MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 97 - JANUARY 2016

PHARMACEUTICAL INDUSTRY CUSTOMER SATISFACTION SURVEY 2016

The VMD will be conducting its online industry customer satisfaction survey from 20 January to 12 February 2016. Mo Gannon & Associates Ltd is carrying out the survey on our behalf and will treat all responses in confidence.

The VMD sent emails to users of our services on 20 January 2016 inviting participation.

Mo Gannon & Associates has designed the questionnaire to ensure you only answer questions that are relevant to your experience of dealing with the VMD. We anticipate you will be able to complete the survey in around 15 minutes.

We would like the views of all of you who have had personal experience of the VMD in the last 12 months. This will be with some or all of our:

- Pharmaceutical assessors
- Biological assessors
- Pharmacovigilance Team
- Inspections (Good Manufacturing Practice (GMP) or Good Distribution Process (GDP)) by VMD inspectors
- Administrative teams
- General Assessment Team (GAT)

Your company may have multiple submissions – regardless of your size or whether you are a NOAH member or not. So please share the questionnaire with other members of your team who have personal experience of the VMD. These colleagues may be in the UK or abroad.

We aim to publish:

- the summarised results on GOV.UK and in MAVIS in April; and
- an action plan by the end of June.

For further information please contact: David Lewsey (VMD, email: d.lewsey@vmd.defra.gsi.gov.uk, 01932 338332).

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Veterinary Medicines Directorate

The Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Tel: +44 (0)1932 336911 Search for VMD on GOV.UK
Email: postmaster@vmd.defra.gsi.gov.uk

NEWS

IMPROVING MAVIS TO MEET YOUR NEEDS

As we approach the 100th edition of MAVIS in October, we thought it would be a good time to get your views on our quarterly newsletter. Does it give you what you need? Is the content comprehensive and accurate? Is the layout and presentation easy for you to read online? We are always looking to improve our regular communications to our MAVIS readers and look forward to your responses.

Please send your comments and suggestions to Matthew Isted (VMD, email: m.isted@vmd.defra.gsi.gov.uk, 01932 338347).

THE VMD ON GOV.UK

In *MAVIS 94* we provided you with an update about our website content on GOV.UK. We have now reviewed and refined all of the guidance previously available as part of the Veterinary Medicines Guidance Note (VMGN) series as well as other information content. All the VMD material you need should be easily accessible and easy to read. Please remember that to find information on GOV.UK you need to use key words in the search box. To make it easier for you to find guidance, application forms and online services you can access these directly through the quick links at the top right of the VMD corporate page:

- **Product Information Database**
  Use this to search for products by name, active or therapeutic group and species. Alternatively you can download the whole database of products to an Excel document and sort as you wish. The database also links to the Summary of Product Characteristic (SPC) and Public Assessment Reports for further up to date information on the Veterinary Medicinal Product (VMP)
- **Veterinary medicines guidance**
  Lists and links to all guidance
- **Apply for a special import**
  Online service for vets
- **Report an adverse event**
  Online reporting for vets and animal owners; animal and human reactions or lack of efficacy to veterinary medicines and microchipping problems
- **MAVIS**
  Link to every publication of our Marketing Authorisation Veterinary Information Service (MAVIS) bulletin for the pharmaceutical industry
- **Veterinary medicines application form**
  Complements the guidance and quick access to the forms and how to apply
- **Report a problem**:
  ⇒ Report illegal animal medicines
  ⇒ Report a supply problem with a veterinary medicine
  ⇒ Report a product defect: veterinary medicine (note: this is not a link for reporting adverse events relating to the use of a VMP)
  ⇒ Report prescription misuse: animal medicine
  ⇒ Report an animal product being marketed as a medicine

To help you get the most out of GOV.UK we thought it would be helpful to give you some tips based on our experience of using the site.

Searching
The GOV.UK search function works like Google and other search engines. You can also search for VMD material directly on Google, etc.

The GOV.UK search engine will search for the words you have entered that are held in the title of the content page or the high level summary statement underneath.

Other content topics on GOV.UK that are contained within a webpage are searchable but will appear much further down in the search results.

The search results will include results from across all government departments.

To avoid finding similar information that the Medicines and Healthcare products Regulatory Agency provides for human health, use “animal” or “veterinary” in your search terms or look for them in the summary statement under the title in the search results.

We have written our website material to reflect words that our stakeholder’s use to search for this content but we are flexible and responsive to change so if our content does not match the words used for searching please contact us.

Keeping up to date
If you sign-up to the RSS Feed or an email alert from our corporate page you will be notified automatically when new material is published. At the bottom of the page there is an historical list of amendments.

The VMD’s ‘home’ page
Enter VMD in the GOV.UK search box to find our corporate ‘home’ page. Here you will find out about what we do, our governance and services standards etc. and information on how to contact us.

Contact us
Please let us know by emailing postmaster@vmd.defra.gsi.gov.uk if you have any problems finding information and tell us what search words you have used. We will do the following:

- check to see if it is available on GOV.UK
- look at the title and the summary on GOV.UK and how it compares to your search words, amending if necessary
- if the information isn’t there, see if it is on the archived VMD website
- if it is, discuss internally to see if it should be added to GOV.UK and re-written if necessary
- if it isn’t, discuss internally if the information should be provided
- reply to your email as soon as possible or within 15 working days at the latest.

If you wish to report a problem on a specific page you can also provide anonymous feedback by clicking on the link at the bottom of the content page.

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

REVIEW OF APPROACH TO ISSUING ANIMAL TEST CERTIFICATES

Following concerns raised by stakeholders during the Red Tape Challenge we have reviewed our approach to issuing Animal Test Certificates (ATCs).

The following changes have been made to streamline the process for authorising ATCs:

- the assessment of ATC applications will now be carried out by the VMD. The Royal College of Veterinary Surgeons (RCVS) will no longer be a part of the ATC process
- the emphasis is now on the benefit:risk assessment to allow more freedom for different applications, rather than a set framework
- with the help of the RCVS, we have updated our approach to Recognised Veterinary Practice which is now more permissive
- blood samples can be taken from animals at intervals through the study, provided the applicant confirms that samples are being taken for the benefit of the animals under observation

The guidance on ATCs on GOV.UK has been updated in line with these changes and can be found at www.gov.uk/guidance/animal-test-certificates.

For further information please contact: Anna Burrows (VMD, email: a.burrows@vmd.defra.gsi.gov.uk, 01932 338312).

THE VMD RESULTS OF THE 2015 CIVIL SERVICE PEOPLE SURVEY

The results of the 2015 Civil Service People Survey show that our staff rate the VMD highly. Our engagement index (the survey's measure of those areas that most shape our experiences at work) is 63% this year. This places us equal 11th out of 96 Government Bodies.

The VMD Highlight Report is at www.gov.uk/government/news/vmd-civil-service-people-survey-2015.

For further information please contact David Lewsey (VMD, email: d.lewsey@vmd.defra.gsi.gov.uk, 01932 338332).

LICENSING

BATCH RELEASE REQUESTS: CLARIFICATION FOR INDUSTRY

The batch release scheme is a digital service and all communication is done via email.

Batch release requests should be sent to batchr@vmd.defra.gsi.gov.uk; please do not send requests to individual team members or to Rick Parker who has left the VMD.

You will receive an automated acknowledgement letting you know that your request has been received. If you do not receive an acknowledgement, please resend your email. In this case, please also check how large the attachments are and consider resending under cover of more than one email.

Requests will be progressed within 10 clock days; clock days are the days the request is with the VMD for action. The clock starts on the day of receipt of the request. If a request is received on a non-working day, or after 4.00pm on a working day, the date of receipt will be the first working day thereafter.

If we require further information from you, we will send you an email and stop the clock while awaiting your response.

We will try and deal with requests as quickly as possible, but you should take into account the overall target when submitting your requests. Please do not chase outstanding requests unless the 10 day target has been exceeded.

If your request is urgent, please state this in the subject line of the email. A request will only be considered urgent if a delay in processing it may adversely affect animal health or welfare.

Approvals or refusals will be sent to the person submitting the request; if you wish your approval/refusal to be sent elsewhere, please say so in the covering email.

For further information please email: batchr@vmd.defra.gsi.gov.uk

TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 OCTOBER 2015 TO 21 DECEMBER 2015

The VMD provides a list on a quarterly basis of the ten 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® Therapy, suspension for subcutaneous injection in dogs	Allergens	2,138
Vet-Goid	Allergens	283
Greer Allergenic Extract Patient Prescription	Allergens	206
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	188
Antepsin	Sucralfate	76
Staphage Lysate (SPL)	Staphylococcus aureus	71
Botulism Vaccine	Clostridium botulinum type C toxoid	60
Artuvetrin® Test, injection fluid for intracutaneous use in dogs	Allergens	59
Duphafral AD3E Forte	Alpha Tocopheryl Acetate Cholecalciferol Vitamin A	56
BioRelease deslorelin	Deslorelin Acetate	52

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* one seizure notice has been published.

Racing Pigeon Supplies at the Racing Pigeon Show, Telford. Ten dropper bottles of 2% Ivermectin solution were seized as they were not authorised for use in the UK.

■ IMPROVEMENT NOTICES

Since the last edition of *MAVIS* five improvement notices have been published.

Pharmavet (Pharma Group), Conway, Gwynedd. The prescribing and supply of NFA-VPS products on the www.petremedies.co.uk website is carried out without the necessary checks in place i.e. details of animals, competency of user, that the product is to be used for the purpose intended.

The improvements are to:

- Cease supply of NFA-VPS products on www.petremedies.co.uk website until a more comprehensive questionnaire is in place, and transactions cannot proceed until such questionnaire has been verified by an SQP
- Provide confirmation of actions taken and further intended actions to be taken to ensure that the requirements for the supply of NFA-VPS medicines will be complied with

Badgers Oak Veterinary Clinic, Rye, East Sussex. Veterinary medicines had been supplied for/administered to food producing animals without the required records being kept as set out in regulation 23 (records of the receipt and supply of prescription products) and 24 (records of products administered to a food-producing animal under the cascade) of the Veterinary Medicines Regulations (VMR).

Improvements are to ensure that when veterinary medicines are administered or supplied for food producing animals, the practice records the information required by regulations 23 and 24 of the Veterinary Medicines Regulations.

Highland Industrial Supplies, Kirkwall, Orkney. Suitably Qualified Person (SQP) supplying POM-VPS products from premises not on the register for premises approved to retail veterinary medicinal products.

Improvement required is for the premise to either reapply for approval for the retail of veterinary medicinal products by SQPs or remove all POM-VPS and NFA-VPS products and cease all supplies and notify the VMD that supplies have ceased.

Horse Health Ltd, Southampton, Hampshire. Sarcoid Cleansing Salve, a product presented for use in the treatment of sarcoids in horses is being offered for sale on the UK market without a marketing authorisation.

The VMD has requested that the company remove all claims presenting the product for use in the treatment of sarcoids including amending the product name. The company has failed to respond in a satisfactory manner to ensure the product is marketed in accordance with the Regulations.

Improvement required is for all marketing of Sarcoid Cleansing Salve to cease until such time as the product has either obtained a marketing authorisation or all the product material has been amended so that it is no longer presented for the treatment of an adverse health condition.

H&C Phillips, Llanwrda, Carmarthenshire. Veterinary medicines have been used for food producing animals without the required records being kept as set out in regulation 19 (records of acquisition and administration) and 20 (retention of records) of the Veterinary Medicines Regulations.

Improvements are to update and maintain the veterinary medicines records as specified in regulation 19 of the VMR and retain these for five years as stated in regulation 20 of the VMR.

■ OUTCOMES OF PROSECUTIONS

On 22 October 2015 at Manchester and Salford Magistrates Court, Mr Hugh Beglin pleaded guilty to five charges of importation and five charges of possession with intent to supply under the Veterinary Medicines Regulations.

Mr Beglin was fined a total of £770 (including costs and victim surcharges).

This case related to the importation of various non UK authorised antibiotics for food producing animals and vaccines and wormers for dogs. These were discovered by Border Force at a UK airport.

Please report any information you have about suspected illegal medicines or breaches of the Veterinary Medicines Regulations to enforcement@vmd.defra.gsi.gov.uk.

If it is regarding a non medicinal product (product making unauthorised claims etc.) please submit an 'Unauthorised Product Complaint Reporting Form' which is available on GOV.UK.

All information will be treated confidentially.

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.

PHARMACOVIGILANCE INSPECTIONS UPDATE

Since March 2015, the VMD has conducted pharmacovigilance inspections of 22 UK marketing authorisation holders. The top five areas for inspection findings were:

1. **Adverse events**: not reporting all adverse events
2. **Pharmacovigilance training**: not training staff, insufficient training materials (e.g. poor presentation material) and incomplete training records
3. **Quality management systems**: insufficient documentation of pharmacovigilance procedures or failure to follow documented procedures
4. **Audits**: no recent internal pharmacovigilance audits, not auditing distributors
5. **Archiving**: not archiving documents in a secure manner and not keeping all pharmacovigilance source documentation e.g. initial call notes from sales staff

When preparing for an inspection, if you are sending multiple documents via Eudralink, please submit these in zip file format in order to save us having to download each document individually. It is also extremely helpful to the conduct of the inspection if inspectors are provided with WiFi access.

For further information please contact: Victoria Warnock (VMD, 01932 338448, email: v.warnock@vmd.defra.gsi.gov.uk).

PERIODIC SAFETY UPDATE REPORTS (PSURs)

All PSURs with a start date of 1 January 2016 or later should include any significant new information or changes received during the current PSUR period relating to reports included within the previous PSUR. To avoid confusion, these reports should be excluded from incidence calculations and included within the PSUR in a separate clearly identified section. If this additional information changes the previously reported incidence calculations this should also be made clear within this separate section. This change has been agreed following discussions at a European level between regulators at the Pharmacovigilance Working Party and with industry at the Consultative Group for Veterinary Pharmacovigilance Systems.

Marketing authorisation holders are also reminded that any changes in the PSUR cycle, requests for further pharmacovigilance activities and SPC changes are communicated within the PSUR assessment reports. It is therefore essential that you read these reports carefully when we send them to you.

For further information please contact: Alice Barnard (VMD, 01932 338424, email: a.barnard@vmd.defra.gsi.gov.uk).

QUARTERLY REPORT

During the period 1 October to 31 December 2015, the VMD received 1,475 suspected adverse event reports involving animals. Of these, 41 reports related to unauthorised or unidentified products, two reports involved animal trials under Animal Test Certificates (ATCs) and five further reports from studies not requiring ATCs.

Excluding these three categories, the remaining 1,427 suspected adverse event reports were associated with 361 authorised products in the following distribution categories:

1,288	Prescription Only Medicine - Veterinarian (POM-V)
82	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
16	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
36	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
5	Products sold under the Exemption for Small Pet Animals (N/A)

During the quarter 36 reports of human suspected adverse reactions and no environmental incident reports were received.

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

ANTIMICROBIAL RESISTANCE

Concerns about the impact of antimicrobial resistance has led to increasing consideration about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. A cross-Government AMR Strategy has been developed to address this issue. The Veterinary Medicines Directorate is responsible for delivering the animal health aspects of this Strategy. The following articles describe the most recent actions that we have taken.

DARC GROUP UPDATE

The most recent meeting of the Defra Antimicrobial Resistance Co-ordination (DARC) group was on 8 September 2015 and discussed recent trends in antibiotic resistance in bacteria of importance to human and animal health. The University of Exeter and the Royal Veterinary College gave presentations on current AMR research. The group discussed various topics such as Livestock Associated Meticillin Resistant *Staphylococcus aureus* (LA-MRSA), the VMD's support for the Pig Industry Medicine Hub, and the European Antibiotic Awareness Day. The next DARC meeting is scheduled for 9 February 2016.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

The 2014 UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report was published on 18 November 2015. The report presents 2014 antibiotic sales data as collected from UK Marketing Authorisation Holders alongside antibiotic resistance data generated by the VMD's AMR surveillance programme. Additionally, a high level summary report was also published alongside the main report. This report and previous reports can be found at: https://www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2014.

EUROPEAN ANTIBIOTIC AWARENESS DAY (EAAD) ACTIVITIES

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

As in previous EAADs (2013 and 2014), the VMD acted jointly with Public Health England (PHE) to co-ordinate EAAD 2015 activities – such as promoting the PHE Pledge Campaign to reach a target of 100,000 pledges by March 2016. 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. If you wish to make a pledge to become an Antibiotic Guardian you can do so at https://antibioticguardian.com/.

The VMD was also responsible for several activities which were orientated around EAAD including:

- RUMA-VMD conference on responsible use of antibiotics held on 3 November 2015
- Publication of various articles in the Vet Record, Vet Times, Cat World and Dog World)
- An advert poster distributed at the London Vet Show and published online.

UK AMR STRATEGY

The most recent meeting of the High Level Steering Group (HLSG) for the AMR Strategy took place on 20 October 2015. Activities to deliver the aims of the Strategy are being implemented in line with the guidance of the HLSG. The second year report and a detailed action plan for activity in the remaining three years of the Strategy will be published in January 2016. The report will set out the work achieved in the past year, including activities implemented by the various private organisations in the animal sector, and will include potential additional measures to be taken over the next three years to respond to the risk of AMR and to promote the responsible use of antibiotics.

HEADS OF MEDICINES AGENCY (VETERINARY) (HMA-V) UPDATE

The VMD chairs the Heads of Medicines Agencies – Veterinary (HMA-V) group, 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 last meeting was held on 12 January 2016.

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.

■ MEETINGS OF THE VPC

The VPC met in October 2015. Summary minutes of the meetings held from October 2014 are available on GOV.UK at www.gov.uk/government/organisations/veterinary-products-committee/about/membership.

Minutes of meetings held between 2009 and May 2014 are available on the National Archives website at webarchive.nationalarchives.gov.uk/20140909095305/http:/www.vmd.defra.gov.uk/vpc/.

Comments or requests for further information on the summary minutes should be sent to Lea Stott (VMD, email: l.stott@vmd.defra.gsi.gov.uk, 01932 338490).

■ MEMBERSHIP OF THE VPC

Defra Ministers have appointed the following new members to serve on the VPC from January 2016 until 31 December 2019: Professor Jason Weeks (Environmental Scientist), Dr Karin Burnett (Toxicologist), Mr Jonathan Statham (Veterinary Surgeon) and Mr Mark Jelley (Working Farmer). The Chairman and six existing members have been reappointed to the committee to serve a further term of four years. Further details of these appointments can be found in a Defra information bulletin and on the VPC pages on GOV.UK

Requests for further information on membership of the VPC should be made to Lea Stott (VMD, email: l.stott@vmd.defra.gsi.gov.uk, 01932 338490).

RESIDUES CONTROLS AND MONITORING

The VMD operates the National Surveillance Scheme (NSS) which implements EU legislation and therefore has a statutory basis. This programme monitors the use of veterinary medicines and unauthorised substances in UK food producing animals and is funded by the industry sectors in accordance with EU legislation.

■ RESULTS OF STATUTORY SURVEILLANCE

2015 Results

Sampling commenced in January 2015 and full details of UK results, together with information on any action taken, can be found by using the search term 'residue surveillance' on GOV.UK.

For further information please contact: Carol Brailsford (VMD, email: c.brailsford@vmd.defra.gsi.gov.uk, 01932 338330).

STAFF CHANGES

The following staff changes took place during this quarter:

New Staff

- Nicole Batey returned from a loan period with the Common Agriculture Policy and Rural Payments Agency on promotion to the Research and Development team on 14 December 2015

Departing Staff

- Sharda Mistry commenced a career break on 13 December 2015
- Rick Parker left the VMD on 30 December 2015 and transferred to the MHRA
- Crispin Madavo commenced a two year secondment to the EMA on 1 January 2016

Promotions

- Ines Morreale was temporarily promoted within the Licensing Administration team on 1 December 2015
- Carol Brailsford was temporarily promoted within the Residues team on 11 January 2016
- Jakki Steer, Bruce Hunter and Phil Howe were temporarily promoted within the IT team on 9 November 2015

Transfers

- Sandra Russell temporarily transferred to the Licensing Administration team on 18 January 2016

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 10 SEPTEMBER - 24 NOVEMBER 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Ceva Animal Health Ltd	15052/4075	Coglapix Suspension for Injection for Pigs	Actinobacillus pleuropneumoniae	POM-V
	15052/4070	Eprecis 20 mg/ml Solution for Injection for Cattle	Eprinomectin	POM-VPS
	15052/4073	Exflow 10 mg/g Powder for Use in Drinking Water for Cattle (Calves), Pigs, Chickens, Turkeys and Ducks	Bromhexine Hydrochloride	POM-V
Diversey Ltd	15985/4035	Thixoshield 40 mg/g Teat Dip Solution		AVM-GSL
Elanco Europe Ltd	00879/4000	MiPet Benazapet 2.5 mg Tablets for Cats and Dogs		POM-V
	00879/4002	MiPet Benazapet 5 mg Tablets for Dogs		POM-V
	00879/4001	MiPet Benazapet 20 mg Tablets for Dogs		POM-V
HCS bvba	35501/4004	Fipronil + S-methoprene HCS 50 mg/60 mg Spot-on Solution for Cats and Ferrets		POM-V
	35501/4005	Fipronil + S-methoprene HCS 67 mg/60.3 mg Spot-on Solution for Small Dogs		POM-V
	35501/4001	Fipronil + S-methoprene HCS 134 mg/120.6 mg Spot-on Solution for Medium Dogs	(S)-Methoprene, Fipronil	POM-V
	35501/4002	Fipronil + S-methoprene HCS 268 mg/241.2 mg Spot-on Solution for Large Dogs		POM-V
	35501/4003	Fipronil + S-methoprene HCS 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs		POM-V
Huvepharma N.V.	30282/4023	Pigfen 40 mg/g Granules for Pigs	Fenbendazole	POM-V
Industrial Veterinaria S.A.	36547/4005	Rhemox 500 mg/g Powder for Use in Drinking Water for Pigs, Chicken Broilers, Duck Broilers and Turkeys for Meat Production	Fenbendazole	POM-V
Krka d.d. Novo Mesto	01656/4095	Amatib 800 mg/g Oral Powder for Pigs and Chickens	Amoxicillin Trihydrate	POM-V
	01656/4091	Ataxxa 200 mg/40 mg Spot-on Solution for Dogs up to 4 kg	Imidacloprid, Permethrin (Cis:Trans 40:60)	POM-V
	01656/4093	Ataxxa 1,250 mg/250 mg Spot-on Solution for Dogs over 10 kg up to 25 kg		POM-V
	01656/4103	Milprazin 2.5 mg/25 mg Tablets for Small Dogs and Puppies Weighing at Least 0.5 kg		POM-V
	01656/4104	Milprazin 4 mg/10 mg Film-coated Tablets for Small Cats and Kittens Weighing at Least 0.5 kg	Milbemycin Oxime (A3 and A4), Praziquantel	POM-V
	01656/4101	Milprazin 12.5 mg/125 mg Tablets for Dogs Weighing at Least 5 kg		POM-V
	01656/4102	Milprazin 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg		POM-V
Krka Dd	01656/4096	Fipronil KRKA 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs	Fipronil	POM-V
Le Vet Beheer B.V.	41821/4028	Bupredine Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats	Buprenorphine, Buprenorphine Hydrochloride	POM-V
	41821/4027	Bupredine Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Buprenorphine, Buprenorphine Hydrochloride	POM-V
	41821/4022	Prednicortone 5 mg Tablets for Dogs and Cats	Prednisolone	POM-V
	41821/4023	Prednicortone 20 mg Tablets for Dogs and Cats	Prednisolone	POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Merial Animal Health Ltd	08327/4266	AVINEW NEO Effervescent Tablet for Chickens	Newcastle disease virus	POM-V
	08327/4267	Frontline Comboline Spot-on Cat	(S)-Methoprene, Fipronil	POM-V
	08327/4270	Frontline Comboline Spot-on Dog S		POM-V
	08327/4269	Frontline Comboline Spot-on Dog M		POM-V
	08327/4268	Frontline Comboline Spot-on Dog L		POM-V
	08327/4271	Frontline Comboline Spot-on Dog XL		POM-V
Zoetis UK Limited	42058/4183	CEFSHOT DC 250 mg Intramammary Suspension for Cattle	Cephalonium	POM-V
	42058/4188	Orbolan Lactating 200 mg Intramammary Suspension for Cattle and Sheep	Cloxacillin, Cloxacillin Sodium Monohydrate	POM-V

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 10 SEPTEMBER - 24 NOVEMBER 2015

Company Name	Product Name	Brief Details	Legal Category
Alfamed	Alfamed Fipronil 50 mg Spot-on Solution for Cats	To change the invented name of the product from Alfamed Fipronil to Firpralone+D6	AVM-GSL
	Alfamed Fipronil 67 mg Spot-on Solution for Small Dogs		AVM-GSL
	Alfamed Fipronil 134 mg Spot-on Solution for Medium Dogs		AVM-GSL
	Alfamed Fipronil 268 mg Spot-on Solution for Large Dogs		AVM-GSL
	Alfamed Fipronil 402 mg Spot-on Solution for Very Large Dogs		AVM-GSL
Bioniche Animal Health Europe Ltd	Folltropin 700 IU Powder and Solvent for Solution for Injection	Change in distributor	POM-V
	Folltropin 700 IU Powder and Solvent for Solution for Injection	Change of legal entity	POM-V
Bob Martin (UK) Ltd	Bob Martin Clear Wormer 20 mg Spot-on Solution for Cats and Kittens	Shelf life change	AVM-GSL
Boehringer Ingelheim Ltd	Pimovita 1.25 mg Chewable Tablets for Dogs	Change in the invented name of the medicinal product from Pimovita to Vetmedin Chew	POM-V
	Pimovita 2.5 mg Chewable Tablets for Dogs		POM-V
	Pimovita 5 mg Chewable Tablets for Dogs		POM-V
	Pimovita 10 mg Chewable Tablets for Dogs		POM-V
	Prascend 1 mg Tablets for Horses	Shelf life change	POM-V
C&H Generics Ltd	Voxical 230/20 mg Flavoured Film-Coated Tablets for Cats	To change the invented name from Voxical 230/20 mg Flavoured Film-Coated Tablets for Cats to Beaphar WORMclear 230/20 mg film-coated tablets for cats	NFA-VPS
	Voxical Plus Tablets for Dogs	To change the invented name from Voxical Plus Tablets For Dogs to Beaphar WORMclear tablets for dogs	NFA-VPS
Ceva Animal Health Ltd	Prid Delta 1.55 g Vaginal Delivery System for Cattle	Variation to add a new pack size	POM-V
Cyton Biosciences Ltd	Penethaone 236.3 mg/ml Powder and Solvent for Suspension for Injection for Cattle	Change of legal entity	POM-V
	Permacyl 236.3 mg/ml Powder and Solvent for Suspension for Injection for Cattle		POM-V
	Penethaone 236.3 mg/ml Powder and Solvent for Suspension for Injection for Cattle	Change in distributor	POM-V
	Permacyl 236.3 mg/ml Powder and Solvent for Suspension for Injection for Cattle		POM-V

Company	Product Name	Brief Details	Legal Category
Dechra Limited	Felidale 2.5 mg Coated Tablets for Cats	Change of Marketing Authorisation holder address	POM-V
	Felidale 5 mg Coated Tablets for Cats		POM-V
	Felimazole 1.25 mg Coated Tablet for Cats		POM-V
	Felimazole 2.5 mg Coated Tablets for Cats		POM-V
	Felimazole 5 mg Coated Tablets for Cats		POM-V
	HyperCard 10 mg Coated Tablets for Cats		POM-V
	Pethidine 50 mg/ml Solution for Injection		POM-V
	Vetivex 3 (Sodium Chloride 0.9 % w/v and Glucose 5% w/v Intravenous Infusion BP (Vet))		POM-V
	Vetivex 9 (Ringers Solution for Injection)		POM-V
EU Pharmaceuticals Ltd	Controline Spot-on Solution Cat 50 mg	To change the invented name of the medicinal product from Controline to Ridaflea	NFA-VPS
	Controline Spot-on Solution Dog S 67 mg		NFA-VPS
	Controline Spot-on Solution Dog M 134 mg		NFA-VPS
	Controline Spot-on Solution Dog L 268 mg		NFA-VPS
	Controline Spot-on Solution Dog XL 402 mg		NFA-VPS
Evans Vanodine International Plc	3TX 1:3 2.15% w/v Concentrate for Teat Dip and Teat Spray Solution	Change in distributor	AVM-GSL
	Golden 0.535% w/v Ready to Use Teat Dip and Teat Spray Solution		AVM-GSL
Intervet UK Ltd	AquaVac PD3 Emulsion for Injection for Atlantic Salmon	Shelf life change	POM-V
Laboratorios Hipra SA	Unistrain PRRS Lyophilisate and Solvent for Suspension for Injection for Pigs	Variation to include additional presentations of the solvent (glass containers)	POM-V
Le Vet B.V.	Equibactin Vet. (333 mg/g + 67 mg/g) Oral Paste for Horses	Variation to add a pack size	POM-V
Le Vet Beheer B.V.	Amoxibactin 50 mg Tablets for Dogs and Cats	Change in distributor	POM-V
	Amoxibactin 250 mg Tablets for Dogs		POM-V
	Amoxibactin 500 mg Tablets for Dogs		POM-V
Norbrook Laboratories Ltd	Clavapet 50 mg Tablets for Dogs and Cats	To change the invented name of the medicinal product from Clavapet to Synuclav	POM-V
	Clavapet 250 mg Tablets for Dogs		POM-V
	Clavapet Palatable Tablets 500 mg for Dogs		POM-V
	Clavapet Suspension for Injection		POM-V
	Fiproclear 2.5 mg/ml Cutaneous Spray Solution for Cats and Dogs	Shelf life change	NFA-VPS
	Flydown 10 mg/ml Spot-On Solution for Cattle and Sheep		POM-VPS
	Norbrook Deltamethrin 10 mg/ml Spot-On Solution for Cattle and Sheep		POM-VPS
	Spotinor 10 mg/ml Spot-on Solution for Cattle and Sheep		POM-VPS
Prionics Lelystad B.V.	Tuberculin PPD Kit	Shelf life change	POM-V
Sogeval	Libeo 10 mg Chewable Tablets for Dogs	Shelf life change	POM-V
	Libeo 40 mg Chewable Tablets for Dogs		POM-V
	Perlium Amoxival 100 mg/g Premix for Medicated Feeding Stuff for Pigs	Change in distributor	POM-V
	Therios 75 mg Chewable Tablets for Cats		POM-V
	Xeden 200 mg Tablet for Dogs		POM-V
Vale Pharmaceuticals Ltd	FleaCidal 50 mg Spot-on Solution for Cats	Variation to delete a pack size	NFA-VPS
	FleaCidal 67 mg Spot-on Solution for Small Dogs		NFA-VPS
	FleaCidal 134 mg Spot-on Solution for Medium Dogs		NFA-VPS

Company	Product Name	Brief Details	Legal Category
Vale Pharmaceuticals Ltd continued	FleaCidal 268 mg Spot-on Solution for Large Dogs	Variation to delete a pack size	NFA-VPS
	FleaCidal 402 mg Spot-on Solution for Very Large Dogs		NFA-VPS
	FleaCidal 50 mg Spot-on Solution for Cats	Variation to add a pack size	NFA-VPS
	FleaCidal 67 mg Spot-on Solution for Small Dogs		NFA-VPS
	FleaCidal 134 mg Spot-on Solution for Medium Dogs		NFA-VPS
	FleaCidal 268 mg Spot-on Solution for Large Dogs		NFA-VPS
	FleaCidal 402 mg Spot-on Solution for Very Large Dogs		NFA-VPS
Vetpharma Animal Health, S.L	Atipazole 5 mg/ml Solution for Injection for Dogs and Cats	Change in distributor	POM-V
	Sededorm 1 mg/ml Solution for Injection for Dogs and Cats		POM-V
Zoetis UK Limited	Covexin 10 Suspension for Injection for Sheep and Cattle	Shelf life change	POM-VPS
	Duramune DAPPi+LC Lyophilisate and Solvent for Suspension for Injection for Dogs		POM-V
	Duramune Pi + LC		POM-V
	Rispoval 3 BRSV Pi3 BVD Lyophilisate and Suspension for Suspension for Injection for Cattle	Variation to add a pack size	POM-V
Zylavet Pharmaceuticals Ltd	Pimovita 1.25 mg Chewable Tablets for Dogs	Change of legal entity	POM-V
	Pimovita 2.5 mg Chewable Tablets for Dogs		POM-V
	Pimovita 5 mg Chewable Tablets for Dogs		POM-V
	Pimovita 10 mg Chewable Tablets for Dogs		POM-V

EUCE AUTHORISATIONS ISSUED BETWEEN 10 SEPTEMBER - 24 NOVEMBER 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Ceva-Phylaxia Veterinary Biologicals Co. Ltd	EU/2/15/188/001-003	Vectormune ND Suspension and Solvent for Suspension for Injection for Chickens	Turkey herpesvirus	POM-V
Intervet International BV	EU/2/15/182/001-002	Innovax-ILT	Herpesvirus of turkey (HVT) expressing gD and gI glycoproteins of Infectious laryngotracheitis virus	POM-V
	EU/2/015/187/001-004	Porcilis PCV ID	Porcine circovirus-2	POM-V
Le Vet Beheer B.V.	EU/2/15/186/001-002	Novaquin 15 mg/ml Oral Suspension for Horses	Meloxicam	POM-V
Novartis Animal Health UK Ltd	EU/2/15/185/001-002	Fortekor Plus 1.25 mg/2.5 mg Tablets	Benazepril Hydrochloride, Pimobendan	POM-V
	EU/2/15/185/003-004	Fortekor Plus 5 mg/10 mg Tablets		POM-V
Vetoquinol SA	EU/2/15/184/001-002	UpCard 0.75 mg Tablet	Torasemide Anhydrous	POM-V
	EU/2/15/184/003-004	UpCard 3 mg Tablet		POM-V
	EU/2/15/184/005-006	UpCard 7.50 mg Tablet		POM-V
	EU/2/15/184/007-008	UpCard 18 mg Tablet		POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 10 SEPTEMBER - 24 NOVEMBER 2015

Company	Product Name	Brief Details	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	Semintra 4 mg/ml Oral Solution for Cats	Variation to include a new presentation	POM-V
	Semintra 4 mg/ml Oral Solution for Cats	Variation to amend the SPC	POM-V
Ceva Sante Animale	Meloxidyl 0.5 mg/ml Oral Suspension for Cats	Variation to add a new pack size	POM-V
Laboratorios Hipra SA	Startvac Emulsion for Injection for Cattle	Variation to add a new presentation	POM-V
Orion Corporation	Sileo 0.1 mg/ml Oromucosal Gel for Dogs	Variation to extend the shelf-life	POM-V
Prevtec Microbia GmbH	Coliprotec F4 Lyophilized Live Non-Pathogenic Escherichia Coli Vaccine for Oral Use in Swine	Variation to extend the shelf-life	POM-V

MARKETING AUTHORISATIONS EXPIRED BETWEEN 10 SEPTEMBER - 24 NOVEMBER 2015

Company	Vm Number	Product Name	Legal Category
Ballinskelligs Veterinary Products	12828/4002	Vetical 40+M Solution for Injection	POM-VPS
Intervet UK Ltd	01708/4543	Plerion Chewable Tablets for Dogs from 2.5 kg	NFA-VPS
	01708/4544	Plerion Chewable Tablets for Dogs from 5 kg	NFA-VPS
Krka d.d. Novo Mesto	01656/4022	Marfloquin 100 mg/ml Solution for Injection for Cattle and Pigs (Sows)	POM-V
Norbrook Laboratories Ltd	02000/4338	Dunlop's Multivitamin Solution for Injection	POM-VPS
Novartis Animal Health UK Ltd	12501/4111	Swaycop 1.25% w/v Solution for Injection	POM-VPS
	12501/4108	Wilko Single Dose Wormer for Small Dogs and Puppies 100 mg Film Coated Tablets	AVM-GSL
	12501/4109	Wilko Single Dose Wormer for Dogs and Puppies 500 mg Film Coated Tablets	AVM-GSL
Pfizer Ltd	00057/4318	Fevaxyn iCHP	POM-V
Virbac	05653/4060	Canovel Long-Acting Flea and Tick 2% w/v Cutaneous Spray Solution	AVM-GSL
Zoetis UK Limited	42058/4102	Poulvac IB H120 Vaccine	POM-VPS
	42058/4198	PropoFlo 10 mg/ml Emulsion for Injection for Dogs and Cats	POM-V
	42058/4200	PropoFlo Vet 10 mg/ml Emulsion for Injection	POM-V

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK UP TO 31 DECEMBER 2015

Annex I

Our published standards are on GOV.UK

Key: Dark Green *Excellent 100%* | Light Green *Excellent, but some targets missed* | Amber *Effective* | Red *Ineffective*

Published Standard – No. 1 – Quality of Documentation

	App Type	Total No.	Performance
1	Authorisation Documentation	1,756	97.8%

Published Standard – No.2 – European Applications

	App Type	No. of Apps	Performance
2	Centralised: New MAs / Extensions	7	100%
3	Centralised – UK as Rapp: Variations	14	100%
4	Centralised – UK as Rapp: Renewals	2	100%
5	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 70)	36	100%
6	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 120)	50	100%
7	DCP – UK as RMS: New MAs / Extensions (Phase 2)	47	100%
8	DCP – UK as CMS: New MAs / Extensions (Phase 1)	34	100%
9	DCP – UK as CMS: New MAs / Extensions (Phase 2)	24	100%
10	MRP – UK as RMS: New MAs / Extensions (Phase 1)	7	100%
11	MRP – UK as RMS: New MAs / Extensions (Phase 2)	9	100%
12	MRP – UK as CMS: New MAs / Extensions (Phase 2)	20	100%
13	MRP – UK as RMS: Type IA Variations	73	100%
14	MRP – UK as RMS: Type IB & II Variations (Phase 1)	103	100%
15	MRP – UK as CMS: Type IB & II Variations (Phase 1)	142	100%
16	MRP – UK as CMS: Type IB & II Variations (Phase 2)	61	100%
17	MRP – UK as RMS: Renewals (Phase 1)	27	100%
18	MRP – UK as CMS: Renewals (Phase 1)	47	100%
19	MRP – UK as CMS: Renewals (Phase 2)	39	100%

Published Standard – No. 2 – National Applications

	App Type	No of Apps	Performance	Target Days	Average Days
20	New MAs / Extensions: Initial Assessment	**25**	100%	-	-
	75 Day Clock	2		75	55
	90 Day Clock	23		90	84
21	New MAs / Extensions: Sign-Off	**25**	96.0%	-	-
	130 Day Clock	4		130	116
	150 Day Clock	21		180	112
22	New Homeopathic	**0**	0%	50	0
23	Type IA Variations	**129**	99.2%	30	23.8
24	Admin Variations	**25**	100%	-	-
	< 10 Changes	25		30	14.5
	> 10 Changes	0		60	0
25	Type IB / II Variations: Initial Assessment	**182**	98.9%	-	-
	Type IB	145		30	21.4
	Type II	37		60	48.9
26	Type IB / II Variations: Sign-Off	**127**	98.4%	-	-
	Type IB	102		30	16
	Type II	25		60	38.2
27	Renewals: Initial Assessment	**2**	100%	60	49.5
28	Renewals: Sign-Off	**4**	100%	60	34
29	Batch Release	**1,961**	99.5%	10	2.5
30	AVA, NFABBA & ESCCA	**8**	100%	45	News: 15.7 Vars: 17.4
31	ATCs	**33**	97.0%	-	-
	Type A/S	16		30	9.5
	Type B	7		50	35.4
	Variations / Renewals	10		30	6.4
32	Specific Batch Control	**29**	100%	20	1.4
33	Validation of applications	**771**	100%	-	-
34	Mock-Ups (post New MA)	**142**	100%	-	-
35	Mock-Ups (post EU Variations / Renewals	**474**	99.2%	-	-
36	Issue of authorisation documentation	**1,018**	100%	-	-

Published Standard – No. 3 – Import and Export Certificates

	App Type	No. of Apps	Performance	Target Days	Average Days
37	STC / SIC Requiring Assessment – New products	**75**	100%	15	4
38	STC / SIC Requiring Assessment – other products	**4,674**	99.9%	-	-
	Urgent	346		2	1
	Non-Urgent	4,328		10	2
39	WDIC – not previously assessed	**5**	100%	15	3
40	WDIC – other applications	**106**	100%	-	-
	Urgent	6		2	1
	Non-Urgent	100		10	3
41	Export	**573**	100%	10	6

Published Standard – No. 4 – Public Assessment Reports

	App Type	No. of Apps	Performance	Target Days	Average Days
42	Make publicly available via GOV.UK the SPC for New MAs	**143**	98.6%	-	-
	SPC for MAs	129		30	14
	Link to EMA	14		30	14
43	Make publicly available via GOV.UK the PAR for New MAs	**84**	100%	120	99
44	Make publicly available via GOV.UK the post authorisation assessment	**665**	99.8%	60	44

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
45	Human & Animal AERs	**4,640**	99.3%
46	Human & Animal AERs – Follow Up	**2,134**	99.2%
47	Environmental SAR	**1**	100%
48	Inspections	**23**	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
49	GMP Inspections within 3 years of last inspection	**40**	100%	-	-
50	GDP inspections within 5 years of last inspection	**32**	100%	-	-
51	Send deficiency or post inspections letter	**73**	100%	30	
	GMP	42			24
	GDP	31			23
52	Issue GMP Certificates and final inspection reports	**36**	100%	90	80
53	Send final inspection report to wholesaler site	**31**	100%	90	77

ORGANOGRAM JANUARY 2016

Annex 2