MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 92 - OCTOBER 2014

NEWS

THE OPEN MEETINGS OF THE VETERINARY MEDICINES DIRECTORATE AND THE VETERINARY PRODUCTS COMMITTEE (VPC)

The VMD and VPC held their open meetings on 8 October 2014 at the Animal and Plant Health Agency, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3NB www.gov.uk/government/organisations/animal-and-plant-health-agency.

A recording of the meeting is available at www.vmd.defra.gov.uk.

For further information please contact Colin Bennett (VMD, email: c.bennett@vmd.defra.gsi.gov.uk, 01932 338490).

DEPARTURE OF DIRECTOR OF AUTHORISATIONS

Jackie Atkinson left the VMD on 3 October 2014.

Since joining the VMD in 1989 and taking up the Director of Authorisations role in 2007, Jackie has played a pivotal role in setting the strategic direction for the VMD and made a huge contribution to our success and high reputation in the UK and worldwide. We wish her well in her new career.

ELECTRONIC INVOICES

If you are still receiving paper invoices from the VMD and would like to receive these electronically please send an email to: financepost@vmd.defra.gsi.gov.uk quoting your customer reference number and the email address for invoices to be sent to.

For further information please contact: Hazel Birch (VMD, email: h.birch@vmd.defra.gsi.gov.uk, 01932 338378).

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Veterinary Medicines Directorate

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NEWS

THE SECOND ROUND OF VPP INSPECTIONS WILL START ON 1 OCTOBER 2014

From 1 October 2014, we will begin the second round of inspections of those veterinary practice premises (VPPs) that are not part of the RCVS's Practice Standards Scheme.

Our first inspections were advisory – to explain the requirements of the Veterinary Medicines Regulations (VMR) to vets - and to 'benchmark' current compliance. On the second and subsequent inspections, we will deal with deficiencies (non-compliances) in accordance with our published Enforcement Strategy www.vmd.defra.gov.uk/pdf/EnforcementStrategy.pdf. The Strategy categorises deficiencies as minor, major and critical and sets out how those deficiencies are dealt with.

The inspection criteria
The inspection criteria for VPPs are set out in Annex B of VMGN 3: *Guidance for Retailers* www.vmd.defra.gov.uk/pdf/vmgn/VMGNote03.pdf.

The criteria include legal requirements and good practice requirements: the legal requirements are highlighted in bold type.

Dealing with non-compliance
From the second inspection, only non-compliance with legal requirements will be reported as 'deficiencies'. Failure to comply with the good practice requirements will be noted as 'recommendations'.

Non-compliance with legal requirements that were reported at the previous inspection and which haven't been corrected, will be escalated to a 'next level' deficiency e.g. a repeated minor deficiency will be cited as a 'major'. This is an important point, as the number and type of deficiencies determine the interval to the next inspection. For further information about this risk-based inspection policy, please see paragraph 58 of VMGN 3.

Commonly found deficiencies
At the second inspection we will focus on the most commonly found deficiencies:

◊ Controlled Drugs (CDs).
- not storing CDs in a secure cabinet
- not restricting access to the CD cabinet to specifically authorised staff
- failing to accurately maintain the CD Register or not having a CD Register in the format required by the Misuse of Drugs Regulations
- faxing requisition orders for Schedule 2 and 3 CDs to wholesalers and not sending a hard copy order signed by a vet.

For further information about CDs, please see VMGN 20: *Controlled Drugs* *www.vmd.defra.gov.uk/pdf/vmgn/VMGNote20.pdf*.

◊ Not properly recording the supply/administration of prescription only medicines (POMs) to food producing species.
- when administering POM-V and POM-VPS medicines on farm, vets not entering the details in the farmer's medicines records (or not supplying the farmer with the relevant details at the time for the farmer to enter in his or her records)
- when administering products under the cascade to food-producing animals, not recording the identification of the animal(s) or the clinical assessment on clients' records
- not recording batch details of medicines administered to 'pet chickens', which are food-producing animals.

◊ Not recording 'broach dates' on containers (where required by a product's SPC).

◊ Using out-of-date medicines, including those past their 'broached' use-by date.

◊ Not including all of the required information on labels of products supplied under the cascade e.g. the name of the prescribing vet, the species and the expiry date if supplied without the original packaging.

We will also check that the temperatures of fridges used to store medicines, such as vaccines, are being appropriately monitored and recorded.

Further information
Practices are strongly advised to review their first inspection report and make sure that they continue to comply with the requirements of the VMR.

For further information please contact: Inspections Administration Team (VMD, email: inspections@vmd.defra.gsi.gov.uk, 01932 338474).

ISO 9001 AND ISO 27001: SUCCESSFUL ANNUAL SURVEILLANCE VISITS

Following the VMD's certification and re-certification last year for, respectively, ISO 9001 (quality management requirements) and ISO 27001 (our Information Security Management System), we underwent surveillance visits in September. These visits happen every year over the three year period that the certifications last and check that we are continuing to meet the requirements of the standards including demonstrating continual improvement.

We are very pleased to say that the auditors have recommended our continued certification for both international standards. They also did not raise any non-conformities against either standard. The auditors suggested areas where we may need to consider improving our processes and procedures. We are considering these recommendations and, where appropriate, we will be implementing them as part of our ongoing continual improvement work.

For further information please contact: Matthew Isted (VMD, email: m.isted@vmd.defra.gsi.gov.uk, 01932 338347).

PROPOSALS FROM THE EU COMMISSION FOR REVISED LAW ON VETERINARY MEDICINES AND MEDICATED FEEDINGSTUFFS

The EU Commission released the proposals for revised law on veterinary medicines and medicated feedingstuffs on 10 September 2014. The proposals can be found on the Commission website at:

http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm - Veterinary medicines proposal

http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_en.htm - Medicated feed proposal

Stakeholder workshops to seek and understand the industries views on the impact of the proposals are due to take place on the following dates:

- Monday 10 November – Marketing Authorisations, including approval and post authorisation actions
- Tuesday 18 November – Medicated feed
- Monday 24 November – supply and use of Veterinary Medicines, including advertising

Each workshop will be held on the VMD site and start at 10 am with tea and coffee available from 9.30 am. A lunch will be provided.

Feedback from these workshops will be used to inform the UK negotiation position.

For further information please contact: Jo Cawthorne (VMD, email: j.cawthorne@vmd.defra.gsi.gov.uk, 01932 338317) or Lea Reynolds (VMD, email: l.reynolds@vmd.defra.gsi.gov.uk, 01932 338321).

HORSE MEDICINES: REVISED INFORMATION FOR OWNERS AND KEEPERS

A revised printable leaflet aimed at horse owners and keepers is now available at www.vmd.defra.gov.uk/public/leaflets.aspx.

For further information please contact: Vivienne Saville (VMD, email: v.saville@vmd.defra.gsi.gov.uk, 01932 338438).

IMPORTANT INFORMATION FOR CAT AND DOG OWNERS – PERMETHRIN: DON'T PUT YOUR CAT AT RISK

Information and advice written for cat and dog owners is now available as a printable pdf file. www.vmd.defra.gov.uk/vet/adverse.aspx.

For further information please contact: Giles Davis (VMD, email: g.davis@vmd.defra.gsi.gov.uk, 01932 338467).

LICENSING

JOINT-LABELLING[1] BETWEEN THE UK AND IRELAND: GUIDANCE FOR THE PHARMACEUTICAL INDUSTRY

Following your feedback, the VMD and HPRA[2] have reviewed the procedures for obtaining and maintaining joint-labelling.

A revised clarification paper has been drafted and published on the VMD and HPRA websites (http://www.vmd.defra.gov.uk/pdf/clarification_JointLabelling.pdf); this replaces the previous clarification papers on harmonisation and joint-labelling procedures and provides clearer guidance on the procedure to be followed for maintaining joint-labelling.

The clarification paper provides guidance on:

- obtaining joint-labelling at the end of a new Mutual Recognition or Decentralised procedure
- obtaining joint-labelling for mutually recognised products as a stand-alone procedure
- obtaining joint-labelling for nationally authorised products *(previously known as harmonisation)*
- maintenance of joint-labelling.

By reviewing these procedures both the VMD and HPRA have taken the opportunity to ensure staff are trained in these procedures and are aware of their responsibilities in achieving and maintaining joint-labelling.

It is also recognised that in the UK mock-ups should be submitted within 20 days but in Ireland this is 30 days. Therefore, for procedures involving joint-labelling only, 20 days should be the target, but the UK are content for mock-ups to be provided by 30 days to enable a consistent approach with Ireland.

At the beginning of a joint-labelling procedure you will be given the timetable and name of the lead country; two things you asked for in the recent customer survey.

We hope this review has resulted in much clearer guidance and more streamlined procedures; however, we always welcome your feedback and the opportunity to continually improve our service, so please send any comments to the email address below.

[1] Joint-labelling is where a single label is agreed, which can be used on packs destined for Ireland and / or the UK.

[2] Formerly known as the Irish Medicines Board (IMB). Please note, as this paper was published before 1 July, reference is made to the IMB rather than HPRA. HPRA stands for Health and Products Regulatory Authority.

For further information please contact: Natalie Shilling (VMD, email: n.shilling@vmd.defra.gsi.gov.uk, 01932 338452).

CHANGE OF LEGAL CATEGORY[1] FOR NATIONAL OR MUTUALLY RECOGNISED PRODUCTS[2]: GUIDANCE FOR THE PHARMACEUTICAL INDUSTRY

Changing a product's legal category is a Type II variation, which will be dealt with on a national basis regardless of the scope of the authorisation, i.e. national or mutually recognised[3].

This variation can result in changes to the product's Summary of Product Characteristics (SPC) and/or labels and package leaflet, which means that other member states will need to be involved in the case of mutually recognised products in order to maintain the harmonised status of the product's SPC, labels and package leaflet.

To achieve this we have introduced a new step into the procedure for mutually recognised products, where changes are proposed to the SPC and/or labels and package leaflet, so that we may agree proposed changes with other member states before approving the change of legal category variation. The changes, we believe, will result in a more efficient and effective process and will avoid the scenario of the VMD approving a change that other member states may not agree with, or vice versa.

The changes are as follows. Once we have assessed the variation (and, where appropriate, obtained advice from the Veterinary Products Committee) and it is likely that the variation will be approved, the clock will stop and we will ask you to submit a suitable variation to the RMS and CMSs to obtain approval of the proposed changes to the SPC and/or labels and package leaflet. Once this European variation is complete, and assuming that we are content with the outcome, the clock will restart on the national variation and the change of legal category will be approved.

We hope this additional step will ensure a much smoother process for all; however, we always welcome your feedback and the opportunity to continually improve our service, so please send any comments to the email address below.

[1] Also known as 'distribution category', e.g. AVM-GSL, POM-V, etc

[2] This article does not cover legal category changes in relation to centrally authorised products

[3] Authorised via the mutual recognition or decentralised procedure.

For further information please contact: Natalie Shilling (VMD, email: n.shilling@vmd.defra.gsi.gov.uk, 01932 338452).

VALIDATION OF NEW MARKETING AUTHORISATION APPLICATIONS DURING THE CHRISTMAS PERIOD

The last validation meeting to discuss applications for new Marketing Authorisations (MAs) will take place on 19 December 2014. Applications to be considered for validation must be received on or before 16 December 2014.

For further information please contact: Abigail Seager (VMD, email: a.seager@vmd.defra.gsi.gov.uk, 01932 338465).

DISTRIBUTION OF VETERINARY MEDICINAL PRODUCTS (VMPS): GUIDANCE FOR THE PHARMACEUTICAL INDUSTRY

The Veterinary Medicines Regulations (VMR) set out that the holders of a Manufacturing Authorisation (ManA) or Wholesale Dealers' Authorisation (WDA) may wholesale supply VMPs in accordance with the terms of their authorisation. Marketing Authorisation Holders (MAH) may also wholesale supply products for which they hold the Marketing Authorisation (MA) without the need for a WDA. As such, only a ManA holder, WDA holder, or the MAH of a product may be named as a distributor on an MA.

The difference between a wholesaler of VMPs and a named distributor of a VMP is that a named distributor is approved as part of the product's MA and their name and address can appear on the product's labels, i.e. 'distributed by …', instead of the MAH name and address, i.e. 'Marketing Authorisation Holder …'. A named distributor may also have its own livery, i.e. branding.

In the UK, named distributors are recorded on a product's memorandum document, which accompanies a product's MA documentation.

In summary:

1. To be a named distributor on a product's MA, you must hold a ManA, WDA, or be the MAH of that product.
2. An MAH does not need to hold a WDA in order to wholesale supply their own products; however, they must still comply with Good Distribution Practice (GDP).
3. An MAH does need to hold a WDA if they wish to wholesale supply, or be a named distributor of another MAH's product.
4. Either the MAH's name and address, or the name and address of a named distributor must appear on a product's labels.
5. A named distributor, who is not the MAH, may be based anywhere in the EU and should hold a WDA granted by the member state in which the site is based, or a ManA, which permits the holder to wholesale supply.
6. The name and address of a local representative should appear on the labels if the MAH, or named distributor is based outside of the UK. Please note, whilst this is not a legislative requirement, it is VMD policy and good practice to include a UK name and address on the labels to ensure that users are able to contact someone easily to discuss any problems or concerns with the product.
7. If a WDA is provided in support of a named distributor, the name and address on the WDA must be the same as the proposed named distributor.
8. There may be more than one named distributor on an MA, but the details of the product including its name, Vm number etc. remain the same regardless of who is distributing the product. The only difference on the labels will be the name and address of the named distributor (or local representative) and, possibly, the livery in which it is to be distributed.

New MAs

If the name and address of a proposed named distributor is not provided with an application to obtain a new MA, it will be assumed that the MAH is to be the named distributor and this will be noted on the product's memorandum document. If the holder of a WDA or ManA is to be a named distributor, a copy of the WDA or ManA should be submitted with the application.

Changes to named distributor details

A change (addition/deletion/amendment) to distributor details is an unforeseen variation dealt with as a Type IB on a national basis regardless of the scope[1] of the MA, i.e. mutually recognised or nationally authorised; refer to link www.vmd.defra.gov.uk/pdf/UnforeseenVariations.pdf.

Applicants **should not** submit this change under the category C.II.6 (a), a Type IA variation, which deals with changes including those to the administrative information concerning the holder's representation, i.e. local representative.

Local representatives and named distributors perform different roles, although a single company may perform both roles for a specific Marketing Authorisation.

Mock-Ups

Mock-ups of all liveries should be provided with applications in accordance with the guidance provided in Veterinary Medicines Guidance Note (VMGN) No.2, which is available on the VMD website. If the livery is the same for all named distributors, the VMD is happy to accept one set of mock-ups with a declaration that the name and address of the other authorised distributors will be shown accordingly.

[1] For centralised products, please contact the European Medicines Agency (EMA) for further information.

For further information about the legislative aspects of this issue, please contact Lea Reynolds (VMD, l.reynolds@vmd.defra.gsi.gov.uk, 01932 338321).

For further information about changes to distributor details or other procedural issues, please contact Natalie Shilling (VMD, n.shilling@vmd.defra.gsi.gov.uk, 01932 338452).

NEW QUALIFIED PERSON (QP) DECLARATION TEMPLATE

Annex 5.19 of all Marketing Authorisation application forms should be submitted in the format of the "QP declaration template" as published by the EMA (EMA/334808/2014) effective from June 2014**.** The declaration is applicable to all new Marketing Authorisations and appropriate variations. Failure to submit this declaration will result in your application being deferred at validation. Information is available from the EMA website www.ema.europa.eu.

For further Information please contact: Howard Stenson (VMD, email: h.stenson@vmd.defra.gsi.gov.uk, 01932 338484).

PRE-ASSESSMENT OF RESPONSES WHEN ACTING AS REFERENCE MEMBER STATE (RMS)

The VMD has been asked on occasion to pre-assess applicant's responses to questions presented in the list of questions. While in our role as RMS we are happy to provide support to applicants which includes providing clarity on any questions that have been asked, it is generally not possible to pre-assess responses given our high work load and many priorities.

In the situation where the original question has been asked by a CMS it is not possible to reliably predict whether the CMS will be satisfied by a particular response and as a consequence any pre-assessment could be misleading. The other point we have to consider is that a fundamental principle of the RMS, and of a National Competent Authority, is that we must remain impartial whilst leading assessment in a procedure. We are not in a position to be able to offer you detailed assistance in developing your response to a particular question. There is a fine balance to be struck where we have to maintain our role as a regulator without straying into the area of consultancy.

Therefore, we would not expect to be asked to pre-assess responses. However, in exceptional circumstances and for a small number of particularly difficult questions assessors are happy to discuss with you the general approach to such questions and to provide some points to consider to help you finalise your responses.

For further information please contact: Alex Tait (VMD, email: a.tait@vmd.defra.gsi.gov.uk, 01932 338391).

AUTOGENOUS VACCINES – CHANGES TO APPLICATION PROCESS

Manufacturers of autogenous vaccines may apply for a specialist manufacturing authorisation, an Autogenous Vaccine Authorisation (AVA), to permit them to make and supply under specific circumstances that vaccine in the UK. Autogenous vaccines are manufactured from pathogens or antigens obtained from one animal source and used for the treatment of the same animal and/or other animals within the same epidemiological unit or in the same rearing chain. There are two types of AVA, an AVA-I (individual) or AVA-S (standard). An AVA-I covers the production of a single batch of product and will be valid for one year from the date it was granted. An AVA-S covers the ongoing production of the products specified in the authorisation. This authorisation will be valid continuously, subject to satisfactory re-inspection of the production premises.

Since 1 May 2014, AVAs will only be granted if a veterinary surgeon has confirmed a need and fully justified the use of the autogenous vaccine in preference to alternative UK or EU authorised veterinary medicines. Therefore, in addition to completion of the appropriate application form, the manufacturer as the applicant is also required to provide a signed declaration (annex 1), which has been completed by an RCVS registered UK veterinary surgeon. The premises where the autogenous vaccine is to be administered should be specified as should the species to be treated and the disease. The veterinary surgeon should justify the clinical need to use an autogenous vaccine for each pathogen. Details are required as to what authorised veterinary medicines have been considered or administered and why these are thought to be unsatisfactory. Where it is argued that an authorised veterinary medicine has proven to be ineffective, the veterinary surgeon will be expected to confirm that they have reported this suspected lack of efficacy to the Marketing Authorisation Holder or the VMD.

Application forms for new or variations to existing AVAs are available at www.vmd.defra.gov.uk/pharm.aspx.

Further information on autogenous vaccine authorisations can be found within VMGN 15 at www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

For further information please contact: Alison Young (VMD, a.young@vmd.defra.gsi.gov.uk, 01932 338408).

SHEEP FLY STRIKE TREATMENT PRODUCTS

The VMD is aware that due to the mild autumn there may be an increased demand for UK authorised products to treat fly strike in sheep.

The VMD has contacted Marketing Authorisation holders for relevant UK authorised veterinary medicinal products indicated for the treatment/prevention of fly strike to confirm the availability status. Although supply of certain veterinary medicinal products may become intermittent over the coming months, alternative products are available.

The VMD would recommend UK veterinary surgeons to contact the relevant Marketing Authorisation holder for further information on how to obtain an available product(s).

Information on all veterinary medicinal products currently authorised in the UK is available at www.vmd.defra.gov.uk/ProductInformationDatabase/.

If veterinary surgeons are aware of any alternative EU authorised products, import certificate applications may be submitted online, via the VMD at www.vmd.defra.gov.uk/sis/default.aspx. Each application will be assessed on its individual merits and is subject to the provision of suitable justification as to why currently available veterinary medicinal products are not suitable for use.

For further information please contact: Renee Sheehan (VMD, email: r.sheehan@vmd.defra.gsi.gov.uk, 01932 338374).

THE VMD PHASES OUT THE IMPORTATION OF VIRGINIAMYCIN FOR VETERINARY USE

The VMD previously announced (10 July 2012) that it would be phasing out the importation of products containing Virginiamycin for veterinary use over a two year period. Virginiamycin is the active ingredient in Founderguard, a veterinary medicine used to prevent laminitis, a painful hoof condition, in horses.

Since 1 October 2014, the VMD is no longer issuing import certificates permitting the importation of products containing Virginiamycin into the UK. This includes issuing repeat applications.

Existing import certificates for Founderguard will remain valid until the date of expiry cited on the certificate.

Any remaining product held upon expiry of the existing certificate should be disposed of immediately in accordance with local requirements.

It is an offence to be in possession of any imported veterinary medicinal products without a valid certificate granted by the Secretary of State under the Veterinary Medicines Regulations 2013.

WHY?

Virginiamycin is a streptogramin defined by the World Health Organisation as a class of antibiotics **critically important** in human medicines. The VMD decided to phase out the use of Founderguard as there is no robust evidence to suggest that the continued use of Virginiamycin will not pose a risk in terms of antimicrobial resistance developing.

In addition, there is no robust evidence that Founderguard prevents laminitis. This condition can be managed through animal husbandry and pasture management.

The phasing out of the use of Founderguard is part of the UK's approach to reduce the risk of organisms developing resistance to antibiotics and therefore helping to safeguard human health and animal health.

The VMD encourages veterinary surgeons and horse owners to explore alternative arrangements in the management of laminitis.

The VMD's decision has been welcomed by the British Equine Veterinary Association (BEVA) and the British Veterinary Association (BVA).

For further Information please contact: Abi Seager (VMD, email: a.seager@vmd.defra.gsi.gov.uk, 01932 338465).

TOP 10 IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 JULY - 30 SEPTEMBER 2014

The VMD provides a list on a quarterly basis of the 10 products for which the most Special Import and Special Treatment Certificates (SIC and STC) have been granted. This list contains details of the product, the active ingredient and the number of certificates issued. Where appropriate it will also indicate those imported products where a UK product is now authorised and available; no further imports of these products will be permitted.

We hope the pharmaceutical industry find this list helpful in considering where there might be a need for a UK authorised product.

Product	Active Ingredient	No. of Certificates Issued
Artuvetrin - Injectable Suspension	Allergens	1,831
Greer Allergy - Injectable Solution	Allergens	595
Apoquel 16 mg film-coated tablets for dogs *	Oclacitinib maleate	590
Apoquel 5.4 mg film-coated tablets for dogs *	Oclacitinib maleate	568
Apoquel 3.6 mg film-coated tablets for dogs *	Oclacitinib maleate	553
Vet-Goid	Allergens	259
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	199
ACTT Allergy Drops	Allergens	78
Staphage Lysate (SPL)	Staphylococcus Aureus	62
Botulism Vaccine	Clostridium botulinum type C toxoid	59

* *Supply problem with UK labelled product*

For further information please contact: Abi Seager (VMD, email: a.seager@vmd.defra.gsi.gov.uk, 01932 338465)

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.

SEIZURE NOTICES

Since the last edition of *MAVIS* no seizure notices have been published.

IMPROVEMENT NOTICES

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

Farmsense Ltd, Lytham St Annes, Lancashire, was offering for sale a veterinary medicine, Rotaplus, without having a marketing authorisation for the product. The notice required all marketing, sale and supply of Rotaplus in the UK to cease.

IFGA at BEVA Congress, Birmingham, West Midlands, was advertising unauthorised veterinary medicines for administration to animals. The notice required the advertising to cease.

OUTCOMES OF PROSECUTIONS

On 4 September 2014 at Croydon Crown Court, Mr Meddes was ordered to make a payment of £39,353.68 within six months under the Proceeds of Crime Act and Ms Regine Lansley was ordered to make a payment of £41,417.93 within six months under the Proceeds of Crime Act. Failure to pay will result in a default prison sentence of 14 months in both cases. Mr Meddes was previously sentenced to 28 months imprisonment after admitting illegal importation and supply of veterinary medicines under the Veterinary Medicines Regulations and Ms Lansley was previously sentenced to 20 months imprisonment after admitting illegal importation and supply of veterinary medicines under the Veterinary Medicines Regulations.

SALES OF NFA-VPS ONLINE – USE OF DISCLAIMERS

We have noticed an increase in disclaimers appearing on websites, implying that RQPs (vets, pharmacists and suitably qualified persons) do not need to be actively involved in sales.

The Veterinary Medicines Regulations requires retailers selling NFA-VPS veterinary medicines to make sure their customer is competent to use the product. When selling over the internet, this obligation cannot be shifted onto the customer by using disclaimers.

Online retailers should also ask for sufficient information about the animal to be treated to allow their RQP to check that the medicine will be used for an authorised use. The RQP must also advise the customer on how to use the product safely and about any warnings or contra-indications.

Further information on this issue can be found at www.vmd.defra.gov.uk/index.aspx.

Reports of non-compliance can be sent to the Enforcement team at: enforcement@vmd.defra.gsi.gov.uk. Reports are actively pursued and are treated in the strictest confidence.

For further information please contact: Simon Hack (VMD, email: enforcement@vmd.defra.gsi.gov.uk, 01932 338306).

PHARMACOVIGILANCE

Pharmacovigilance is defined by the World Health Organisation as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem."

International veterinary regulatory guidance defines an adverse event as "any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of a veterinary medicinal product (off-label and on-label uses). Included are events related to a suspected lack of expected efficacy according to approved labelling or noxious reactions in humans after being exposed to a veterinary medicinal product."

European legislation also requires that reports of environmental incidents and cases where the approved maximum residue limits have been exceeded following use of veterinary medicinal products are monitored.

■ QUARTERLY REPORT

During the period 1 July to 30 September 2014, the VMD received 1,390 suspected adverse event reports involving animals. Of these, 27 reports related to unauthorised or unidentified products and 36 reports involved animal trials under Animal Test Certificates (ATCs). Excluding these two categories, the remaining 1,327 suspected adverse event reports were associated with 346 authorised products.

The 1,327 reports were divided by distribution categories as follows:

1,103	Prescription Only Medicine - Veterinarian (POM-V)
131	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
42	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
39	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
12	Small Animal Exemption Scheme (N/A)

During the quarter 28 reports of human suspected adverse reactions were received. In addition 24 environmental incidents were received, although they all related to incidents occurring some years ago.

For further information please contact: Roy Savory (VMD, email: r.savory@vmd.defra.gsi.gov.uk, 01932 338427).

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance is of concern in human and veterinary medicines, resulting in increasing consideration 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 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 UPDATE

The joint DARC-ARHAI subgroup met on 2 September 2014 at the VMD. The group discussed recent trends in antibiotic sales/prescription data and resistance data, collected via VMD and Public Health England (PHE) surveillance programmes. The group discussed the production of a future joint medical:veterinary report. It was agreed that a short headline paper would be produced by March 2015, with the purpose of presenting headline 2013 sales/prescription data. A more detailed report would be compiled in Autumn 2015 to present the 2014 sales/prescription and resistance datasets as collected by VMD and PHE surveillance programmes.

The next DARC meeting is planned for 11 December 2014.

All summary reports of meetings: www.vmd.defra.gov.uk/public/antibiotic_darc.aspx.

■ HMA-VETERINARY ACTION PLAN ON ANTIMICROBIAL ISSUES

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

The group has recently focused on removal of fluroquinolone combination products from the market; consideration of the need for appropriate antibiotic pack sizes to encourage responsible use; and on development of a target veterinary pathogen surveillance programme.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

The 'UK Veterinary Antibiotic Resistance and Sales Surveillance Report (UKVARSS-2013) 2013' is currently being finalised. This report compiles 2013 UK antimicrobial sales data and England and Wales data on the antibiotic susceptibility of veterinary pathogens and foodborne pathogens to form a joint UK report. The first draft of the report was presented for comment at the DARC meeting on 24 September 2014.

Copies of all the published reports detailing veterinary antimicrobial sales from 2006 to 2012 can be obtained at www.vmd.defra.gov.uk/public/antibiotic_salesdata.aspx.

EUROPEAN ANTIBIOTIC AWARENESS DAY (EAAD)

European Antibiotic Awareness Day is an annual European public health initiative that takes place on 18 November to raise awareness about the threat to public health of antibiotic resistance and prudent antibiotic use.

In 2013 the VMD, in collaboration with the British Veterinary Association (BVA), acted as co-ordinator for veterinary EAAD activities and worked with PHE and the Department of Health (DH) to ensure a joint human and veterinary approach was taken where possible.

After the success of 2013, the VMD is acting jointly with PHE to co-ordinate EAAD 2014 activities – the most notable of which is the PHE Antibiotic Guardian Pledge Campaign http://antibioticguardian.com/. The campaign plans to target healthcare and veterinary professionals, as well as the general public, to raise awareness of and gain support for the prudent use of antimicrobials. The VMD are responsible for several activities orientated around EAAD, including organisation of an AMR Summit on the 18 November 2014 for the animal health and livestock sectors. Discussion will centre on responsible use of antimicrobials.

UK AMR STRATEGY

The most recent meeting of the High Level Steering Group (HLSG) for the AMR Strategy took place in September. Activities to deliver the aims of the Strategy are being implemented in line with the guidance of the HLSG. The first year report and a detailed action plan for activity in the remaining four years of the Strategy are under development and will be published later this year.

Following the publication of the Strategy, the House of Commons Science and Technology Committee launched an inquiry into AMR. The Committee published their report in July and the Government response was published in September.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/353295/42917_2902606_Cm_8919_WEB_Accessible.pdf

In order to strengthen surveillance of antimicrobial use in the animal health sector, the VMD initiated a scoping project to explore options for collection of antibiotic prescription and/or consumption data. The first phase of the project has now been completed and the second phase, development of a central data collection hub, is underway. In addition the VMD has expanded the UK surveillance programme of resistance in veterinary zoonotic and commensal bacteria, in line with new statutory EU requirements.

For further information please contact: Callum Harris (VMD, email: c.harris@vmd.defra.gsi.gov.uk, 01932 338390).

VETERINARY PRODUCTS COMMITTEE (VPC)

The VPC is a statutory committee established to:

i) provide the Secretary of State with scientific[1] 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 VPC will publish a report of its activities and those of its Sub-Committees.

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

The VPC is consulted by the Veterinary Medicines Directorate (VMD) where it requires advice on specific scientific issues relating to Marketing Authorisations (MAs), Exceptional MAs, or Animal Test Certificates (ATCs). Having considered that advice it is the VMD, not the VPC, that makes the decision whether to grant or refuse an MA or an ATC, grant one that is different from that which was applied for, vary it other than on the application of the holder, suspend or revoke it, or refuse to grant a variation applied for by the holder. The VPC also considers reports of suspected adverse events relating to veterinary medicines and provides advice to the VMD. Further information is available on our website www.vmd.defra.gov.uk/vpc.

MEETINGS OF THE VPC

The VPC met in October 2014. Summary minutes of all meetings held since 2009 are available on its website www.vmd.defra.gov.uk/vpc/meetings/summary.aspx.

Comments on the website or requests for further information on the summary minutes please contact Colin Bennett (VMD, email: c.bennett@vmd.defra.gsi.gov.uk, 01932 338490).

VETERINARY RESIDUES COMMITTEE (VRC)

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.

MEETINGS OF THE VRC

A meeting of the VRC took place on 11 September 2014 at the Animal Health and Veterinary Laboratories Agency, Weybridge.

The Committee reviewed the results to date of the 2014 Statutory and Non-Statutory Surveillance programmes for Great Britain and Northern Ireland and received an update on the testing of imports under the National Monitoring Plan.

Papers from the meeting are available on the VRC website.

The Committee also held a separate Open Meeting on the same day which was attended by representatives from the veterinary, food, equine and agriculture industries as well as other regulatory public bodies. Attendees received presentations on:

- The work of the Committee during 2013
- The Matrix Rank System for risk-based surveillance
- Flukicide use and the possible impact of recent flooding
- Imports surveillance and the work of the Border Inspection Posts

Papers from the meeting can be found on the VRC website.

The Committee published its Annual Report for 2013 surveillance year in June. The report can be found at www.vmd.defra.gov.uk/vrc/pdf/reports/vrcar2013.pdf

The next meeting will take place on 20 November 2014.

Details about all VRC meetings including minutes and papers, together with reports, results and general information about surveillance for veterinary residues can be found on the Committee's website www.vmd.defra.gov.uk/vrc

For further information please contact: Justin Murphy (VMD, email: j.murphy@vmd.defra.gsi.gov.uk, 01932 338327).

RESIDUES CONTROLS AND 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 food products of animal origin 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 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.

2014 PROGRAMME

Sampling commenced in January for the majority of species. Details of sample results since the report in *MAVIS 91* are set out below.

Species Type	Number of Samples Analysed	Number of Non-Compliant Samples	Analyte Detected
Cattle	2,454	14	Alpha-nortestosterone (2) Alpha-nortestosterone & beta-nortestosterone (1) Beta-testosterone (1) Cadmium (2) Florfenicol (2) Oxytetracycline (1) Taleranol (2) Thiouracil (3)
Pigs	1,064	1	Chlortetracycline (1)
Sheep	1,686	6	Alpha-boldenone (2) Beta-nortestosterone (1) Oxytetracycline (1) Thiouracil (2)
Horses	26	0	
Poultry	2,398	0	
Game	9	0	
Fish	289	0	
Milk	572	1	Dihydrostreptomycin (1)
Eggs	289	0	
Honey	111	0	

RESULTS OF 2014 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. Sample collection for the 2014 rolling programme commenced in May 2014. Details of analyses completed since the report in *MAVIS 91* are set out below:

Sample	Analysed Completed	Number of Non-Compliant Samples	Analyte Detected
Farmed Warm Water Crustaceans	64	0	
Imported Farmed Fish	81	2	Oxytetracycline (1) Sulfadiazine (1)
Imported Poultry Muscle	94	0	
Imported Raw Beef	138	0	

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/meetings/papers.html or by contacting Dawn Greener (VMD, email: d.greener@vmd.defra.gsi.gov.uk, 01932 338325).

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

STAFF CHANGES

The following staff changes have taken effect during this quarter:

New Staff

- Kate Smith transferred from the Animal Health and Veterinary Laboratories Agency and joined the Committee and Office Support team on 4 August 2014
- Callum Harris joined the Antimicrobial Resistance Control and Surveillance team on 1 August 2014
- Georgina Blanc joined the Pharmaceuticals and Feed Additives Vets team on 1 September 2014
- Elizabeth Marier transferred from the Animal Health and Veterinary Laboratories Agency and joined the Antimicrobial Resistance Control and Surveillance team on 17 September 2014
- Jennifer Blenkinsop joined the Pharmacovigilance team on 20 October 2014

Departing Staff

- Jack Kay resigned from the VMD on 31 August 2014
- Diane Biggs retired from the VMD on 26 September 2014
- Jackie Atkinson resigned from the VMD on 3 October 2014

Promotions

- Gemma Adam was promoted and transferred to the Directors' Support team on 18 August 2014
- Natalie Shilling was temporarily promoted within the Licensing Administration team on 1 September 2014
- Jo Young was temporarily promoted within the Licensing Administration team on 1 September 2014
- Sarah Norton was promoted within the Pharmaceuticals and Feed Additives Quality team on 29 September 2014
- Flavia Iacurti was temporarily promoted within the Licensing Administration team on 29 September 2014
- Anna-Maria Brady was temporarily promoted to Director of Authorisations on 6 October 2014
- Noemi Garcia del Blanco was temporarily promoted within the Biologicals team on 6 October 2014

Transfers

- Mark Newman transferred to the Licensing Administration team on 4 August 2014

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 4 JUNE - 8 SEPTEMBER 2014

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Alfamed	17902/4075	Alfamed Fipronil/Permethrin 26.8 mg/240 mg Spot-On Solution for Very Small Dogs		POM-V
	17902/4076	Alfamed Fipronil/Permethrin 67 mg/600 mg Spot-On Solution for Small Dogs		POM-V
	17902/4077	Alfamed Fipronil/Permethrin 134 mg/1200 mg Spot-On Solution for Medium Dogs	Fipronil, Permethrin (Cis:Trans 40:60)	POM-V
	17902/4078	Alfamed Fipronil/Permethrin 268 mg/2400 mg Spot-On Solution for Large Dogs		POM-V
	17902/4079	Alfamed Fipronil/Permethrin 402 mg/3600 mg Spot-On Solution for Very Large Dogs		POM-V
	17902/4070	Fiperm 26.8 mg/240 mg Spot-on Solution for Very Small Dogs		POM-V
	17902/4071	Fiperm 67 mg/600 mg Spot-on Solution for Small Dogs		POM-V
	17902/4072	Fiperm 134 mg/1200 mg Spot-on Solution for Medium Dogs	Fipronil, Permethrin (Cis:Trans 40:60)	POM-V
	17902/4073	Fiperm 268 mg/2400 mg Spot-on Solution for Large Dogs		POM-V
	17902/4074	Fiperm 402 mg/3600 mg Spot-on Solution for Very Large Dogs		POM-V
	17902/4064	Milprotect 2.5 mg/25 mg Film-Coated Tablets for Small Dogs and Puppies		POM-V
	17902/4068	Milprotect 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens	Milbemycin Oxime (A3 and A4), Praziquantel	POM-V
	17902/4065	Milprotect 12.5 mg/125 mg Film-Coated Tablets for Dogs		POM-V
	17902/4069	Milprotect 16 mg/40 mg Film-Coated Tablets for Cats		POM-V
Andersen, S.A.	39897/4001	Ketoxyme 100 mg/ml Solution for Use in Drinking Water	Ketoprofen	POM-V
Bayer plc	00010/4182	Baycox 25 mg/ml, Solution for Use in Drinking Water for Chickens and Turkeys	Toltrazuril	POM-V
Beaphar B.V.	41941/4000	Fiprotec 50 mg Spot On Solution for Cats		NFA-VPS
	41941/4001	Fiprotec 67 mg Spot On Solution for Small Dogs		NFA-VPS
	41941/4002	Fiprotec 134 mg Spot On Solution for Medium Dogs	Fipronil	NFA-VPS
	41941/4003	Fiprotec 268 mg Spot On Solution for Large Dogs		NFA-VPS
	41941/4004	Fiprotec 402 mg Spot On Solution for Extra Large Dogs		NFA-VPS
Bela-Pharm GmbH & Co. KG	41816/4000	Oxytobel 10 IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats	Oxytocin	POM-V
Boehringer Ingelheim Ltd	00015/4088	Pimobendan Vetmedica 0.75 mg/ml Solution for Injection for Dogs	Pimobendan	POM-V
Chanelle Animal Health Ltd	11990/4059	Clindaseptin 25 mg Capsules for Dogs	Clindamycin, Clindamycin Hydrochloride	POM-V
Dopharma Research B.V.	28365/4005	Amoxy Active 697 mg/g Oral Powder for Pigs and Chickens	Amoxicillin, Amoxicillin Trihydrate	POM-V
Industrial Veterinaria, S.A.	36547/4004	Espacox, 50 mg/ml Oral Suspension for Pigs	Toltrazuril	POM-V
Laboratorios Karizoo S.A	31223/4003	K-Flor 100 mg/ml Solution for Use in Drinking Water for Pigs	Florfenicol	POM-V
Le Vet Beheer B.V.	41821/4017	Sporimune 50 mg/ml Oral Solution for Dogs	Ciclosporin A	POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Norbrook Laboratories Limited	02000/4384	Fleanil 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs	Fipronil	POM-V
	02000/4382	Flydown 10 mg/ml Spot-On Solution for Cattle and Sheep	Deltamethrin	POM-VPS
	02000/4342	Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle	Eprinomectin	POM-VPS
	02000/4383	Norbrook Deltamethrin 10 mg/ml Spot-On Solution for Cattle and Sheep	Deltamethrin	POM-VPS
	02000/4385	Pestigon 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs	Fipronil	POM-V
	02000/4381	Spotinor 10 mg/ml Spot-on Solution for Cattle and Sheep	Deltamethrin	POM-VPS
Novartis Animal Health UK Ltd	12501/4190	Protect Flea and Worm Treatment Tablets for Very Small Dogs	Lufenuron, Milbemycin Oxime (A3 and A4)	POM-V
	12501/4189	Protect Flea and Worm Treatment Tablets for Small Dogs		POM-V
	12501/4188	Protect Flea and Worm Treatment Tablets for Medium Dogs		POM-V
	12501/4187	Protect Flea and Worm Treatment Tablets for Large Dogs		POM-V
	12501/4185	Winvil 3 Micro Emulsion for Injection for Atlantic Salmon	Aeromonas salmonicida subsp. Salmonicida, Infectious pancreatic necrosis virus, Moritella viscosa	POM-V
Sogeval	20749/4041	Sogecoli 2 000 000 IU/ml Concentrate for Oral Solution for Calves, Lambs, Pigs, Chickens and Turkeys	Colistin Sulphate	POM-V
Support Pharma S.L.	42120/4000	Marbofloxacin 40 mg/ml Solution for Injection for Pigs	Marbofloxacin	POM-V
Vetoquinol UK Ltd	08007/4136	Libbox 50 mg Spot-on Solution for Cats	Fipronil	NFA-VPS
	08007/4137	Libbox 67 mg Spot-on Solution for Small Dogs		NFA-VPS
	08007/4138	Libbox 134 mg Spot-on Solution for Medium Dogs		NFA-VPS
	08007/4139	Libbox 268 mg Spot-on Solution for Large Dogs		NFA-VPS
	08007/4140	Libbox 402 mg Spot-on Solution for Very Large Dogs		NFA-VPS
Vetpharma Animal Health, S.L	32509/4018	Indupart 75 Micrograms/mL Solution for Injection for Cattle, Pigs and Horses	d-Cloprostenol	POM-V
	32509/4017	Nifencol 100 mg/ml Solution for Use in Drinking Water for Pigs	Florfenicol	POM-V
Veyx-Pharma GmbH	27569/4003	Hypophysin LA 35 microgram/ml Solution for Injection for Cattle and Pigs	Carbetocin	POM-V
	27569/4004	Hypophysin LA 70 microgram/ml Solution for Injection for Cattle and Pigs	Carbetocin	POM-V
Virbac S.A.	05653/4178	Curacef Duo 50 mg/ml /150 mg/ml Suspension for Injection for Cattle	Ceftiofur, Ketoprofen, Ceftiofur Hydrochloride	POM-V
	05653/4185	Effitix 26.8 mg/240 mg Spot-On Solution for Very Small Dogs	Fipronil, Permethrin (Cis:Trans 40:60)	POM-V
	05653/4186	Effitix 67 mg/600 mg Spot-On Solution for Small Dogs		POM-V
	05653/4187	Effitix 134 mg/1200 mg Spot-On Solution for Medium Dogs		POM-V
	05653/4188	Effitix 268 mg/2400 mg Spot-On Solution for Large Dogs		POM-V
	05653/4189	Effitix 402 mg/3600 mg Spot-On Solution for Very Large Dogs		POM-V
	05653/4181	Milpro 2.5 mg/25 mg Film-Coated Tablets for Small Dogs and Puppies	Milbemycin Oxime (A3 and A4), Praziquantel	POM-V
	05653/4183	Milpro 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens		POM-V
	05653/4182	Milpro 12.5 mg/125 mg Film-Coated Tablets for Dogs		POM-V
	05653/4184	Milpro 16 mg/40 mg Film-Coated Tablets for Cats		POM-V
	05653/4177	Neoprinil Pour-On 5 mg/ml Pour-On Solution for Cattle	Eprinomectin	POM-VPS
	05653/4179	Virbakor 5 mg Film-coated Tablets for Dogs and Cats	Benazepril Hydrochloride	POM-V
Zoetis UK Limited	42058/4179	Alverin 18.7 mg/g Oral Paste for Horses	Ivermectin	POM-VPS

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 4 JUNE - 8 SEPTEMBER 2014

Company Name	Product Name	Brief Details	Legal Category
Alfasan Nederland BV	Euthanimal 20% 200 mg/ml Solution for Injection	Shelf-life Change	POM-V
	Euthanimal 40% 400 mg/ml Solution for Injection		POM-V
aniMedica GmbH	Dolocarp Flavour 20 mg Chewable Tablet for Dogs	Shelf-life Change	POM-V
	Dolocarp Flavour 50 mg Chewable Tablet for Dogs		POM-V
	Dolocarp Flavour 100 mg Chewable Tablet for Dogs		POM-V
	Torphasol 10 mg/ml Solution for Injection for Horses		POM-V
Bayer plc	Bob Martin 2 in 1 Dewormer Tablets for Cats and Kittens	Change of name from Bob Martin 2 in 1 Dewormer Tablets for Cats and Kittens to Bob Martin Clear Wormer 20/230 mg Tablets for Cats and Kittens	AVM-GSL
Bela-Pharm GmbH & Co. KG	Oxytobel 10 bela-pharm IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats	Change of name from Oxytocin 10 bela-pharm IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats to Oxytobel 10 IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats	POM-V
Bob Martin (UK) Ltd	Bob Martin Clear Spot On 50 mg Spot On Solution for Cats	Change of name from Bob Martin Clear Spot on 50 mg Spot On solution for Cats to Bob Martin Fipronil 50 mg Spot On Solution for Cats	NFA-VPS
	Bob Martin Clear Spot On 67mg Spot On Solution for Small Dogs	Change of name from Bob Martin Clear Spot On 67mg Spot On Solution for Small Dogs to Bob Martin Fipronil 67 mg Spot On Solution for Small Dogs	NFA-VPS
	Bob Martin Clear Spot On 134 mg Spot On Solution for Medium Dogs	Change of name from Bob Martin Clear Spot On 134 mg Spot On Solution for Medium Dogs to Bob Martin Fipronil 134 mg Spot On Solution for Medium Dogs	NFA-VPS
	Bob Martin Clear Spot On 268 mg Spot On solution for Large Dogs	Change of name from Bob Martin Clear Spot on 268 mg Spot On Solution for Large Dogs to Bob Martin Fipronil 268 mg Spot On Solution for Large Dogs	NFA-VPS
	Bob Martin Clear Spot On 402 mg Spot On Solution for Extra Large Dogs	Change of name from Bob Martin Clear Spot On 402 mg Spot On Solution for Extra Large Dogs to Bob Martin Fipronil 402 mg Spot On Solution for Extra Large Dogs	NFA-VPS
	Bob Martin Easy to Use Dewormer Granules for Cats and Kittens 222.2 mg	Change of name from Bob Martin Easy to Use Dewormer Granules for Cats and Kittens 222.2 mg to Bob Martin Clear Wormer 222.2 mg Granules for Cats and Kittens	AVM-GSL
	Bob Martin Flea Shampoo for Dogs and Puppies	Change of name from Bob Martin Flea Shampoo for Dogs and Puppies to Bob Martin Clear Flea Shampoo for Dogs and Puppies 1.9 mg/g / 4.9 mg/g	AVM-GSL
	Bob Martin FleaClear Spot On Solution 50 mg for Cats	Change of name from Bob Martin FleaClear Spot On Solution 50 mg for Cats to Bob Martin Clear Spot On Solution 50mg for Cats	AVM-GSL
	Bob Martin FleaClear Spot On Solution 67 mg for Small Dogs	Change of name from Bob Martin FleaClear Spot On Solution 67 mg for Small Dogs to Bob Martin Clear Spot On Solution 67 mg for Small Dogs	AVM-GSL
	Bob Martin FleaClear Spot On Solution 134 mg for Medium Dogs	Change of name from Bob Martin FleaClear Spot On Solution 134 mg for Medium Dogs to Bob Martin Clear Spot On Solution 134 mg for Medium Dogs	AVM-GSL
	Bob Martin FleaClear Spot On Solution 268 mg for Large Dogs	Change of name from Bob Martin FleaClear Spot On Solution 268 mg for Large Dogs to Bob Martin Clear Spot On Solution 268 mg for Large Dogs	AVM-GSL
	Bob Martin FleaClear Spot On Solution 402 mg for Extra Large Dogs	Change of name from Bob Martin FleaClear Spot On Solution 402 mg for Extra Large Dogs to Bob Martin Clear Spot On Solution 402 mg for Extra Large Dogs	AVM-GSL

Company	Product	Brief Details	Legal Category
Ceva Sante Animale	Vetrimoxin L.A. 150 mg/ml Suspension for Injection for Cattle and Pigs	Change of Marketing Authorisation Holder from Ceva Santé Animale to Ceva Animal Health Ltd	POM-V
Chanelle Animal Health Ltd	Bob Martin All in One Dewormer 500 mg Film Coated Tablets for Dogs	Change of name from Bob Martin All in One Dewormer 500 mg Film Coated Tablets for Dogs to Bob Martin Clear Wormer 500mg Film Coated Tablets for Dogs	AVM-GSL
	Bob Martin All in One Dewormer 100 mg Film Coated Tablets for Small Dogs and Puppies	Change of name from Bob Martin All in One Dewormer 100 mg Film Coated Tablets for Small Dogs and Puppies to Bob Martin Clear Wormer 100mg Film Coated Tablets for Small Dogs and Puppies	AVM-GSL
	Clavucill Tablets 50 mg	Shelf-life Change	POM-V
	Clavucill Tablets 250 mg		POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	Cazitel Plus Tablets for Dogs	Change of distributor from Pfizer Ltd to Zoetis UK Limited	NFA-VPS
Dechra Veterinary Products A/S	Fucithalmic Vet 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits	Change of name from Fucithalmic Vet 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits to Isathal 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits	POM-V
Delaval International AB	Bovidip 2% w/v Concentrate for Teat Dip or Spray Solution for Cows	Change of Marketing Authorisation Holder name from DeLaval International AB to DeLaval NV	AVM-GSL
Dopharma Research B.V.	Butagran Equi 200 mg/g Oral Powder for Horses	Shelf-life Change	POM-V
Eco Animal Health Ltd	Bimectin 5 mg/ml Pour-on Solution for Cattle	Shelf-life Change	POM-VPS
	Ecomectin 5 mg/ml Pour-on Solution for Cattle		POM-VPS
	Qualimec 5 mg/ml Pour-on Solution for Cattle		POM-VPS
Eli Lilly & Company Ltd	Ovispec S & C 10% w/v Oral Suspension	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited to Cross Vetpharm Group Ltd	POM-VPS
	Ovispec S & C 2.5% w/v Oral Suspension		POM-VPS
Eurovet Animal Health B.V.	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses	Change in the storage conditions of the finished product	POM-V
	Thyforon Flavoured 200 Microgram Tablets for Dogs	Change of distributor from Eurovet Animal Health Ltd to Dechra Veterinary Products Limited	POM-V
	Thyforon Flavoured 400 Microgram Tablets for Dogs		POM-V
	Thyforon Flavoured 600 Microgram Tablets for Dogs		POM-V
	Thyforon Flavoured 800 Microgram Tablets for Dogs		POM-V
Gibraltar (Uk) Limited	Hornex 42.7% w/w Cutaneous Paste	Change of Marketing Authorisation Holder address to Animal House, Boundary Road, Lytham, Lancashire, FY8 5LT	POM-VPS
	Hornex 42.7% w/w Cutaneous Paste	Removal of Agri-Lloyd Ltd, Glendower Road, Leominster, Herefordshire, HR6 ORL as a Distributor. Change of address for the Distributor Farmsense Ltd to Animal House, Boundary Road, Lytham, Lancashire, FY8 5LT	POM-VPS
Intervet UK Ltd	Enzovax Solution for Injection for Sheep	Shelf-life Change	POM-V
	Nobivac Tricat Trio Lyophilisate and Solvent for Suspension for Injection for Cats	Addition of Intervet Ireland Ltd as a distributor for Northern Ireland	POM-V

Company	Product	Brief Details	Legal Category
Intervet UK Ltd	Paracox-5 Oral Suspension	Addition of Intervet Ireland Ltd. as a distributor for Northern Ireland	POM-VPS
	Receptal 0.004 mg/ml Solution for Injection	Addition of a 50 ml pack size	POM-V
iron4u APS	Ferroferon 200 mg/ml Solution for Injection for Pigs	Change of distributor from Serumwerk Bernburg AG, Germany to Nutrapet Ltd, England	POM-VPS
Kela N.V.	Kelacyl 100 mg/ml Solution for Injection for Cattle and Pigs	Change of distributor from KELA N.V. to ANUPCO	POM-V
Krka Dd	Ectofend 50 mg Spot-on Solution for Cats	Change of name from Ectofend 50 mg Spot-on Solution for Cats to Fyperix 50 mg Spot-on Solution for Cats	NFA-VPS
	Ectofend 67 mg Spot-on Solution for Dogs	Change of name from Ectofend 67 mg Spot-on Solution for Dogs to Fyperix 67 mg Spot-on Solution for Dogs	NFA-VPS
	Ectofend 134 mg Spot-on Solution for Dogs	Change of name from Ectofend 134 mg Spot-on Solution for Dogs to Fyperix 134 mg Spot-on Solution for Dogs	NFA-VPS
	Ectofend 268 mg Spot-on Solution for Dogs	Change of name from Ectofend 268 mg Spot-on Solution for Dogs to Fyperix 268 mg Spot-on Solution for Dogs	NFA-VPS
	Ectofend 402 mg Spot-on Solution for Dogs	Change of name from Ectofend 402 mg Spot-on Solution for Dogs to Fyperix 402 mg Spot-on Solution for Dogs	NFA-VPS
	Ectofend 50 mg Spot-on Solution for Cats	Change in the storage conditions of the finished product	NFA-VPS
	Ectofend 67 mg Spot-on Solution for Dogs		NFA-VPS
	Ectofend 134 mg Spot-on Solution for Dogs		NFA-VPS
	Ectofend 268 mg Spot-on Solution for Dogs		NFA-VPS
	Ectofend 402 mg Spot-on Solution for Dogs		NFA-VPS
	Quiflor S 100 mg/ml Solution for Injection for Cattle	Shelf-life Change	POM-V
Laboratorios Hipra SA	Unistrain PRRS Lyophilisate and Solvent for Suspension for Injection for Pigs	Shelf-life Change	POM-V
Le Vet B.V.	Clavubactin 50/12.5 mg Tablets for Cats and Dogs	Addition of Carton containing 25 aluminium/ aluminium blister strips each strip with 10 tablets	POM-V
	Clavubactin 250/62.5 mg Tablets for Dogs		POM-V
	Clavubactin 500/125 mg Tablets for Dogs		POM-V
	Clavubactin 50/12.5 mg Tablets for Cats and Dogs	Addition of Carton containing 1 aluminium/ aluminium blister strips each strip with 10 tablets	POM-V
	Clavubactin 250/62.5 mg Tablets for Dogs		POM-V
	Clavubactin 500/125 mg Tablets for Dogs		POM-V
Norbrook Laboratories Limited	Aloquan 18.7 mg/g + 140.3 mg/g Oral Paste for Horses	Change of name from Iverpraz, 18.7 mg/g + 140.3 mg/g Oral Paste for Horses to Aloquan, 18.7 mg/g + 140.3 mg/g Oral Paste for Horses	POM-VPS
	Closiver Solution for Injection for Sheep	Change of distributor address to 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom	POM-VPS
	Closiver 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle		POM-VPS
	Closamectin Solution for Injection for Sheep		POM-VPS
	Closivet Solution for Injection for Cattle		POM-VPS
	Enovex 1.0% w/v Solution for Injection for Cattle		POM-VPS
	Norocillin LA Suspension for Injection		POM-VPS
	Ovidown SC Oral Suspension for Sheep		POM-VPS
	Norofas Solution for Injection		POM-VPS

Company Name	Product Name	Brief Details	Legal Category
Norbrook Laboratories Limited	Midaspot 40 mg Spot-On Solution for Small Cats and Small Dogs		NFA-VPS
	Midaspot 80 mg Spot-On Solution for Large Cats		NFA-VPS
	Midaspot 100 mg Spot-On Solution for Medium Dogs	Change of distributor from Norbrook Laboratories (GB) Ltd. to Bob Martin UK Ltd	NFA-VPS
	Midaspot 250 mg Spot-On Solution for Large Dogs		NFA-VPS
	Midaspot 400 mg Spot-On Solution for Very Large Dogs		NFA-VPS
	Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle	Shelf-life Change	POM-VPS
	Peptizole 370 mg/g Oral Paste for Horses		POM-V
	Spot & Clear 67 mg Spot-On Solution for Small Dogs	Change of name from Spot & Clear 67 mg Spot-On Solution for Small Dogs to Flick 67 mg Spot-On Solution for Small Dogs	AVM-GSL
	Spot & Clear 134 mg Spot-On Solution for Medium Dogs	Change of name from Spot & Clear 134 mg Spot-On Solution for Medium Dogs to Flick 134 mg Spot-On Solution for Medium Dogs	AVM-GSL
	Spot & Clear 268 mg Spot-On Solution for Large Dogs	Change of name from Spot & Clear 268 mg Spot-On Solution for Large Dogs to Flick 268 mg Spot-On Solution for Large Dogs	AVM-GSL
	Spot & Clear 402 mg Spot-On Solution for Very Large Dogs	Change of name from Spot & Clear 402 mg Spot-On Solution for Very Large Dogs to Flick 402 mg Spot-On Solution for Very Large Dogs	AVM-GSL
	Flick 67 mg Spot-On Solution for Small Dogs	Change in distributor from Beaphar UK Ltd to Lintbells Ltd	AVM-GSL
	Flick 134 mg Spot-On Solution for Medium Dogs		AVM-GSL
	Flick 268 mg Spot-On Solution for Large Dogs		AVM-GSL
	Flick 402 mg Spot-On Solution for Very Large Dogs		AVM-GSL
	Spot and Clear 50 mg Spot-On Solution for Cats	Change of name from Spot and Clear 50 mg Spot-On Solution for Cats to Johnsons Fipronil 50 mg Spot-On Solution for Cats	AVM-GSL
	Sureseal 2.6 g Intramammary Suspension for Cattle	Change of name from Sureseal 2.6 g Intramammary Suspension for Cattle to Cepralock 2.6 g Intramammary Suspension for Cattle	POM-V
Novartis Animal Health UK Ltd	Capstar 11.4 mg Tablets for Cats and Small Dogs	Addition of a 1 blister pack containing 1 tablet size	AVM-GSL
	Capstar 57 mg Tablets for Large Dogs	Addition of a 1 blister pack containing 1 tablet size	AVM-GSL
Novartis Animal Vaccines Ltd	Mydiavac	Change of distributor from Novartis Animal Vaccines Limited to Benchmark Vaccines Limited	POM-V
	Mydiavac	Change of Marketing Authorisation Holder from Novartis Animal Health Vaccines Limited to Benchmark Health Limited	POM-V
Pfizer Ltd	Clamoxyl Long Acting 150 mg/ml Suspension for Injection	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Clamoxyl Palatable Tablets 40 mg		POM-V
	Clamoxyl Palatable Tablets 200 mg		POM-V
	Clamoxyl Ready-To-Use 150 mg/ml Suspension for Injection		POM-V
	Orbenin L.A. 200 mg Intramammary Suspension		POM-V
	Orbenin Dry Cow 500 mg Intramammary Suspension		POM-V
	Orbenin Extra Dry Cow 600 mg Intramammary Suspension		POM-V
	Dermisol Cream		POM-V
	Dermisol Multicleanse Cutaneous Solution		POM-V

Company Name	Product Name	Brief Details	Legal Category
Pfizer Ltd	Clamoxyl Long Acting 150 mg/ml Suspension for Injection		POM-V
	Clamoxyl Palatable Tablets 40 mg		POM-V
	Clamoxyl Palatable Tablets 200 mg		POM-V
	Clamoxyl Ready-To-Use 150 mg/ml Suspension for Injection		POM-V
	Orbenin L.A. 200 mg Intramammary Suspension	Change of distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Orbenin Dry Cow 500 mg Intramammary Suspension		POM-V
	Orbenin Extra Dry Cow 600 mg Intramammary Suspension		POM-V
	Dermisol Cream		POM-V
	Dermisol Multicleanse Cutaneous Solution		POM-V
	Colombovac PMV	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-VPS
	Colombovac PMV/Pox		POM-VPS
	Colombovac PMV	Change of distributor from Pfizer Ltd to Zoetis UK Limited	POM-VPS
	Colombovac PMV/Pox		POM-VPS
	Duphacycline XL Oxytetracycline 30% w/v Solution for Injection		POM-V
	Duphacycline XL Oxytetracycline 30% w/v Solution for Injection	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Duphamox LA 150 mg/ml Suspension for Injection		POM-V
	Duphamox LA 150 mg/ml Suspension for Injection	Change to distributor details from Pfizer Ltd to Zoetis UK Limited	POM-V
	Equip T	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Equip FT		POM-V
	Equip F		POM-V
	Equip T	Change of distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Equip FT		POM-V
	Equip F		POM-V
	Flectron Fly Ear Tags for Cattle 935 mg		POM-VPS
	Flectron Fly Ear Tags for Cattle 935 mg	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-VPS
	Lincocin Sterile Solution 100 mg/ml Sterile Solution for Injection	Change of Distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Lincocin Sterile Solution 100 mg/ml Sterile Solution for Injection	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Meflosyl 5% Solution for Injection	Change of Distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Meflosyl 5% Solution for Injection	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Synulox Bolus 500 mg Film-Coated Tablets	Change of distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Synulox Ready-to-Use Suspension for Injection		POM-V
	Synulox Palatable Tablets 50 mg		POM-V
	Synulox Palatable Tablets 250 mg		POM-V
	Synulox Palatable Tablets 500 mg		POM-V
	Synulox Palatable Drops Powder for Oral Suspension		POM-V
	Synulox Lactating Cow Intramammary Suspension		POM-V
	Synulox Bolus 500 mg Film-Coated Tablets	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Synulox Ready-to-Use Suspension for Injection		POM-V
	Synulox Palatable Tablets 50 mg		POM-V
	Synulox Palatable Tablets 250 mg		POM-V
	Synulox Palatable Tablets 500 mg		POM-V
	Synulox Palatable Drops Powder for Oral Suspension		POM-V
	Synulox Lactating Cow Intramammary Suspension		POM-V
	Terramycin/LA 200 mg/ml Solution for Injection		POM-V
	Terramycin/LA 200 mg/ml Solution for Injection	Change of distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Torbutrol Tablets 10 mg		POM-V
	Torbutrol Tablets 10 mg	Change of Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V

Company Name	Product Name	Brief Details	Legal Category
Sogeval	Libeo 10 mg Chewable Tablets for Dogs	Shelf-life Change	POM-V
	Libeo 40 mg Chewable Tablets for Dogs		POM-V
Telsol Ltd	Cosecure Cattle Bolus Continuous Release Intraruminal Device	Change of distributor for Bimeda (R) a division of Cross Vetpharm Group UK	POM-VPS
Vetpharma Animal Health, S.L	Nifencol 300 mg/ml Solution for Injection for Cattle and Pigs	Addition of the 100 ml pack size	POM-V
Virbac S.A.	Cyclavance 100 mg/ml Oral Solution for Dogs	Addition of a 50 ml pack size	POM-V
Virbac Tierarzneimittel GmbH	Stabox 1000 mg/g Powder for Use in Drinking Water for Chickens, Ducks, Turkeys	Shelf-life Change	POM-V
Zoetis UK Limited	Dopram V Drops 20 mg/ml Oral Drops Solution		POM-VPS
	Gletvax 6	Shelf-life Change	POM-VPS
	Rispoval IBR-Marker Inactivated		POM-V
	Vanguard Rabies	To remove the 20 ml pack size	POM-V

EUCE AUTHORISATIONS ISSUED BETWEEN 4 JUNE - 8 SEPTEMBER 2014

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Ceva Sante Animale	EU/2/14/165/001-005	Vectra Felis 423 mg/42.3 mg Spot-on Solution for Cats	Dinotefuran, Pyriproxyfen	POM-V
Laboratorios Hipra SA	EU/2/14/166/001-007	Eryseng Suspension for Injection for Pigs	Erysipelothrix rhusiopathiae	POM-V
	EU/2/14/167/001-007	Eryseng Parvo Suspension for Injection for Pigs	Erysipelothrix rhusiopathiae, Porcine parvovirus	POM-V
Novartis Sante Animale S.A.S.	EU/2/14/170/001-004	Osurnia Ear Gel for Dogs	Betamethasone acetate, Florfenicol, Terbinafine, Betamethasone	POM-V
Zoetis Belgium	EU/2/14/171/001-002	Versican Plus L4 Suspension for Injection for Dogs	Leptospira bratislava, Leptospira canicola, Leptospira icterohaemorrhagiae, Leptospira kirschneri	POM-V
	EU/2/03/041/006-008	Draxxin 25 mg/ml Solution for Injection for Pigs	Tulathromycin	POM-V
	EU/2/14/168/001-002	Versican Plus Pi Lyophilisate and Solvent for Suspension for Injection for Dogs	Canine parainfluenza virus	POM-V
	EU/2/14/169/001-002	Versican Plus DHPPi Lyophilisate and Solvent for Suspension for Injection for Dogs	Canine adenovirus, Canine distemper virus, Canine parvovirus	POM-V
	EU/2/14/172/001-002	Versican Plus Pi/L4 Lyophilisate and Solvent for Suspension for Injection for Dogs	Canine parainfluenza virus, Leptospira bratislava, Leptospira canicola, Leptospira icterohaemorrhagiae, Leptospira kirschneri	POM-V
	EU/2/14/173/001-002	Versican Plus Pi/L4R Lyophilisate and Solvent for Suspension for Injection for Dogs	Canine parainfluenza virus, Leptospira bratislava, Leptospira canicola, Leptospira icterohaemorrhagiae, Leptospira kirschneri, Rabies virus	POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 4 JUNE - 8 SEPTEMBER 2014

Company	Product Name	Brief Details	Legal Category
Intervet International BV	Activyl Tick Plus 75 mg + 240 mg Spot-on Solution for Very Small Dogs		POM-V
	Activyl Tick Plus 150 mg + 480 mg Spot-on Solution for Small Dogs		POM-V
	Activyl Tick Plus 300 mg + 960 mg Spot-on Solution for Medium Dogs	Shelf-life change	POM-V
	Activyl Tick Plus 600 mg + 1920 mg Spot-on Solution for Large Dogs		POM-V
	Activyl Tick Plus 900 mg + 2880 mg Spot-on Solution for Extra Large Dogs		POM-V
Merial	Previcox 57 mg Chewable Tablets for Dogs	Addition of a 60-count bottle to each presentation	POM-V
	Previcox 227 mg Chewable Tablets for Dogs		POM-V
	Previcox 57 mg Chewable Tablets for Dogs	Shelf-life change	POM-V
	Previcox 227 mg Chewable Tablets for Dogs		POM-V
Zoetis Belgium	Stronghold 60 mg Spot-on Solution	Additon of a six tube pack for the 60 mg	POM-V
	Stronghold 360 mg Spot-on Solution	Addition of a six tube pack for the 360 mg	POM-V

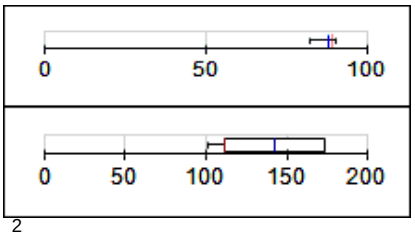
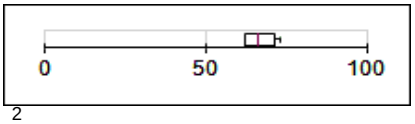
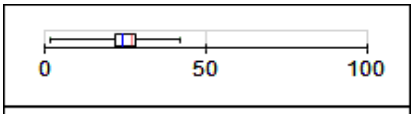
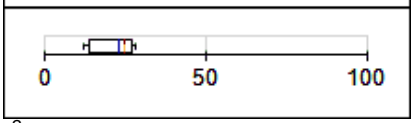
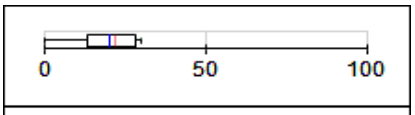
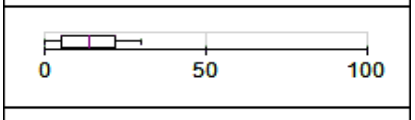
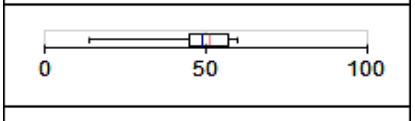
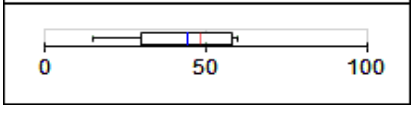
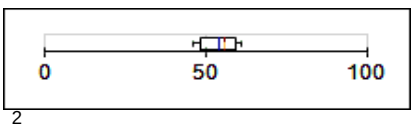
MARKETING AUTHORISATIONS EXPIRED BETWEEN 4 JUNE - 8 SEPTEMBER 2014

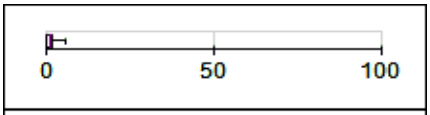
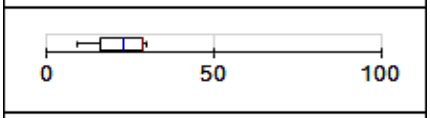
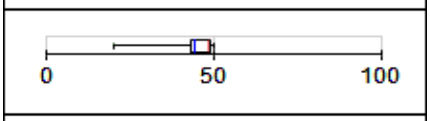
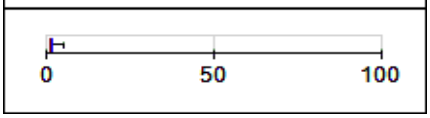
Company	Vm Number	Product Name	Legal Category
Battle, Hayward & Bower Ltd	00676/4106	Dual Action Worming Tablets for Dogs	AVM-GSL
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4016	Floxibac 100 mg/ml Solution for Injection for Cattle and Pigs	POM-V
	08749/4015	Floxibac 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	POM-V
Dechra Limited	10434/4022	Auroto Ear Drops	POM-V
	10434/4038	Hexamine and Sodium Acid Phosphate Tablets	POM-V
	10434/4037	Hyalovet 20 mg Solution for Injection	POM-V
	10434/4024	Millophyline-V 100 mg Oral Tablets	POM-V
	10434/4023	Millophyline-V 140 mg/ml Solution for Injection	POM-V
	10434/4021	Millophyline-V 200 mg Oral Tablets	POM-V
	10434/4020	Millophyline-V 300 mg Oral Tablets	POM-V
Evans Vanodine International Plc	03940/4057	Countrywide Farmers Concentrate Iodine Teat Dip and Teat Spray Solution 2.15% w/v	AVM-GSL
Greer Laboratories Ltd	37026/4000	Veterinary Allergenic Extracts for the Treatment of Atopic Dermatitis in Dogs	POM-V
Intervet UK Ltd	01708/4429	Panacur 2.5% Oral Suspension	POM-VPS
Schering-Plough Ltd	00201/4064	Tribrissen Oral Paste	POM-V
	00201/4069	Tribrissen Tablets	POM-V
Virbac S.A.	05653/4028	Auriplak 1.2 g Insecticidal Ear Tag	POM-VPS
Zoetis UK Limited	42058/4049	Duramune DAPPi	POM-V
	42058/4136	Suvaxyn Ery	POM-VPS

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK 2014/2015

Annex I

The following is a summary of VMD's performance against its published standards for 1 April to 30 September 2014 (www.vmd.defra.gov.uk/pdf/PublishedStandards.pdf.)

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days)[1]	Average time in days	Box Whisker Plots Key: ------- = Median _____ = Average
National					
MA and MAPIs					
Initial assessment	35	Excellent	90	88	
Sign off (Applications validated >1/4/2011)	12	Excellent	180	142	
Sign off and issue (Applications validated <1/4/2011)	0		210		[2]
MAPIs for MR products & copy-cats					
Initial assessment	6	Excellent	75	67	
Sign off	0		130		[2]
Variations					
Type 1A - decision (30 days)	64	Effective	30	24	
Admin - Less than 10 changes	12	Excellent	30	23	
Admin - 10 or more changes	0		60		[2]
Type 1B - initial assessment	91	Excellent	30	20	
Type 1B - sign off	51	Excellent	30	14	
Type II - initial assessment	29	Excellent	60	49	
Type II - sign off	14	Excellent	60	44	
Renewals					
Initial assessment	8	Ineffective	60	54	
Sign off	3	Excellent	60	55	[2]
Batch release (Immunologicals)					
Issue	1261	Excellent	15	3	

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: ------- = Median ____ = Average
AVAS and NFABBA (inc variations)					
Assess	1	Excellent	45	41	
ATCs					
Type A, S and B - validate	18	Effective	5	1	
Type A and S - sign off	5	Excellent	30	23	
Type B - sign off	7	Excellent	50	44	
Type A, S and B - issue	14	Excellent	5	2	
Specific Batch Control					
Validation	38	Excellent	3	1	
Initial assessment	37	Excellent	10	2	
Assess response	37	Excellent	10	1	
Issue	37	Excellent	3	1	
Validation/Issue					
Validation	191	Excellent	10	5	
Issue	425	Excellent	10	7	
SARs					
Enter human SARs	63	Excellent	2		
Enter serious animal SARs	1863	Excellent	2		
Enter environmental SARs	24	Ineffective	2		
Enter non-serious SARs	846	Excellent	10		
Report to Eudravigilance	2281	Excellent	15		
SIC/STC					
Urgent products not previously imported	2	Excellent	5	<1	
Routine products not previously imported	45	Excellent	15	4	
Urgent products previously imported	288	Excellent	2	<1	
Routine products previously imported	2448	Excellent	10	3	
On-line instantaneous issue of certificates	8403	Excellent	-		

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: ------- = Median ____ = Average
Inspections					
GMP inspections performed on a risk-basis within 3 yrs of last inspection	**28**	**Excellent**			
GDP inspections performed on a risk-basis within 5 years of last inspection	**21**	**Excellent**			
Written deficiency reports sent after GMP and GDP inspection	**49**	**Excellent**	**30**	**22**	
Issue GMP Certificate after last day at site	**28**	**Excellent**	**90**	**81**	
Updated documentation for GDP site issued after last day at site	**21**	**Excellent**	**90**	**73**	
UKPARs					
Make publicly available via the VMD internet & SPC for New MA.	**124**	**Excellent**	**30**	**14**	
Make publicly available via the VMD internet the relevant hyperlink to the EMA website for centralised products within 30 days of issue.	**18**	**Excellent**	**30**	**13**	
Make publicly available via Product Information Database	**43**	**Excellent**	**120**	**101**	
Make publicly available after issue of post-authorisation assessments	**482**	**Excellent**	**60**	**42**	

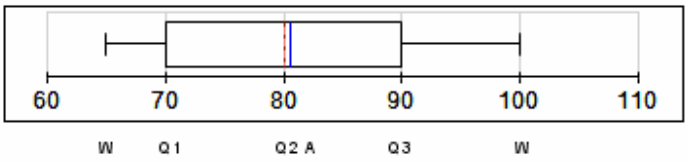
Box-and-Whisker Plots

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

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



Category/application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days[1])
European			
Centralised			
Rapp - Initial assessment by 70 days	4	Excellent	70
Co-Rapp - Provide comments on assessment report by 85 days	0		85
UK as Member only - LOQ by 100 days	5	Excellent	100
Mutual Recognition			
RMS			
Production of Final Assessment Report by day 90 (Phase 1)	4	Excellent	90
RMS Circulate the Consolidated List of Questions by day 57	0		57
Assessment of Responses by day 70 (Phase 2)	0		70
Procedure completed by day 90 (Phase 2)	1	Excellent	90
CMS			
CMS send any UK comments by day 54 (Phase 2)	5	Excellent	54
Procedure completed by day 90 (Phase 2)	5	Excellent	90
Decentralised			
RMS			
Production of Assessment Report by day 70 (Phase 1)	28	Excellent	70
Production of Assessment Report by day 120 (Phase 1)	22	Excellent	120
RMS Circulate Consolidated List of Questions by day 30 (Phase 2)	24	Excellent	30
Assessment of Responses by 70 days (Phase 2)	44	Excellent	70
RMS send confirmation of acceptance/referral by Day 90 (Phase 2)	44	Excellent	90
CMS			
UK comments sent by 100 days (Phase 1)	13	Excellent	100
CMS Send any UK Comments by day 25 (Phase 2)	20	Excellent	25
UK acceptance/referral sent by 90 days [2nd phase]	32	Excellent	90[210]
European Variations			
Type 1B EUCE Rapp			
Initial Assessment Completed according to EMA timetable	1	Excellent	
Type II EUCE Rapp			
Initial Assessment Completed according to EMA timetable	3	Excellent	
Type II - Mutual Recognition RMS			
PAR circulated by day 40 (Phase 1)	20	Excellent	40
CLOQ or decision circulated by day 59 (Phase 1)	22	Excellent	59
Type IB - Mutual Recognition RMS			
CLOQ or decision circulated by day 30 (Phase 1)	62	Excellent	30
Type IA - Mutual Recognition RMS			
Determined within 30 days	41	Excellent	30
Type II Mutual Recognition CMS			
UK comments sent by day 55 (Phase 1)	36	Excellent	55
UK comments sent by day 80 (Phase 2)	28	Excellent	80
Type IB Mutual Recognition CMS			
UK comments sent by day 20 (Phase 1)	36	Excellent	20
UK comments sent by day 50 (Phase 2)	9	Excellent	50

Category/application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days[1])
European Renewals			
Mutual Recognition RMS			
PAR circulated by day 40 (Phase 1)	**15**	**Excellent**	**40**
CLOQ circulated by day 59 (Phase 1)	**15**	**Excellent**	**59**
Mutual Recognition CMS			
UK Comments sent by day 55 (Phase 1)	**22**	**Excellent**	**55**
UK Comments sent by day 80 (Phase 2)	**31**	**Excellent**	**80**
Others (Centralised)			
UK as Rapporteur - Complete IA according to EMA timetable	**1**	**Excellent**	
Customer Relations			
Unreturned authorisation documents			
Right first time (Authorisations)	**1101**	**Excellent**	

1 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.
2 Box whisker plots have been omitted due to low numbers of applications.