Veterinary Medicines Directorate (VMD) and the Food Standards Agency (FSA) on:*

- i) the incidence and concentrations of residues of veterinary medicines with particular reference to food safety and the observance of withdrawal periods for veterinary medicines;*
- ii) the scope and operation of the VMD statutory surveillance programme;*
- iii) formulating an annual non-statutory plan and advising on the scope and results of relevant FSA surveys; and*
- iv) publishing its Annual Report on Surveillance for Veterinary Residues in food in the UK.*

## ■ VETERINARY RESIDUES COMMITTEE OPEN MEETING

The Veterinary Residues Committee held its Open Meeting at the Food Standards Agency Headquarters in Kingsway, London on 12 October 2011. Members and advisors gave presentations explaining the work of the Committee as follows:

- Introduction to the Veterinary Residues Committee by Dorothy Craig;
- The Need for Veterinary Medicines A Farming Perspective by Tim Brigstocke;
- How residues surveillance fits into the authorisation process for veterinary medicines by Declan O'Rourke;
- Analysis of samples for Residues by Matthew Sharman, FERA ;
- The role of the Fish Health Inspectorate in the NSS for Veterinary Residues in Farmed Fish by Jon Hulland, CEFAS;
- FSA's review of the safety of imported food by Alan Curran, FSA;
- Significance of veterinary medicine surveillance results for consumers by Andy Spencer, FSA.

There were open sessions in the morning and afternoon to allow the attendees to ask questions of the Committee. Among the topics raised were:

- How the VRC communicates with its stakeholders and in particular how communication with beekeepers can be improved;
- How residues of a Veterinary Medicinal Product not licensed in the EU would be handled if they were found in an imported product;
- Whether any data is supplied by the industry and what is their reliance on the results of the residues programmes;
- Why the VMD is pressing for changes at a European level to ensure that the testing arrangements will in future concentrate surveillance on where risk is greatest;
- The presentations given at the meeting and the minutes are available on the VRC's website [www.vmd.defra.gov.uk/vrc](http://www.vmd.defra.gov.uk/vrc).

## ■ VETERINARY RESIDUES COMMITTEE MEETING ON 7 DECEMBER 2011

As well as discussing and advising on the latest results from the surveillance schemes, the Committee advised the VMD to reduce the monitoring thresholds for naturally occurring steroids such as boldenone and nortestosterone. The Committee also considered data on a number of thiouracil non-compliances which were linked to brassica-rich animal feed rather than any evident misuse of thiouracil. As a result, the Committee recommends that the European Reference Laboratory EURL recommended level of 10 µg/L should be adopted in the UK for the monitoring of thiouracil.

The Committee also received information on the following:

- Review of EU legislation on residues surveillance;
- Imports of veterinary medicines from countries inside and outside the EU;
- Issues relating to Communications – Annual Report, website and Open Meetings.

The agenda and papers of this meeting are available on the VRC website and the minutes will be published in due course.

**Further information: Caroline Povey (VMD, 01932 338327, e-mail: [c.povey@vmd.defra.gsi.gov.uk](mailto:c.povey@vmd.defra.gsi.gov.uk)).**

# RESIDUES CONTROLS & MONITORING

The VMD operates two complementary surveillance programmes for residues of veterinary medicines and other substances. The larger programme, the National Surveillance Scheme (NSS), implements EU legislation and therefore has a statutory basis. This programme covers the products set out below and is funded by the industry sectors in accordance with EU legislation.

The second programme is smaller and non-statutory. It focuses more on surveillance of imports of certain products where the presence of banned substances are most likely to be found. The programme is funded by Defra.

The independent Veterinary Residues Committee scrutinises and advises on the content of the VMD's (and FSA's) surveillance work.

## ■ RESULTS OF 2011 STATUTORY SURVEILLANCE

The VMD operates the statutory surveillance programme for residues of veterinary medicines and unauthorised substances in UK food producing animals as set out below.

Sampling commenced in January 2011 for the majority of species. Details of sample results since the report in MAVIS 80 are set out below.

Species	Number of Samples Analysed	Number of Non-Compliant Samples	Analyte Detected
Cattle	2230	22	Thiouracil(12) Alpha-nortestosterone(3) Alpha-boldenone(1) Neomycin(1) Taleranol (3) Taleranol + zeranol(2)
Pigs	993	2	Thiouracil
Sheep/Goats	1618	34	Thiouracil(1) Oxfendazole + fenbendazole(1) Cypermethrin(1) Alpha-nortestosterone(23) Alpha-boldenone(3) Alpha-nortestosterone + Alpha-boldenone(5)
Horses	27	0	
Rabbits	0	0	
Poultry	1617	0	
Farmed Game	39	0	
Wild Game	36	0	
Farmed Fish	235	0	
Milk	239	1	Nitroxylin
Eggs	133	2	Diclazuril
Honey	46	0	

The follow up investigations completed for samples where residues of thiouracil have been detected have concluded that the most likely cause of the residues are due to the animals being fed a brassica-rich diet.

Follow up investigations for residues of alpha-nortestosterone have shown no level of abuse of an unauthorised substance and the cause was most likely to be natural occurrence.

Please note that the cut-off dates for MAVIS and the VRC reports currently differ, so the number of non-compliant samples may not be the same.

Full details of all results together with information on any action taken can be found on the Veterinary Residues Committee's website [www.vmd.defra.gov.uk/vrc](http://www.vmd.defra.gov.uk/vrc) or by contacting Carol Brailsford (VMD, 01932 338330, e-mail: [c.brailsford@vmd.defra.gsi.gov.uk](mailto:c.brailsford@vmd.defra.gsi.gov.uk)).

## ■ RESULTS OF 2011 NON-STATUTORY SURVEILLANCE

The Non-statutory Surveillance programme mainly looks for the presence of prohibited substances in food from third countries. The programme can also carry out short surveys for areas of potential concern based on intelligence received. Samples for the programme are being collected from April 2011 to February 2012. Details of sample results since the report in MAVIS 80 are set out below.

Sample Type	Number of Samples Analysed	Number of Non-Compliant Samples	Analyte Detected
Farmed Warm Water Crustaceans	73	1	AOZ*
Imported Corned Beef	5	1	Abamectin
Imported Farmed Fish	88	2	Malachite green/leucomalachite green (2)
Imported Honey	25	1	Lincomycin
Imported Raw Beef	23	0	
Imported Raw Poultry	40	0	

Key: \*AOZ, 3-amino-2-oxazolidone, a metabolite of furazolidone

Please note that the cut-off dates for MAVIS and the VRC reports currently differ, so the number of non-compliant samples may not be the same.

**Full details of all results together with information on any action taken can be found on the Veterinary Residues Committee's website [www.vmd.defra.gov.uk/vrc](http://www.vmd.defra.gov.uk/vrc) or by contacting Dawn Greener (VMD, 01932 338325, e-mail: [d.greener@vmd.defra.gsi.gov.uk](mailto:d.greener@vmd.defra.gsi.gov.uk)).**

**MARKETING AUTHORISATIONS ISSUED  
BETWEEN 01 SEPTEMBER 2011 - 28 NOVEMBER 2011**

<b>Company</b>	<b>Vm Number</b>	<b>Product Name</b>	<b>Legal Category</b>
<b>aniMedica GmbH</b>	24745/4018	Dolocarp Flavour, 100 mg, Chewable Tablet for Dogs	POM-V
	24745/4016	Dolocarp Flavour, 20 mg, Chewable Tablet for Dogs	POM-V
	24745/4017	Dolocarp Flavour, 50 mg, Chewable Tablet for Dogs	POM-V
	24745/4013	Suispirin 1000 mg/g Oral Powder for Pigs	POM-V
<b>Bayer plc</b>	00010/4172	Baytril Inject 100 mg/ml Solution for Injection for Pigs	POM-V
	00010/4173	Seresto 1.25 g + 0.56 g, Collar for Cats	POM-V
	00010/4175	Seresto 1.25 g + 0.56 g, Collar for Cats and Dogs = 8 kg	POM-V
	00010/4174	Seresto 1.25 g + 0.56 g, Collar for Dogs = 8 kg	POM-V
	00010/4176	Seresto 4.50 g + 2.03 g, Collar for Dogs >8 kg	POM-V
<b>Chemo Iberica SA</b>	21690/4002	Prilben Vet 20 mg Film-Coated Tablet for Dogs	POM-V
<b>Eurovet Animal Health BV</b>	16849/4023	Eurofen 100 mg Tablets for Dogs	POM-V
	16849/4025	Eurofen 20 mg Tablets for Dogs	POM-V
	16849/4024	Eurofen 50 mg Tablets for Dogs	POM-V
	16849/4038	Forthyron 600 Microgram Tablets for Dogs	POM-V
	16849/4039	Forthyron 800 Microgram Tablets for Dogs	POM-V
	16849/4015	Soludox 500 mg/g Powder for Use in Drinking Water for Pigs and Chickens	POM-V
	16849/4014	Soludox 500 mg/g Powder for Use in Drinking Water for Pigs and Chickens	POM-V
	16849/4034	Thyforon Flavoured 200 Microgram Tablets for Dogs	POM-V
	16849/4035	Thyforon Flavoured 400 Microgram Tablets for Dogs	POM-V
	16849/4036	Thyforon Flavoured 600 Microgram Tablets for Dogs	POM-V
16849/4037	Thyforon Flavoured 800 Microgram Tablets for Dogs	POM-V	
<b>Krka Dd</b>	01656/4022	Marfloquin 100 mg/ml Solution for Injection for Cattle and Pigs (Sows)	POM-V
	01656/4025	Marfloquin 20 mg/ml Solution for Injection for Cattle (Calves) and Pigs	POM-V
	01656/4034	Toltarox 50 mg/ml Oral Suspension for Pigs	POM-V
	01656/4035	Toltranil 50 mg/ml Oral Suspension for Pigs	POM-V
	01656/4031	Eliminall 134 mg Spot-on Solution for Dogs	NFA-VPS
	01656/4032	Eliminall 268 mg Spot-on Solution for Dogs	NFA-VPS
	01656/4033	Eliminall 402 mg Spot-on Solution for Dogs	NFA-VPS
	01656/4029	Eliminall 50 mg Spot-on Solution for Cats	NFA-VPS
01656/4030	Eliminall 67 mg Spot-on Solution for Dogs	NFA-VPS	
<b>Laboratorios Calier, SA</b>	20634/4006	Banacep Vet 20mg Film-Coated Tablet for Dogs	POM-V
<b>Miklich Laboratorios S.L.</b>	35084/4001	Ubiflox 100 mg/ml Solution for Injection for Cattle and Pigs (Sows)	POM-V
	35084/4000	Ubiflox 20 mg/ml Solution for Injection for Cattle and Pigs	POM-V
	35084/4002	Ubiflox Cattle 100 mg/ml Solution for Injection for Cattle	POM-V
<b>Norbroad Laboratories Ltd</b>	02000/4301	Propentofylline 100 mg Film Coated Tablets for Dogs	POM-V
	02000/4300	Propentofylline 50 mg Film Coated Tablets for Dogs	POM-V
<b>Novartis Animal Health UK Ltd</b>	12501/4183	Atopica 100 mg/ml Oral Solution for Cats	POM-V
	12501/4178	Zobuxa 100 mg Tablets for Dogs	POM-V
	12501/4176	Zobuxa 15 mg Tablets for Cats and Small Dogs	POM-V
	12501/4179	Zobuxa 150 mg Tablets for Dogs	POM-V
	12501/4177	Zobuxa 50 mg Tablets for Cats and Dogs	POM-V
<b>Richter Pharma AG</b>	22080/4003	Bupaq Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats	POM-V
<b>Sogeval SA</b>	20749/4022	Doxyval 500 mg/g Powder for Use in Drinking Water for Sows, Broiler Breeders and Laying Hens	POM-V
	20749/4024	Kesium 250 mg Chewable Tablets for Dogs	POM-V
	20749/4023	Kesium 50 mg Chewable Tablets for Cats and Dogs	POM-V
	20749/4025	Kesium 500 mg Chewable Tablets for Dogs	POM-V
	20749/4026	Kesium 62.5 mg Chewable Tablets for Cats and Dogs	POM-V
<b>Vetoquinol UK Ltd</b>	08007/4126	Flevox 134 mg Spot-on Solution for Medium Dogs	NFA-VPS
	08007/4127	Flevox 268 mg Spot-on Solution for Large Dogs	NFA-VPS
	08007/4128	Flevox 402 mg Spot-on Solution for Very Large Dogs	NFA-VPS
	08007/4124	Flevox 50 mg Spot-on Solution for Cats	NFA-VPS
	08007/4125	Flevox 67 mg Spot-on Solution for Small Dogs	NFA-VPS
<b>Vetpharma Animal Health, S.L.</b>	32509/4007	Hipnoton 10 mg/ml Solution for Injection for Horses and Cattle	POM-V

**ALL MARKETING AUTHORISATIONS VARIED BY THE VMD  
BETWEEN 01 SEPTEMBER 2011 - 28 NOVEMBER 2011**

Company	Product Name	Brief Details
<b>Agrimin Ltd</b>	Rumbul Rumen Bullet 15 g Continuous Release Intraruminal Device, Sheep/Calves	} Change in the address of the marketing authorisation holder <i>from</i> The Flarepath, Elsham Wold Industrial Estate, Brigg, North Lincolnshire, DN20 0SP <i>to</i> Arlanda Way, Humberside Airport, Kirmington, North Lincolnshire, DN39 6YH.
	Rumbul Rumen Bullet 40 g Continuous Release Intraruminal Device, Cattle	
<b>Animax Ltd</b>	Copinox Cattle 24 g Capsule, Hard	Changes to the content and layout of the product literature.
<b>Arthroparm(Europe)Ltd</b>	Anarthron 100 mg/mL Solution for Injection	Change in immediate packaging of the finished product. Shelf-life change. Change in the storage conditions of the finished product.
<b>AST Beheer B.V.</b>	Clavubactin 500/125 mg Tablets for Dogs	} Change of the Marketing Authorisation Holder <i>from</i> AST Beheer B.V., Willeskop 212, 3421 GW Oudewater, Netherlands <i>to</i> Le Vet Beheer B.V., Wilgenweg 7, 3421 TV Oudewater, Netherlands.
	Clavoral 250/62.5 mg Tablets for Dogs	
	Clavoral 50/12.5 mg Tablets for Cats	
<b>Bayer Plc</b>	Baytril Max 10% Solution for Injection	} Change to the (invented) product name <i>from</i> Baytril Max 10% Solution for Injection <i>to</i> Baytril Max 100 mg/ml Solution for Injection for Cattle. Change in product name <i>from</i> Drontal Cat Tablets <i>to</i> Drontal Cat Film-coated Tablets. Change in product name <i>from</i> Drontal Plus Tablets <i>to</i> Bob Martin All in One Plus Dewormer Tablets for Dogs. Change in product name <i>from</i> Drontal Plus XL Tablets <i>to</i> Bob Martin All in One Plus XL Dewormer Tablets for Dogs.
	Drontal Cat Tablets	
	Drontal Plus Tablets	
	Drontal Plus XL Tablets	
<b>Bob Martin (UK) Ltd</b>	FleaClear Spot On Solution 134 mg for Medium Dogs	} Change the legal category <i>from</i> NFA-VPS <i>to</i> AVM-GSL.
	FleaClear Spot On Solution 268 mg for Large Dogs	
	FleaClear Spot On Solution 402 mg for Extra Large Dogs	
	FleaClear Spot On Solution 50 mg for Cats	
	FleaClear Spot On Solution 67 mg for Small Dogs	
<b>Ceva Animal Health Ltd</b>	Cevac Chlamydia	} Addition of warnings concerning rare cases of abortions and hypersensitivity reactions.
	Regulin 18 mg Implant	
	Cevac Transmune Lyophilisate for Suspension for Injection with Solvent for Chicken	
	Colibird Poultry, 2 MIU/ml Solution for Use in Drinking Water	
	Coliscour Oral Solution of Colistin Sulphate 2 MIU/ml	
Enzaprost 5 mg/ml Solution for Injection for Cattle and Pigs	} Change of address of the Marketing Authorisation Holder <i>from</i> 90 The Broadway, Chesham, Buckinghamshire, HP23 5HE <i>to</i> Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB.	

Company	Product Name	Brief Details
<b>Ceva Animal Health Ltd</b>	Equidronate 500 mg Lyophilisate for Solution for Infusion	Change of address of the Marketing Authorisation Holder <i>from</i> 90 The Broadway, Chesham, Buckinghamshire, HP23 5HE <i>to</i> Unit 3, Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB.
	Erythrocin 16.5% w/w Soluble Powder for Oral Solution	
	PRID 1.55 g Progesterone Releasing Intra-Vaginal Device	
	Spectam Injectable 10% w/v Solution for Injection	
	Spectam Scour Halt Oral Solution 50 mg/ml	
	Tiamvet Solution 12.5%	
	Cestem Flavoured Tablets for Large Dogs	
	Cestem Flavoured Tablets for Medium and Small Dogs	
	Proworm Flavoured Tablets for Large Dogs	Change in the (invented) name of the product <i>from</i> Proworm Flavoured Tablets for Large Dogs <i>to</i> Prowormer Flavoured Tablets for Large Dogs.
	Proworm Flavoured Tablets for Medium and Small Dogs	Change in the (invented) name of the product <i>from</i> Proworm Flavoured Tablets for Medium and Small Dogs <i>to</i> Prowormer Flavoured Tablets for Medium and Small Dogs.
	Seleen Shampoo 1% w/v	Change of address of the Marketing Authorisation Holder <i>from</i> 90 The Broadway, Chesham <i>to</i> Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB.
<b>Ceva Salute Animale S.p.A</b>	Galastop 50 ug/ml Oral Solution	Change to the name and address of the Marketing Authorisation Holder <i>from</i> Ceva Vetem S.p.A, Via Colleoni, 15 - 20041 Agrate Brianza (MI), Italy <i>to</i> Ceva Salute Animale S.p.A, Viale Colleoni, 15 - 20864 Agrate Brianza (MB), Italy.
<b>CP Pharma Handelsgesellschaft mbH</b>	Medetor 1 mg/ml Solution for Injection for Dog and Cat	Change in immediate packaging of the finished product.
	Medetor 1 mg/ml Solution for Injection for Dog and Cat	
<b>Eco Animal Health Ltd</b>	Ecomectin 10 mg/ml Solution for Injection Qualimec 10 mg/ml Solution for Injection	Change in immediate packaging of the finished product.
<b>Ecuphar NV</b>	Actikor 20 mg Film-coated Tablets for Dogs	Shelf-life change.
	Actikor 5 mg Film-coated Tablets for Dogs	
<b>Eli Lilly &amp; Company Ltd</b>	Pulmotil AC 250 mg/ml Concentrate for Oral Solution for use in drinking water or milk replacer	Shelf-life change.
<b>Eurovet Animal Health BV</b>	Soludox, 500 mg/g, Water Soluble Powder for Pigs	To update SPC following Commission decision.
<b>Evans Vanodine International Plc</b>	1:3 Concentrate Teat Dip/Teat Spray Solution and Udder Wash 2.15% w/v	Additional 1000 litre pack size for the finished product.
	Masodine 1:3 2.15% w/v Concentrate for Teat Dip and Spray Solution	Additional wording to the label under the heading for use as a pre-dipping disinfectant.

Company	Product Name	Brief Details
<b>Evans Vanodine International Plc</b>	Venture IO-Care 0.535% w/v Ready to Use Teat Dip and Teat Spray Solution	Additional 1000 litre pack size for the finished product.
<b>Fort Dodge Animal Health Ltd</b>	Duphacycline Aerosol 3.6% w/w Cutaneous Solution Spray	Change of Marketing Authorisation holder <i>from</i> Fort Dodge Animal Health Ltd, Flanders Road, Hedge End, Southampton, Hampshire, SO30 4QH <i>to</i> Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP.
<b>GEA Farm Technologies Ltd</b>	Suredip Repel 3.7% w/v Concentrate for Teat Dip or Teat Spray Solution	Change in the name of the Marketing Authorisation Holder and Distributor <i>from</i> GEA Farm Technologies Ltd <i>to</i> GEA Technologies (UK) Ltd.
	Suredip 0.74% w/v Teat Dip/Teat Spray, Solution-Ready to Use	
	Silkidip 0.5% w/v Teat Dip/Teat Spray, Solution-Ready to Use	
	Sensospray 70V Teat Dip/Teat Spray, Solution-Ready to Use	
	Luxspray 50V Teat Dip/Teat Spray, Solution-Ready to Use	
	Clinidip L Concentrate 2.0% w/v Concentrate for Teat Dip or Teat Spray Solution	
	Clinidip 2.5% w/v Superconcentrate Concentrate for Teat Dip or Teat Spray Solution	
<b>Intervet UK Ltd</b>	AquaVac Vibrio Immersion and Injection	Change of the Marketing Authorisation Holder in Portugal only <i>from</i> Schering-Plough II-Veterinaria, Lda <i>to</i> Intervet Portugal - Saude Animal, Lda.
	AquaVac Vibrio Oral	
	M+PAC	
	Regumate Porcine, 0.4% w/v Oral Solution	Additional user warning statement for the carton.
<b>Janssen-Cilag Ltd</b>	Furexel Combi Oral Paste	To add therapeutic indication.
<b>Johnson Diversey Ltd</b>	CPF Dairyclene Iodine (0.52%) RTU Teat Dip and Spray Solution	Change in the name of the Marketing Authorisation Holder <i>from</i> JohnsonDiversey UK Limited <i>to</i> Diversey Limited.
	Dairyclene Chlorhexidine Gluconate 0.425% w/w RTU Teat Dip and Teat Spray Solution	
	Dairyclene Iodine 2 % w/v Concentrate for Teat Dip and Spray Solution	
	Deosan Summer Teatcare Plus (0.425% w/w ) Teat Dip and Teat Spray Emulsion	
	Deosan Super Excel 0.52% w/v Teat Dip and Spray Solution	
	Deosan Super Iodip Iodine 2% w/v Concentrate Teat Dip and Teat Spray Solution	
	Deosan Teatcare Plus 0.425% w/w Teat Dip and Teat Spray Emulsion	
	Deosan Thixodip BA, 4.0% w/w Teat Dip Solution	

Company	Product Name	Brief Details
<b>JohnsonDiversey Ltd</b>	Iodine 2% w/v Concentrate for Teat Dip and Spray Solution	} Change in the name of the Marketing Authorisation Holder <i>from</i> Johnson Diversey UK Limited <i>to</i> Diversey Limited.
	MV Chlorhexidine (0.425%) RTU Teat Dip and Spray Solution	
	MV Iodine RTU Teat Dip/Spray	
	Star Iodocare Concentrate Teat Dip and Teat Spray Solution 2.00% w/v	
	Star Ready Dip, Iodine 0.58% w/v Teat Dip and Teat Spray Solution	
<b>Laboratorios Calier, SA</b>	Zipyran Plus Tablets for Dogs	Addition of a flavouring component to the final product.
<b>Le Vet B.V.</b>	Equibactin Vet (333 mg/g + 67 mg/g) Oral Paste for Horses	Shelf-life change.
	Floxabactin 15 mg Tablets for Cats and Dogs	} Change of Distributor <i>from</i> Le Vet B.V <i>to</i> Bimeda, A division of Cross Vetpharm Group UK Ltd.
	Floxabactin 150 mg Tablets for Dogs	
	Floxabactin 50 mg Tablets for Dogs	
<b>Norbrook Laboratories Ltd</b>	Pen & Strep Suspension for Injection	Shelf-life change.
<b>Novartis Animal Health UK Ltd</b>	Milbemax Chewable Tablets for Dogs	} Minor change to the primary pack.
	Milbemax Chewable Tablets for Small Dogs and Puppies	
<b>Novartis Animal Vaccines Ltd</b>	Ermogen	Change to eliminate the package leaflet and modify the text of the label so previous information found on both will only be on the label.
<b>Pfizer Ltd</b>	Cylap	Minor change to vial dimensions
	Duphaphen + Strep Procaine Penicillin 200 mg & Dihydrostreptomycin Sulphate 250 mg Suspension	Change in the storage conditions of the finished product.
	Duvaxyn EHV 1,4	Change in the name of the medicinal product <i>from</i> Duvaxyn EHV1,4, <i>to</i> Equip EHV1,4.
	KetoProPig 100 mg/ml Oral Solution for Use in Drinking Water for Pigs	Change in the name and/or address of the Marketing Authorisation holder in Poland.
	KetoProPig 100 mg/ml Oral Solution for Use in Drinking Water for Pigs	Change the Marketing Authorisation holder and distributor <i>from</i> Pfizer Limited <i>to</i> Labiana Life Sciences S.A.U. Spain.
	Synulox Palatable Drops, Powder for Oral Suspension	Change in immediate packaging of the finished product.
	Dysect Sheep Pour-on, Alphacypermethrin 12.5 g/l Pour-on Solution	Change in the storage conditions of the finished product.
	Zermex 0.5% w/v Pour-on Solution for Cattle	Changes to the withdrawal period for milk to 6 days (144 hours).
<b>Schering-Plough Ltd</b>	Imizol 85 mg/ml Solution for Injection	Change of Marketing Authorisation Holder and Distributor <i>from</i> Schering Plough Ltd <i>to</i> Intervet UK Ltd.
	Otomax Ear Drops Suspension	Change in description and composition of the final product.
	Resflor 300/16.5 mg/ml Solution for Injection for Cattle	} Change of Marketing Authorisation Holder and Distributor <i>from</i> Schering-Plough Ltd <i>to</i> Intervet UK Ltd.
	Slice 2 mg/g Premix for Medicated Feeding Stuff	
<b>Vetpharma Animal Health, S.L</b>	Sededorm 1 mg/ml Solution for Injection for Dogs and Cats, Medetomidine Hydrochloride	Change of Distributor <i>from</i> Codifar NV <i>to</i> Bimeda, a division of Cross Vetpharm Group (UK) Ltd.

Company	Product Name	Brief Details
<b>Virbac S.A.</b>	Nobivac FeLV, Suspension for Injection for Cats Powerflox 100 mg/ml Solution for Injection for Cattle and Pigs Enrofloxacin Powerflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats Enrofloxacin	Change to vial label to improve legibility. Shelf-life change.
<b>Vita (Europe) Ltd</b>	Apiguard Gel (25% Thymol) for Beehive Use	Change in the address of the Marketing Authorisation Holder <i>from</i> Vita (Europe) Limited, 21/23 Wote Street, Basingstoke, Hampshire, RG21 7NE, UK <i>to</i> Vita (Europe) Limited, Vita House, London Street, Basingstoke, Hampshire, RG21 7PG.

### EXPIRED MARKETING AUTHORISATIONS BETWEEN 01 SEPTEMBER 2011 - 28 NOVEMBER 2011

Company	Vm Number	Product Name	Legal Category
<b>Agrimin Ltd</b>	04261/4001	Bloat Guard Premix 53% w/w Poloxalene Premix for Medicated Feeding Stuff	POM-V
<b>Agrimin Ltd</b>	04261/4002	Bloat Guard Drench, 83.33% w/v Poloxalene in an Oral Solution	POM-VPS
<b>Bayer Plc</b>	00010/4111	Fleegard 10 mg for Dogs Spot-on Solution	POM-V
	00010/4112	Fleegard 20 mg for Dogs Spot-on Solution	POM-V
	00010/4108	Fleegard 4 mg for Cats Spot-on Solution	POM-V
	00010/4110	Fleegard 4 mg for Dogs Spot-on Solution	POM-V
	00010/4109	Fleegard 8 mg for Cats Spot-on Solution	POM-V
<b>Bio-Tech Solutions Ltd</b>	20889/4001	Bio-Tech's Anti-Flea and Anti-Tick Drops for Dogs	AVM-GSL
	20889/4004	Bio-Tech's Flea and Tick Drops for Dogs	AVM-GSL
<b>Bob Martin (UK) Ltd</b>	00715/4084	Vetzyme Antiseptic Cutaneous Powder	AVM-GSL
<b>Eurovet Animal Health BV</b>	16849/4003	Soludox 500 mg/g Powder for use in Drinking Water for Pigs and Chickens	POM-V
<b>Intervet International BV</b>	06376/4055	Zitac Vet 50 mg Tablets for Dogs	POM-V
<b>Kilco Chemicals Ltd</b>	01936/4013	Action Actodine New Formulation	AVM-GSL
	01936/4012	Supercare Summer TG	AVM-GSL
<b>Mr J J &amp; Mrs M A Zakarias</b>	00292/4003	Sulphur Colecton (Horses & Ponies)	AVM-GSL
<b>Novartis Animal Vaccines Ltd</b>	18343/4014	Furogen 2	POM-V
<b>Pfizer Ltd</b>	00057/4408	Duramune DAPPI + L	POM-V
	00057/4252	Lincocin Tablets 100 mg	POM-V
	00057/4253	Lincocin Tablets 500 mg	POM-V
	00057/4230	Pregsure BVD Emulsion for Injection	POM-V
	00057/4418	Zulvac 1 Bovis, Suspension for Injection for Cattle	POM-V
	00057/4417	Zulvac 1 Ovis Suspension for Injection for Sheep	POM-V
<b>Schering-Plough Ltd</b>	00201/4221	Florvetol 300 mg/ml Solution for Injection for Cattle	POM-V
	00201/4220	Florvetol 300 mg/ml Solution for Injection for Swine	POM-V
	00201/4223	Procyon Dog Lepto	POM-V
	00201/4168	Coopers Ectoforce Sheep Dip 60% w/w Concentrate for Dip Solution	POM-VPS
<b>Sogeval SA</b>	20749/4000	Amoxival 40 mg Tablet Cat	POM-V

**EUCE AUTHORISATIONS ISSUED  
BETWEEN 01 SEPTEMBER 2011 - 28 NOVEMBER 2011**

<b>Company</b>	<b>Vm Number</b>	<b>Product Name</b>	<b>Legal Category</b>
<b>CF PHARMA LTD</b>	EU/2/11/133/001-003	Recocam 20mg/ml Meloxicam Solution for Injection for Use in Cattle, Pigs and Horses	POM-V
<b>Intervet International BV</b>	EU/2/11/132/001-004	Nobivac Myxo-RHD	POM-V
<b>Nexcyon Pharmaceuticals Ltd</b>	EU/2/11/127/001	Recuvyra 50 mg/ml Transdermal Solution for Dogs	POM-V
<b>Norbrook Laboratories Ltd</b>	EU/2/08/090/019-22	Loxicom 1 mg Chewable Tablets for Dogs	POM-V
	EU/2/08/090/023-026	Loxicom 2.5 mg Chewable Tablets for Dogs	POM-V