MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 95 - JULY 2015

INVITATION TO ATTEND THE OPEN MEETING OF THE VETERINARY MEDICINES DIRECTORATE

The Veterinary Medicines Directorate (VMD) will hold its Open Meeting on Friday 2 October 2015 at the Animal and Plant Health Agency (APHA) Weybridge, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3NB. The meeting will begin at 10.30am and close by 1pm. 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.

Please note: We will be broadcasting the open meeting via web seminar technology, which can be used with a browser on any platform to enable you to view the presentations and listen to the audio in real time if you are unable to attend in person. We have only a limited number of spaces available, so to secure your space please contact Chris Abbott, contact details below.

Questions for the VMD should be sent to Chris Abbott, contact details below, by Friday 14 August.

Requests for tickets: should be sent to Chris Abbott, Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS (VMD, email: openmeeting@vmd.defra.gsi.gov.uk, 01932 338353) by Friday 4 September. Please include the names of all attendees. Tickets will be issued shortly afterwards.

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

INVESTORS IN PEOPLE | Silver

NEWS

NEW LOOK VETERINARY MEDICINES GUIDANCE

We have been busy rewriting our guidance to meet better your needs and make it easier and quicker to know how to comply with the law, use our services, etc. on GOV.UK.

Our rewritten guidance replaces the Veterinary Medicines Guidance Notes, known as VMGNs. It focusses on what you need to know to comply with the Veterinary Medicines Regulations in all the activities you do that involve using, making, buying or selling veterinary medicines. What the guidance requires you to do or recommends you do has not changed. It is simply shorter, clearer and more succinct yet still covers everything you need to know.

Go on the VMD page on GOV.UK to find our guidance or simply type "veterinary medicines guidance" in your search engine.

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

RE-ACCREDITATION TO THE INVESTORS IN PEOPLE (IIP) SILVER STANDARD

The VMD is proud to announce that we have achieved re-accreditation to the Investors in People (IIP) Silver standard following our reassessment in June. This is our fifteenth year of IIP accreditation.

The IIP standard provides a benchmark of good practice in the way organisations lead, manage and develop their people.

By continuing to invest in our staff we are able to provide an excellent service to all our stakeholders.

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

THE VETERINARY MEDICINES DIRECTORATE ANNUAL REPORT AND ACCOUNTS 2014/15

The VMD published its 2014/15 Annual Report and Accounts on 30 June 2015. You can find the publication on our corporate page of GOV.UK. Please follow the link to order a printed copy.

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

MEMBERSHIP OF THE VETERINARY PRODUCTS COMMITTEE (VPC)

An exercise to appoint a clinical toxicologist, environmental scientist, toxicologist, working farmer and veterinary surgeon (large animal), is expected to begin in August 2015. Application forms and further information will be available on http://publicappointments.cabinetoffice.gov.uk/.

The closing date for applications is to be announced. In the meantime expressions of interest, or requests for further information on membership of the VPC should be made to Nina Dorian (VMD, 01932 338491, email: n.dorian@vmd.defra.gsi.gov.uk).

MINUTES OF THE VETERINARY MEDICINES DIRECTORATE MANAGEMENT BOARD AND AUDIT AND RISK COMMITTEE MEETINGS

The VMD will now publish minutes of its quarterly Management Board and Audit and Risk Committee meetings on GOV.UK.

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

LICENSING

RENEWAL REMINDERS: MARKETING AUTHORISATIONS (MAs) AND VETERINARY HOMEOPATHIC REMEDIES (VHRs)

The procedure for sending renewal reminders is changing. Instead of receiving individual renewal reminders for each MA/VHR nine months in advance, you will now receive one reminder at the beginning of the year listing all MAs/VHRs due for renewal in the following calendar year.

To start this new process, you will shortly receive a reminder listing all MAs and VHRs due for renewal in 2016.

Thereafter, in January of each year you will receive a reminder listing all MAs/VHRs due for renewal in that year.

Renewal applications should be submitted at least six months prior to the date of renewal.

If you do not wish to renew your MA/VHR, please email the VMD at postmaster@vmd.defra.gsi.gov.uk and put 'Expiry of an MA' in the subject line.

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

TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 APRIL - 30 JUNE 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 - Injectable Suspension	Allergens	2,375
Vet-Goid	Allergens	357
Greer Allergenic Extract Patient Prescription	Allergens	237
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	193
Botulism Vaccine	Clostridium Botulinum Type C Toxoid Clostridium Botulinum Type D Toxoid	166
ACTT Allergy Drops	Allergens	65
Antepsin 1g Tablet	Sucralfate	65
European Viper Venom Antiserum (solution for injection) (Poland)	European Viper Venom Antiserum	62
European Viper Venom Antiserum (solution for injection) 100 mg/ml (Croatia)	European Viper Venom Antiserum	61
Ekyflogyl 125mls (Solution of Prednisolone 2mg/ml, Lidocaine 0.01 g/ml, Dimethyl Sulphoxide 0.8 ml/ml)	Prednisolone Acetate Lidocaine Hydrochloride Dimethyl Sulphoxide	58

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

SUMMARY: COMPANY VISIT QUESTIONNAIRES – APRIL 2014 TO MARCH 2015

Background

This is the sixth 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 2014/15 are similar to previous years, with consistently high levels of satisfaction.

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 2014/15 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 out of 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 2014 and 31 March 2015 a total of 75 meetings were held at the request of companies in order to discuss potential projects – a 19% increase in the total number of meetings held during the previous year. A total of 34 completed questionnaires were received from companies reporting on the experiences that they had in arranging and attending meetings. 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.

The VMD also complete a questionnaire to assess industry contribution and preparedness.

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 4.6.
- Ease of arranging meetings – all companies rated this as 4 or above with the average being 4.7.
- Respondents thought that the VMD staff were well prepared for these meetings with the average score being 4.6.
- The VMD returned the draft set of minutes with our comments to the company within an average of 16 calendar days from receipt.
- VMD's assessment of industry contribution for five criteria yielded an average score of 4.7

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 approachability of VMD staff is also a noted quality. Companies come well prepared and willing to discuss and exchange views.

The VMD welcomes the early provision of agendas and would encourage all companies to continue to provide these at least one week prior to the meeting. 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, 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* the VMD has published three seizure notices.

Donnington Grove Veterinary Surgery, Newbury Berkshire. Twenty-two boxes labelled as 'Yunnan Baiyao Jiaonang' were seized as they were not authorised for use in the UK.

Jacopo Tedaldi, non-UK resident. Sixteen bottles of anabolic injections were seized as they were not authorised in the UK.

Ercole Landoni, non-UK resident. Seventeen bottles of anabolic injections were seized as they were not authorised in the UK.

IMPROVEMENT NOTICES

Since the last edition of *MAVIS* the VMD has published one improvement notice.

Bowerings Animal Feed, Bridgwater, Somerset. The records of products manufactured using VMPs were inaccurate and did not reconcile with the products in stock. Improvement required is to put in place a system that accurately records the amounts of medicines bought, used and in stock, including the batch numbers.

RECENT PROSECUTION

On 19 June 2015 at Newport Magistrates Court, Mr Andrew Kennard pleaded guilty to one charge under the Fraud Act. Mr Kennard had previously entered guilty pleas at an earlier hearing for six offences under the Veterinary Medicines Regulations.

Mr Kennard was fined a total of £855 (including costs and victim surcharge).

This case related to the sale of NFA-VPS products, such as Drontal, Frontline and Advantage, via eBay.

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.

PHARMACOVIGILANCE

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

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

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

PHARMACOVIGILANCE INSPECTIONS

Most UK Marketing Authorisation Holders (MAHs) can expect an inspection within the next 2-3 years. MAHs with centrally authorised products will be included within our inspection programme, but where a CVMP-requested inspection in the UK is scheduled they will be carried out together, to avoid duplication of work. Following this round of national inspections, we are planning to move to a risk-based system with a maximum inspection frequency of 5 years. Currently CVMP requested inspections are carried out at a maximum interval of 3 years.

Since re-launching the inspection programme, our findings have been generally positive but all inspections to date have identified some minor or major non-compliances. Common themes include: unsatisfactory training, under-reporting, difficulty recognising when the minimum criteria for adverse event reporting have been met, inaccurate causality assessment, poor documentation of procedures, lack of VeDDRA coding and absence of veterinary expertise accessible to the QPPV.

Through our inspection programme, we hope we can build upon the good working relationship we have with MAHs and improve understanding and compliance.

To ensure smooth and efficient inspections, we ask that MAHs provide all documentation requested prior to the inspection in good time and cooperate fully with the inspector's requests for information when areas of non-compliance are identified during inspections.

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

EUDRAVIGILANCE VETERINARY WEBTRADER (EV WEB) TRAINING

We are currently investigating the possibility of providing basic training, particularly for smaller MAHs, on the use of EV WEB for sending and receiving reports to and from the VMD. We are hoping to run a course here at the VMD before the end of the year, but before making preparations we would like to canvass the level of interest. If you would like to receive hands-on tuition on the use of EV WEB please contact Victoria Warnock by 10 September 2015.

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

IDENTIFYING PRODUCTS INVOLVED IN ADVERSE EVENTS

During discussions at the Consultative Group for Veterinary Pharmacovigilance Systems, regulators and industry agreed to make greater efforts to identify all products mentioned by reporters of adverse events, even if they are thought to be concurrent or belong to another MAH.

In cases where this information is genuinely not obtainable, an educated "best guess" on the strength/size and pharmaceutical form should be made, where possible, using details from the report (e.g. the animal's age, weight or breed). The fact that the exact product identity is assumed rather than known should be clearly stated in the case narrative.

For further information please contact: Gillian Diesel (VMD, email: g.diesel@vmd.defra.gsi.gov.uk, 01932 338419).

QUARTERLY REPORT

During the period 1 April to 30 June 2015 the VMD received 1,443 suspected adverse event reports involving animals. Of these, 46 reports related to unauthorised or unidentified products, five reports involved animal trials under Animal Test Certificates (ATCs) and one report involved a Report from Study. Excluding these three categories, the remaining 1,391 suspected adverse event reports were associated with 330 authorised products.

The 1,389 reports were divided by distribution categories as follows:

1,237	Prescription Only Medicine - Veterinarian (POM-V)
100	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM - VPS)
30	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
16	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
5	Small Animal Exemption Scheme (N/A)
1	Autogenous vaccine

During the quarter 27 reports of human suspected adverse reactions were received. In addition, two historic 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

Antimicrobial resistance is of concern in human and veterinary medicines, resulting in increasing consideration about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. A 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 2 June 2015 and discussed recent trends in antibiotic resistance in bacteria of importance to human and animal health. There was an update on work being undertaken for the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project to look at antibiotic use in the UK livestock sectors, and a review of the results from a VMD-funded project investigating ways of optimising antibiotic use in broiler chickens and turkeys in order to minimise the selection of resistant pathogens for discussion with the DARC group.

HMA-VETERINARY ACTION PLAN ON ANTIMICROBIAL ISSUES

The VMD chairs and provides secretariat for the Heads of Medicines Agencies – Veterinary (HMA-V) Task Force, which is tasked with the progression of the HMA Antimicrobial Issues Strategy and Action Plan. The most recent discussion took place on 10 June 2015. The task force confirmed that the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) work on the additional collection of usage data in pigs in 2015 was not going to go ahead, and the focus would instead be on preparing a standard protocol and template. A recent request from the European Commission for a joint EFSA-EMA scientific opinion on measures to adopt to reduce reliance on antimicrobials in animal husbandry was noted, as were the recent adoption of the WHO global action plan on antimicrobial resistance and a World Organisation for Animal Health (OIE) resolution on antimicrobial resistance.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

Data for the 2014 UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report are currently being prepared. The antibiotic sales data for 2014 have been collected from the UK Marketing Authorisation Holders and these data are currently being collated and validated. Antibiotic resistance data obtained from the VMD's surveillance activities in 2014 are also being collated and work on interpreting these results will begin in August 2015. As in previous years, the sales data will be combined with England and Wales data on the antibiotic susceptibility of veterinary and foodborne pathogens to form the UK-VARSS Report, with an expected publication date in November this year.

This report and previous reports can be found at:
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.

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

VETERINARY PRODUCTS COMMITTEE (VPC)

The VPC is a statutory committee established to:

i) provide the Secretary of State with scientific[1] advice on any aspect of veterinary medicinal products and specified feed additives;

ii) hear representations on decisions relating to the granting, refusal, variation, suspension or revocation of a marketing authorisation for a veterinary medicinal product or an animal test certificate;

iii) promote the collection of information relating to suspected adverse reactions for the purpose of enabling the advice at i) above to be given.

Each year the VPC will publish a report of its activities and those of its Sub-Committees.

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

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

■ MEETINGS OF THE VPC

The VPC met in May 2015. Summary minutes of the meetings held in October 2014 and January 2015 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 Nina Dorian (VMD, email: vpc@vmd.defra.gsi.gov.uk, 01932 338491).

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

Noel Joseph starts a two year posting as a “seconded national expert” with the European Commission SANTE.DDG1.D.6 "Medicinal products – quality, safety and efficacy" on 1 September 2015. This is an exciting opportunity for Noel to work within the Commission and we wish him all the best. After his two year secondment he will return to the VMD.

The following staff changes took place during this quarter:

New Staff

- Gamini Withanage joined the Biologicals team on 20 July 2015

Departing Staff

- Ravinder Ivimey commenced a career break on 27 May 2015
- Abigail Bowden resigned on 1 May 2015
- Colin Bennett retired on 2 June 2015
- Dawn Greener retired on 8 July 2015

Promotions

- Darren Moore was temporarily promoted within the Finance team on 1 May 2015
- Alison Barry was temporarily promoted within the Finance team on 1 June 2015
- Andrew Parker was temporarily promoted to work part time in the General Assessment team and part time in the Licensing Administration team with effect from 1 June and 20 July 2015 respectively

Transfers

- Lea Stott transferred to the Committee and Office Support team on 21 July 2015

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 6 MARCH - 15 JUNE 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Allifax	43241/4000	Soliphen 60 mg Tablets for Dogs	Phenobarbital	POM-V
aniMedica Espana, S.L.U	43173/4000	Colfive 5,000,000 IU/ml Concentrate for Oral Solution for Calves, Pigs, Lambs, Chickens and Turkeys	Colistin Sulphate	POM-V
Billev Pharma aps	18585/4003	Milquantel 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
	18585/4004	Milquantel 16 mg/40 mg Film Coated Tablets for Cats Weighing at Least 2 kg		POM-V
Bob Martin (UK) Ltd	00715/4129	Bob Martin Clear Wormer 20 mg Spot-on Solution for Cats and Kittens	Praziquantel	AVM-GSL
Boehringer Ingelheim Ltd	00015/4090	Ingelvac PRRSFLEX EU Lyophilisate and Solvent for Suspension for Injection for Pigs	Porcine respiratory and reproductive syndrome virus	POM-V
	00015/4089	ReproCyc PRRS EU Lyophilisate and Solvent for		POM-V
C&H Generics Ltd	40162/4014	Dinelix Plus Tablets for Dogs	Febantel Praziquantel Pyrantel Pyrantel Embonate	NFA-VPS
	40162/4007	Johnsons One Dose Wormer 230/20 mg Film-Coated Tablets for Cats and Kittens	Praziquantel Pyrantel Embonate	NFA-VPS
	40162/4009	Milaxyn 230/20 mg Flavoured Film-Coated Tablets for Cats		NFA-VPS
	40162/4015	Milaxyn Plus Tablets for Dogs	Febantel Praziquantel Pyrantel Pyrantel Embonate	NFA-VPS
	40162/4010	MoleCare Cat Wormer 230/20 mg Film Coated Tablets	Praziquantel Pyrantel Embonate	NFA-VPS
	40162/4012	Quantilex 230/20 mg Flavoured Film-Coated Tablets for Cats		NFA-VPS
	40162/4013	Rofectan Plus Tablets for Dogs	Febantel Praziquantel Pyrantel Pyrantel Embonate	NFA-VPS
	40162/4008	Target Wormer 230/20 mg Film-Coated Tablets for Cats	Praziquantel Pyrantel Embonate	NFA-VPS
	40162/4011	Voxical 230/20 mg Film-Coated Tablets for Cats		NFA-VPS
	40162/4016	Voxical Plus Tablets for Dogs	Febantel Praziquantel Pyrantel Pyrantel Embonate	NFA-VPS
Ceva Animal Health Ltd	15052/4078	Hyogen Emulsion for Injection for Pigs	Mycoplasma hyopneumoniae	POM-V
	15052/4071	Strectis 121 mg/60 mg Spot-on Solution for Cats 5-10 kg	(S)-Methoprene Fipronil	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4048	RidaWorm 20 mg Spot-on Solution Cats and Kittens	Praziquantel	AVM-GSL
Cross Vetpharm Group Ltd	12597/4062	Alonate-P 400 mg/g Oral Paste for Horses and Ponies	Pyrantel Embonate	POM-VPS
Dopharma Research B.V.	28365/4006	Doxylin, 433 mg/g Powder for Use in Drinking Water for Chickens and Turkeys	Doxycycline Doxycycline Hyclate	POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Forte Healthcare Ltd	27819/4005	Bovigen Scour Emulsion for Injection for Cattle	Bovine coronavirus Bovine rotavirus Escherichia coli	POM-VPS
Intervet UK Ltd	01708/4610	AquaVac PD3 Emulsion for injection for Atlantic salmon	Aeromonas salmonicida subsp. Salmonicida Infectious pancreatic necrosis virus Salmon pancreas disease virus	POM-V
Kernfarm B.V.	43877/4000	Rispoval RS + PI3 IntraNasal	Bovine parainfluenza virus 3 Bovine respiratory syncytial virus	POM-V
Krka Dd	01656/4072	Amflee 2.5 mg/ml Cutaneous Spray Solution for Cats and Dogs		POM-V
	01656/4086	Amflee 50 mg Spot-on Solution for Cats		NFA-VPS
	01656/4087	Amflee 67 mg Spot-on Solution for Small Dogs	Fipronil	NFA-VPS
	01656/4088	Amflee 134 mg Spot-on Solution for Medium Dogs		NFA-VPS
	01656/4089	Amflee 268 mg Spot-on Solution for Large Dogs		NFA-VPS
	01656/4090	Amflee 402 mg Spot-on Solution for Extra Large Dogs		NFA-VPS
	01656/4084	Milprazon 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens Weighing at Least 0.5 kg	Milbemycin Oxime (A3 and A4) Praziquantel	POM-V
	01656/4085	Milprazon 16 mg/40 mg Film-Coated Tablets for Cats Weighing at least 2 kg		POM-V
Laboratorios Karizoo S.A	31223/4005	Karidox 125 mg/g Premix for Medicated Feeding Stuff for Pigs	Doxycycline Doxycycline Hyclate	POM-V
Le Vet Beheer B.V.	41821/4019	Canergy 100 mg Tablets for Dogs	Propentofylline	POM-V
Norbrook Laboratories Limited	02000/4398	Flick 50 mg Spot-On Solution for Cats	Fipronil	AVM-GSL
Orion Corporation	06043/4005	Vivelin 1.25 mg Chewable Tablet for Cats	Amlodipine Amlodipine Besilate	POM-V
Sinclair Animal and Household Care Ltd	16516/4036	PetStar Soft Flea Collar 180 mg/g Medicated Collar	Permethrin (Cis:Trans 40:60)	AVM-GSL
Sogeval	20749/4044	Amodip 1.25 mg Chewable Tablets for Cats	Amlodipine Amlodipine Besilate	POM-V
Triveritas Ltd	21759/4004	Dectospot 10 mg/ml Spot-on Solution for Cattle and Sheep	Deltamethrin	POM-VPS
	21759/4003	Ectospot 10 mg/ml Spot-on Solution for Cattle and Sheep		POM-VPS
Veyx-Pharma GmbH	27569/4005	Gonavet Veyx 50 micrograms/ml Solution for Injection for Cattle, Pigs and Horses	Gonadorelin[6-D-Phe] Gonadorelin[6-D-Phe]acetate	POM-V
Zoetis UK Limited	42058/4180	Ketavet 100 mg/ml Solution for Injection for Dogs, Cats and Horses	Ketamine Ketamine Hydrochloride	POM-V
Zylavet Pharmaceuticals Ltd	44020/4000	Pimovita 1.25 mg Chewable Tablets for Dogs	Pimobendan	POM-V
	44020/4001	Pimovita 2.5 mg Chewable Tablets for Dogs		POM-V
	44020/4002	Pimovita 5 mg Chewable Tablets for Dogs		POM-V
	44020/4003	Pimovita 10 mg Chewable Tablets for Dogs		POM-V

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 6 MARCH - 15 JUNE 2015

Company Name	Product Name	Brief Details	Legal Category
Alstoe Ltd (Alstoe Animal Health)	Gleptosil 200 mg per ml Solution for Injection	Change of Marketing Authorisation Holder from Sogeval UK Ltd to Ceva Animal Health Ltd	POM-VPS
	Vetergesic 0.3 mg/ml Solution for Injection for Dogs and Cats	Change to the distributor from Alstoe Ltd to Ceva Animal Health Ltd	POM-V
	Vetergesic Multidose 0.3mg/ml, Solution for Injection for Dogs and Cats		POM-V
Animalcare Ltd	Vitofyllin 50 mg Film-Coated Tablets for Dogs	Change in the shelf-life	POM-V
	Vitofyllin 100 mg Film-Coated Tablets for Dogs		POM-V
Animax Ltd	Paracide 62 Diazinon 62% w/v Concentrate for Dip Emulsion	Change in the name of the medicinal product to Paracide 62 % w/v Concentrate for Dip Emulsion	POM-VPS
Beaphar B.V.	Fiprotec 50 mg Spot-On Solution for Cats	Pack size limited to 6 pipettes	NFA-VPS
	Fiprotec 67 mg Spot-On Solution for Small Dogs		NFA-VPS
	Fiprotec 134 mg Spot-On Solution for Medium Dogs		NFA-VPS
	Fiprotec 268 mg Spot-On Solution for Large Dogs		NFA-VPS
	Fiprotec 402 mg Spot-On Solution for Extra Large Dogs		NFA-VPS
Bob Martin (UK) Ltd	Bob Martin Easy to Use Dewormer Granules for Dogs 888.8 mg	Change of distributor from Bob Martin (UK) Ltd to Chanelle Pharmaceuticals Manufacturing Ltd Change of Marketing Authorisation Holder from Bob Martin (UK) Ltd to Chanelle Pharmaceuticals Manufacturing Ltd	AVM-GSL
Ceva Animal Health Ltd	Fiprospot Duo Spot-On Solution for Dogs 2-10 kg and Cats > 5 kg	Variation to change the medicinal product name from Fiprospot Duo to Duoflect	POM-V
	Fiprospot Duo Spot-On Solution for Dogs 10-20 kg		POM-V
	Fiprospot Duo Spot-On Solution for Dogs 20-40 kg		POM-V
	Fiprospot Duo Spot-On Solution for Dogs 40-60 kg		POM-V
	Strectis Spot-on Solution for cats 1-5 kg	Variation to change the medicinal product name from Strectis to Duoflect	POM-V
	Strectis 121 mg/60 mg spot-on solution for cats 5-10kg		POM-V
Chanelle Animal Health Ltd	Clavucill Tablets 50 mg	Change of Marketing Authorisation Holder from Chanelle Animal Health Limited to V.M.D.n.v.	POM-V
	Clavucill Tablets 250 mg		POM-V
	Clavucill Tablets 500 mg		POM-V
	Zerofen 4% w/w Premix for Medicated Feeding Stuff	To change the medicinal product name from Zerofen to Ecozole	POM-VPS
CP Pharma Handelsgesellschaft mbH	Carprosol 50 mg/ml Solution for Injection for Dogs and Cats	Change in the shelf-life	POM-V
Dechra Limited	Buprenodale Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Change of Marketing Authorisation Holder address from Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW to Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW	POM-V
	Intubeaze 20 mg/ml Oromucosal Spray		POM-V
	Intra-Epicaine 2.0% w/v Solution for Injection		POM-V
	Vetivex 1 (9 mg/ml) Solution for Infusion for Cattle, Horses, Dogs and Cats	Change in the shelf-life of the finished product filled into 500 ml, 1000 ml and 2000 ml pack sizes from 18 months to 2 years	POM-V
	Vetivex 11 Solution for Infusion for Cattle, Horses, Dogs and Cats	To change the name of the medicinal product in the UK and Ireland only from Vetivex 11 solution for infusion for cattle, horses, dogs and cats to Vetivex 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats	POM-V
	Vetivex 11 Solution for Infusion for Cattle, Horses, Dogs and Cats	Change in the shelf-life	POM-V

Company	Product	Brief Details	Legal Category
Dechra Limited continued	Vetivex 20 (Sodium Chloride 7.2% w/v Intravenous Infusion BP (Vet))	To change the name of the medicinal product from Vetivex 20 (Sodium Chloride 7.2% w/v Intravenous Infusion BP (vet)) to Hypertonic 7.2% w/v Solution for Infusion	POM-V
Intervet UK Ltd	Estrumate 250 µg/ml Solution for Injection	To delete the storage precaution 'Do not store above 25 °C'	POM-V
	Leventa 1 mg/ml Oral Solution for Dogs	Change in the shelf-life	POM-V
Kela N.V.	FLORFENIKEL 300 mg/ml solution for injection for Cattle and Pigs	Variation to change distributor from KELA N.V. to ANUPCO	POM-V
Krka Dd	Anthelmin Plus Flavour Tablets for Dogs	Variation to remove PHA (UK) Limited as a distributor	NFA-VPS
	Anthelmin Plus XL Tablets for Dogs		NFA-VPS
	Fenflor 300 mg/ml Solution for Injection for Cattle, Florfenicol	Variation to remove Eurovet Animal Health Ltd as a distributor	POM-V
	Fenflor 300 mg/ml Solution for Injection for Pigs		POM-V
	Floron 40 mg/g Premix for Medicated Feeding Stuff for Swine	Variation to delete Virbac Ltd as the distributor	POM-V
	Tolracol 50 mg/ml Oral Suspension for Pigs, Cattle and Sheep	Change in the shelf-life	POM-V
	Tolracol 50 mg/ml Oral Suspension for Pigs, Cattle and Sheep	Variation to remove Henry Schein Animal Health as the distributor	POM-V
Laboratorios Calier, SA	Zipyran Tablets for Dogs	Change in pack size of the finished product	NFA-VPS
	Zipyran XL Tablets for Dogs		NFA-VPS
Le Vet Beheer B.V.	Finilac 50 microgram/ml Oral Solution for Dogs and Cats	Change in distributor from Le Vet. Beheer B.V. to Ecuphar NV	POM-V
Niche Generics Ltd	Adocam 1.5 mg/ml Oral Suspension for Dogs	Variation to change the Marketing Authoristion Holder from Niche Generics Ltd to aniMedica GmbH	POM-V
Norbrook Laboratories Limited	Norofas Pour-on Solution for Cattle	Change to the distributor details, from Norbrook Laboratories (GB) Limited to Norbrook Laboratories (GB) Limited on behalf of Downland Marketing Limited	POM-VPS
Novartis Animal Health UK Ltd	Milbemax Chewable Tablets for Dogs	To add a new pack size	POM-V
Pfizer Ltd	Kloxerate Gold DC Intramammary Suspension	Change in distributor from Pfizer Ltd to Zoetis UK Limited	POM-V
	Kloxerate Plus DC Intramammary Suspension, Dry Cow		POM-V
	Kloxerate Plus Milking Cow Intramammary Suspension		POM-V
	Terramycin Soluble Powder Concentrated 20% w/w Oral Powder		POM-V
	Kloxerate Gold DC Intramammary Suspension	Change in the Marketing Authorisation Holder from Pfizer Ltd to Zoetis UK Limited	POM-V
	Kloxerate Plus DC Intramammary Suspension, Dry Cow		POM-V
	Kloxerate Plus Milking Cow Intramammary Suspension		POM-V
	Terramycin Soluble Powder Concentrated 20% w/w Oral Powder		POM-V
Support Pharma S.L.	Marbofloxacin 40 mg/ml Solution for Injection for Pigs	Change in the medicinal product name from Marbofloxacin to Masterflox	POM-V
	Masterflox 40 mg/ml Solution for Injection for Pigs	Change of Marketing Authorisation Holder from Support Pharma S.L. to FATRO S.p.A.	POM-V
Vetcare Limited	Detogesic 10 mg/ml Solution for Injection for Horses	Change of Marketing Authorisation Holder address	POM-V

Company	Product	Brief Details	Legal Category
Virbac S.A.	Premadex Pour-On Solution for Cattle 5 mg/ml	Variation to change the name of the medicinal from Premadex Pour-On Solution for Cattle 5 mg/ml to Ivermectin Pour-On Solution for Cattle 5 mg/ml Virbac	POM-VPS
VMD NV	Clavucill Tablets 50 mg	Change in the name of the medicinal product from Clavucill Tablets 50 mg to Clavucill 40 mg/10 mg Tablets for Dogs and Cats	POM-V
	Clavucill Tablets 250 mg	Change in the name of the medicinal product from Clavucill Tablets 250 mg to Clavucill 200 mg/50 mg Tablets for Dogs	POM-V
	Clavucill Tablets 500 mg	Change in the name of the medicinal product from Clavucill Tablets 500 mg to Clavucill 400 mg/100 mg Tablets for Dogs	POM-V
Zoetis UK Limited	Bronchi-Shield Lyophilisate and Solvent for Suspension for Nasal Drops for Dogs	Change in the shelf-life	POM-V
	Colfen 200 SP 200 mg/g Granules for Use in Drinking Water for Pigs	Change of Marketing Authorisation Holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium	POM-V
	Colfen 200 SP, 200 mg/g Granules for Use in Drinking Water for Pigs	Change of distributor from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium	POM-V
	Rispoval RS + Pi3 IntraNasal	Change in pack size	POM-V

EUCE AUTHORISATIONS ISSUED BETWEEN 6 MARCH - 15 JUNE 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	EU/2/97/004/050-053	Metacam 40 mg/ml Solution for Injection for Cattle and Horses	Meloxicam	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	EU/2/07/078	Rheumocam 330mg granules for Horses	Meloxicam	POM-V
Orion Corporation	EU/2/15/181/001–005	Sileo 0.1 mg/ml Oromucosal Gel for Dogs	Dexmedetomidine Hydrochloride	POM-V
Prevtec Microbia GmbH	EU/2/14/180/001-003	Coliprotec F4 Lyophilized Live Non-Pathogenic Escherichia Coli Vaccine for Oral Use in Swine	Escherichia coli	POM-V
Zoetis Belgium	EU/2/06/062/005	Cerenia 10 mg/ml Solution for Injection for Dogs and Cats	Maropitant Maropitant citrate monohydrate	POM-V
	EU/2/99/014/015	Stronghold 60 mg Spot-On Solution for Cats 7.6–10.0 kg	Selamectin	POM-V
	EU/2/99/014/014	Stronghold 360 mg Spot-On Solution for Dogs	Selamectin	POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 6 MARCH - 15 JUNE 2015

Company	Product Name	Brief Details	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	Pexion 100 mg Tablets for Dogs	Variation to update the SPC and package leaflet	POM-V
	Pexion 400 mg Tablets for Dogs		POM-V
IDT BIOLOGIKA GMBH	Ecoporc Shiga Suspension for Injection for Pigs	Change to Shelf-life	POM-V
Merial	Broadline Spot-on Solution for Cats < 2.5 kg	Change to Shelf-life	POM-V
	Broadline Spot-on Solution for Cats 2.5 - 7.5 kg		POM-V
	Oncept IL-2		POM-V
Merial Animal Health Ltd	NexGard 11 mg Chewable Tablets for Dogs 2-4 kg	Variation to update the SPC and package leaflet	POM-V
	NexGard 28 mg Chewable Tablets for Dogs 4-10 kg		POM-V
	NexGard 68 mg Chewable Tablets for Dogs 10-25 kg		POM-V
	NexGard 136 mg Chewable Tablets for Dogs 25-50 kg		POM-V
Zoetis Belgium	Palladia 10 mg Film-Coated Tablets for Dogs	Change to Shelf-life	POM-V
	Palladia 15 mg Film-Coated Tablets for Dogs		POM-V
	Palladia 50 mg Film-Coated Tablets for Dogs		POM-V
	Suvaxyn PCV Suspension for Injection for Pigs		POM-V

MARKETING AUTHORISATIONS EXPIRED BETWEEN 6 MARCH - 15 JUNE 2015

Company	Vm Number	Product Name	Legal Category
Beaphar UK Ltd	13907/4001	Beaphar Flea Spray 0.25% w/w Cutaneous Spray Solution	AVM-GSL
Denes Natural Pet Care Ltd	01615/4024	Garlic Sugar Coated Tablets	AVM-GSL
	01615/4025	Greenleaf Sugar Coated Tablets	AVM-GSL
	01615/4031	Kidney Sugar Coated Tablets	AVM-GSL
GEA Farm Technologies (UK) Ltd	01808/4014	Suredip Repel 3.7% w/v Concentrate for Teat Dip or Teat Spray Solution	AVM-GSL
Intervet UK Ltd	01708/4592	Tribrissen 24% Suspension for Injection	POM-V
	01708/4269	Unisolve	POM-VPS
Kilco (International) Ltd	21357/4008	Emprasan Lanolin Teat Dip Concentrate	AVM-GSL
Listow Limited	41687/4001	Co Trimazine Tablets 120 mg	POM-V
	41687/4005	Cycloprost 5 mg/ml Solution for Injection	POM-V
	41687/4008	Dynaclav Suspension for Injection for Cattle	POM-V
	41687/4010	Memocal 40 CM Solution for Injection	POM-VPS
	41687/4003	Water for Injection 100% v/v Solvent For Parenteral Use (Animalcare)	POM-V
	41687/4011	Zalcal 20 CMD Solution for Injection	POM-VPS
Norbrook Laboratories Limited	02000/4314	Duphamox Palatable Tablets 40 mg	POM-V
	02000/4313	Duphamox Palatable Drops 50 mg/ml	POM-V
	02000/4315	Duphamox Palatable Tablets 200 mg	POM-V
Pfizer Ltd	00057/4430	Avatec 150 G (Game Birds) 150 mg/g Premix for Medicated Feeding Stuff	POM-V
	00057/4322	Colombovac Paratyphus Suspension for Injection for Pigeons	POM-VPS
	00057/4154	Copprite 2 g Hard Capsule	AVM-GSL
	00057/4142	Copprite 4 g Hard Capsule	AVM-GSL
	00057/4144	Copprite 24 g Hard Capsule	AVM-GSL
	00057/4305	Cylap	POM-V
	00057/4328	Duphacillin 150 mg Suspension for Injection	POM-V
	00057/4352	Duphatrim 20 Tablets Trimethoprim 20 mg and Sulfadiazine 100 mg	POM-V

Company	Vm Number	Product Name	Legal Category
Pfizer Ltd continued	00057/4309	Duphatrim 80 Tablets Sulfadiazine 400 mg and Trimethoprim 80 mg	POM-V
	00057/4350	Duphatrim Bolus Trimethoprim 200 mg and Sulfadiazine 1.0 g Tablet	POM-V
	00057/4353	Duphatrim Equine Formula Trimethoprim 2.6 g and Sulfadiazine 13.0 g Oral Paste	POM-V
	00057/4393	Duphatrim Granules for Horses Trimethoprim 2.5 g and Sulfadiazine 12.5 g	POM-V
	00057/4355	Duramune DAP	POM-V
	00057/4306	Duramune DAP + L	POM-V
	00057/4312	Duramune DAPPi + L	POM-V
	00057/4336	Duramune Pi + L	POM-V
	00057/4320	Fevaxyn FeLV	POM-V
	00057/4302	Galaxy DAP + L Lyophilisate and Solvent for Suspension for Injection for Dogs	POM-V
	00057/4303	Galaxy Pi + L, Lyophilisate and Solvent for Suspension for Injection	POM-V
	00057/4279	Insuvet Lente 100 IU/ml Suspension for Injection	POM-V
	00057/4275	Insuvet Neutral 100 IU/ml Solution for Injection	POM-V
	00057/4276	Insuvet Protamine Zinc 100 IU/ml Suspension for Injection	POM-V
	00057/4396	Kloxerate DC 500 mg Intramammary Suspension Dry Cow	POM-V
	00057/4194	Rimadyl for Horses 50 mg/ml Solution for Injection	POM-V
	00057/4192	Rimadyl Granules 8.75% w/w	POM-V
	00057/4190	Rimadyl Tablets 20 mg	POM-V
	00057/4191	Rimadyl Tablets 50 mg	POM-V
	00057/4243	Solu-Medrone V 500 mg	POM-V
	00057/4087	Terramycin Q-100 mg/ml Solution for Injection	POM-V
	00057/4084	Terramycin Soluble Powder 5% w/w Oral Powder	POM-V
	00057/4398	Torbutrol Tablets 5 mg	POM-V
	00057/4270	Uniprim 150 Powder 150 g/kg Premix for Medicated Feed	POM-V
	00057/4244	Water for Injection, Solvent for Parenteral Use	POM-V
Sinclair Animal and Household Care Ltd	16516/4031	Beaphar Cat Flea Powder Cutaneous Powder	AVM-GSL
	16516/4028	Beaphar Dog Flea Powder Cutaneous Powder	AVM-GSL
Virbac Ltd	11188/4014	Albenil Low Dose 10% w/v Oral Suspension	POM-VPS
Zoetis UK Limited	42058/4176	Zulvac SBV Suspension for Injection for Cattle	POM-V

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK UP TO 30 JUNE 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	560	**97.15%**

Published Standard – No. 2 – European Applications

	App Type	No. of Apps	Performance
2	Centralised: New MAs / Extensions	5	**100%**
3	Centralised – UK as Rapp: Variations	7	**100%**
4	Centralised – UK as Rapp: Renewals	1	**100%**
5	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 70)	10	**100%**
6	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 120)	25	**100%**
7	DCP – UK as RMS: New MAs / Extensions (Phase 2)	17	**100%**
8	DCP – UK as CMS: New MAs / Extensions (Phase 1)	11	**100%**
9	DCP – UK as CMS: New MAs / Extensions (Phase 2)	14	**100%**
10	MRP – UK as RMS: New MAs / Extensions (Phase 1)	7	**100%**
11	MRP – UK as RMS: New MAs / Extensions (Phase 2)	1	**100%**
12	MRP – UK as CMS: New MAs / Extensions (Phase 2)	3	**100%**
13	MRP – UK as RMS: Type IA Variations	31	**100%**
14	MRP – UK as RMS: Type IB & II Variations (Phase 1)	32	**100%**
15	MRP – UK as CMS: Type IB & II Variations (Phase 1)	42	**100%**
16	MRP – UK as CMS: Type IB & II Variations (Phase 2)	13	**100%**
17	MRP – UK as RMS: Renewals (Phase 1)	2	**100%**
18	MRP – UK as CMS: Renewals (Phase 1)	18	**100%**
19	MRP – UK as CMS: Renewals (Phase 2)	12	**100%**

Published Standard – No. 2 – National Applications

	App Type	No of Apps	Performance	Target Days	Average Days
20	New MAs / Extensions: Initial Assessment	**7**	**100%**	-	-
	75 Day Clock	1		75	60
	90 Day Clock	6		90	88
21	New MAs / Extensions: Sign-Off	**1**	**100%**	-	-
	130 Day Clock	1		130	109
	150 Day Clock	0		180	0
22	New Homeopathic	**0**	**100%**	50	0
23	Type IA Variations	**41**	**97.6%**	30	24
24	Admin Variations	**8**	**100%**	-	-
	< 10 Changes	8		30	15
	> 10 Changes	0		60	0
25	Type IB / II Variations: Initial Assessment	**69**	**97.1%**	-	-
	Type IB	49		30	21
	Type II	20		60	50
26	Type IB / II Variations: Sign-Off	**36**	**100%**	-	-
	Type IB	34		30	18
	Type II	2		60	32
27	Renewals: Initial Assessment	**1**	**100%**	60	39
28	Renewals: Sign-Off	**4**	**100%**	60	34
29	Batch Release	**596**	**100%**	10	0.9
30	AVA, NFABBA & ESCCA	**3**	**100%**	45	14
31	ATCs	**3**	**100%**	-	-
	Type A/S	1		30	26
	Type B	1		50	39
	Variations / Renewals	1		30	14
32	Specific Batch Control	**13**	**100%**	-	-
	Initial Assessment			10	1
	Sign-Off			10	1
33	Validation	**263**	**100%**	-	-
34	Mock-Ups (post New MA)	**31**	**100%**	-	-
35	Mock-Ups (post EU Variations / Renewals)	**155**	**100%**	-	-
36	Issue	**323**	**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	**25**	**100%**	15	3
38	STC / SIC Requiring Assessment – other products	**1,777**	**99.83%**	-	-
	Urgent	173		2	0
	Non-Urgent	1,604		10	2
39	WDIC – not previously assessed	**0**	**100%**	15	0
40	WDIC – other applications	**41**	**100%**	-	-
	Urgent	2		2	2
	Non-Urgent	39		10	4
41	Export	**185**	**100%**	10	5.7

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	**38**	**100%**	-	-
	SPC for MAs	32		30	15
	Link to EMA	6		30	16
43	Make publicly available via GOV.UK the Public Assessment Report (PAR) for New MAs	**26**	**100%**	120	96
44	Make publicly available via GOV.UK the Post Authorisation Assessment (PAA)	**237**	**100%**	60	48

Published Standard – No. 5 – Pharmacovigilance

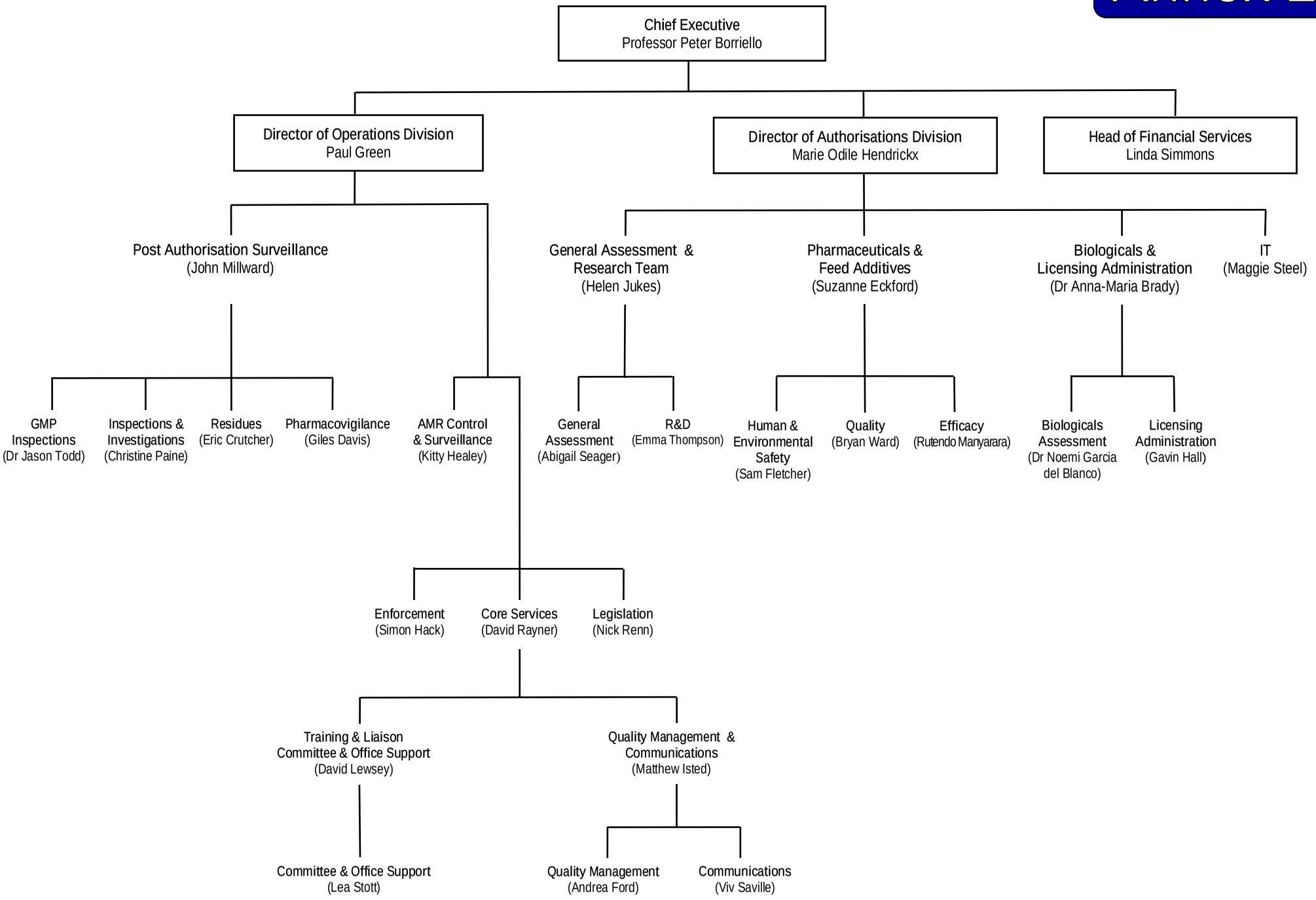
	Task	No.	Performance
45	Human & Animal AERs	**1,566**	**99.5%**
46	Human & Animal AERs – Follow Up	**761**	**99.4%**
47	Environmental SAR	**0**	**100%**
48	Inspections	**10**	**100%**

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
49	GMP Inspections within 3 years of last inspection	**11**	**100%**	-	-
50	GDP inspections within 5 years of last inspection	**12**	**100%**	-	-
51	Send deficiency or post inspections letter	**22**	**100%**	30	25
52	Issue GMP Certificates and final inspection reports	**11**	**100%**	90	80
53	Send final inspection report to wholesaler site	**12**	**100%**	90	77

ORGANOGRAM JULY 2015

Annex 2

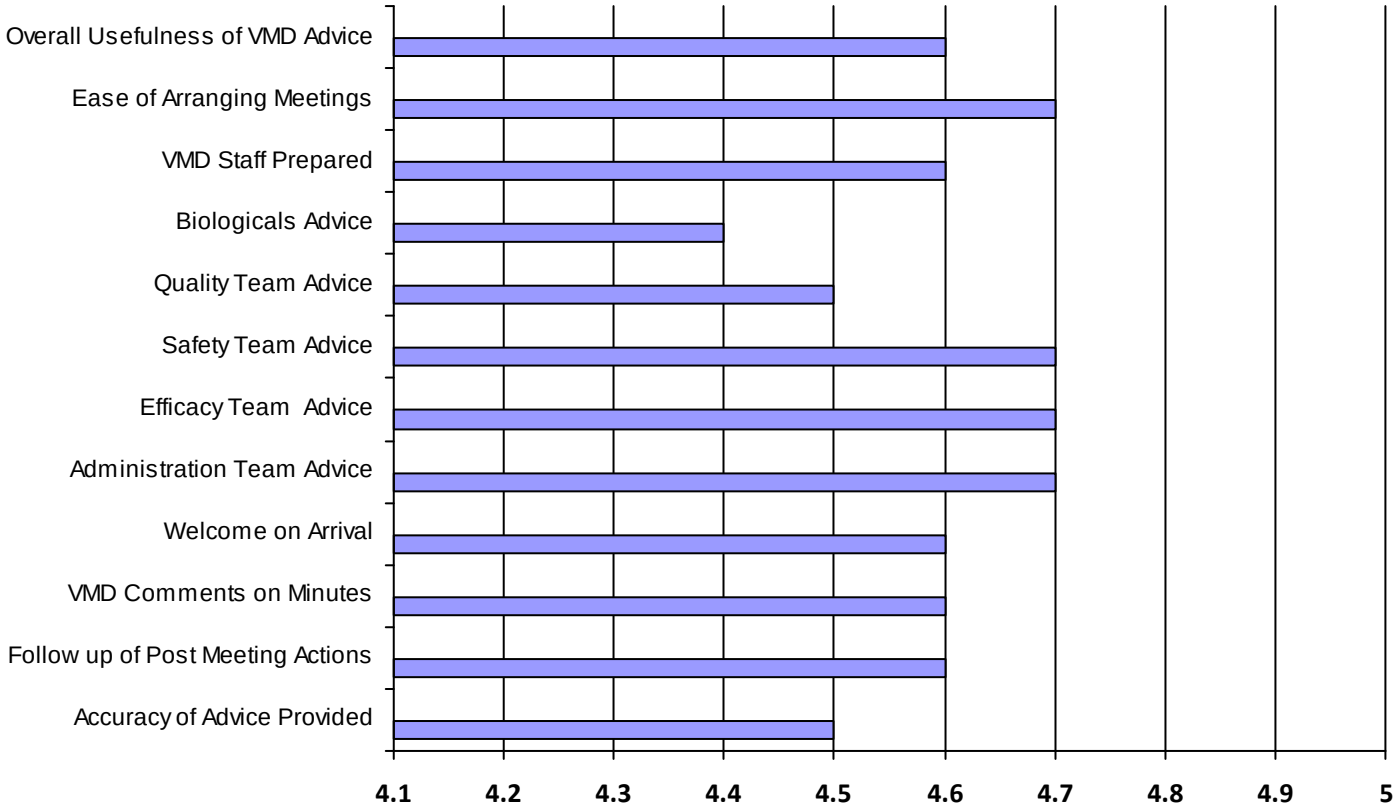


Annex 3

RESULTS: COMPANY VISIT QUESTIONNAIRES APRIL 2014 TO MARCH 2015

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

Biologicals	4.4
Quality	4.5
Safety	4.7
Efficacy	4.7
Admin	4.7



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.