MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 96 - OCTOBER 2015

ISO 9001 AND ISO 27001: SUCCESSFUL ANNUAL SURVEILLANCE VISITS

We underwent annual surveillance audits in September as part of our ongoing certification for the ISO 9001 – Quality Management Systems and ISO 27001 – Information Security Management Systems international standards. These audits take place every year over the three year period that our certifications last and check that we continue to meet the requirements of the standards.

We are very pleased to say that the auditors have recommended our continued certification for both standards and they did not raise any non-conformities against either. This means that we will have gone through the 3-year certification cycles for both standards without any non-conformities. We feel this independent, external validation demonstrates that our systems and processes are effective and robust enabling us to continue to provide excellent services to our stakeholders. We are considering the auditors' suggestions for possible improvements to certain aspects of our systems and processes. Where we judge them to be valuable to improving our business we will implement 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).

CONTENTS

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

VMD FAX NUMBER

Due to the low volumes of faxes received and sent by the VMD, we have decided to discontinue the use of the fax machine as of 1 January 2016. After this date the fax number, 01932 336618, will no longer be available.

If you wish to contact the VMD, please do so as follows:

By email:

- General email: postmaster@vmd.defra.gsi.gov.uk
- Individual staff: initial.surname@vmd.defra.gsi.gov.uk
- Special import scheme: importcert@vmd.defra.gsi.gov.uk
- Export certificate scheme: exportcert@vmd.defra.gsi.gov.uk
- Finance invoices: financepost@vmd.defra.gsi.gov.uk

Using online systems available on GOV.UK for:

- getting Special Import (SIC) and Special Treatment (STC) Certificates
  www.vmd.defra.gov.uk/sis/default.aspx
- getting Export Certificates
  www.gov.uk/government/publications/apply-to-export-an-animal-medicine-from-the-uk
- reporting Adverse Reactions ('Yellow Forms')
  www.gov.uk/report-veterinary-medicine-problem

By telephone:

- Switchboard: 01932 336911
- Individual staff: 01932 33 [+ Ext no.]
- Reporting an adverse reaction: 01932 338427

By post:
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

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

OPEN MEETING OF THE VETERINARY MEDICINES DIRECTORATE

The VMD held its open meeting on 2 October 2015.

The presentations given at the meeting are available at:
www.gov.uk/government/organisations/veterinary-medicines-directorate

For further information please contact Lea Stott (VMD, email: l.stott@vmd.defra.gsi.gov.uk, 01932 338490).

LICENSING

APPLICATIONS: DATE OF ISSUE/APPROVAL

There is an inconsistency in the information that is included on the authorisation certificates issued at the end of a procedure between European MA variations and National Type IA variations, and all other application types. This includes all applications for Marketing Authorisations, Veterinary Homeopathic Remedies, Animal Test Certificates, and Specific Manufacturing Authorisations, e.g. Autogenous Vaccines.

At the moment two dates appear on the authorisation certificate for all EU variations and National Type IA variations:

- the date the procedure ended
- the date the authorisation certificate was issued

Only the date of issue is included on the certificates for all other application types.

This information is misleading as it implies that the VMD has approved the variation from the date the procedure ended when in fact the date of approval for all applications is the date the certificate is issued.

Therefore, to ensure consistency across all application types, only the date of approval will be shown on the certificates, i.e. the date the certificate is issued.

This change will be implemented from 1 October 2015, and will not be applied retrospectively.

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

VALIDATION OVER THE CHRISTMAS PERIOD 2015

New Marketing Authorisation Applications

The last validation meeting to discuss applications for new Marketing Authorisations (MAs) will take place on 23 December 2015. Applications to be considered for validation must be received on or before 21 December 2015. The validation meetings will resume week commencing 4 January 2016.

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

Manufacturing and Wholesale Dealers Authorisation Applications (New and Variations)

The last day for validation application discussions for Manufacturing (ManAs) and Wholesale Dealers Authorisation (WDAs) applications (new and variations) will be on Friday 18 December 2015. Applications to be considered for validation by this date must be received on or before Wednesday 16 December 2015. The validation discussions will resume week commencing 4 January 2016.

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

CHANGES TO THE VALIDATION PROCEDURES FOR VARIATIONS TO MARKETING AUTHORISATIONS (MAs) AUTHORISED ON THE BASIS OF INFORMED CONSENT i.e. COPYCAT MAs

The VMD has changed the way in which variations to copycat MAs should be applied for, validated and charged for:

- A parent MA holder is responsible for notifying a Copycat MA holder when changes have been made to the parent MA and should provide the Copycat MA holder with at least the categories used for the variation(s) (and ideally the application number).
- Copycat MA holders are now required to use the relevant category for the change concerned for a variation to a copycat product. It is no longer acceptable to use an unforeseen Type IB 'z' category.
- For Type II variations, if a Copycat MA holder wishes to benefit from the allocation of a reduced (Type IB) fee and timetable, the Copycat MA holder must submit the copycat variation within two months of issue of the parent variation. Submission after the two month period will result in a full (Type II) fee and timetable being applied.
- For a Type II grouped change, a Type IB grouped fee will apply to the copycat MA.
- Do not submit data with the Copycat variation. The application should rely solely on data already assessed for the Parent MA. If data are provided, a reduced fee and timetable will not apply.

Further information and current guidance about how to apply for a variation can be found at: www.gov.uk/guidance/apply-to-change-a-marketing-authorisation-for-an-animal-medicine

SPECIAL IMPORT SCHEME

The Special Import Scheme (SIS) is an online service used by vets to obtain a Special Import Certificate (SIC) or Special Treatment Certificate (STC).

To access the online system, please click the 'Apply for a Special Import' link available on the VMD homepage on GOV.UK.

If you have a query regarding the SIS, please email importcert@vmd.defra.gsi.gov.uk.

Please do not call the VMD; the SIS is a digital service and **all** queries will be dealt with promptly by email.

Further guidance about the scheme and the timescales for processing an application is available at www.gov.uk/guidance/apply-for-a-certificate-to-import-a-veterinary-medicine-into-the-uk.

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

TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 JULY 2015 - 30 SEPTEMBER 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	2,188
Vet-Goid	Allergens	350
Spectrum Hyposensitisation Vaccine - injectable solution	Allergens	237
Greer Allergenic Extract Patient Prescription	Allergens	231
Antepsin	Sucralfate	80
Staphage Lysate (SPL)	Staphylococcus aureus	59
Artuvetrin® Test, injection fluid for intracutaneous use in dogs	Allergens	56
Ekyflogyl 125 mls (solution of Prednisolone 2mg/ml, Lidocaine 0.01 g/ml, Dimethyl sulphoxide 0.8 ml/ml)	Prednisolone acetate Lidocaine hydrochloride Dimethyl sulphoxide	56
Oncept (Canine Melanoma Vaccine)	Canine melanoma DNA	52
Palladia 10 mg film-coated tablets for Dogs	Toceranib	51

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* one improvement notice has been published.

Botanica International Ltd, Rostrevor, County Down. Multiple products presented on the Botanica International website, botanica.ie for the purpose of the treatment and prevention of adverse health conditions.

The notice required that they:

- remove from the website all medicinal claims and references highlighted in the sample pages provided
- remove or amend any similar medicinal claims found elsewhere in Botanica International Ltd marketing material, this includes publicity via social media
- provide written confirmation that no further claims for the treatment or prevention of adverse health conditions in animals will be made for Botanica International Ltd products without the proper authorisation.

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.

QUARTERLY REPORT

During the period 1 July to 30 September 2015 the VMD received 1,366 suspected adverse event reports involving animals. Of these, 74 reports related to unauthorised or unidentified products, two reports involved animal trials under Animal Test Certificates (ATCs) and two further reports from studies not requiring an ATC.

Excluding these three categories, the remaining 1,288 suspected adverse event reports were associated with 337 authorised products in the following distribution categories:

1,137	Prescription Only Medicine - Veterinarian (POM-V)
81	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
31	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
27	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
12	Small Animal Exemption Scheme (N/A)

During the quarter the VMD received 40 reports of human suspected adverse reactions and four environmental incident reports.

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 Defra Antimicrobial Resistance Co-ordination (DARC) group met 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 Resistance Staphylococcus aureus (LA-MRSA), the VMD's Pig Industry Medicine Hub, and European Antibiotic Awareness Day. The next DARC meeting is scheduled for 24 November 2015.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

We are formalising the 2014 UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report. The report draws together data on antibiotic sales collected from UK Marketing Authorisation Holders with antibiotic resistance data from the VMD's surveillance programmes. We expect to publish the Report in November this year.

This report and previous reports can be found at:
https://www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2013

UK AMR STRATEGY

The most recent meeting of the High Level Steering Group (HLSG) for the AMR Strategy took place on 25 June 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 November 2015. 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.

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 scientific₁ 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.

₁Scientific 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).

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:

Departing Staff

- Tom Nash resigned on 6 August 2015
- Luke Wakefield resigned on 14 October 2015

Promotions

- Ken Stapleton was temporarily promoted within the Pharmaceuticals and Feed Additives team on 1 September 2015
- Anna Burrows was promoted and transferred to the Legislation team on 19 October 2015
- June Mullins was promoted within the Quality Management and Design Services team on 19 October 2015
- Amanda Baker was temporarily promoted within the Enforcement team on 19 October 2015

Transfers

- Sam Fowler transferred to the Enforcement team on 17 August 2015
- Bijal Mistry temporarily transferred to the Enforcement team on 29 October 2015

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 15 JUNE - 10 SEPTEMBER 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Alfamed	17902/4092	Ectoline Combo 50 mg/60 mg Spot-on Solution for Cats	Fipronil Pyriproxyfen	POM-V
	17902/4088	Ectoline Combo 67 mg/20 mg Spot-on Solution for Small Dogs		POM-V
	17902/4093	Ectoline Combo 100 mg/120 mg Spot-on Solution for Very Large Cats		POM-V
	17902/4089	Ectoline Combo 134 mg/40 mg Spot-on Solution for Medium Dogs		POM-V
	17902/4090	Ectoline Combo 268 mg/80 mg Spot-on Solution for Large Dogs		POM-V
	17902/4091	Ectoline Combo 402 mg/120 mg Spot-on Solution for Very Large Dogs		POM-V
	17902/4094	Fipralone Combo 50 mg/60 mg Spot-on Solution for Cats		POM-V
	17902/4084	Fipralone Combo 67 mg/20 mg Spot-on Solution for Small Dogs		POM-V
	17902/4095	Fipralone Combo 100 mg/120 mg Spot-on Solution for Very Large Cats		POM-V
	17902/4085	Fipralone Combo 134 mg/40 mg Spot-on Solution for Medium Dogs		POM-V
	17902/4086	Fipralone Combo 268 mg/80 mg Spot-on Solution for Large Dogs		POM-V
	17902/4087	Fipralone Combo 402 mg/120 mg Spot-on Solution for Very Large Dogs		POM-V
aniMedica GmbH	24745/4023	Procapen Injector 3 g Intramammary Suspension for Cattle	Procaine Benzylpenicillin	POM-V
Ceva Animal Health Ltd	15052/4072	Eprecis 5 mg/ml Pour-on Solution for Cattle	Eprinomectin	POM-VPS
Ceva Sante Animale	14966/4012	Fipronil-(S)-Methoprene Ceva Spot-on Solution for Cats 1-5 kg	(S)-Methoprene Fipronil	POM-V
	14966/4013	Fipronil-(S)-Methoprene Ceva Spot-on Solution for Dogs 2-10 kg and Cats > 5kg		POM-V
	14966/4014	Fipronil-(S)-Methoprene Ceva Spot-on Solution for Dogs 10-20 kg		POM-V
	14966/4015	Fipronil-(S)-Methoprene Ceva Spot-on Solution for Dogs 20-40 kg		POM-V
	14966/4016	Fipronil-(S)-Methoprene Ceva Spot-on Solution for Dogs 40-60 kg		POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4046	ExiTape 20 mg Spot-on Solution for Cats and Kittens	Praziquantel	AVM-GSL
	08749/4047	Ezi-Wormer 20 mg Spot-on Solution for Cats and Kittens		AVM-GSL
	08749/4050	TapeNil 20 mg Spot-on Solution for Cats and Kittens		AVM-GSL
	08749/4051	Wormax 20 mg Spot-on Solution for Cats and Kittens		AVM-GSL
	08749/4052	WormCat 20 mg Spot-on Solution for Cats and Kittens		AVM-GSL
	08749/4049	WormIt 20 mg Spot-on Solution for Cats and Kittens		AVM-GSL
Chemicals Laif S.P.A	23101/4001	API-Bioxal 886 mg/g Powder for In-hive Use	Oxalic Acid	AVM-GSL
Dechra Limited	10434/4086	Osphos 51 mg/ml Solution for Injection for Horses	Clodronic Acid Clodronate Disodium Tetrahydrate	POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Divasa - Farmavic S.A	33229/4004	Penethaone 236.3 mg/ml Powder and Solvent for Suspension for Injection for Cattle	Penethamate Hydriodide micronised Potassium Dihydrogen Phosphate	POM-V
	33229/4005	Permacyl 236.3 mg/ml Powder and Solvent for Suspension for Injection for Cattle		POM-V
Kernfarm B.V.	43877/4001	Linco-Spectin 100, 222/444.7 mg/g Powder for Use in Drinking Water for Pigs and Chickens	Lincomycin Spectinomycin Lincomycin Hydrochloride Spectinomycin Sulphate	POM-V
Krka Dd	01656/4082	Milbactor 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
Laboratoire TVM	35079/4003	EMEDOG 1 mg/ml Solution for Injection for Dogs	Apomorphine Hydrochloride	POM-V
Le Vet Beheer B.V.	41821/4024	Carporal 40 mg Tablets for Dogs	Carprofen	POM-V
	41821/4025	Carporal 160 mg Tablets for Dogs		POM-V
Norbrook Laboratories Limited	02000/4392	Marbodex Aural Ear Drops Suspension for Dogs	Clotrimazole Dexamethasone Marbofloxacin Dexamethasone Acetate	POM-V
	02000/4391	NorOtic Ear Drops Suspension for Dogs		POM-V
Richter Pharma AG	22080/4007	Spasmium Comp 500 mg/ml + 4 mg/ml Solution for Injection	Hyoscine Butylbromide Metamizole sodium monohydrate Hyoscine Metamizole	POM-V
Vale Pharmaceuticals Ltd	20692/4000	FleaCidal 50 mg Spot-on Solution for Cats	Fipronil	NFA-VPS
	20692/4001	FleaCidal 67 mg Spot-on Solution for Small Dogs		NFA-VPS
	20692/4002	FleaCidal 134 mg Spot-on Solution for Medium Dogs		NFA-VPS
	20692/4003	FleaCidal 268 mg Spot-on Solution for Large Dogs		NFA-VPS
	20692/4004	FleaCidal 402 mg Spot-on Solution for Very Large Dogs		NFA-VPS
Virbac S.A.	05653/4192	Twinox 40 mg/10 mg Tablets for Cats and Dogs	Amoxicillin Clavulanic acid Amoxicillin Trihydrate Potassium Clavulanate	POM-V
	05653/4191	Twinox 200 mg/50 mg Tablets for Dogs		POM-V
	05653/4193	Twinox 400 mg/100 mg Tablets for Dogs		POM-V
Warburton Technology Limited	42511/4000	Multimin Solution for Injection for Cattle	Copper Manganese Selenium Zinc Copper sulphate Pentahydrate Magnesium Carbonate Anhydrous Sodium selenite Zinc oxide	POM-V

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 15 JUNE - 10 SEPTEMBER 2015

Company Name	Product Name	Brief Details	Legal Category
Abbott Laboratories Ltd	PropoFlo Plus 10 mg/ml Emulsion for Injection for Dogs and Cats		POM-V
	PropoFlo Vet 10 mg/ml Emulsion for Injection		POM-V
	PropoFlo 10 mg/ml Emulsion for Injection for Dogs and Cats	Change of legal entity	POM-V
	IsoFlo 100% w/w Inhalation Vapour Liquid		POM-V
	IsoFlo Vet 100% w/w Inhalation Vapour Liquid		POM-V
	PropoFlo Plus 10 mg/ml Emulsion for Injection for Dogs and Cats		POM-V
	PropoFlo Vet 10 mg/ml Emulsion for Injection		POM-V
	PropoFlo 10 mg/ml Emulsion for Injection for Dogs and Cats	Change in distributor details	POM-V
	IsoFlo 100% w/w Inhalation Vapour Liquid		POM-V
	IsoFlo Vet 100% w/w Inhalation Vapour Liquid		POM-V
	Isothesia 1000 mg/g Inhalation Vapour Liquid for Horses, Dogs, Cats, Ornamental Birds, Reptiles, Rats, Mice, Hamsters, Chinchillas, Gerbils, Guinea Pigs and Ferrets	Change of legal entity	POM-V
	PropoFlo Plus 10 mg/ml, Emulsion for Injection for Dogs and Cats	Shelf-life change	POM-V
Alstoe Ltd (Alstoe Animal Health)	Vetergesic 0.3 mg/ml Solution for Injection for Dogs and Cats		POM-V
	Vetergesic Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Variation to change legal entity	POM-V
	Vetergesic Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats		POM-V
Animalcare Ltd	Aqupharm 1 0.9% w/v Solution for Infusion	Additional pack sizes	POM-V
	Aqupharm 1 0.9% w/v Solution for Infusion		POM-V
	Aqupharm 9 Ringer's Solution for Infusion	Shelf-life change	POM-V
	Aqupharm No 11 Solution for Infusion		POM-V
aniMedica GmbH	Suifertil 4 mg/ml Oral Solution for Pigs	Shelf-life change	POM-V
B. Braun Melsungen AG	Propofol-Lipuro Vet 10 mg/ml Emulsion for Injection	Change in distributor details	POM-V
Bayer plc	Advantix Spot-on Solution for Dogs up to 4 kg		POM-V
	Advantix Spot-on Solution for Dogs over 4 kg up to 10 kg	Additional pack sizes	POM-V
	Advantix Spot-on Solution for Dogs over 10 kg up to 25 kg		POM-V
	Advantix Spot-on Solution for Dogs over 25 kg		POM-V
	Hyonate 10 mg/ml Solution for Injection	Change of legal entity	POM-V
	Hyonate 10 mg/ml Solution for Injection	Change of distributor details	POM-V
Bela-Pharm GmbH & Co. KG	Oxytobel 10 IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats	Change of distributor details	POM-V
Billev Pharma aps	Milquantel 12.5 mg/125 mg Tablets for Dogs Weighing at least 5 kg		POM-V
	Milquantel 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens Weighing at Least 0.5 kg	Change in legal entity	POM-V
	Milquantel 2.5 mg/25 mg Tablets for Small Dogs and Puppies Weighing at least 0.5 kg		POM-V
	Milquantel 16mg/40mg Film Coated Tablets for Cats Weighing At Least 2 kg		POM-V
C&H Generics Ltd	Voxical 230/20 mg Flavoured Film-Coated Tablets for Cats	Change in distributor details	NFA-VPS
	Voxical Plus Tablets for Dogs		NFA-VPS
Ceva Animal Health Ltd	Gleptosil 200mg/ml Solution for Injection	Change of distributor details	POM-VPS

Company	Product	Brief Details	Legal Category
Chanelle Pharmaceuticals Manufacturing Ltd	Clindaseptin 25 mg/ml Oral Solution for Cats and Dogs	Shelf-life change	POM-V
	Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats		POM-V
	Fenoflox 100 mg/ml Solution for Injection for Cattle and Pigs		POM-V
Coophavet	Allevinix 50 mg/ml Solution for Injection for Cattle, Pigs and Horses	Change in legal entity	POM-V
Dechra Limited	Libromide 325 mg Tablets for Dogs	Change of MAH address	POM-V
	Urilin 40 mg/ml Syrup for Dogs		POM-V
Ecolab Ltd	Milk-Line Teat Plus 0.50% w/v Teat Dip/Teat Spray Solution	Change in the distrubutor details, from Ecolab Redwing Centre Warehouse to Norbert Dentressangle Logistics Limited	AVM-GSL
Forum Products Limited	Cephorum 250 mg Film Coated Tablets for Dogs	Change of distributor details	POM-V
Huvepharma N.V.	Colfen 200 SP 200 mg/g Granules for Use in Drinking Water for Pigs	To change the invented name of the veterinary medicinal product from 'Colfen 200 SP' to 'Amphen'	POM-V
Intervet UK Ltd	Regumate Porcine 0.4% w/v Oral Solution	Shelf-life change	POM-V
Krka Dd	Enrox Flavour 15 mg Tablets for Dogs and Cats	Change of distributor details	POM-V
	Enrox Flavour 50 mg Tablets for Dogs		POM-V
	Enrox Flavour 150 mg Tablets for Dogs		POM-V
	Toltarox 50 mg/ml Oral Suspension for Pigs	Shelf-life change	POM-V
	Toltarox 50 mg/ml Oral Suspension for Pigs		POM-V
	Toltranil 50 mg/ml Oral Suspension for Pigs, Cattle and Sheep		POM-V
	Toltranil 50 mg/ml Oral Suspension for Pigs, Cattle and Sheep		POM-V
Le Vet Beheer B.V.	Carprofelican 50 mg/ml Solution for Injection for Dogs and Cats	Shelf-life change	POM-V
	Carprofelican 50 mg/ml Solution for Injection for Dogs and Cats	Additional pack sizes	POM-V
Neptune Pharma Ltd	Azasure 500 mg/g Powder for Suspension for Fish Treatment	Shelf-life change	POM-V
Norbrook Laboratories Ltd	Depidex Pour-on Solution 0.5% w/v	Change in the name of the medicinal product from Depidex Pour-on Solution 0.5% w/v to Premadex 5 mg/ml Pour-on Solution	POM-VPS
Pharmacosmos A/S	Uniferon 20% Solution for Injection	Change in distributor details	POM-VPS
Richter Pharma AG	Aurimic Ear Drops and Cutaneous Suspension for Dogs and Cats	Shelf-life change	POM-V
Sogeval	Libeo 10 mg Chewable Tablets for Dogs	Change of distributor details	POM-V
	Libeo 40 mg Chewable Tablets for Dogs		POM-V
	Nelio 2.5 mg Tablet for Cats		POM-V
	Nelio 5 mg Tablet for Dogs		POM-V
	Nelio 5 mg Tablet for Cats		POM-V
	Nelio 20 mg Tablet for Dogs		POM-V
Solvay Chemicals International S.A.	Paramove 49.5% w/w Hydrogen Peroxide Concentrate for Solution for Fish Treatment	Additional pack sizes	POM-VPS
Triveritas Ltd	Dectospot 10 mg/ml Spot-on Solution for Cattle and Sheep	Change in legal entity and the introduction of a new pharmacovigilance system	POM-VPS

Company	Product	Brief Details	Legal Category
Triveritas Ltd continued	Ectospot 10 mg/ml Spot-on Solution for Cattle and Sheep	Change in the name of the medicinal product from Ectospot 10 mg/ml Spot-on Solution for Cattle and Sheep to Ectron 10 mg/ml Spot-on Solution for Cattle and Sheep	POM-VPS
	Ectospot 10 mg/ml Spot-on Solution for Cattle and Sheep	Change in legal entity and the introduction of a new pharmacovigilance system	POM-VPS
Vetpharma Animal Health, S.L	Indupart 75 Micrograms/m Solution for Injection for Cattle, Pigs and Horses	Shelf-life change	POM-V
Virbac S.A.	Neoprinil Pour-On 5 mg/ml Pour-On Solution for Cattle	Shelf-life change	POM-VPS
Zoetis UK Limited	Fevaxyn iCHPChlam	Change in the name of Fevaxyn iCHP Chlam to Fevaxyn Quatrifel Suspension for Injection for Cats in the UK and IE.	POM-V
	Suvaxyn MH-One Emulsion for Injection for Pigs	Shelf-life change	POM-V

EUCE AUTHORISATIONS ISSUED BETWEEN 15 JUNE - 10 SEPTEMBER2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Intervet International BV	EU/2/15/183/001/003	Canigen L4 Suspension for Injection for Dogs	Leptospira australis Leptospira canicola Leptospira grippotyphosa Leptospira icterohaemorrhagiae	POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 15 JUNE - 10 SEPTEMBER 2015

Company	Product Name	Brief Details	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	Metacam 5 mg/ml Solution for Injection for Dogs and Cats	Variation concerning the deletion of the precautionary statement in both the SPC (section 4.5) and the package leaflet (section 12) for cats, as new data were submitted together with the previous application for Metacam and additional assessment is therefore not required	POM-V
Le Vet B.V.	Meloxidolor 20 mg/ml Solution for Injection for Cattle, Pigs and Horses	Variations concerning the addition of three multi-packs - Meloxidolor 5 mg/ml, a 5 x 20 ml and a 10 x 20 ml pack; Meloxidolor 20 mg/ml, addition of a 12 x 100 ml pack	POM-V
	Meloxidolor 5 mg/ml Solution for Injection for Dogs, Cats, Cattle and Pigs		POM-V
Merial	Eurican Herpes 205 Powder and Solvent for Emulsion for Injection	Variation concerning the amendment of sections 4.2 and 4.4 of the SPC following assessment of the latest PSUR, the alignment of the product information with version 8 of the QRD template and the introduction of a clarification in the wording of the section 4.9 of the SPC	POM-V
Novartis Sante Animale S.A.S.	Osurnia Ear Gel for Dogs	Shelf-life Change	POM-V
OPK Biotech Netherlands B.V.	Oxyglobin 130 mg/ml Solution for Infusion for Dogs	Shelf-life Change	POM-V
Pfizer Ltd	Suvaxyn CSF Marker Lyophilisate and Solvent for Suspension for Injection for Pigs	Shelf-life Change	POM-V

MARKETING AUTHORISATIONS EXPIRED BETWEEN 15 JUNE - 10 SEPTEMBER 2015

Company	Vm Number	Product Name	Legal Category
Continental Farmaceutica	41966/4000	Truleva Flow 50 mg/ml Suspension for Injection for Pigs and Cattle	POM-V
CP Pharma Handelsgesellschaft mbH	20916/4013	Melosolute 5 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	POM-V
	20916/4014	Melosolute 20 mg/ml Solution for Injection for Cattle, Pigs and Horses	POM-V
Cross Vetpharm Group Ltd	12597/4007	Oxycomplex NS Solution for Injection	POM-V
	12597/4054	Selenate Long Acting 50 mg/ml Suspension for Injection for Cattle	POM-V
Dechra Limited	10434/4085	Osphos 60 mg/ml Solution for Injection for Horses	POM-V
Eurovet Animal Health B.V.	16849/4025	Eurofen 20 mg Tablets for Dogs	POM-V
	16849/4024	Eurofen 50 mg Tablets for Dogs	POM-V
	16849/4023	Eurofen 100 mg Tablets for Dogs	POM-V
Evans Vanodine International Plc	03940/4059	Countrywide Farmers 0.535% w/v Ready to Use Teat Dip and Teat Spray Solution	AVM-GSL
Kilco (International) Ltd	21357/4013	High Emollient 0.5% w/v Ready to Use Teat Dip/Teat Spray Solution	AVM-GSL
Norbrook Laboratories Limited	02000/4131	Multivitamin Solution for Injection	POM-VPS
	02000/4109	Norbet 0.25 mg Tablets	POM-V
Pfizer Ltd	EU/2/06/064/001-002	Promeris 160 mg Spot-on Solution for Small Cats	POM-V
	EU/2/06/064/003-004	Promeris 320 mg Spot-on Solution for Large Cats	POM-V
	EU/2/06/065/001-002	Promeris Duo 100.5 mg + 100.5 mg Spot-on for Small Dogs	POM-V
	EU/2/06/065/003-004	Promeris Duo 199.5 mg + 199.5 mg Spot-on for Medium Sized Dogs	POM-V
	EU/2/06/065/005-006	Promeris Duo 499.5 mg + 499.5 mg Spot-on for Medium/Large Sized Dogs	POM-V
	EU/2/06/065/007-008	Promeris Duo 799.5 mg + 799.5 mg Spot-on for Large Dogs	POM-V
	EU/2/06/065/009-010	Promeris Duo 999 mg + 999 mg Spot-on for Extra Large Dogs	POM-V
VetPlus Ltd	00844/4214	Tensolvet Gel	POM-VPS

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK UP TO 30 SEPTEMBER 2015

Annex I

Our published standards are on GOV.UK

Published Standard – No. 1 – Quality of Documentation

	App Type	Total No.	Performance
1	Authorisation Documentation	939	**97.27%**

Published Standard – No. 2 – European Applications

	App Type	No. of Apps	Performance
2	Centralised: New MAs / Extensions	3	**100%**
3	Centralised – UK as Rapp: Variations	9	**100%**
4	Centralised – UK as Rapp: Renewals	2	**100%**
5	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 70)	24	**100%**
6	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 120)	31	**100%**
7	DCP – UK as RMS: New MAs / Extensions (Phase 2)	43	**100%**
8	DCP – UK as CMS: New MAs / Extensions (Phase 1)	15	**100%**
9	DCP – UK as CMS: New MAs / Extensions (Phase 2)	20	**100%**
10	MRP – UK as RMS: New MAs / Extensions (Phase 1)	7	**100%**
11	MRP – UK as RMS: New MAs / Extensions (Phase 2)	4	**100%**
12	MRP – UK as CMS: New MAs / Extensions (Phase 2)	10	**100%**
13	MRP – UK as RMS: Type IA Variations	51	**100%**
14	MRP – UK as RMS: Type IB & II Variations (Phase 1)	73	**100%**
15	MRP – UK as CMS: Type IB & II Variations (Phase 1)	91	**100%**
16	MRP – UK as CMS: Type IB & II Variations (Phase 2)	39	**100%**
17	MRP – UK as RMS: Renewals (Phase 1)	16	**100%**
18	MRP – UK as CMS: Renewals (Phase 1)	29	**100%**
19	MRP – UK as CMS: Renewals (Phase 2)	21	**100%**

Published Standard – No. 2 – National Applications

	App Type	No. of Apps	Performance	Target Days	Average Days
20	New MAs / Extensions: Initial Assessment	**18**	**100%**	-	-
	75 Day Clock	2		75	55
	90 Day Clock	16		90	62
21	New MAs / Extensions: Sign-Off	**10**	**100%**	-	-
	130 Day Clock	3		130	122
	150 Day Clock	7		180	122.6
22	New Homeopathic	**0**	**0%**	50	0
23	Type IA Variations	**88**	**98.9%**	30	24.2
24	Admin Variations	**18**	**100%**	-	-
	< 10 Changes	18		30	10.6
	> 10 Changes	0		60	0
25	Type IB / II Variations: Initial Assessment	**129**	**98.45%**	-	-
	Type IB	98		30	21
	Type II	31		60	48
26	Type IB / II Variations: Sign-Off	**90**	**98.9%**	-	-
	Type IB	77		30	17
	Type II	13		60	35
27	Renewals: Initial Assessment	**1**	**100%**	60	39
28	Renewals: Sign-Off	**4**	**100%**	60	34
29	Batch Release	**1,271**	**100%**	10	1.1
30	AVA, NFABBA & ESCCA	**6**	**100%**	45	16.2
31	ATCs	**23**	**95.65%**	-	-
	Type A/S	12		30	15
	Type B	6		50	36
	Variations / Renewals	5		30	8
32	Specific Batch Control	**22**	**100%**	-	-
	Initial Assessment			10	1
	Sign-Off			10	0
33	Validation of applications	**535**	**100%**	-	-
34	Mock-Ups (post New MA)	**83**	**100%**	-	-
35	Mock-Ups (post EU Variations / Renewals	**326**	**98.77%**	-	-
36	Issue of authorisation documentation	**695**	**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	**58**	**100%**	15	4
38	STC / SIC Requiring Assessment – Other products	**3,266**	**99.91%**	-	-
	Urgent	283		2	0
	Non-Urgent	2,983		10	2
39	WDIC – not previously assessed	**3**	**100%**	15	0
40	WDIC – other applications	**77**	**100%**	-	-
	Urgent	4		2	1
	Non-Urgent	73		10	3
41	Export	**361**	**100%**	10	6.2

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	**90**	**100%**	-	-
	SPC for MAs	83		30	13
	Link to EMA	7		30	14
43	Make publicly available via GOV.UK the PAR for New MAs	**55**	**100%**	120	95
44	Make publicly available via GOV.UK the post authorisation assessment	**455**	**100%**	60	50

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
45	Human & Animal AERs	**2,898**	**99.55%**
46	Human & Animal AERs – Follow Up	**1,330**	**99.47%**
47	Environmental SAR	**0**	**100%**
48	Inspections	**16**	**100%**

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
49	GMP Inspections within 3 years of last inspection	**23**	**100%**	-	-
50	GDP inspections within 5 years of last inspection	**17**	**100%**	-	-
51	Send deficiency or post inspections letter	**40**	**100%**	30	
	GMP	22			24
	GDP	18			24
52	Issue GMP Certificates and final inspection reports	**25**	**100%**	90	82
53	Send final inspection report to wholesaler site	**21**	**100%**	90	80

ORGANOGRAM OCTOBER 2015

Annex 2