MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 100 - OCTOBER 2016

OPEN MEETING OF THE VETERINARY MEDICINES DIRECTORATE

The VMD held its open meeting on 16 September 2016.

The presentations given at the meeting are available on GOV.UK following the 'YouTube' link under 'What We Do'.

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

MAVIS - NEW LOOK

As we mentioned at the Open Meeting, we are going to change the look and feel of MAVIS to make it more readable and easier to search its contents for information you need.

The content of MAVIS is not changing and it will still be accessible by a quick link on the VMD's GOV.UK home page.

Its new appearance as a GOV.UK webpage should make it easier to read than the current columnar format. A major advantage of its webpage format is that it allows you to search in MAVIS using keywords rather than having to scroll through a PDF document.

A mock-up of how the new MAVIS will look, subject to final cosmetic tweaks, is at Annex 2.

The next edition of MAVIS will be published in the new style. Previous editions of MAVIS will continue to be available on GOV.UK.

If you have any questions or comments please contact Matthew Isted (VMD, email: m.isted@vmd.defra.gsi.gov.uk, 01932 338347).

CONTENTS

Veterinary Medicines Directorate

The Veterinary Medicines Directorate
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Email: postmaster@vmd.defra.gsi.gov.uk

NEWS

STAKEHOLDER WORKSHOPS

Following the initial workshops of 2014 we held three further stakeholder workshops in June 2016, giving an update on the current position with the proposals for a new Regulation on Veterinary Medicinal Products and a new Regulation on Medicated Feedingstuffs.

Summaries of the discussions at each of these workshops have been prepared and, along with copies of the presentations given, are available on request from Lorna Shelley.

For further information please contact: Lorna Shelley (VMD, email: l.shelley@vmd.defra.gsi.gov.uk, 01932 338320).

VMD ON TWITTER – WHAT DO YOU THINK?

The VMD is looking at the benefits of having a Twitter account. We are always keen to improve our communication with you and we know that some of you use Twitter.

Would you find it useful to receive VMD tweets? On what issues? How regularly?

Tell us what you think.

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

VET SKILL LTD

On 26 August 2016 Vet Skill Ltd was authorised as a suitable body to maintain a register for suitably qualified persons (SQPs) to prescribe and supply veterinary medicines classified as POM-VPS and NFA-VPS.

An SQP is a professionally qualified person who is allowed to prescribe, supply and advise on the safe use of these categories of medicines in the UK, such as worming and flea treatments.

The authorisation means that Vet Skill Ltd has adequately demonstrated that they can fulfil all the necessary requirements of the Veterinary Medicines Regulations.

For further information please contact: Lorna Shelley (VMD, email: l.shelley@vmd.defra.gsi.gov.uk, 01932 338320).

REVISED RETAIL GUIDANCE FOR REGISTERED QUALIFIED PERSONS (RQPs)

The guidance for Retail of Veterinary Medicines on GOV.UK has been updated to include the VMD's expectation of the information the RQP should assess before supplying a veterinary medicine.

When retail supplying NFA-VPS products, RQPs must satisfy themselves by all reasonable means that the customer is competent to use the product safely and that the product is suitable for the animal concerned.

For pets/companion animals:

- species
- number of animal(s)
- weight (of each animal if more than one)
- age
- whether the animal is in general good health
- whether the animal is pregnant or lactating
- whether the animal is on any other medication
- whether the customer knows how to use the product safely/effectively
- whether the customer knows what the product is supposed to do
- whether the customer has been provided with the warnings on the SPC

Disclaimers

The requirements on the RQP are non-delegable and cannot be transferred to the customer. 'Disclaimers' that, for example, simply inform a customer that they must answer yes or no to a list of questions will not be considered by the VMD to meet this requirement.

Further guidance can be found on GOV.UK.

LICENSING

SPECIAL IMPORT SCHEME (SIS) CHANGES

Changes have been made to the online system to further simplify the application process and reduce administrative burden.

Certificates (SIC and STC) are now shorter and only detail essential information.

WDIC (wholesale dealer import) certificates are now available to apply for online from GOV.UK. We will no longer accept postal or email WDIC applications from 1 November 2016.

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

VALIDATION DURING THE CHRISTMAS PERIOD 2016

New Marketing Authorisation applications

The last validation meeting to discuss applications for new Marketing Authorisations (MAs) will take place on 22 December 2016. Applications to be considered for validation must be received on or before 19 December 2016. Weekly validation meetings will resume week commencing 1 January 2017.

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

Manufacturing and Wholesale Dealers Authorisation applications (new and variations)

The last day for validation application discussions for Manufacturing Authorisations (ManAs) and Wholesale Dealer Authorisations (WDAs) (new and variations) will be on 16 December 2016. To be considered for validation by this date, please ensure that your application reaches us by 14 December 2016. The validation discussions will resume week commencing 1 January 2017.

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

TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 JULY TO 30 SEPTEMBER 2016

The VMD provides a list on a quarterly basis of the ten products for which 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	2,674
Filavac VHD K C+V	Rabbit Haemorrhagic Disease (Inactivated)	1,780
Vet-Goid	Allergens	297
Pneumabort-K +1b	Equine Rhinopneumonitis Virus	227
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	202
Greer Allergenic Extract Patient Prescription	Allergens	176
Staphage Lysate (SPL)	Staphylococcus Aureus	76
Artuvetrin® Test, injection fluid for intracutaneous use in dogs	Allergens	74
Oncept (Canine Melanoma Vaccine)	Canine Melanoma DNA	73
ACTT Allergy Drops	Allergens	73

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* three seizure notices have been published.

World of Water, Bracknell, Berkshire. The following products were seized as they are not authorised in the UK:

- 3 x Fluke T powder (manufactured by TAP)
- 4 x Chloramine powder (manufactured by TAP)
- 4 x Potassium Permanganate powder (manufactured by TAP)

This is an offence under Regulation 27 (Supply of an unauthorised veterinary medicinal product) of the Veterinary Medicines Regulations.

The UK Border Force at Stansted Airport, Essex, stopped a shipment which was subsequently seized. This shipment contained two drums addressed to premises in the UK. The drums contained 55 kilograms of Dimetridazole (DMZ). The medicine was seized under Regulation 25 (Importation of unauthorised veterinary medicinal products) of the Veterinary Medicines Regulations.

Mr Saunders, Hatfield. The following products were seized:

- 1 bottle Vitbee 100 (UK Authorised)
- 1 bottle Super A-100 Injection (Non UK Authorised)
- 1 bottle Super Vit-A Injection (Non UK Authorised)

The medicines were seized under Regulation 7 (Classification, supply and possession of the product) and Regulation 26 (Possession of unauthorised veterinary medicinal products) of the Veterinary Medicines Regulations.

IMPROVEMENT NOTICES

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

APG Supplies & Services, Belcoo, County Fermanagh. Failure to maintain the retail premises on the register of approved retailers of veterinary medicinal products, contrary to the Veterinary Medicines Regulations.

The annual fee was due in May. Despite numerous reminders and re-issues of the invoice, payment has not been received. Retail sale of POM-VPS medicines has continued at the premises.

Premises to restore to the register of retailers, or to cease the supply of veterinary medicines and to provide evidence that the sales have ceased and all POM-VPS stock removed.

G.T. Farm Supplies, Ballymena, County Antrim.
Supplies of POM-VPS medicines occurring from outwith the registered premises, namely from a trailer unit. This breaches the Veterinary Medicines Regulations, Schedule 3, paragraph 14 (4) – Supply by a suitably qualified person.

Evidence showed stock within the trailer unit did not have sales documentation to show that the supply occurred at the registered premises and order sheets provided did not correspond with stock seen.

Improvements are for procedures and documentation to be put in place to demonstrate that supplies only occur at the registered premises and no POM-VPS stock to be carried in the trailer unless accompanied by a delivery note.

OUTCOMES OF PROSECUTIONS

On 22 September 2016 at Bournemouth Magistrates Court, Emilia Przemielewska pleaded guilty to 13 charges under the Veterinary Medicines Regulations. These were:

- Five charges of possession of unauthorised veterinary medicinal products under the Veterinary Medicines Regulations.
- Five charges of importation of unauthorised veterinary medicinal products under the Veterinary Medicines Regulations
- Three charges of supply of unauthorised veterinary medicinal products under the Veterinary Medicines Regulations

Ms Przemielewska was given a three year conditional discharge and fined £100 costs and a £15 victim surcharge.

This case related to the importation and sale of a number of unauthorised companion animal products, mainly flea treatments and wormers.

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 and search for "Complaint unauthorised".

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 2016, the VMD received 1,819 suspected adverse event reports involving animals. Of these, 30 reports related to unauthorised or unidentified products, six reports involved animal trials under Animal Test Certificates (ATCs) and nine further reports were from studies not requiring ATCs.

Excluding these three categories, the remaining 1,774 suspected adverse event reports were associated with 403 authorised products in the following distribution categories:

1,546	Prescription Only Medicine - Veterinarian (POM-V)
128	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
39	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
50	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
11	Products sold under the Exemption for Small Pet Animals (N/A)

During the quarter 49 reports of human suspected adverse reactions and three environmental incident reports were received.

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

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.

THE GOVERNMENT RESPONSE TO 'THE REVIEW ON ANTIMICROBIAL RESISTANCE'

In July 2014, the then UK Prime Minister commissioned an Independent Review on antimicrobial resistance, which was chaired by Lord O'Neill, and committed the government to take forward its recommendations.

In May 2016, the Review Team published its final report which includes a number of recommendations for reducing unnecessary use of antibiotics in animals globally through infection prevention and control and alternative therapies.

In response, Defra has made three initial top level commitments:

- To set an overall target for antibiotic use in livestock and fish farmed for food, reducing use to the level suggested (50 mg/kg) by 2018.
- To work closely with the livestock industry and veterinary profession to agree tailored sector-specific targets by 2017 which will focus on reducing future antibiotic use based on best practice and responsible use of antibiotics.
- To ensure stewardship of antibiotics which are of highest priority and critical importance for human health, including restrictions or bans if this is necessary to protect human health.

A fuller government response to the report was published on 16 September 2016 and is available on GOV.UK.

The VMD met the farming and companion animals industries on 14 September 2016 to discuss the AMR review report and its recommendations, the government's response to these recommendations and the next steps forward.

EUROPEAN ANTIBIOTIC AWARENESS DAY (EAAD) ACTIVITIES

European Antibiotic Awareness Day is an annual European public health initiative that occurs on 18 November with the aim to raise awareness about the threat to public health of antibiotic resistance and prudent antibiotic use. As in previous years (2013-2015), the VMD will act jointly with Public Health England (PHE) and other animal health organisations to co-ordinate EAAD 2016 activities. Plans for this year's activities are currently in progress, and will focus on maintaining animal health and responsible use of antibiotics in livestock and pets.

Further information about EAAD can be found at:
http://ecdc.europa.eu/en/eaad/Pages/Home.aspx

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

The 2015 UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report is currently being formalised. The report collates data on antibiotic sales from UK Marketing Authorisation Holders and antibiotic resistance data from the VMD's surveillance programmes. We expect to publish the report in November this year.

UK-VARSS 2014 and previous reports are available on GOV.UK.

For further information please contact: Stacey Brown (VMD, email: s.brown@vmd.defra.gsi.gov.uk, 01932 338393).

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 September 2016. Summary minutes of the meetings held from October 2014 are available 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

Sampling commenced in January and full details of UK results, together with information on any action taken, can be found 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

- Victoria Herbert joined the Pharmaceuticals and Feed Additives team on 8 August
- Simon Archer joined the Pharmaceuticals and Feed Additives team on 12 September
- Adriana Chirilov joined the Inspection and Investigations team on transfer from the Animal and Plant Health Agency on 19 September

Departing Staff

- Maggie Steel retired on 2 August
- Sam Fowler transferred to the Medicines and Healthcare products Regulatory Agency on 15 August
- Denise Burge transferred to the National Office of Statistics on 5 September

Promotions

- Christine Paine was promoted to the Head of the Inspection and Investigations team on 1 August
- Gillian Diesel was promoted to the Head of the Pharmacovigilance team on 22 August
- Francine Fernandez was promoted within the Pharmaceuticals and Feed Additives team on 22 August
- Hannah Reeves was promoted and transferred to the Pharmaceuticals and Feed Additives team on 19 September
- Dan Finn was promoted within the IT team on 19 September

Transfers

- Jenny Cass permanently transferred to the General Assessment team on 8 August
- Lee Grist transferred to the Inspections and Investigations team on 21 September
- Myles Munro transferred to the Enforcement team on 26 September

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 13 JUNE 2016 - 6 SEPTEMBER 2016

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Alvetra u. Werfft GmbH	32802/4001	Carofertin 10 mg/ml emulsion for Injection for Cattle and Pigs	B Carotene	POM-V
ANDRES PINTALUBA, S.A.	32508/4000	Colistin APSA 1,200,000 IU/g Premix for Medicated Feeding Stuff for Pigs	Colistin Sulphate	POM-V
Animalcare Ltd	10347/4037	Acecare 2 mg/ml Solution for Injection for Dogs and Cats	Acepromazine	POM-V
	10347/4036	Isocare 1000 mg/g Inhalation Vapour, Liquid	Isoflurane	POM-V
aniMedica Espana, S.L.U	43173/4001	Rhemox Forte 1000 mg/g Powder for Use in Drinking Water for Chickens, Ducks, Turkeys	Amoxicillin Trihydrate	POM-V
Bela-Pharm GmbH & Co. KG	41816/4001	Biocillin 1000 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin Trihydrate	POM-V
C&H Generics Ltd	40162/4005	Fenbendazole Wormer Granules 888 mg for Adult Dogs	Fenbendazole	AVM-GSL
Ceva Animal Health Ltd	15052/4130	Pracetam 400 mg/ml Solution for Use in Drinking Water for Pigs	Paracetamol	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4076	Niltrem 34 mg/ml Oral Suspension for Cattle	Oxyclozanide	POM-VPS
	08749/4077	Rumenil 34 mg/ml Oral Suspension for Cattle		POM-VPS
Eurovet Animal Health B.V.	16849/4055	Metaxol 20/100 mg/ml Solution for Use in Drinking Water for Pigs and Chickens	Sulfamethoxazole, Trimethoprim	POM-V
Genera Inc.	43676/4001	Canihelmin Plus 50 mg/144 mg/150 mg Tablets for Dogs	Febantel, Praziquantel, Pyrantel Embonate	POM-V
Huvepharma N.V.	30282/4032	HuveGuard NB Suspension for Ocular or Oral Use for Chickens	Eimeria brunetti, Eimeria necatrix	POM-V
Jurox (UK) Limited	25296/4002	Buprelieve Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Buprenorphine	POM-V
Kernfarm B.V.	43877/4007	Pluset Powder and Solvent for Solution for Injection	Follicle Stimulating Hormone (porcine), Luteinising Hormone (Porcine)	POM-V
Krka d.d., Novo Mesto	01656/4113	Amflee Combo 50 mg/60 mg Spot-on Solution for Cats and Ferrets	(S)-Methoprene, Fipronil	POM-V
	01656/4114	Amflee Combo 67 mg/60.3 mg Spot-on Solution for Small Dogs		POM-V
	01656/4110	Amflee Combo 134 mg/120.6 mg Spot-on Solution for Medium Dogs		POM-V
	01656/4111	Amflee Combo 268 mg/241.2 mg Spot-on Solution for Large Dogs		POM-V
	01656/4112	Amflee Combo 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs		POM-V
Laboratorios Karizoo S.A	31223/4006	Citramox 1000 mg/g Powder for Use in Drinking Water for Chickens, Turkeys, Ducks and Pigs	Amoxicillin Trihydrate	POM-V
Le Vet Beheer B.V.	41821/4031	Thyroxanil 200 Microgram Tablets for Dogs and Cats	L Thyroxine Sodium	POM-V
	41821/4032	Thyroxanil 600 Microgram Tablets for Dogs and Cats		POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Norbrook Laboratories Limited	02000/4404	Betafuse 1 mg/g + 5 mg/g Gel for Dogs	Betamethasone, Fusidic Acid	POM-V
	02000/4403	Closone 50 mg/ml Oral Suspension for Sheep	Closantel	POM-VPS
	02000/4401	Flukenil 50 mg/ml Oral Suspension for Sheep	Closantel	POM-VPS
	02000/4405	Inflabac 1 mg/g + 5 mg/g Gel for Dogs	Betamethasone, Fusidic Acid	POM-V
	02000/4402	Solantel 50 mg/ml Oral Suspension for Sheep	Closantel	POM-VPS
Oropharma n.v	13058/4005	Ornicure 150 mg/g, Powder for Use in Drinking Water for Racing Pigeons and Ornamental Birds	Doxycycline Hyclate	POM-V
Pharmsure International Ltd	42983/4000	Amprol 12% w/v Solution for Use in Drinking Water	Amprolium Hydrochloride	POM-V
QALIAN	41623/4001	Amproline 400 mg/mL Solution for Use in Drinking Water for Chickens and Turkeys	Amprolium	POM-V
SP Veterinaria, S.A.	36967/4005	Hidrocol, 4000000 IU/ml Solution for Use in Drinking Water/Milk		POM-V
Vet-Agro Trading Sp. Z o.o.	41715/4001	Fiprex S 75 mg Spot-on Solution for Dogs	Fipronil	NFA-VPS
	41715/4002	Fiprex M 150 mg Spot-on Solution for Dogs		NFA-VPS
	41715/4003	Fiprex L 300 mg Spot-on Solution for Dogs		NFA-VPS
	41715/4004	Fiprex XL 412.5 mg Spot-on Solution for Dogs		NFA-VPS
Zoetis UK Limited	42058/4190	CattleMarker IBR Inactivated Emulsion for Injection for Cattle	Infectious bovine rhinotraceitis virus	POM-V

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 13 JUNE 2016 - 6 SEPTEMBER 2016

Company Name	Product Name	Brief Details	Legal Category
Bayer plc	Drontal Dog Tasty Bone 150/144/50 mg Tablets	Shelf life change	NFA-VPS
	Endectrid 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets	Addition of new pack size	POM-V
	Endectrid 40 mg + 10 mg Spot-on Solution for Small Dogs		POM-V
	Endectrid 80 mg + 8 mg Spot-on Solution for Large Cats		POM-V
	Endectrid 100 mg + 25 mg Spot-on Solution for Medium Dogs		POM-V
	Endectrid 250 mg + 62.5 mg Spot-on Solution for Large Dogs		POM-V
	Endectrid 400 mg + 100 mg Spot-on Solution for Extra-Large Dogs		POM-V
Boehringer Ingelheim Ltd	Pimobendan Vetmedica 0.75 mg/ml Solution for Injection for Dogs	Change in the name to Vetmedin 0.75 mg/ml Solution for Injection for Dogs	POM-V
C&H Generics Ltd	Extrontel Plus XL Tablets for Dogs	Shelf life change	NFA-VPS
	Ezi-Wormer Plus XL Tablets for Dogs		NFA-VPS
	Ridaworm Plus XL Tablets for Dogs		NFA-VPS
	VetUK XL Dog Wormer Tablets	Shelf life change and change in the name to VetUK XL Dog Wormer Tablets 504 mg pyrantel embonate, 175 mg Praziquantel, 525 mg Febantel	NFA-VPS
Ceva Animal Health Ltd	Zodon 25 mg/ml Oral Solution for Cats and Dogs	Shelf life change	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	Zepromec 5 mg/ml Pour-on Solution for Beef and Dairy Cattle	Change in the name to Unomec 5 mg/ml Pour-on Solution for Beef and Dairy Cattle	POM-VPS
Cross Vetpharm Group Ltd	Endofluke 100 mg/ml Oral Suspension	Addition of a new value pack of the finished product	POM-VPS
Dechra Limited	Ovuplant 2.1 mg Implantation Tablets for Horses (Mares)	Change in the address of the Marketing Authorisation Holder	POM-V
Elan Pharma International Limited	FleaCidal 50 mg Spot-on Solution for Cats	Change in the name of the Marketing Authorisation Holder	AVM-GSL
	FleaCidal 67 mg Spot-on Solution for Small Dogs		AVM-GSL
	FleaCidal 134 mg Spot-on Solution for Medium Dogs		AVM-GSL
	FleaCidal 268 mg Spot-on Solution for Large Dogs		AVM-GSL
	FleaCidal 402 mg Spot-on Solution for Very Large Dogs		AVM-GSL
Eurovet Animal Health B.V.	Octacillin 697 mg/g Powder for Use in Drinking Water for Chickens	Change in distributor details	POM-V
	Forthyron 200 Microgram Tablet		POM-V
	Forthyron 400 Microgram Tablet		POM-V
	Rapidexon 2 mg/ml Solution for Injection		POM-V
	Soludox 500 mg/g Powder for Use in Drinking Water for Pigs and Chickens		POM-V
	Bovocycline Pessary 2000 mg Intrauterine Tablet for Cattle		POM-V
	Comfortan 10 mg/ml, Solution for Injection for Dogs and Cats		POM-V
	Pimocard 1.25 mg Flavoured Tablets for Dogs		POM-V
	Pimocard 2.5 mg Flavoured Tablets for Dogs		POM-V
	Pimocard 5 mg Flavoured Tablets for Dogs		POM-V
	Pimocard 10 mg Flavoured Tablets for Dogs		POM-V
	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses		POM-V
	Nimatek 100 mg/ml Solution for Injection for Dogs, Cats and Horses		POM-V

Company	Product Name	Brief Details	Legal Category
Forum Products Limited	Cephorum 500 mg Film-coated Tablets for Dogs	Addition of a new value pack of the finished product	POM-V
	Cephorum 500 mg Film-coated Tablets for Dogs	Change of legal entity	POM-V
	Cephorum 500 mg Film-coated Tablets for Dogs	Change in distributor details	POM-V
HCS bvba	Fypermid 50 mg/ 60 mg Spot-on Solution for Cats	Change in the name to Fiprotec Combo 50 mg/ 60 mg Spot-on Solution for Cats	NFA-VPS
	Fypermid 67 mg/ 60.3 mg Spot-on Solution for Small Dogs	Change in the name to Fiprotec Combo 67 mg/ 60.3 mg Spot-on Solution for Small Dogs	NFA-VPS
	Fypermid 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs	Change in the name to Fiprotec Combo 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs	NFA-VPS
	Fypermid 268 mg/ 241.2 mg Spot-on Solution for Large Dogs	Change in the name to Fiprotec Combo 268 mg/ 241.2 mg Spot-on Solution for Large Dogs	NFA-VPS
	Fypermid 402 mg/ 361.8 mg Spot-on Solution for Extra Large Dogs	Change in the name to Fiprotec Combo 402 mg/ 361.8 mg Spot-on Solution for Extra Large Dogs	NFA-VPS
Kela N.V.	Kelactin 50 Microgram/ml Oral Solution for Dogs and Cats	Change in distributor details	POM-V
Krka d.d., Novo Mesto	Anthelmin Plus Flavour Tablets for Dogs	Shelf life change	NFA-VPS
	Endogard Plus Flavour Tablets for Dogs		NFA-VPS
	Flimabend 100 mg/g Suspension for Use in Drinking Water for Chickens and Pigs	Addition of new pack size	POM-VPS
	Flimabend 100 mg/g Suspension for Use in Drinking Water for Chickens and Pigs	Shelf life change	POM-VPS
Merial Animal Health Ltd	Eurican Lmulti Suspension for Injection	Shelf life change	POM-V
Novartis Animal Health UK Ltd	Bob Martin Clear Flea 11.4 mg Tablets for Cats, Small Dogs and Puppies	Change of legal entity	AVM-GSL
	Bob Martin Clear Flea 57 mg Tablets for Large Dogs		AVM-GSL
	Beaphar One Dose Wormer for Dogs, 500 mg Film Coated Tablets		AVM-GSL
	Beaphar One Dose Wormer for Small Dogs and Puppies 100 mg Film Coated Tablets		AVM-GSL
	Johnson's 4Fleas 11.4 mg Tablets for Cats and Kittens		AVM-GSL
	Johnson's 4Fleas 11.4 mg Tablets for Small Dogs and Puppies		AVM-GSL
	Johnson's 4Fleas 57 mg Tablets for Dogs		AVM-GSL
	Johnson's One Dose Easy Wormer for Small Dogs and Puppies, 100 mg Film Coated Tablets		AVM-GSL
	Johnson's One Dose Easy Wormer for Dogs and Puppies 500 mg Film Coated Tablets		AVM-GSL
Orion Corporation	Domitor 1 mg/ml Solution for Injection	Shelf life change	POM-V
	Domitor 1 mg/ml Solution for Injection	Change in the storage conditions of the finished product	POM-V
Richter Pharma AG	Aurimic Ear Drops and Cutaneous Suspension for Dogs and Cats	Change of local representative	POM-V
Shep Fair Products Ltd	Golden Hoof Plus 99.6% w/w Powder for Cutaneous Solution	Change of address of the Marketing Authorisation Holder	AVM-GSL
	Golden Hoof 100% w/w Powder for Cutaneous Solution		AVM-GSL
Sogeval	Adaxio Shampoo for Dogs	Change of legal entity	POM-V
	Amodip 1.25 mg Chewable Tablets for Cats		POM-V
	Amoxival 500 mg/g Oral Powder for Pigs and Chickens		POM-V
	Doxyval 500 mg/g Powder for Use in Drinking Water for Pigs and Chickens		POM-V
	Libeo 10 mg Chewable Tablets for Dogs		POM-V
	Libeo 40 mg Chewable Tablets for Dogs		POM-V

Company	Product Name	Brief Details	Legal Category
Sogeval continued	Modulis 100 mg/ml Oral Solution for Dogs		POM-V
	Nelio 2.5 mg Tablet for Cats		POM-V
	Nelio 5 mg Tablet for Cats		POM-V
	Nelio 5 mg Tablet for Dogs		POM-V
	Nelio 20 mg Tablet for Dogs		POM-V
	Perlium Amoxival 100 mg/g Premix for Medicated Feeding Stuff for Pigs		POM-V
	Sogecoli 2 000 000 IU/ml Concentrate for Oral Solution for Calves, Lambs, Pigs, Chickens and Turkeys	Change of legal entity	POM-V
	Therios 75 mg Chewable Tablets for Cats		POM-V
	Xeden 200 mg Tablet for Dogs		POM-V
	Zodon 25 mg/ml Oral Solution for Cats and Dogs		POM-V
	Zodon 88 mg Chewable Tablets for Dogs		POM-V
	Zodon 150 mg Chewable Tablets for Dogs		POM-V
	Zodon 264 mg Chewable Tablets for Dogs		POM-V
	Dolagis 50 mg Tablets for Dogs		POM-V
	Dolagis 120 mg Chewable Tablets for Dogs		POM-V
	Efex 10 mg Chewable Tablets for Cats and Dogs		POM-V
	Efex 40 mg Chewable Tablets for Dogs		POM-V
	Efex 100 mg Chewable Tablets for Dogs		POM-V
	Pracetam 10% Premix for Medicated Feeding Stuff for Pigs		POM-V
	Pracetam 200 mg/ml Solution for Use in Drinking Water for Pigs	Change of legal entity and distributor	POM-V
	Tempora 10 mg Chewable Tablets for Dogs		POM-V
	Tempora 50 mg Chewable Tablets for Dogs		POM-V
	Tempora 100 mg Chewable Tablets for Dogs		POM-V
	Therios 300 mg Palatable Tablets for Dogs		POM-V
	Therios 750 mg Palatable Tablets for Dogs		POM-V
	Xeden 15 mg Tablet for Cats		POM-V
	Xeden 50 mg Tablet for Dogs		POM-V
	Xeden 150 mg Tablet for Dogs		POM-V
	Kesium 50 mg Chewable Tablets for Cats and Dogs		POM-V
	Kesium 62.5 mg Chewable Tablets for Cats and Dogs		POM-V
	Kesium 250 mg Chewable Tablets for Dogs	Change of legal entity	POM-V
	Kesium 500 mg Chewable Tablets for Dogs		POM-V
	Kesium 625 mg Chewable Tablets for Dogs		POM-V
Support Pharma S.L.	Pronestesic 40 mg/ml / 0.036 mg/ml Solution for Injection for Horses, Cattle, Pigs and Sheep	Change of legal entity	POM-V

EUCE AUTHORISATIONS ISSUED
BETWEEN 13 JUNE 2016 - 6 SEPTEMBER 2016

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Chanelle Pharmaceuticals Manufacturing Ltd	EU/2/16/196/001–002	Sevohale 100% v/v Inhalation Vapour, Liquid for Dogs	Sevoflurane	POM-V
Intervet International BV	EU/2/13/158/018-019	Bravecto 112.5 mg Spot-on Solution for Small Cats (1.2 – 2.8 kg)	Fluralaner	POM-V
	EU/2/13/158/022-023	Bravecto 250 mg Spot-on Solution for Medium-sized Cats (>2.8 – 6.25 kg)		POM-V
	EU/2/13/158/026-027	Bravecto 500 mg Spot-on Solution for Large Cats (>6.25 – 12.5 kg)		POM-V
	EU/2/13/158/016-017	Bravecto 112.5 mg Spot-on Solution for Very Small Dogs (2 – 4.5 kg)		POM-V
	EU/2/13/158/020-021	Bravecto 250 mg Spot-on Solution for Small Dogs (>4.5 – 10 kg)		POM-V
	EU/2/13/158/024-025	Bravecto 500 mg Spot-on Solution for Medium-sized Dogs (>10 - 20 kg)		POM-V
	EU/2/13/158/028-029	Bravecto 1000 mg Spot-on Solution for Large Dogs (>20 – 40 kg)		POM-V
	EU/2/13/158/030-031	Bravecto 1400 mg Spot-on Solution for Very Large Dogs (>40 – 56 kg)		POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 13 JUNE 2016 - 6 SEPTEMBER 2016

Company	Product Name	Brief Details	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	Metacam 5 mg/ml Solution for Injection for Dogs and Cats	Deletion of the precautionary statement in the SPC (section 4.5) and the package leaflet (section 12)	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	Sevocalm 100% v/v Inhalation Vapour, Liquid for Dogs	Change in the name to Sevohale 100% v/v Inhalation Vapour, Liquid for Dogs	POM-V
Eco Animal Health Ltd	Aivlosin 625 mg/g Granules for Use in Drinking Water for Chickens		POM-V
	Aivlosin 625 mg/g Granules for Use in Drinking Water for Pigs		POM-V
	Aivlosin 625 mg/g Granules for Use in Drinking Water for Pheasants	Shelf life change	POM-V
	Aivlosin 42.5 mg/g Oral Powder for Pigs		POM-V
	Aivlosin 625 mg/g Granules for Use in Drinking Water for Turkeys		POM-V
	Aivlosin 625 mg/g Granules for Use in Drinking Water for Chickens		POM-V
	Aivlosin 625 mg/g Granules for Use in Drinking Water for Pigs		POM-V
	Aivlosin 625 mg/g granules for Use in Drinking Water for Pheasants	Storage condition change	POM-V
	Aivlosin 42.5 mg/g Oral Powder for Pigs		POM-V
	Aivlosin 625 mg/g Granules for Use in Drinking Water for Turkeys		POM-V
Elanco Europe Ltd	Zolvix 25 mg/ml Oral Solution for Sheep	To delete the immediate packaging container aluminium bags for Zolvix Oral solution 25 mg/ml	POM-V
Intervet International BV	Canigen L4, Suspension for Injection for Dogs	Changes to the SPC and package leaflet	POM-V
	Nobilis IB4-91, Lyophilisate for Suspension	Shelf life change	POM-V
	Nobivac L4 Suspension for Injection for Dogs	Change to the SPC (section 4.6) and package leaflet	POM-V
Laboratorios Hipra SA	Startvac Emulsion for Injection for Cattle	New presentation of 125 doses (250 ml), bottled in PET vials	POM-V
Merial	Broadline Spot-on Solution for Cats < 2.5 kg	New pack size of 15 applicators in spot-on applicator (COC) with polymer cap	POM-V
	Broadline Spot-on Solution for Cats 2.5 - 7.5 kg		POM-V
Merial Animal Health Limited	Ibraxion Emulsion for Injection	Change of the name to Bovalto Ibraxion Emulsion for Injection	POM-V
Norbrook Laboratories Limited	Loxicom 1.5 mg/ml Oral Suspension for Dogs	Change in pack size of the finished product	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
Orion Corporation	Sileo 0.1 mg/ml Oromucosal Gel 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
Prevtec Microbia GmbH	Coliprotec F4 Lyophilized Live Non-Pathogenic Escherichia Coli Vaccine for Oral Use in Swine	Shelf life change	POM-V

MARKETING AUTHORISATIONS EXPIRED BETWEEN 13 JUNE 2016 - 6 SEPTEMBER 2016

Company	Vm Number	Product Name	Legal Category
Armitage Bros Ltd	02650/4016	Wilko Cat Flea Spray	AVM-GSL
	02650/4015	Wilko Dog Flea Spray	AVM-GSL
Bayer plc	00010/4152	Baycox 50 mg/ml Oral Suspension	POM-V
	00010/4144	Baycox Bovis 50 mg/ml Oral Suspension	POM-V
CP Pharma Handelsgesellschaft mbH	20916/4022	Xylasol 100 mg/ml, Solution for Injection for Cattle and Horses	POM-V
	20916/4021	Xylasol 20 mg/ml, Solution for Injection for Cattle, Horses, Dogs and Cats	POM-V
Listow Limited	41687/4004	Co Trimazine Tablets 480 mg	POM-V
Norbrook Laboratories Limited	02000/4205	Downlands Calcium Borogluconate 20% w/v PMD Solution for Injection	POM-VPS
	02000/4112	Life Aid Xtra Powder for Oral Solution	AVM-GSL
Zoetis UK Limited	42058/4018	Colfen 300 mg/ml Solution for Injection for Cattle and Pigs	POM-V
	42058/4155	Torbutrol Tablets 10 mg	POM-V

MARKETING AUTHORISATIONS FOR PARALLEL IMPORTS GRANTED BY THE VMD BETWEEN 13 JUNE 2016 - 6 SEPTEMBER 2016

Company	Vm Number	Product Name	Legal Category
Kernfarm B.V.	43877/4008	Flubenvet 5 % w/w Premix for Medicated Feeding Stuff	POM-VPS
	43877/4009	Vecoxan 2.5 mg/ml Oral Suspension	POM-VPS

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK UP TO 30 SEPTEMBER 2016

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 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	13	100%
2	Centralised – UK as Rapp: Variations / Renewals	7	100%

Published Standard – No. 1 – Applications (DCP)

	App Type	No. of Apps	Performance
3	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 70)	8	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	17	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	20	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	32	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	26	100%

Published Standard – No. 1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	12	100%
9	MRP – UK as RMS: New MAs (Phase 2)	9	100%
10	MRP – UK as CMS: New MAs (Phase 2)	12	100%
11	MRP – UK as RMS: Type IA Variations	44	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	104	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	118	98.3%
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	45	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	80	100%

Published Standard – No. 1 – Applications (National)

	App Type	No of Apps	Performance	Target Days	Average Days
16	New MAs & Variation-Extensions:	**13**	**100%**		
	Initial Assessment				
	75 Day Clock	0		75	-
	90 Day Clock	13		90	73.7
17	New MAs & Variation-Extensions	**14**	**85.7%**		
	Sign-Off				
	130 Day Clock	2		130	72.5
	180 Day Clock	12		180	159
18	New Homeopathic	**0**	**-**	50	-
19	Type IA Variations	**67**	**100%**	30	21.2
20	Type IB / II Variations:	**96**	**100%**		
	Initial Assessment				
	Type IB	58		30	15.6
	Type II	25		60	52.0
	Renewal	13		60	58.6
21	Type IB / II Variations:	**115**	**99.1%**		
	Sign-Off				
	Type IB	84		30	4.6
	Type II	22		60	32.3
	Renewals	9		60	54.1
22	Admin Variations	**18**	**100%**		
	< 10 Changes	18		30	24.3
	> 10 Changes	0		60	-
23	ATCs	**10**	**100%**		
	Type A/S	6		30	21.2
	Type B	3		50	18.7
	Variations / Renewals	1		30	0
24	Batch Release	**1,544**	**100%**	10	1.3
25	Specific Batch Control	**4**	**100%**	20	0.3
26	AVA	**2**	**-**	45	33.5

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	**268**	**98.1%**
28	Validation	**527**	**100%**
29	Issue of authorisation documentation	**676**	**99.9%**

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	1364	**97.5%**

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	**73**	**100%**	15	5.0
32	All other applications	**1729**	**99.9%**		
	Urgent	158		2	0
	Non-Urgent	1571		10	2
33	Export	**333**	**100%**	10	6.3

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	**80**	**100%**	30	15.0
35	Publish PAR within 120 days	**45**	**100%**	120	98.0
36	Update PAA within 60 days	**303**	**99.3%**	60	9.0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	**3483**	**100%**
38	Human, Animal & Environmental AERs – Follow Up	**1436**	**99.4%**
39	PSURs	**922**	**99.2%**
40	Inspections	**7**	**100%**

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	**18**	**100%**	-	-
42	GDP inspections within 5 years of last inspection	**20**	**100%**	-	-
43	Send deficiency or post inspections letter	**34**	**100%**		
	GMP	16		30	21
	GDP	18			
44	Issue GMP Certificates and final inspection reports	**16**	**100%**		
45	Send final inspection report to wholesaler site	**31**	**100%**	90	77

Annex 2

GOV.UK

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Departments Worldwide How government works Get involved
Policies Publications Consultations Statistics Announcements

News story

MAVIS 100

From: Veterinary Medicines Directorate
Preview

The Marketing Authorisation Veterinary Information Service - Edition 100

MAVIS
MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE
EDITION 100 - OCTOBER 2016

News

Open Meeting of the Veterinary Medicines Directorate

The VMD held its open meeting on 16 September 2016.

The presentations given at the meeting are available on YouTube.

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

Licensing

Special Import Scheme (SIS) Changes

Changes have been made to the online system, to further simplify the application process and reduce administrative burden.

Certificates (SIC and STC) are now shorter and only detail essential information.

WDIC (wholesale dealer import) certificates are now available to apply for online from GOV.UK. We will no longer accept postal or email WDIC applications from 1 November 2016.

For further information please email import.cert@vmd.defra.gsi.gov.uk.

ORGANOGRAM OCTOBER 2016

Annex 3