MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 99 - JULY 2016

INVITATION TO ATTEND THE OPEN MEETING OF THE VETERINARY MEDICINES DIRECTORATE

The VMD will hold its Open Meeting on Friday 16 September 2016 at the Animal and Plant Health Agency (APHA) Weybridge, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3NB. The meeting will begin at 10.30 and close by 13.00. Admission is free but will be by ticket only.

VMD staff will give presentations based on the advance questions received followed by an open question and answer session.

Tea and coffee will be available before and after the meeting.

Questions for the VMD should be sent to Chris Abbott at the contact details below, by Friday 12 August.

Requests for tickets should be sent to Chris Abbott, contact details below, by Friday 12 August. Please include the names of all attendees. We will issue tickets afterwards.

For information please contact Chris Abbott (email: openmeeting@vmd.defra.gsi.gov.uk, 01932 338353).

SUSPENSION OF VELACTIS FOLLOWING ADVERSE EVENTS IN DAIRY CATTLE

On the 20 July the VMD suspended the marketing and use of Velactis in the UK.

This prescription only veterinary medicine, marketed by CEVA Sante Animale, the Marketing Authorisation Holder (MAH), contains the active substance cabergoline, and is used in the herd management programme of dairy cows as an aid in abrupt drying-off, by reducing milk production.

The product was authorised through the European Medicines Agency in December 2015 and was first sold in the UK in April 2016.

The VMD has been made aware of reports of serious adverse events, predominantly occurring in Denmark, involving recumbency (lying down and unable to rise) and some deaths. CEVA Sante Animale has initiated a voluntary product recall. We are encouraging vets and farmers to submit to the VMD any outstanding reports of adverse events associated with use of Velactis using our online reporting form or directly to CEVA Sante Animale for further investigation by the MAH as necessary.

More detailed information is available on GOV.UK and the EMA website.

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Veterinary Medicines Directorate

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LICENSING

PROPOSED CHANGES TO PUBLISHING LICENSING INFORMATION IN MAVIS

To continually improve the way we communicate with our stakeholders and to avoid unnecessary duplication of effort, we are reviewing the way we publish information in MAVIS, in particular:

- Marketing Authorisations
- Annex 1 – Quarterly reporting against VMD Published Standards for licensing work

Marketing Authorisations

We currently publish information in MAVIS on products that have been authorised, varied, or expired in the previous three months. However, this information is also available elsewhere, e.g. the VMD's Product Information Database (click on 'recently updated').

Information on authorised products and clinically significant variations is also published in the Veterinary Record; and information about centrally authorised products is available on the European Medicines Agency (EMA) website.

Therefore, we no longer consider it necessary to publish this information in MAVIS, but we would like to hear your feedback before making any changes.

Quarterly reporting against VMD Published Standards for licensing work

We propose to stop publishing this information in MAVIS; instead we intend to publish it on a monthly basis under 'latest' on the VMD homepage on GOV.UK. This will provide you with a timelier update on our progress against targets.

Comments

Tell us what you think by 15 September 2016.

Please send comments to Natalie Shilling at n.shilling@vmd.defra.gsi.gov.uk and put 'Changes to MAVIS' in the subject line.

TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 APRIL TO 30 JUNE 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	2,518
Vet-Goid	Allergens	281
Filavac VHD K C+V	Rabbit Haemorrhagic Disease (Inactivated)	245
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	228
Botulism Vaccine	Clostridium botulinum type C toxoid Clostridium botulinum type D toxoid	207
Greer Allergenic Extract Patient Prescription	Allergens	194
Pneumabort-K +1b	Equine Rhinopneumonitis Virus	172
European Viper Venom Antiserum (Antytoksyna Jadu Zmij - Poland)	European Viper Venom Antiserum	114
Sucrabest 1g Tabletten	Sucralfate	80
Smartshot B12 Prime Lamb	Hydroxocobalamin	78

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

SUMMARY: COMPANY VISIT QUESTIONNAIRES 1 APRIL 2015 TO 31 MARCH 2016

Background

This is the seventh full year of the VMD seeking feedback from companies who request a meeting with us, on the effectiveness, accuracy and relevance of the advice provided. The outcomes for 2015/16 are similar to previous years, with consistently high levels of satisfaction being achieved.

These qualitative results complement the many quantitative measures we have in place; and help to provide a more rounded summary of the performance and service that industry can expect to receive.

For the 2015/16 Financial Year, the VMD set a target that the overall median score from meeting questionnaires for individual VMD company meetings should be not less than 4 for at least 90% of the meetings.

In addition, any feedback received is used to enable the VMD to continue to provide a service that meets the industry need and helps to identify areas where improvements can be made.

Meetings

Between 1 April 2015 and 31 March 2016 a total of 58 meetings were held at the request of companies in order to discuss potential projects. A total of 22 completed questionnaires were received from companies reporting on the experiences that they had in arranging and attending meetings, which was a lower return rate than in previous years. In addition feedback was provided on the effectiveness, accuracy and relevance of the advice given.

The VMD would like to thank those who took the time to respond to this questionnaire. Your feedback is valued and we will be looking at the individual comments made to see where we can improve further. We are disappointed not to have received more completed questionnaires. We appreciate everyone is very busy and this is an additional task but we would like to encourage all companies on all occasions to provide us with feedback.

Results

Details are at Annex 3.

The questionnaire relies on a simple scoring system from 1 to 5 with 1 being at the lower end of the scale and 5 at the top end.

- 100% of all respondents rated the overall usefulness of these meetings as 4 or above. The average score was 4.65.
- Ease of arranging meetings – all companies rated this as 4 or above with the average being 4.55.
- Respondents thought that VMD staff were well prepared for these meetings with the average score being 4.5.
- The VMD returned the draft set of minutes with our comments to the company within an average of 16 calendar days from receipt.

Conclusions

From the results received it is clear that industry welcomes the VMD's open approach to meetings. Company meetings are easy to arrange, usually within the timescale requested by the company. Appropriate qualified people attend these meetings which enables constructive debate around the agenda points. It is clear that the advice offered by VMD staff across all disciplines is valued, relevant and of good quality. The friendliness of VMD staff is also a noted quality. Furthermore, companies come well prepared and willing to discuss and exchange views.

The VMD welcomes the early provision of agendas with key points or questions for discussion clearly indicated. We would encourage all companies to continue to provide these at least one week prior to the meeting to provide sufficient time for preparation, enabling more focused discussions to take place. Furthermore, the VMD encourages companies to provide draft minutes so that these can be reviewed, ratified and consequently retained as a record of the discussions and of any agreements which may have been reached. It is important when completing the minutes that sufficient detail and key points / agreements are recorded. Often there can be a gap between the meeting itself and the project being progressed to the point of submission or in compiling the dossier. The minutes provide a valuable reference point for both parties, especially when personnel may have changed during the intervening period.

If you would like any further information on this item, please contact Gavin Hall (VMD, email: g.hall@vmd.defra.gsi.gov.uk, 01932 338431). Should you wish to arrange a meeting please contact Chris Abbott (VMD, email: c.abbott@vmd.defra.gsi.gov.uk, 01932 338353).

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.

Mr Samuel Boylett, Telford. A large number of Prescription Only–Veterinary (POM-V), antibiotics and human medicines were seized. These products had been obtained and administered illegally. This was a case in which the VMD supported the RSPCA lead.

Mr Black, Strabane, Northern Ireland. Five bottles of Micotil 300 and seven bottles of Tylo 200 were seized as they were not authorised for use in the UK.

UK Border Force at International Logistic Centre, Langley, Berkshire stopped a shipment which was then subsequently seized. This shipment contained 88 parcels addressed to premises in the UK. The parcels contained both UK authorised and non-UK authorised veterinary medicines, the majority being flea treatments and wormers for companion animals. The medicines were seized under Regulation 9 (Importation of authorised veterinary medicinal products) and Regulation 25 (Importation of unauthorised veterinary medicinal products) of the Veterinary Medicines Regulations.

■ IMPROVEMENT NOTICES

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

Church Farm, Winfarthing, Norfolk. Unacceptable levels of spillage, rubbish and dust found in mixing area, no batch records of POM-V medicines and inappropriate weighing of zinc oxide.

Measures to be taken:

- Area of mixer to be thoroughly cleaned and tidied and maintained accordingly
- Batch records of POM-V medicines to be included on each occasion
- Appropriate weighing equipment to be implemented.

CV Pharma Ltd, Godalming Surrey. An unauthorised medicine, CV247, containing sodium salicylate being presented to UK customers for use in treating cancer in animals. This is in breach of the Veterinary Medicines Regulations.

Measures to be taken:

- All references to using CV247 within the UK for treating animals with cancer must be removed from all publicly available material published by or on behalf of CV Pharma Ltd
- All reference to using CV247 in animals must be removed from all digital material published by or on behalf of CV Pharma Ltd. including CV Therapy.com and CV Pharma Ltd social media outlets.

Maisemore Apiaries, Gloucester. Veterinary medicinal products containing Oxalic Acid were being presented for sale whilst not authorised for use in the UK. Also, unauthorised veterinary products were being presented for sale with claims to treat or prevent disease. These are offences under Regulation 4 (Placing a veterinary medicinal product on the market) of the Veterinary Medicines Regulations.

The improvements are to:

- Cease marketing and sale of any unauthorised prepared Oxalic Acid from the UK market
- Remove all medicinal claims and references highlighted in previous correspondence from the Maisemore Apiaries website
- Remove medicinal claims found elsewhere in Maisemore Apiaries marketing material including social media, leaflets, product descriptions and customer testimonials.

■ OUTCOMES OF PROSECUTIONS

On 1 April 2016 at Manchester Magistrates Court, Mr Shahin Shah pleaded guilty to 15 charges of importation of unauthorised veterinary medicinal products under the Veterinary Medicines Regulations.

Mr Shah was given a two year conditional discharge and fined £85 costs and a £15 victim surcharge.

This case related to the importation of various non-UK authorised antibiotics for use in pigeons. The products were discovered by Immigration Officers at Manchester 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 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.

STANDARDISED PERIODIC SAFETY UPDATE REPORT (PSUR) TEMPLATE

Following a number of requests from Marketing Authorisation Holders (MAHs), the pharmacovigilance team have created a standardised PSUR template, which is now available on GOV.UK at PSUR checklist template.

We are aware that most MAHs already have their own structure and templates; therefore this is an entirely optional template that is aimed to assist new PSUR formation. It provides a simple framework for the report, detailing all the information you should include in a PSUR. You can adapt the structure and format as you wish, however your PSUR must include all the required information.

If you have any further questions on PSURs please do not hesitate to contact our administration team at psur.submissions@vmd.defra.gsi.gov.uk

QUARTERLY REPORT

During the period 1 April to 30 June 2016, the VMD received 1,515 suspected adverse event reports involving animals. Of these, 47 reports related to unauthorised or unidentified products, one report involved animal trials under Animal Test Certificates (ATCs) and three further reports were from studies not requiring ATCs.

Excluding these three categories, the remaining 1,464 suspected adverse event reports were associated with 366 authorised products in the following distribution categories:

1,330	Prescription Only Medicine - Veterinarian (POM-V)
80	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
23	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
28	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
3	Products sold under the Exemption for Small Pet Animals (N/A)

During the quarter 57 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.

DARC GROUP UPDATE

The Defra Antimicrobial Resistance Co-ordination (DARC) group met on 1 June 2016 to discuss recent trends in antibiotic resistance in bacteria of importance to human health. The group discussed various topics including guidance for Livestock Associated Meticillin Resistant *Staphylococcus aureus* (LA-MRSA); the Independent Review on Antimicrobial Resistance published on 19 May 2016; and the collection of antibiotic consumption data in a number of livestock sectors, including the launch of 'eMB-Pigs' in April - an electronic Medicines Book for monitoring antibiotic usage in the pig sector. The next DARC meeting is scheduled for 21 September 2016.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

Data for the 2015 UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARRS) Report are currently being prepared. The antibiotic sales data for 2015 have been collected from the UK Marketing Authorisation Holders and these data are currently being collated and validated. As in previous years, the sales data will be combined with data for England and Wales on the antibiotic susceptibility of veterinary and foodborne pathogens to form the UK-VARSS Report, with an expected publication date of November this year. The UK-VARSS 2014 Report was published on 18 November 2015. This report and previous reports can be found at https://www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2014

EUROPEAN SURVEILLANCE OF ANTIMICROBIAL CONSUMPTION (ESVAC)

The ESVAC species expert advisory group (EAG) met at the European Medicines Agency (EMA) on 10-11 May 2016. The group prepared a concept note to introduce the parameters that will feature as part of the guidance document for the collection of antimicrobial usage data by species. This guidance note will be published on the EMA website in summer 2016 for a period of public consultation.

The ESVAC technical units are now available on the EMA website at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001493.jsp&mid=WC0b01ac0580a2fcf5

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 May 2016. Summary minutes of the meetings held since May 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

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

- Aaron Hunter joined the Licensing Administration team on 1 June
- Jamie Jardine joined the Pharmacovigilance team on 6 June
- Tareq Sulaiman, Pavitra Tanwar and Ann Baker joined the Committee and Office Support team on 14 June
- Caroline Millward joined the Finance team on 28 June
- John O'Neill joined the Good Manufacturing Practice Inspections team on 4 July

Departing Staff

- Anna-Maria Brady retired on 3 May
- Elizabeth Childs resigned on 13 May

Promotions

- John Millward was promoted to the Head of the Compliance Unit on 1 May
- Noemi Garcia del Blanco was promoted to the post of Head of the Biologicals Assessor and Licensing Administration team on 16 May
- Lea Reynolds was promoted within the Legislation team on 1 July
- Amanda Baker was promoted within the Enforcement team on 1 July
- Alison Reynolds was promoted within the General Assessment and Research team on 4 July
- Andrew Parker was temporarily promoted within the Licensing Administration team on 4 July

Transfers

- Sarah Gibbons transferred to the Pharmaceuticals and Feed Additives team on 9 May
- Giles Davis transferred to the Head of Legislation post on 16 May
- Jenny Cass temporarily transferred to the General Assessment and Research team on 4 July
- Alice Barnard transferred to the General Assessment and Research team on 18 July

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 10 MARCH 2016 - 13 JUNE 2016

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Alfamed	17902/4097	Perfikan 26.8 mg/240 mg Spot-on Solution for Very Small Dogs		POM-V
	17902/4100	Perfikan 67 mg/600 mg Spot-on Solution for Small Dogs		POM-V
	17902/4096	Perfikan 134 mg/1200 mg Spot-on Solution for Medium Dogs	Fipronil, Permethrin (Cis:Trans 25:75)	POM-V
	17902/4099	Perfikan 268 mg/2400 mg Spot-on Solution for Large Dogs		POM-V
	17902/4098	Perfikan 402 mg/3600 mg Spot-on Solution for Very Large Dogs		POM-V
Bela-Pharm GmbH & Co. KG	41816/4002	Calcibel 240/60/60 mg/ml Solution for Infusion for Horses, Cattle, Sheep, Goats and Pigs	Magnesium Chloride Hexahydrate, Calcium Gluconate Monohydrate, Boric Acid	POM-V
Ceva Animal Health Ltd	15052/4088	Cevac Mass L Lyophilisate for Oculonasal Suspension for Chicken	Infectious bronchitis virus	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4066	Chanazone 1 g, Oral Powder for Horses	Phenylbutazone	POM-V
	08749/4070	Chanotal Plus Tablets for Dogs	Pyrantel Embonate, Pyrantel, Praziquantel, Febantel	NFA-VPS
	08749/4055	Euthoxin 500 mg/ml Solution for Injection	Pentobarbital Sodium	POM-V
	08749/4067	EvictaWorm Cat Tablets 230/20 mg	Pyrantel Embonate, Praziquantel	NFA-VPS
	08749/4069	EvictaWorm Dog Tablets 50/50/150 mg	Pyrantel, Praziquantel, Febantel	NFA-VPS
	08749/4068	Extrontel 230/20 mg Flavoured Film-coated Tablets for Cats	Pyrantel Embonate, Praziquantel	NFA-VPS
CZ Veterinaria S.A.	30824/4003	Entericolix, Emulsion for Injection for Pigs	*E. coli* strain P4 (F6 adhesins), inactivated *E. coli* strain P5 (F18 adhesins), inactivated *E. coli* strain P6 (F4ac adhesins), inactivated *E. coli* strain P9 (F18 adhesins), inactivated *E. coli* strain P10 (F5 + F41 adhesins), inactivated Beta toxoid of *Clostridium perfringens* type C	POM-V
Dechra Limited	10434/4087	Adrestan 10 mg Hard Capsules for Dogs		POM-V
	10434/4088	Adrestan 30 mg Hard Capsules	Trilostane	POM-V
	10434/4089	Adrestan 60 mg Hard Capsules		POM-V
Eurovet Animal Health B.V.	16849/4050	Primazym 40000 Ph. Eur. U. Capsules for Dogs	Pancreatin	POM-V
	16849/4052	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin	POM-V
Fatro S.p.A	11557/4002	Pronestesic 40 mg/ml / 0.036 mg/ml Solution for Injection for Horses, Cattle, Pigs and Sheep	Procaine Hydrochloride, Epinephrine Acid Tartrate	POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Genera Inc.	43676/4000	Avishield ND, Lyophilisate for Suspension, for Chickens and Turkeys	Newcastle disease virus	POM-V
Krka d.d., Novo Mesto	01656/4108	Fyperix Combo 50 mg/60 mg Spot-on Solution for Cats and Ferrets	Fipronil, (S)-Methoprene	POM-V
	01656/4109	Fyperix Combo 67 mg/ 60.3 mg Spot-on Solution for Small Dogs		POM-V
	01656/4105	Fyperix Combo 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs		POM-V
	01656/4106	Fyperix Combo 268 mg/ 241.2 mg Spot-on Solution for Large Dogs		POM-V
	01656/4107	Fyperix Combo 402 mg/ 361.8 mg Spot-on Solution for Extra Large Dogs		POM-V
Laboratorios Calier, SA	20634/4009	Apitraz 500 mg Bee-hive Strips for Honey Bees	Amitraz	AVM-GSL
Merial Animal Health Limited	08327/4276	Eurican DAP Lyophilisate and Solvent for Suspension for Injection	Canine parvovirus, Canine distemper virus, Canine adenovirus	POM-V
	08327/4277	Eurican DAPPi Lyophilisate and Solvent for Suspension for Injection	Canine parvovirus, Canine parainfluenza virus, Canine distemper virus, Canine adenovirus	POM-V
Norbrook Laboratories Limited	02000/4400	Normazole 5 mg/ml Oral Solution for Cats	Thiamazole	POM-V
	02000/4399	Thyronorm 5 mg/ml Oral Solution for Cats		POM-V
SP Veterinaria, S.A.	36967/4003	Mycoflor 200 mg/ml, Solution for Use in Drinking Water for Pigs	Florfenicol	POM-V
Vetcare Oy	42810/4000	Caremast Vet 600 mg Intramammary Suspension for Lactating Cows	Procaine Benzylpenicillin	POM-V
Vetoquinol UK Ltd	08007/4144	Tylucyl 200 mg/ml Solution for Injection for Cattle and Pigs	Tylosin	POM-V
Vetpharma Animal Health, S.L	32509/4022	Somnipron 10 mg/ml Solution for Injection for Horses and Cattle	Detomidine Hydrochloride	POM-V
VetPlus Ltd	00844/4215	Epilease 250 mg Capsules for Dogs	Potassium Bromide	POM-V
Virbac	05653/4194	Zoletil 100 (50 mg/ml+50 mg/ml) Lyophilisate and Solvent for Solution for Injection for Dogs and Cats	Zolazepam, Tiletamine	POM-V
Zoetis UK Limited	42058/4191	Tardastrex 10 mg/ml Suspension for Injection for Dogs and Cats	Delmadinone Acetate	POM-V
	42058/4192	Versican Plus DHP Lyophilisate and Solvent for Suspension for Injection for Dogs	Canine Adenovirus, Canine Distemper virus, Canine Parvovirus	POM-V
	42058/4193	Versican Plus P Lyophilisate and Solvent for Suspension for Injection for Dogs	Canine Parvovirus	POM-V

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 10 MARCH 2016 - 13 JUNE 2016

Company Name	Product Name	Brief Details	Legal Category
aniMedica GmbH	Dolocarp Flavour 20 mg Chewable Tablet for Dogs		POM-V
	Dolocarp Flavour 50 mg Chewable Tablet for Dogs	Shelf life change	POM-V
	Dolocarp Flavour 100 mg Chewable Tablet for Dogs		POM-V
	Dolocarp Flavour 20 mg Chewable Tablet for Dogs		POM-V
	Dolocarp Flavour 50 mg Chewable Tablet for Dogs	Change of manufacturer	POM-V
	Dolocarp Flavour 100 mg Chewable Tablet for Dogs		POM-V
Bayer plc	Baycox Sheep 50 mg/ml Oral Suspension		POM-V
	Advantage 40 mg Feline and Bunny Spot-on Solution		NFA-VPS
	Advantage 80 mg Feline and Bunny Spot-on Solution		NFA-VPS
	Bob Martin Double Action Spot-on Solution 250 mg for Large Dogs		AVM-GSL
	Bob Martin Double Action Spot-on Solution 400 mg for Extra Large Dogs		AVM-GSL
	Baycox 50 mg/ml Oral Suspension		POM-V
	Drontal Plus Flavour Tablets for Dogs		NFA-VPS
	Drontal Plus XL Flavour Tablets for Dogs		NFA-VPS
	Baycox 50 mg/ml Oral Suspension for Piglets, Calves and Lambs		POM-V
	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		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
	Bob Martin Spot On Solution Dewormer 20 mg		AVM-GSL
	Baycox Bovis 50 mg/ml Oral Suspension		POM-V
	Bob Martin Clear Wormer 20/230 mg Tablets for Cats and Kittens		AVM-GSL
	Bob Martin Double Action Spot-on Solution 100 mg for Small to Medium Dogs		AVM-GSL
	Top Drop 80 Spot-on Solution for Large Cats		POM-V
	Bob Martin Clear 3 in 1 Wormer XL 525/504/175 mg Tablets for Large Dogs		AVM-GSL
	Advantage 80 mg Spot-on Solution for Large Cats and Pet Rabbits		NFA-VPS
	Drontal Cat XL Film-coated Tablets	Change of distributor	NFA-VPS
	Equitape 90 mg/g Oral Gel for Horses		POM-VPS
	Top Drop 40 Spot-on Solution for Small Cats		POM-V
	Top Drop 40 Spot-on Solution for Small Dogs		POM-V
	Top Drop 100 Spot-on Solution for Medium Dogs		POM-V
	Top Drop 250 Spot-on Solution for Large Dogs		POM-V
	Top Drop 400 Spot-on Solution for Extra Large Dogs		POM-V
	Baytril Max 100 mg/ml Solution for Injection for Cattle		POM-V
	Droncit Spot-on 20 mg Solution		AVM-GSL
	Baycox 2.5% w/v Oral Solution		POM-V
	Drontal Plus Flavour Bone Shaped Tablets		NFA-VPS
	Bob Martin Double Action Spot-on Solution 40 mg for Cats and Small Dogs		AVM-GSL
	Advantage 40 mg Spot-on Solution for Small Cats, Small Dogs and Pet Rabbits		NFA-VPS
	Advantage 40 Spot-on Solution for Cats		NFA-VPS
	Advantage 40 Spot-on Solution for Dogs		NFA-VPS
	Advantage 80 Spot-on Solution for Cats		NFA-VPS
	Advantage 100 Spot-on Solution for Dogs		NFA-VPS
	Advantage 250 Spot-on Solution for Dogs		NFA-VPS
	Advantage 400 Spot-on Solution for Dogs		NFA-VPS
	Drontal Oral Suspension for Puppies Febantel 15 mg/ml / Pyrantel 5 mg/ml		NFA-VPS
	Baytril 100 mg/ml Solution for Injection		POM-V
	Baytril 2.5% Oral Solution		POM-V
	Baytril Piglet Doser 0.5% Oral Solution		POM-V

Company	Product Name	Brief Details	Legal Category
Bayer plc continued	Droncit Tablets 50 mg	Change of distributor	AVM-GSL
	Rompun 2% w/v Solution for Injection		POM-V
	Baytril 25 mg/ml Solution for Injection		POM-V
	Bolfo 0.25% Flea Spray		AVM-GSL
	Rompun Dry Substance 500 mg Powder and Solvent for Solution for Injection		POM-V
	Droncit Solution for Injection 5.68%		POM-V
	Bayvarol 3.6 mg Bee-hive Strips for Honey Bees		AVM-GSL
	Baytril 10% Oral Solution		POM-V
	Drontal Cat Film-coated Tablets		NFA-VPS
	Bob Martin Clear 3 in 1 Wormer 150/144/50 mg Tablets for Dogs		AVM-GSL
	Baytril Flavour Tablets 15 mg		POM-V
	Baytril Flavour Tablets 50 mg		POM-V
	Baytril Flavour Tablets 150 mg		POM-V
	Baytril 50 mg/ml Solution for Injection		POM-V
Boehringer Ingelheim Ltd	Vetmedin 0.75 mg/ml Solution for Injection for Dogs	Change in the invented name of the medicinal product to Boehringer Pimobendan 0.75 mg/ml solution for injection for dogs	POM-V
	Vetmedin Chew 2.5 mg Chewable Tablets for Dogs	Change of distributor	POM-V
C&H Generics Ltd	Milaxyn Plus Tablets for Dogs	Change in the (invented) name of the medicinal product to VetUK Dog Wormer Flavoured	NFA-VPS
	Quantilex 230/20 mg Flavoured Film-Coated Tablets for Cats	Change in the (invented) name of the medicinal product to VetUK Cat Wormer Film Coated Tablets	NFA-VPS
Cross Vetpharm Group Ltd	Dectospot 10 mg/ml Spot-on Solution for Cattle and Sheep	Change in pack size of the finished product	POM-VPS
Delaval International AB	Proactive 0.15% w/w Teat Dip/Spray Solution	Change the name of the MAH from DeLaval International AB to DeLaval NV	AVM-GSL
	Blockade 0.25 % w/w Iodine Teat Dip Solution		AVM-GSL
Elanco Europe Ltd	Program Plus Film-coated Tablets 2.3 mg/46 mg	Variation to change the marketing authorisation holders in both Spain and Italy.	POM-V
	Program Plus Film-coated Tablets 5.75 mg/115 mg		POM-V
	Program Plus Film-coated Tablets 11.5 mg/230 mg		POM-V
	Program Plus Film-coated Tablets 23 mg/460 mg		POM-V
EU Pharmaceuticals Ltd	Ridaflea Spot-on Solution Cat 50mg	Change of distributor	AVM-GSL
	Ridaflea Spot-on Solution Dog S 67 mg		AVM-GSL
	Ridaflea Spot-on Solution Dog M 134 mg		AVM-GSL
	Ridaflea Spot-on Solution Dog L 268 mg		AVM-GSL
	Ridaflea Spot-on Solution Dog XL 402 mg		AVM-GSL
Intervet UK Ltd	Panacur Equine Granules 22.2% w/w	Shelf life change	POM-VPS
	Panacur Granules 22.2% w/w		POM-VPS
Laboratorios Calier, SA	Ivertin 10 mg/ml Solution for Injection for Cattle and Pigs	Change of MAH from Laboratorios Calier, S.A. to Kela N.V.	POM-VPS
Le Vet Beheer B.V.	Bupredine Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Change in the invented name in Germany only	POM-V
	Carprodolor 50mg/ml Solution for Injection for Cattle	Shelf life change	POM-V
Merial Animal Health Limited	Frontline Spray 0.25% w/v Cutaneous Spray Solution	Change storage conditions of the finished product	POM-V
	Frontline Spray 0.25% w/v Cutaneous Spray	Shelf life change	POM-V

Company	Product Name	Brief Details	Legal Category
Neptune Pharma Ltd	Azasure 500 mg/g Powder for Suspension for Fish Treatment	Change in pack size of the finished product. Change to importer, batch release or quality control testing of the finished product. Replacement or additional manufacturing site	POM-V
Norbrook Laboratories Limited	Cefenil RTU 50 mg/ml Suspension for Injection for Swine and Cattle	Shelf life change	POM-V
	Synuclav 250 mg Tablets for Dogs	Change in pack size of the finished product	POM-V
Novartis Animal Health UK Ltd	Denagard 2% w/w Premix for Medicated Feed for Pigs, Chickens, Turkeys and Rabbits		POM-V
	Denagard 10% w/w Premix for Medicated Feeding Stuff for Pigs, Chickens, Turkeys and Rabbits		POM-V
	Denagard 80% w/w Premix for Medicated Feed for Pigs, Chickens and Turkeys		POM-V
	Denagard 12.5% w/v Concentrate for Oral Solution		POM-V
	Denagard 200 mg/ml Solution for Injection		POM-V
	Fortekor 2.5 mg Tablets for Cats and Dogs		POM-V
	Program 40 mg Suspension for Injection		POM-V
	Program 40 mg Suspension for Injection for Cats		POM-V
	Program 80 mg Suspension for Injection		POM-V
	Program 80 mg Suspension for Injection for Cats		POM-V
	Milbemax Chewable Tablets for Small Dogs and Puppies	Change of distributor	POM-V
	Milbemax Film-Coated Tablets for Small Cats and Kittens		POM-V
	Milbemax Film-Coated Tablets for Cats		POM-V
	Milbemax Tablets for Small Dogs and Puppies		POM-V
	Milbemax Tablets for Dogs		POM-V
	Potencil, 10% Premix for Medicated Feed for Pigs		POM-V
	Fortekor 5 mg Film-Coated Tablets for Dogs and Cats		POM-V
	Fortekor 20 mg Film-coated Tablets for Dogs		POM-V
	Fortekor Flavour 5 mg Tablets for Cats and Dogs		POM-V
	Fortekor Flavour 20 mg Tablets for Dogs		POM-V
	Framomycin 150 mg/ml Solution for Injection		POM-V
	Milbemax Chewable Tablets for Dogs		POM-V
	Denagard 10% w/w Premix for Medicated Feeding Stuff for Pigs, Chickens, Turkeys and Rabbits		POM-V
	Denagard 12.5% w/v Concentrate for Oral Solution		POM-V
	Denagard 200 mg/ml Solution for Injection		POM-V
	Denagard 2% w/w Premix for Medicated Feed for Pigs, Chickens, Turkeys and Rabbits		POM-V
	Denagard 80% w/w Premix for Medicated Feed for Pigs, Chickens and Turkeys		POM-V
	Fortekor 2.5 mg Tablets for Cats and Dogs		POM-V
	Program 40 mg Suspension for Injection		POM-V
	Program 40 mg Suspension for Injection for Cats		POM-V
	Program 80 mg Suspension for Injection	Change in Marketing Authorisation holder	POM-V
	Program 80 mg Suspension for Injection for Cats		POM-V
	Milbemax Chewable Tablets for Small Dogs and Puppies		POM-V
	Milbemax Film-Coated Tablets for Small Cats and Kittens		POM-V
	Milbemax Film-Coated Tablets for Cats		POM-V
	Milbemax Tablets for Small Dogs and Puppies		POM-V
	Milbemax Tablets for Dogs		POM-V
	Potencil, 10% Premix for Medicated Feed for Pigs		POM-V
	Fortekor 5 mg Film-Coated Tablets for Dogs and Cats		POM-V
	Fortekor 20 mg Film-coated Tablets for Dogs		POM-V

Company	Product Name	Brief Details	Legal Category
Novartis Animal Health UK Ltd continued	Fortekor Flavour 20 mg Tablets for Dogs	Change in Marketing Authorisation holder	POM-V
	Fortekor Flavour 5 mg Tablets for Cats and Dogs		POM-V
	Framomycin 150 mg/ml Solution for Injection		POM-V
	Milbemax Chewable Tablets for Dogs		POM-V
Pharmaq AS	ALPHA JECT micro 1 PD Emulsion for Injection, Vaccine for Atlantic Salmon	Shelf life change	POM-V
Prionics Lelystad B.V.	Tuberculin PPD Kit	Shelf life change	POM-V
Tulivin Laboratories Ltd	Tramazole 2.5% w/v SC Oral Suspension	Shelf life change	POM-VPS
Vale Pharmaceuticals Ltd	FleaCidal 50 mg Spot-on Solution for Cats	Change in 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
Vetcare Limited	Detogesic 10 mg/ml Solution for Injection for Horses	Change of pack size	POM-V
Vetoquinol UK Ltd	Epiphen Solution 4% w/v, Oral Drops	Change in Marketing Authorisation holder	POM-V
Vetpharma Animal Health, S.L	Tolcox 50 mg/ml Oral Suspension for Pigs	Variation to change the name of the medicinal product to ZORABEL 50 mg/ml oral suspension for pigs	POM-V
	Unisol 100 mg/ml Solution for Injection for Cattle and Pigs	Change of pack size	POM-V
Virbac	Milpro 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies	Shelf life change	POM-V
	Milpro 12.5 mg/125 mg Film-coated Tablets for Dogs		POM-V
	VetUK Dog Wormer 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies		POM-V
	VetUK Dog Wormer 12.5 mg/125 mg Film-coated Tablets for Dogs		POM-V
	Pramilon 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies		POM-V
	Pramilon 12.5 mg/125 mg Film-coated Tablets for Dogs		POM-V
	Milbeworm 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies		POM-V
	Milbeworm 12.5 mg/125 mg Film-coated Tablets for Dogs		POM-V
	Milpro 4 mg/10 mg Film-coated Tablets for Small Cats and Kittens		POM-V
	Milpro 16 mg/40 mg Film-coated Tablets for Cats		POM-V
	VetUK Cat Wormer 4 mg/10 mg Film-coated Tablets for Small Cats and Kittens		POM-V
	VetUK Cat Wormer 16 mg/40 mg Film-coated Tablets for Cats		POM-V
	Pramilon 4 mg/10 mg Film-coated Tablets for Small Cats and Kittens		POM-V
	Pramilon 16 mg/40 mg Film-coated Tablets for Cats		POM-V
	Milbeworm 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens		POM-V
	Milbeworm 16 mg/40 mg Film-Coated Tablets for Cats		POM-V

EUCE AUTHORISATIONS ISSUED
BETWEEN 10 MARCH 2016 - 13 JUNE 2016

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Dechra Limited	EU/2/15/189/001	Zycortal	Desoxycortone pivalate	POM-V
Laboratorios Hipra SA	EU/2/16/194/001–003	Evalon (PB-134)	Eimeria tenella, Eimeria necatrix, Eimeria maxima, Eimeria brunetti, Eimeria acervulina	POM-V
Laboratorios LETI, S.L.	EU/2/16/195/001-008	Letifend	Recombinant protein Q from Leishmania infantum MON-1	POM-V
Zoetis Belgium	EU/2/15/190/001-006	Suvaxyn Circo + MH RTU emulsion for injection for pigs	Recombinant Porcine Circovirus type 1 expressing the Porcine circovirus type 2 ORF2 protein, Mycoplasma hyopneumoniae	POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 10 MARCH 2016 - 13 JUNE 2016

Company	Product Name	Brief Details	Legal Category
Bayer Animal Health GmbH	Advocate Spot-on Solution for Small Cats and Ferrets	Variation to amend the SPC and package leaflet following the outcome of the CVMP discussion on the PSUR	POM-V
	Advocate Spot-on Solution for Large Cats		POM-V
	Advocate Spot-on Solution for Small Dogs		POM-V
	Advocate Spot-on Solution for Medium Dogs		POM-V
	Advocate Spot-on Solution for Large Dogs		POM-V
	Advocate Spot-on Solution for Extra Large Dogs		POM-V
Boehringer Ingelheim Vetmedica Gmbh	Pexion 100 mg Tablets for Dogs	Variation to amend the SPC and package leaflet following the outcome of the CVMP discussion on the PSUR	POM-V
	Pexion 400 mg Tablets for Dogs		POM-V
Ceva-Phylaxia Veterinary Biologicals Co. Ltd	Vectormune ND Suspension and Solvent for Suspension for Injection for Chickens	Shelf life change	POM-V
Eco Animal Health Ltd	Aivlosin 625 mg/g Granules for Use in Drinking Water for Chickens	Change in pack size of the finished product	POM-V
	Aivlosin 625 mg/g Granules for use in Drinking water for Pheasants		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 Turkeys		POM-V
	Aivlosin 42.5 mg/g Premix for Medicated Feeding Stuff for Pigs		POM-V
	Aivlosin 42.5 mg/g Oral Powder for Pigs		POM-V
Eli Lilly and Company Limited	Kexxtone 32.4 g Continuous-Release Intraruminal Device for Cattle	Variation to update safety information	POM-V
Merial	Oncept IL-2	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
Zoetis Belgium	Equip WNV – Emulsion for Injection for Horses	Shelf life change	POM-V
	Suvaxyn PCV Suspension for Injection for Pigs		POM-V

MARKETING AUTHORISATIONS EXPIRED BETWEEN 10 MARCH 2016 - 13 JUNE 2016

Company	Vm Number	Product Name	Legal Category
Baxter Healthcare Ltd	00116/4000	Isocare 100% w/v Inhalation Vapour, Liquid	POM-V
Bimeda Chemicals Ltd	02676/4166	Vetixin 5% Solution for Injection	POM-V
Eurovet Animal Health B.V.	16849/4038	Forthyron 600 Microgram Tablets for Dogs	POM-V
	16849/4039	Forthyron 800 Microgram Tablets for Dogs	POM-V
Evans Vanodine International Plc	03940/4052	Megodine 0.535% w/v Ready to Use Teat Dip and Teat Spray Solution	AVM-GSL
Kilco (International) Ltd	21357/4010	EmpraSan Sovereign, 2.7% w/v, Teat Dip Solution	AVM-GSL
Kilco Chemicals Ltd	01936/4007	Lanodip Gold Teat Dip RTU	AVM-GSL
Norbrook Laboratories Limited	02000/4334	Duphacycline Aerosol 3.6% w/w Cutaneous Spray Solution	POM-V
Zoetis UK Limited	42058/4184	Duphacycline XL Oxytetracycline 30% w/v Solution for Injection	POM-V
	42058/4202	Kloxerate Plus DC Intramammary Suspension, Dry Cow	POM-V
	42058/4203	Kloxerate Plus Milking Cow Intramammary Suspension	POM-V

MARKETING AUTHORISATIONS FOR PARALLEL IMPORTS GRANTED BY THE VMD BETWEEN 10 MARCH 2016 - 13 JUNE 2016

Company	Vm Number	Product Name	Legal Category
Kernfarm B.V.	43877/4004	Tylan 200, 200 mg/ml Solution for Injection	POM-V
	43877/4005	Vecoxan 2.5 mg/ml Oral Suspension	POM-VPS

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK UP TO 30 JUNE 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	8	100%
2	Centralised – UK as Rapp: Variations / Renewals	2	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)	3	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	8	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	13	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	26	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	16	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	6	100%
9	MRP – UK as RMS: New MAs (Phase 2)	3	100%
10	MRP – UK as CMS: New MAs (Phase 2)	9	100%
11	MRP – UK as RMS: Type IA Variations	21	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	44	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	58	100%
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	24	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	56	100%

Published Standard – No. 1 – Applications (National)

	App Type	No. of Apps	Performance	Target Days	Average Days
16	New MAs & Variation-Extensions:	**7**	**100%**		
	Initial Assessment				
	75 Day Clock	0		75	-
	90 Day Clock	7		90	80.3
17	New MAs & Variation-Extensions	**9**	**100%**		
	Sign-Off				
	130 Day Clock	1		130	75
	180 Day Clock	8		180	145
18	New Homeopathic	**0**	**-**	50	-
19	Type IA Variations	**41**	**100%**	30	25.0
20	Type IB / II Variations:	**49**	**100%**		
	Initial Assessment				
	Type IB	27		30	19.0
	Type II	16		60	54.6
	Renewal	6		60	58.8
21	Type IB / II Variations:	**55**	**100%**		
	Sign-Off				
	Type IB	38		30	8.7
	Type II	15		60	30.6
	Renewals	2		60	50.5
22	Admin Variations	**9**	**100%**		
	< 10 Changes	9		30	16.9
	> 10 Changes	0		60	-
23	ATCs	**5**	**100%**		
	Type A/S	3		30	17.7
	Type B	2		50	16.5
	Variations / Renewals	0		30	-
24	Batch Release	**754**	**100%**	10	1.6
25	Specific Batch Control	**1**	**100%**	20	1
26	AVA	**0**	**-**	45	-

Published Standard – No. 1 – Applications (Other)

	App Type	No. of Apps	Performance
27	Mock-Ups	**99**	**98.0%**
28	Validation	**246**	**100%**
29	Issue of authorisation documentation	**336**	**99.7%**

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No.	Performance
30	Authorisation Documentation	709	**98.7%**

Published Standard – No. 3 – Import and Export Certificates

	App Type	No. of Apps	Performance	Target Days	Average Days
31	Applications for new products	**46**	**100%**	15	4.4
32	All other applications	**1617**	**100%**		
	Urgent	155		2	0
	Non-Urgent	1462		10	2
33	Export	**181**	**100%**	10	5.8

Published Standard – No. 4 – Public Assessment Reports

	App Type	No. of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	**47**	**100%**	30	18.5
35	Publish PAR within 120 days	**22**	**100%**	120	108.4
36	Update PAA within 60 days	**174**	**98.9%**	60	13.7

Published Standard – No. 5 – Pharmacovigilance

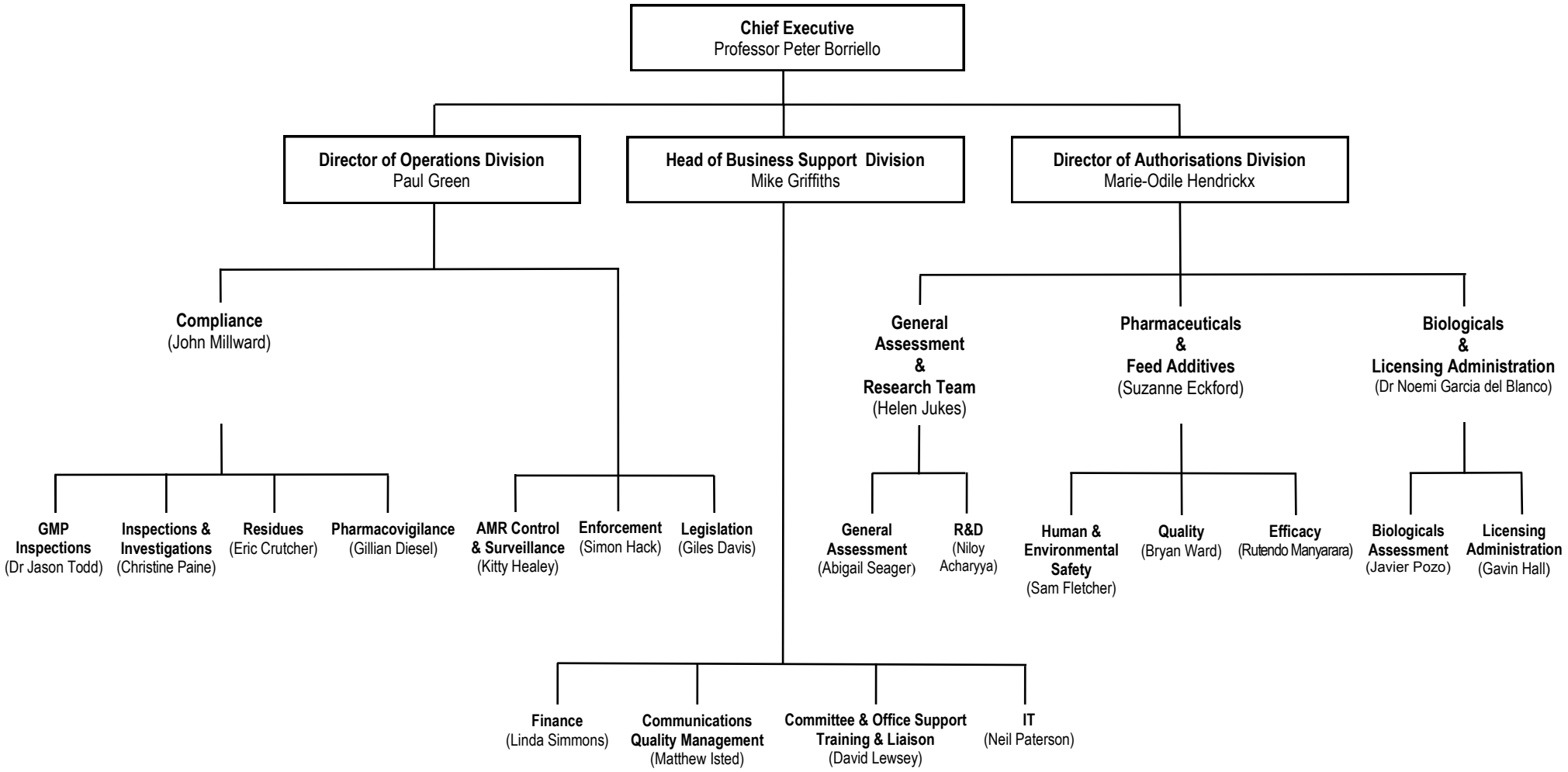
	Task	No.	Performance
37	Human, Animal & Environmental AERs	**1667**	**100%**
38	Human, Animal & Environmental AERs – Follow Up	**903**	**99.0%**
39	PSURs	**494**	**98.6%**
40	Inspections	**5**	**100%**

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	**9**	**100%**	-	-
42	GDP inspections within 5 years of last inspection	**11**	**100%**	-	-
43	Send deficiency or post inspections letter	**17**	**100%**		
	GMP	7		30	24
	GDP	10		30	21
44	Issue GMP Certificates and final inspection reports	**6**	**100%**	90	82
45	Send final inspection report to wholesaler site	**23**	**100%**	90	71

ORGANOGRAM JULY 2016

Annex 2

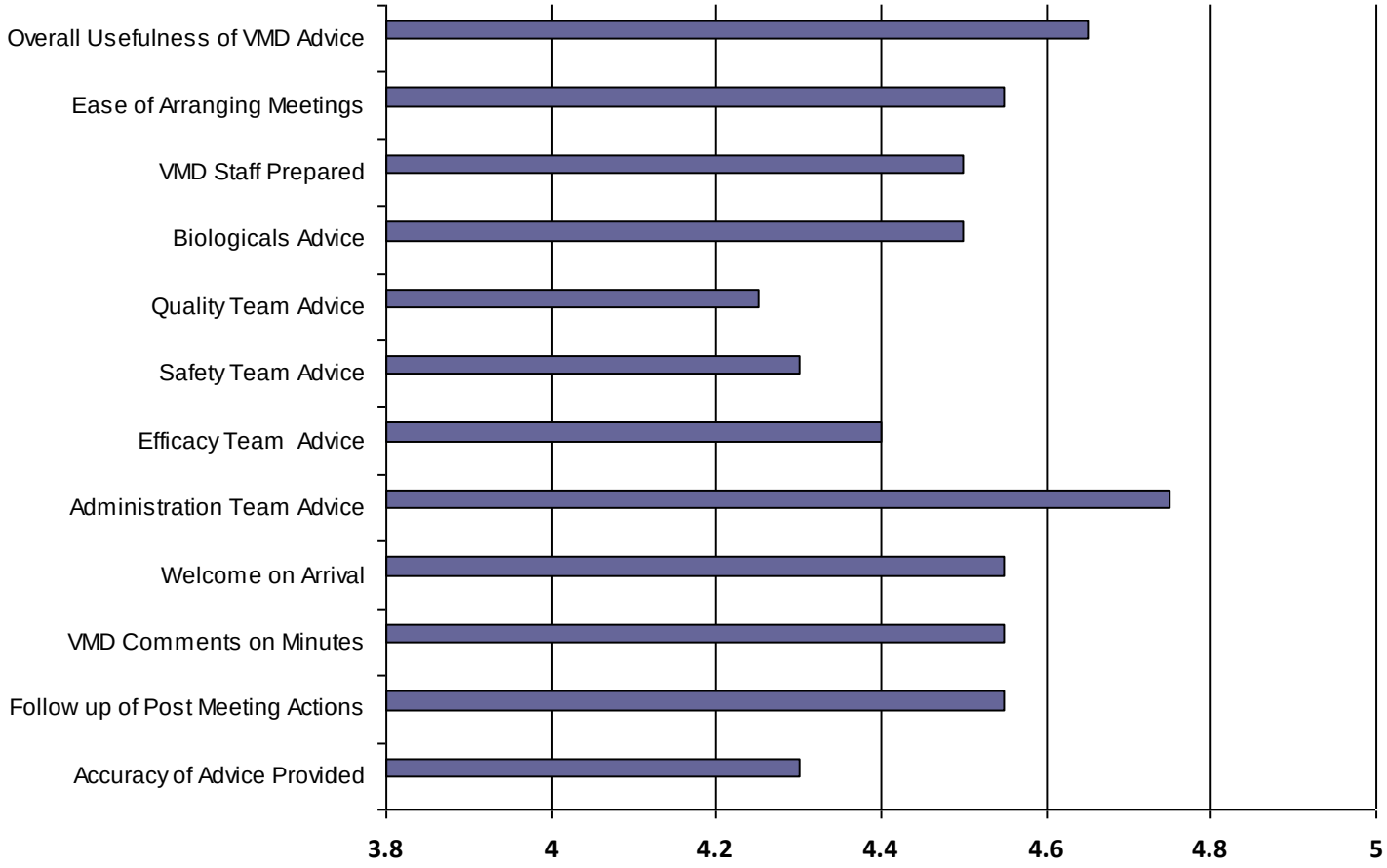


Annex 3

RESULTS: COMPANY VISIT QUESTIONNAIRES 1 APRIL 2015 TO 31 MARCH 2016

On average respondents scored the advice given by each discipline as follows:

Biologicals	4.5
Quality	4.25
Safety	4.3
Efficacy	4.4
Admin	4.75



As a balance to the company views, the VMD also completes a questionnaire after each company meeting. This questionnaire seeks views on the quality of the agenda provided; whether all the agenda points were covered or any additional ones added at the meeting; on the engagement of the company during the meeting; and also on the quality of the minutes provided.