MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 93 - JANUARY 2015

NEWS

NEW DIRECTOR OF AUTHORISATIONS

The VMD is pleased to announce that the new Director of the Authorisations Division is Dr Marie-Odile Hendrickx who will take up her position on 5 May 2015.

Since 2003 Marie has been the Head of the EU Pharmacovigilance group within the animal health company Zoetis. Before this she was a Director of Regulatory Affairs at Merial in France. Her previous roles include: Senior Principal Regulatory Scientist and Principal Clinical Research Investigator at Pfizer Animal Health UK. Prior to joining the pharmaceutical industry, Marie was a veterinary surgeon in a mostly small animal practice near Brighton. Marie has a Veterinary Degree, is a Member of the Royal College of Veterinary Surgeons and has certificates in Pharmacovigilance and Management.

CONTENTS

Veterinary Medicines Directorate

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

NEWS

WE'RE NOW ON GOV.UK

The VMD's website content is now on GOV.UK. The VMD's news, links to frequently used information and services and corporate information are on our GOV.UK landing page at www.gov.uk/government/organisations/veterinary-medicinesdirectorate.

GOV.UK looks very different to our old website: it is designed for users to search for items rather than navigate. By searching using key topic words as you would on Google, the information you need should be readily available. For example, to find Marketing Authorisation forms simply type in "veterinary marketing authorisation". One tip, make sure you include animal or veterinary in the search terms otherwise you may be directed to information on regulatory issues for human medicines.

We have endeavoured to ensure that all the information our users need is on GOV.UK. However, please tell us if there is any information that is not on GOV.UK that you need to use and if you have any problems in finding material.

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

2014 CUSTOMER SATISFACTION SURVEY ACTION PLAN: UPDATE

In the July 2014 edition of *MAVIS* (91) we published a summary of the results from our pharmaceutical industry customer satisfaction survey. Alongside the very positive customer feedback, we identified five headline areas to follow up in our action plan (also published online in July 2014). These comprised joint labelling, the product literature standard (PLS), enforcement, pharmacovigilance and communications. Here is an overview of the progress we've made in response to your feedback in the survey:

Joint labelling and the PLS

- We reviewed and updated our internal guidance documents on assessing labels (including for joint labelling procedures)
- We published a clarification paper on joint labelling (available on GOV.UK)
- We published an update article on joint labelling in *MAVIS 92* (available on GOV.UK)
- We continued our review of the PLS: we have received comments on our draft from our Irish colleagues at the HPRA. We have shared the revised draft with NOAH representatives and are now awaiting their comments. Non-NOAH members may also comment, the draft PLS is available on request. The deadline for comments is 28 February 2015.

Enforcement

- We reviewed the way we communicate our work and as a result, we have made the following changes:
- We developed and put in place a new database to deal with and track the progress of reported unauthorised products. This is up and running and enables an auto-email to be sent to the person who reported the breach to inform them when the case has been closed. Our ability to share details of cases will continue to be limited due to the sensitive nature of this work
- We updated our online information on the work of the enforcement team; this went live with the transition to GOV.UK
- We are putting together a quarterly newsletter to update on enforcement cases etc, with the first issue due to be published in January 2015. This will be circulated to stakeholders.

Pharmacovigilance

- We updated our software system so that it can track the progress of reports, and we have continued to refine our target timelines. Currently we are successfully working to the target of notifying Marketing Authorisation Holders (MAHs) and the European Medicines Agency of reports within 15 calendar days of receipt of the minimum information
- We amended our online adverse event report forms to capture whether the MAH has also been informed, in order to help identify duplicate reports
- We held an industry information day on 26 November 2014 which was well attended and we received positive feedback, despite suffering some technical hitches with the online streaming. The day provided a good forum to discuss the issues our industry stakeholders had raised – more detail can be found in the article on page 7.

Communications

- Recently our communications resources have focused heavily on the transition of our online material to GOV.UK which was completed in November 2014; more information on the GOV.UK move is on this page
- Due to the resource needed for GOV.UK, we put back the planned project on speed of response to enquiries and identification of the right person to contact. We have drawn up a revised plan for this which, given recent events, includes a review of what impact (if any) the move to GOV.UK has had on how effectively people's enquiries are handled, as well as rolling out a communications management software system as part of this work. This project will begin in 2015.

We will continue to provide you with updates on progress in the following areas in the coming months: revision of the PLS, the work of the enforcement team (via the new quarterly newsletter), the GOV.UK project and the handling enquiries project.

For further information please contact: Kitty Healey (VMD, email: k.healey@vmd.defra.gsi.gov.uk, 01932 338468).

BIOLOGICALS INFORMATION DAY ON 17 APRIL 2015

The Veterinary Medicines Directorate (VMD) is holding an information day for companies that produce biological medicines.

Suggested topics for presentations are:

- Update on the Animal Test Certificate review project
- Registration of innovative products: cell therapies, phage therapies, monoclonal antibodies, immunomodulators and other items
- 3Rs: Report on animal use in the QC of Immunological Veterinary Medicinal Products for batch release
- Marketing Authorisations for parallel distribution/ importation of biological products
- Review of Directive: impact on biological products.

Please send your contact details if you wish to attend or suggested items for discussion to Kim Primeau (VMD, email: k.primeau@vmd.defra.gsi.gov.uk, 01932 338315).

THE VMD PHARMACEUTICAL INDUSTRY INFORMATION EVENT ON THURSDAY 25 JUNE 2015

The VMD will be holding an Information Event for the Pharmaceutical Industry on Thursday 25 June 2015. We are currently developing the schedule for the day and we are inviting your suggestions on areas you would like to see covered.

At this stage we have not decided on the duration of the event. We will determine this according to your ideas on topics. We will advise you of the final agenda and timing once this has been confirmed.

Depending on the level of interest we may need to restrict the number of attendees per company.

Please contact Natalie Burge with your suggestions and also if you wish to reserve a place at this free event (VMD, 01932 338349, email: n.burge@vmd.defra.gsi.gov.uk).

POINTS TO BE CONSIDERED BY COMPANIES WHEN ARRANGING A COMPANY MEETING AT THE VMD

The initial request to arrange a company meeting with the VMD should be accompanied by proposed agenda items so that we can identify suitable attendees as well as tentative dates. The request should be sent to Chris Abbott at the email address below.

The company should provide the targeted background information in the week before the meeting which will generally not be longer than one and a half hours. Requests for longer meetings may be considered on an exceptional basis and will be considered in the light of the justification and existing workloads.

Also, at least a week before the meeting please provide the following:

- a final agenda which has been agreed with the VMD along with any presentations
- a list of names of all attendees for security arrangements and; if required
- a request for a projector.

Additional slides and topics should not be added at the meeting. We reserve the right not to comment upon new information or topics.

Meetings can also be organised via teleconference or for some participants to join by teleconference.

Companies are required to take minutes and send them to the VMD within two weeks of the meeting. We aim to review and return them within two weeks so that a final version can be agreed.

For further information please contact Chris Abbott (VMD, email: c.abbott@vmd.defra.gsi.gov.uk, 01932 338353.

LICENSING

FEES PROJECT: NATIONAL VARIATIONS

Earlier this year the VMD completed its review of the fees it charges for national variations, with reductions being made for single IA, IB and Type II applications as well as for grouped and work sharing applications. This was based on evidence from our work recording systems and following the impact of efficiency savings made by the VMD.

As part of that project the VMD gave a commitment to also review the fees it charges for EU variations. We are pleased to say that this work has now started. It is very early days but the expectation is that this review will be completed in time for any outcomes to come into effect at the start of the 2015/16 financial year.

In undertaking this work, the project team has to ensure that the VMD achieves full cost recovery in the fees it charges. Also, as for the previous project, we will be using evidence generated by our work recording systems and will take into account any savings that may have resulted from the move to greater electronic working.

The VMD will **not be** reviewing the charging structure that underpins EU variations as part of this project. The overall structure was considered as part of the review of national variation fees and therefore there is no need for this aspect to be looked at again.

Over the coming few months the project team will be focusing on analysing data generated from our work recording systems. In the meantime we would value any feedback you might have on specific fees or areas of concern related to the charges for EU variations. Please send any feedback to Gavin Hall by **19 February 2015**.

We will continue to keep you updated as the project progresses.

If you wish to discuss this project further, please contact Gavin Hall (VMD, email: g.hall@vmd.defra.gsi.gov.uk, 01932 338431).

TOP 10 IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 OCTOBER - 31 DECEMBER 2014

The VMD provides a list on a quarterly basis of the 10 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	2079
Greer Allergenic Extract Patient Prescription	Allergens	435
Scabivax	Contagious Pustular Dermatitis Virus	293
Vet-Goid	Allergens	263
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	207
BioRelease deslorelin	Deslorelin Acetate	87
Staphage Lysate (SPL)	Staphylococcus Aureus	74
ACTT Allergy Drops	Allergens	66
Calmivet Solution For Injection	Acepromazine Maleate	47
Oncept (Canine Melanoma Vaccine)	Canine Melanoma DNA	44

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

VMD EXPORT CERTIFICATE SCHEME: GUIDANCE FOR EXPORTERS OF VETERINARY MEDICINAL PRODUCTS (VMP)

The VMD has recently implemented changes to its Export Certificate Scheme.

We recognise the importance of helping to facilitate international free trade and make every attempt to help you with your needs. We also continue to show due diligence regarding the certificates we issue and the assurances that these certificates provide to the authorities of importing countries. The changes to the scheme are intended to ensure both these objectives are met. We have also taken the opportunity to remove some administrative burdens.

Content of Certificates

The VMD is only able to confirm details on certificates that it knows to be true; therefore, we can only approve export certificate schedules that contain details found in the UK Manufacturing Authorisation (ManA) and/or Marketing Authorisation (MA) for the veterinary medicine(s) concerned.

The VMD is content that the information provided on its certificates and the certificate schedule are clear and transparent; stating the authorised activities of the manufacturing sites named and the authorisation status of the named exported products. However, we recognise that the authorities of the importing countries have strict rules on the paperwork they must receive from the importer and that this could include information that we cannot verify. Therefore, we have made changes to the scheme by permitting you to submit additional pages as part of Defra-1, Defra-2 and Defra-4 applications, which can be attached to an export certificate. The VMD are happy to approve additional pages but this cannot contradict the information on the Export Certificate, Export Certificate Schedule, Summary of Product Characteristics, Product Literature, Manufacturing Authorisation or Marketing Authorisation.

In all cases, the additional pages must include the following wording in a box at the foot of each page. The VMD will sign and date this upon issue.

Wording for Defra-1 and Defra-4 certificate applications:

> The VMD stamp and signature on this page confirms the site is GMP compliant and holds a Manufacturing Authorisation, but it does not independently verify any of the other information contained on this page. The Qualified Person at the site named on page one is responsible for the veracity and validity of the other information on this document.
>
> Signed:
>
> Name: Miss Sam Ward
>
> Date: <same as certificate>

Wording for Defra-2 certificate applications:

> The VMD stamp and signature on this page confirms the veterinary medicine named on page two holds a Marketing Authorisation in the same name, but does not independently verify any of the other information contained on this page.
>
> Signed:
>
> Name: Miss Sam Ward
>
> Date: <same as certificate>

Removal of administrative burdens

The requirement to provide Indemnity Letters and to provide an annual updated list of the personnel at each company authorised to apply for Export Certificates has been removed.

We would like to remind you to contact us BEFORE you start shipping the VMP from the UK to discuss your needs should the importing authorities request something outside of the usual scope of the Export Scheme.

Timescales

The VMD has introduced a new target of 10 working days to either issue the export documentation to you, or inform you of why a certificate will not be issued.

All applications are subject to validation, which is a check to ensure that all documentation has been provided and properly filled in. If any information is missing, you will be asked to resubmit a new application. You will not be charged for the invalid application. If the application is incomplete for minor reasons, the VMD will contact you and try to resolve the outstanding issues within the 10 day timeframe rather than asking you to resubmit.

The following are examples of reasons why applications are considered invalid:

- Not using the correct schedule templates
- Not using an up to date version of the SPC and/or product literature
- Not using an up to date version of the Manufacturing Authorisation
- Not providing the schedule on company headed paper.

Further information and guidance

The online Export Certificates system will be updated to reflect these changes. Updated guidance will be available soon.

www.vmd.defra.gov.uk/EC/Login.aspx?ReturnUrl=%2fec

For further information please email: exportcert@vmd.defra.gsi.gov.uk or contact Sam Ward (VMD, email: s.ward@vmd.defra.gsi.gov.uk, 01932 338496).

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* there have been four seizure notices published.

Barley Feeds Ltd, Spilsby, Lincolnshire. Seventy-three Drontal tablets and eight boxes of Frontline for cats and dogs of various sizes were seized as they were being offered for sale by a person not permitted to supply them under the Veterinary Medicines Regulations.

Vets 4 Pets, Letchworth, Hertfordshire. Three tubes of Tetracyclin 1% ointment were seized as they were not authorised in the UK.

Squires Bird Products at the UK Parrot Society's National Exhibition, Staffordshire Agricultural Showground. Fifteen bottles of Ivermectin drops were seized as they were not authorised in the UK.

Aurivo (NI) Ltd, Omagh, County Tyrone. Eighteen veterinary medicines were seized as they had been stored in a way that affects their quality and therefore safety and efficacy. The products were vaccines for use in cattle and sheep.

IMPROVEMENT NOTICES

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

Castlehill Veterinary Clinic, Dungannon, County Tyrone were stocking products which are authorised only in the Republic of Ireland (RoI) and also stocking and supplying Aurofac Granules 100 to non registered users for unauthorised use. The improvements are to return all RoI products and not to supply in the future, and to return the Aurofac Granules 100 to the suppliers and not to supply in the future unless to approved premises.

Aurivo (NI) Ltd, Omagh, County Tyrone, was supplying veterinary medicines without the presence of a suitably qualified person (SQP). The improvement required is to remove all POM-VPS products from the retail area and that no further supplies occur. The premises must notify the VMD when an SQP is in place to obtain approval to recommence supplies of POM-VPS products.

IFGA at BEVA Congress, Birmingham, West Midlands, was advertising unauthorised veterinary medicines for administration to animals. The improvement required is to cease the advertising of unauthorised veterinary medicines.

A collection of notices that have been published in the last year can be found on GOV.UK by using the search term 'Illegal animal medicines seizure and improvement notices'.

For further information please contact: Simon Hack (VMD, email: enforcement@vmd.defra.gsi.gov.uk, 01932 338306).

PHARMACOVIGILANCE

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

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

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

QUARTERLY REPORT

During the period 1 October to 31 December 2014, the VMD received 1,402 suspected adverse event reports involving animals. Of these, 39 reports related to unauthorised or unidentified products and 24 reports involved animal trials under Animal Test Certificates (ATCs). Excluding these two categories, the remaining 1,339 suspected adverse event reports were associated with 337 authorised products.

The 1,339 reports were divided by distribution categories as follows:

1,170	Prescription Only Medicine - Veterinarian (POM-V)
98	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
42	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
21	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
8	Small Animal Exemption Scheme (N/A)

During the quarter 38 reports of human suspected adverse reactions and one environmental incident was received.

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

PHARMACOVIGILANCE UNIT INDUSTRY INFORMATION DAY

In response to the results of the 2014 VMD Customer Survey, the Pharmacovigilance Unit held their first Industry Information Day on 26 November 2014. Over 50 industry representatives from across Europe attended in person and more than a dozen watched the live webcast. A total of eight presentations were delivered on various aspects of pharmacovigilance by both scientific and administrative staff, taking into account questions that delegates had submitted in advance.

Over 80% of those attending in person completed feedback forms, scoring all presentations highly for both content and delivery. Overall the day was rated as a great success by those attending in person with an average score (out of 5) of 4.3 for usefulness and 4.4 for organisation.

We would like to thank all attendees for actively participating in the day and providing this feedback which is especially useful for some of the newer members of the team who hadn't presented before. We are sorry that the experience of those attending online was hampered by technical glitches but recordings of all the presentations and copies of the slides are now available on GOV.UK using the search term "phv industry info day" or via the following link www.gov.uk/government/news/pharmacovigilance-industry-information-day-26-november-2014.

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 the VMD has taken to progress this strategy.

DARC GROUP UPDATE

The DARC group met on 11 December 2014 at the VMD. The group discussed progress on delivery of the UK AMR Strategy, revision of EU Legislation on Veterinary Medicinal Products, and recent findings in resistance trends in *Salmonella* and ESBL *E. coli* from livestock. An update was provided on the activity undertaken to promote European Antibiotic Awareness Day (EAAD) and progress was outlined on the joint DARC/ARHAI medical:veterinary 'One-health' report; due to be published in March 2015.

The next DARC meeting is planned for 17 February 2015.

HMA-VETERINARY ACTION PLAN ON ANTIMICROBIAL ISSUES

The VMD chairs 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 VMD also provides the secretariat for the group. The task force discussed: the EU proposals for the Veterinary Medicinal Products and the Medicated Feedstuffs Regulations; availability of appropriate pack sizes for antimicrobial products; the recently published 2012 report issued by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project; and progression of the proposal for a target pathogen monitoring programme.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

The UK Veterinary Antibiotic Resistance and Sales Surveillance Report 2013 (UKVARSS-2013) was published on 18 November 2014. This report compiles 2013 UK antimicrobial sales data and England and Wales data on the antibiotic susceptibility of veterinary pathogens and foodborne pathogens to form a joint UK report. This report and previous reports can be found at www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2013.

EUROPEAN ANTIBIOTIC AWARENESS DAY (EAAD)

European Antibiotic Awareness Day is an annual European public health initiative that takes place on 18 November to raise awareness about the threat to public health of antibiotic resistance and prudent antibiotic use. To highlight European Antibiotics Awareness Day on 18 November 2014, the Veterinary Medicines Directorate organised an animal health UK Antimicrobial Resistance (AMR) Summit.

The aim of the Summit was to reinforce the animal health and livestock production industry's commitment to tackling antibiotic resistance: moving from raising awareness to action at national level. The event was hosted by Professor the Lord Trees of the Ross, Member of the House of Lords, Alick Simmons, the Deputy Chief Veterinary Officer for England, and Professor Peter Borriello, Chief Executive Officer, Veterinary Medicines Directorate. George Eustice MP (Defra Minister for farming, food and marine environment) and Dr Felicity Harvey (Director General for Public Health, Department of Health) both spoke at the event.

This year the VMD also collaborated with Public Health England on the Antibiotic Guardian pledge campaign. The campaign asked people to visit www.antibioticguardian.com and make a pledge on how they would help conserve antibiotic use. There were customised pledges for vets, farmers and pet owners.

UK AMR STRATEGY

The most recent meeting of the High Level Steering Group (HLSG) for the AMR Strategy took place in September 2014. Activities to deliver the aims of the Strategy are being implemented in line with the guidance of the HLSG. The first year report and a detailed action plan for activity in the remaining four years of the Strategy are due to be published in December this year.

Following the publication of the Strategy, the House of Commons Science and Technology Committee launched an inquiry into AMR. The Committee published their report in July and the Government response was published in September.

www.gov.uk/government/uploads/system/uploads/attachment_data/file/353295/42917_2902606_Cm_8919_WEB_Accessible.pdf

In order to strengthen surveillance of antimicrobial use in the animal health sector, the VMD initiated a scoping project to explore options for collection of antibiotic prescription and/or consumption data. The first phase of the project has now been completed and the second phase, development of a central data collection hub, is underway. In addition the VMD has expanded the UK surveillance programme of resistance in veterinary zoonotic and commensal bacteria, in line with new statutory EU requirements.

The first annual progress report on the UK 5 year antimicrobial resistance (AMR) strategy has now been published. The report sets out what work is underway and some important achievements in the first year of the strategy, as well as details of work planned for the next four years.

www.gov.uk/government/publications/progress-report-on-the-uk-five-year-amr-strategy-2014

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 January 2015. Summary minutes of the meetings held in May and October 2014 are available at www.gov.uk/government/organisations/veterinary-products-committee/about/membership. A snapshot of the VPC's previous website, including minutes of meetings held between 2009 and May 2014, is available on the National Archives website at webarchive.nationalarchives.gov.uk/20140909095305/http:/www.vmd.defra.gov.uk/vpc/.

Comments on the website or requests for further information on the summary minutes please contact Colin Bennett (VMD, email: c.bennett@vmd.defra.gsi.gov.uk, 01932 338490).

VETERINARY RESIDUES COMMITTEE (VRC)

The Veterinary Residues Committee (VRC) is an expert committee of Defra. It gives advice to the chief executives of the Veterinary Medicines Directorate (VMD) and the Food Standards Agency (FSA) on:

i) the incidence and concentrations of residues of veterinary medicines with particular reference to food safety and the observance of withdrawal periods for veterinary medicines;

ii) the scope and operation of the VMD statutory surveillance programme;

iii) formulating an annual non-statutory plan and advising on the scope and results of relevant FSA surveys; and

iv) publishing its Annual Report on Surveillance for Veterinary Residues in food in the UK.

■ REVIEW OF THE VETERINARY RESIDUES COMMITTEE (VRC)

Defra conducted a review of the VRC in 2014. The review concluded that the VRC was not the most effective way of providing expert scientific advice on veterinary medicine residues. Ministers accepted the review's recommendations and the last official meeting of the VRC was held on 20 November 2014.

The Committee on Toxicology will consider veterinary residues results and provide advice to the Food Standards Agency and the VMD accordingly.

For further information please contact: Lesley Johnson (VMD, email: l.johnson@vmd.defra.gsi.gov.uk, 01932 338413).

RESIDUES CONTROLS AND MONITORING

The VMD operates two complementary surveillance programmes for residues of veterinary medicines and other substances. The larger programme, the National Surveillance Scheme (NSS), implements EU legislation and therefore has a statutory basis. This programme covers the products set out below and is funded by the industry sectors in accordance with EU legislation.

The second programme is smaller and non-statutory. It focuses more on surveillance of imports of certain food products of animal origin where the presence of banned substances are most likely to be found. The programme is funded by Defra.

RESULTS OF STATUTORY SURVEILLANCE

The VMD operates the statutory surveillance programme for residues of veterinary medicines and unauthorised substances in UK food producing animals as set out below.

2014 PROGRAMME

Sampling commenced in January for the majority of species. Details of sample results since the report in *MAVIS 92* are set out below.

Species Type	Number of Samples Analysed	Number of Non-Compliant Samples	Analyte Detected
Cattle	2,236	23	Alpha-boldenone & beta-boldenone (1) Alpha-nortestosterone (3) Beta-boldenone (1) Cadmium (1) Dihydrostreptomycin (2) Florfenicol (1) Ibuprofen (1) Taleranol (3) Taleranol & zeranol (9) Thiouracil (1)
Pigs	1,109	1	Ochratoxin A (1)
Sheep	1,912	15	Alpha-boldenone (12) Beta-nortestosterone (1) Taleranol & zeranol (2)
Horses	37	0	
Poultry	1,666	0	
Game	46	0	
Fish	409	0	
Milk	826	0	
Eggs	411	1	Narasin* (1)
Honey	41	0	

** This substance was found in a sample of quail egg.*

RESULTS OF 2014 NON-STATUTORY SURVEILLANCE

The Non-statutory Surveillance programme mainly looks for the presence of prohibited substances in food from third countries. The programme can also carry out short surveys for areas of potential concern based on intelligence received. Sample collection for the 2014 rolling programme commenced in May 2014. Details of analyses completed since the report in *MAVIS 92* are set out below:

Sample Type	Number of Analyses Completed	Number of Non-Compliant Samples	Analyte Detected
Farmed Warm Water Crustaceans	126	1	Oxytetracycline (1)
Imported Farmed Fish	161	1	Leucomalachite Green (1)
Imported Poultry Muscle	158	1	Doxycycline (1)
Imported Raw Beef	338	0	

For full details of all results, together with information on any action taken please contact Dawn Greener (VMD, email: d.greener@vmd.defra.gsi.gov.uk, 01932 338325).

STAFF CHANGES

The following staff changes have taken effect during this quarter:

New Staff

- Bijal Mistry joined the Pharmacovigilance team on 3 November 2014
- Sam Fowler joined the Committee and Office Support team on 17 November 2014
- Aline Goult joined the Committee and Office Support team on 17 November 2014
- Myles Munro joined the Information Technology team on 5 January 2015
- Carole Lutley joined the Pharmacovigilance team on 5 January 2015

Departing Staff

- Janis McDonald retired on 13 November 2014
- Clare Collins resigned on 21 November 2014
- Annabel Howe resigned on 25 November 2014
- Alex Tait retired on 31 December 2014
- Vanessa Hudson transferred to the Home Office on 9 January 2014

Promotions

- Francine Fernandez was promoted within the Pharmaceuticals and Feed Additives Human and Environmental Safety team on 10 November 2014
- Lea Reynolds was temporarily promoted within the Legislation team on 1 November 2014
- Lee Grist was promoted and transferred to the Legislation team on 17 November 2014
- Anna Burrows was temporarily promoted and transferred to the Legislation team on 24 November 2014
- Amanda Baker was temporarily promoted within the Enforcement team on 24 November 2014
- Emma Thompson was temporarily promoted on a part-time basis to the Research and Development team on 1 January 2015

Transfers

- Justin Murphy transferred to the Inspections Administration team on 10 December 2014

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 8 SEPTEMBER - 9 DECEMBER 2014

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Alfamed	17902/4062	Pramilon 2.5 mg/25 mg Film-Coated Tablets for Small Dogs and Puppies		POM-V
	17902/4066	Pramilon 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens	Milbemycin Oxime (A3 and A4) Praziquantel	POM-V
	17902/4063	Pramilon 12.5 mg/125 mg Film-Coated Tablets for Dogs		POM-V
	17902/4067	Pramilon 16 mg/40 mg Film-Coated Tablets for Cats		POM-V
Bayer plc	00010/4207	Bayer Praziquantel 20 mg Spot-On Solution	Praziquantel	AVM-GSL
	00010/4209	Bayer Praziquantel 50 mg Tablets		AVM-GSL
	00010/4187	Drontal Dog Tasty Bone 150/144/50 mg Tablets	Febantel Praziquantel Pyrantel	NFA-VPS
	00010/4194	Multi-parasite 40 mg + 4 mg Spot-On Solution for Small Cats and Ferrets	Imidacloprid Moxidectin	POM-V
	00010/4196	Multi-parasite 40 mg + 10 mg Spot-On Solution for Small Dogs		POM-V
	00010/4195	Multi-parasite 80 mg + 8 mg Spot-On Solution for Large Cats		POM-V
	00010/4198	Multi-parasite 100 mg + 25 mg Spot-On Solution for Medium Dogs		POM-V
	00010/4197	Multi-parasite 250 mg + 62.5 mg Spot-On Solution for Large Dogs		POM-V
	00010/4199	Multi-parasite 400 mg + 100 mg Spot-On Solution for Extra-Large Dogs		POM-V
Billev Pharma aps	18585/4001	Milquantel 2.5 mg/25 mg Tablets for Small Dogs and Puppies Weighing at Least 0.5 kg	Milbemycin Oxime (A3 and A4) Praziquantel	POM-V
	18585/4002	Milquantel 12.5 mg/125 mg Tablets for Dogs Weighing at Least 5 kg		POM-V
Huvepharma N.V.	30282/4020	Parofor 70 mg/g Powder for Use in Drinking Water, Milk or Milk Replacer for Pre-Ruminant Cattle and Pigs	Paromomycin, Paromomycin Sulfate	POM-V
Krka Dd	01656/4068	Tolracol 50 mg/ml Oral Suspension for Pigs, Cattle and Sheep	Toltrazuril	POM-V
Laboratorios Karizoo S.A	31223/4004	Citramox 500 mg/g Powder for Use in Drinking Water for Chickens, Turkeys, Ducks and Pigs	Amoxicillin Trihydrate	POM-V
Le Vet Beheer B.V.	41821/4011	Anaestamine 100 mg/ml Solution for Injection	Ketamine, Ketamine Hydrochloride	POM-V
	41821/4012	Fungiconazol 200 mg Tablets for Dogs	Ketoconazole	POM-V
	41821/4013	Fungiconazol 400 mg Tablets for Dogs		POM-V
	41821/4007	Metomotyl 2.5 mg/ml Solution for Injection for Cats and Dogs	Metoclopramide Hydrochloride Metoclopramide	POM-V
	41821/4008	Metomotyl 5 mg/ml Solution for Injection for Cats and Dogs		POM-V

Company	Vm Number	Product Name	Active Ingredient(s)	Legal
Le Vet Beheer B.V. Cont'd	41821/4009	Synthadon 5 mg/ml Solution for Injection for Cats and Dogs	Methadone Hydrochloride	POM-V
	41821/4010	Synthadon 10 mg/ml Solution for Injection for Cats and Dogs		POM-V
Merial Animal Health Ltd	08327/4258	Frontect Spot-on Solution for Dogs 2-5 kg	Fipronil Permethrin (Cis:Trans 40:60)	POM-V
	08327/4259	Frontect Spot-on Solution for Dogs 5-10 kg		POM-V
	08327/4260	Frontect Spot-on Solution for Dogs 10-20 kg		POM-V
	08327/4261	Frontect Spot-on Solution for Dogs 20-40 kg		POM-V
	08327/4262	Frontect Spot-on Solution for Dogs 40-60 kg		POM-V
Norbrook Laboratories Limited	02000/4387	Cefimam LC 75 mg Intramammary Ointment for Lactating Cows	Cefquinome, Cefquinome Sulphate	POM-V
	02000/4388	Cefquinor LC 75 mg Intramammary Ointment for Lactating Cows		POM-V
Sogeval	20749/4042	Adaxio Shampoo for Dogs	Chlorhexidine Gluconate, Chlorhexidine Gluconate Solution Miconazole Nitrate	POM-V
Vetpharma Animal Health, S.L	32509/4019	Maxyl 500 mg/g Powder for Use in Drinking Water for Chickens, Turkeys, Ducks and Pigs	Amoxicillin Trihydrate	POM-V
Zoetis UK Limited	42058/4185	Moxigro 1 mg/ml Oral Solution for Sheep	Moxidectin	POM-VPS
	42058/4186	Moxigro 5 mg/ml Pour-On Solution for Cattle		POM-VPS

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 8 SEPTEMBER - 9 DECEMBER 2014

Company Name	Product Name	Brief Details	Legal Category
Alfamed	Alfamed Fipronil/Permethrin 26.8 mg/240 mg Spot-On Solution for Very Small Dogs		POM-V
	Alfamed Fipronil/Permethrin 67 mg/600 mg Spot-On Solution for Small Dogs		POM-V
	Alfamed Fipronil/Permethrin 134 mg/1200 mg Spot-On Solution for Medium Dogs	Change the invented name of the medicinal product in UK from Alfamed Fipronil/ Permethrin to Ectotix	POM-V
	Alfamed Fipronil/Permethrin 268 mg/2400 mg Spot-On Solution for Large Dogs		POM-V
	Alfamed Fipronil/Permethrin 402 mg/3600 mg Spot-On Solution for Very Large Dogs		POM-V
	Fiperm 26.8 mg/240 mg Spot-on Solution for Very Small Dogs		POM-V
	Fiperm 67 mg/600 mg Spot-on Solution for Small Dogs		POM-V
	Fiperm 134 mg/1200 mg Spot-on Solution for Medium Dogs	Change the invented name of the medicinal product in UK from Fiperm to Fiproxile	POM-V
	Fiperm 268 mg/2400 mg Spot-on Solution for Large Dogs		POM-V
	Fiperm 402 mg/3600 mg Spot-on Solution for Very Large Dogs		POM-V
	Milprazin 2.5 mg/25 mg Film-Coated Tablets for Small Dogs and Puppies		POM-V
	Milprazin 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens	Change the invented name of the medicinal product in UK from Milprazin to Pramilon	POM-V
	Milprazin 12.5 mg/125 mg Film-Coated Tablets for Dogs		POM-V
	Milprazin 16 mg/40 mg Film-Coated Tablets for Cats		POM-V
	Milprotect 2.5 mg/25 mg Film-Coated Tablets for Small Dogs and Puppies		POM-V
	Milprotect 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens	Change the invented name of the medicinal product in UK from Milprotect to VetUK Dog Wormer/VetUK Cat Wormer	POM-V
	Milprotect 12.5 mg/125 mg Film-Coated Tablets for Dogs		
	Milprotect 16 mg/40 mg Film-Coated Tablets for Cats		POM-V
Alstoe Ltd (Alstoe Animal Health)	Vetergesic 0.3 mg/ml Solution for Injection for Dogs and Cats		POM-V
	Vetergesic Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Change the name of the MAH from Alstoe Limited to Sogeval UK Limited	POM-V
	Vetergesic Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses	Change in distributor details from Alstoe Limited to Ceva Animal Health Ltd	POM-V
aniMedica GmbH	Animeloxan 1.5 mg/ml Oral Suspension for Dogs	Shelf-life change	POM-V
Ayrton Saunders Limited	Pentobarbital for Euthanasia 20% w/v Solution for Injection	Shelf-life change	POM-V
Bayer plc	Bob Martin 3 in 1 Dewormer Tablets for Dogs	Change the invented name of the medicinal product from Bob Martin 3 in 1 Dewormer Tablets for Dogs to Bob Martin Clear 3 in 1 Wormer 150/144/50 mg Tablets for Dogs	AVM-GSL
	Bob Martin 3 in 1 Dewormer XL Tablets for Large Dogs	Change the invented name of the medicinal product from Bob Martin 3 in 1 Dewormer XL Tablets for Large Dogs to Bob Martin Clear 3 in 1 Wormer XL 525/504/175 mg Tablets for Large Dogs	AVM-GSL

Company	Product	Brief Details	Legal Category
Boehringer Ingelheim Ltd	Pimobendan Vetmedica 1.25 mg Chewable Tablets for Dogs	Change in the invented name of the veterinary medicinal product in the UK from Pimobendan Vetmedica to Vetmedin	POM-V
	Pimobendan Vetmedica 2.5 mg Chewable Tablets for Dogs		POM-V
	Pimobendan Vetmedica 5 mg Chewable Tablets for Dogs		POM-V
	Vetmedin 1.25 mg Chewable Tablets for Dogs	Shelf-life change	POM-V
	Vetmedin 2.5 mg Chewable Tablets for Dogs		POM-V
	Vetmedin 5 mg Chewable Tablets for Dogs		POM-V
C&H Generics Ltd	Quantilex Plus Tablets For Dogs	Change the MAH from C & H Generics Limited, c/o Michael McEvoy and Co, Seville House, New Dock Street, Galway, Ireland to Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co. Galway, Ireland	NFA-VPS
Ceva Animal Health Ltd	Fiprospot Duo Spot-On Solution for Cats 1-5 kg	Change the invented name of the medicinal product from Fiprospot Duo Spot-On Solution for Cats 1-5 kg to Strectis spot-on solution for cats 1-5 kg in all MS except IT	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	Animec 0.8 mg/ml Oral Solution for Sheep	Change in the invented name of the veterinary medicinal product in UK only, from Animec 0.8mg/ml Oral Solution for Sheep to Topimec 0.8mg/ml Oral Solution for Sheep	POM-VPS
	Cazitel Plus XL Tablets for Dogs	Change to the distributor from Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ to Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE	NFA-VPS
	Forzepril 2.5 mg Film-Coated Tablet for Dogs	Change the invented name of the medicinal product from Forzepril to Bexepril	POM-V
	Forzepril 5 mg Film-Coated Tablet for Dogs		POM-V
	Forzepril 20 mg Film-Coated Tablets for Dogs		POM-V
	Topimec 0.8 mg/ml Oral Solution for Sheep	Change in the invented name of the veterinary medicinal product in UK only, from Topimec 0.8mg/ml Oral Solution for Sheep to Animec 0.8mg/ml Oral Solution for Sheep	POM-VPS
CP Pharma Handelsgesellschaft mbH	Marbotab P 20 mg Tablets for Dogs and Cats	Shelf-life change	POM-V
	Marbotab P 80 mg Tablets for Dogs		POM-V
Cross Vetpharm Group Ltd	Equipaste 1.87% w/w Oral Paste	Change in the invented name of the veterinary medicinal product from Equipaste, 1.87% w/w Oral Paste to Alomec, 18.7 mg/g oral paste	POM-VPS
CZ Veterinaria S.A.	CZV Bovine Tuberculin PPD	Change to add a new vial size: vial of 2ml (20 Doses)	POM-V
Dechra Limited	Clavudale 50 mg Tablet for Cats and Dogs	Change in the MAH address from Dechra House, Jamage Industrial Estate, Talke Pitts, Stoke-on-Trent, Staffordshire, ST7 1XW to Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW	POM-V
	Clavudale 250 mg Tablet for Dogs		POM-V
	Clavudale 500 mg Tablet for Dogs		POM-V
	Equipalazone 1 g Oral Paste		POM-V
	Equipalazone 200 mg/ml Solution for Injection		POM-V
	Equipalazone 1 g Oral Powder		POM-V
	Vetoryl 10 mg Hard Capsules for Dogs		POM-V
	Vetoryl 30 mg Hard Capsules		POM-V
	Vetoryl 60 mg Hard Capsules		POM-V
	Vetoryl 120 mg Hard Capsules		POM-V
Dopharma Research B.V.	Butagran Equi 200 mg/g Oral Powder for Horses	Change to add a 20-sachet pack size	POM-V

Company	Product	Brief Details	Legal Category
Ecolab Ltd (Trading as Adams Healthcare)	Blu-gard 2.00% w/w Teat Dip Solution	Change of distributor from Ecolab Ltd, David Murrey John Building, Swindon, Wiltshire, SN1 1NH to Norbert Dentressangle, Logistics Limited, Euroterminal, Westinghouse Road, Trafford Park, Manchester, M17 1PY	AVM-GSL
	Blu-Gard Teat Spray Solution 2.00% w/w		AVM-GSL
Forum Products Limited	Apometic 10 mg/ml Solution for Injection	Change in the MAH address from Betchworth House, 57-65 Station Road, Redhill, Surrey, RH1 1DL to Crown House, 2-8 Gloucester Road, Redhill, Surrey, RH1 1FH	POM-V
	Cephorum Film Coated Tablets 500 mg		POM-V
	Apometic 10 mg/ml Solution for Injection		POM-V
	Cephorum Film Coated Tablets 500 mg		POM-V
Intervet International BV	Bovilis IBR Marker Live, lyophilisate and solvent for suspension for Cattle	Deletion of pack sizes	POM-V
Intervet UK Ltd	Laurabolin 25 mg/ml, Solution for Injection	Shelf-life change	POM-V
Kela N.V.	Kelapril 2.5 mg Film Coated Tablets for Dogs and Cats	Change to the distributor address from Betchworth House, 57-65 Station Road, Redhill, RH1 1DL to Crown House, 2-8 Gloucester Road, Redhill, Surrey, RH1 1FH	POM-V
	Kelapril 5 mg Film Coated Tablets for Dogs and Cats		POM-V
	Kelapril 20 mg Film Coated Tablets for Dogs		POM-V
	Kelactin 50 mg/ml Oral Solution for Dogs and Cats		POM-V
Krka Dd	Floron 40 mg/g Premix for Medicated Feeding Stuff for Swine	Shelf-life change	POM-V
Laboratorios Dr Esteve SA	Dinalgen 150 mg/ml Solution for Injection for Cattle, Pigs and Horses	Addition of BAYER plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA as a UK distributor	POM-V
Neptune Pharma Limited	Trident 500 mg/g Powder for Suspension for Fish Treatment	To change the invented name of the veterinary medicinal product from Trident to Azasure in the UK	POM-V
Norbrook Laboratories Limited	Bob Martin Clear Double Action Spot-on Solution Imidacloprid 40 mg for Small Cats and Small Dogs	Shelf-life change	AVM-GSL
	Bob Martin Clear Double Action Spot-on Solution Imidacloprid 80 mg for Large Cats		AVM-GSL
	Bob Martin Clear Double Action Spot-on Solution Imidacloprid 100 mg for Medium Dogs		AVM-GSL
	Bob Martin Clear Double Action Spot-on Solution Imidacloprid 250 mg for Large Dogs		AVM-GSL
	Bob Martin Clear Double Action Spot-on Solution Imidacloprid 400 mg for Extra Large Dogs		AVM-GSL
	Carprogesic 50 mg/ml Small Animal Solution for Injection for Cats and Dogs	Change in the storage conditions of the finished product	POM-V
	Cefenil 50 mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs	Shelf-life change	POM-V
	Cefenil 50 mg/ml Powder and Solvent for Solution for Injection for Cattle, Pigs and Horses		POM-V
	Cepralock 2.6 g Intramammary Suspension for Cattle	Change in the storage conditions of the finished product	POM-V
	Clearspot 40 mg Spot-On Solution for Small Cats and Small Dogs	Shelf-life change	NFA-VPS
	Clearspot 80 mg Spot-On Solution for Large Cats		NFA-VPS

Company Name	Product Name	Brief Details	Legal Category
Norbrook Laboratories Limited cont'd	Clearspot 100 mg Spot-On Solution for Medium Dogs		NFA-VPS
	Clearspot 250 mg Spot-On Solution for Large Dogs	Shelf-life change	NFA-VPS
	Clearspot 400 mg Spot-On Solution for Very Large Dogs		NFA-VPS
	Combisyn Suspension for Injection	To change the name and address of the distributor on the Package Leaflet, and remove reference to the distributor on the Carton and Label. The address is changing from Norbrook Laboratories (GB) Limited, The Green, Great Corby, Carlisle, Cumbria, CA4 8LR to MiGroup, 12b Progress Way, Mid Suffolk, Business Park, Eye, Suffolk IP23 7HU	POM-V
	Combisyn 50 mg Tablets for Dogs and Cats		POM-V
	Combisyn 250 mg Tablets for Dogs		POM-V
	Combisyn Palatable Tablets 500 mg for Dogs		POM-V
	Downland Low Volume Calcium Solution for Injection	Change of distributor address from The Green, Great Corby, Carlisle, Cumbria, CA4 8LR to 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX	POM-VPS
	Combisyn Palatable Tablets 500 mg for Dogs		POM-VPS
	Norodyl 100 mg Tablets for Dogs		POM-VPS
	Norofol 10 mg/ml Emulsion for Injection for Cats and Dogs		POM-VPS
	Pyroflam 50 mg/ml Solution for Injection for Cattle, Horses and Pigs		POM-VPS
	Reproval 50 mg/ml Solution for Injection for Dogs and Cats		POM-VPS
	Tri-Lyte Plus Powder for Oral Solution		POM-VPS
	Duphacort Q 0.2% w/v Solution for Injection	Change the distributor from Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ to Zoetis UK Limited, 6 St. Andrew Street, London, EC4A 3AE	POM-V
	Midaspot 40 mg Spot-On Solution for Small Cats and Small Dogs	To change the invented name of the product in the UK only from Midaspot 40 mg Spot-On Solution for Small Cats and Small Dogs to Bob Martin Clear Double Action Spot-On Solution Imidacloprid 40 mg for Small Cats	NFA-VPS
	Midaspot 80 mg Spot-On Solution for Large Cats	To change the invented name of the product in the UK only from Midaspot 80 mg Spot-On Solution for Large Cats to Bob Martin Clear Double Action Spot-On Solution Imidacloprid 80 mg for Large Cats	NFA-VPS
	Midaspot 100 mg Spot-On Solution for Medium Dogs	To change the invented name of the product in the UK only from Midaspot 100 mg Spot-On Solution for Medium Dogs to Bob Martin Clear Double Action Spot-On Solution Imidacloprid 100 mg for Medium Dogs	NFA-VPS
	Midaspot 250 mg Spot-On Solution for Large Dogs	To change the invented name of the product in the UK only from Midaspot 250 mg Spot-On Solution for Large Dogs to Bob Martin Clear Double Action Spot-On Solution Imidacloprid 250 mg for Large Dogs	NFA-VPS
	Midaspot 400 mg Spot-On Solution for Very Large Dogs	To change the invented name of the product in the UK only from Midaspot 400 mg Spot-On Solution for Very Large Dogs to Bob Martin Clear Double Action Spot-On Solution Imidacloprid 400 mg for Extra Large Dogs	NFA-VPS
	Noroseal 2.6 g Intramammary Suspension for Cattle	Addition of warming advice to the SPC and package leaflet. Under cold conditions the product may be warmed to room temperature in a warm environment to aid syringeability. The product should be warmed in tepid water for 5 minutes	POM-V
	Reproval 50 mg/ml Solution for Injection for Dogs and Cats	Change in the storage conditions of the finished product	POM-V
	Streptacare Suspension for Injection	Shelf-life change	POM-V

Company Name	Product Name	Brief Details	Legal Category
Norbrook Laboratories Limited cont'd	Vectin 0.08% w/v Oral Solution Sheep Wormer	Change of distributor details	POM-VPS
	Vectin 0.08% w/v Oral Solution Sheep Wormer	To change the invented name of the product from Vectin 0.08% w/v Oral Solution Sheep Wormer to Premadex 0.8 mg/ml Oral Solution Drench for Sheep	POM-VPS
Novartis Animal Health UK Ltd	Depidex Pour-on Solution 0.5% w/v	To change the MAH from Novartis Animal Health UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR to Norbrook Laboratories Limited, Station Works, Newry, Co. Down, BT35 6JP, Northern Ireland	POM-VPS
Orion Corporation	Antisedan 5 mg/ml Solution for Injection	To change the distributor from Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Vetoquinol UK Limited, Vétoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA	POM-V
	Domitor 1 mg/ml Solution for Injection		POM-V
	Domosedan 10 mg/ml Solution for Injection		POM-V
	Domosedan Gel 7.6 mg/ml Oromucosal Gel		POM-V
Piramal Healthcare UK Limited	Iso-Vet 1000 mg/g Inhalation Vapour, Liquid	Deletion of Piramal Healthcare UK Limited, 1st Floor Alpine House, Unit II, Honeypot Lane, London, NW9 9RX as a distributor	POM-V
Provivo Oy	Equimidine 10 mg/ml Solution for Injection for Horses	Addition of a 15 ml vial size presentation	POM-V
Sogeval	Nelio 5 mg Tablet for Cats	Shelf-life change	POM-V
	Nelio 5 mg Tablet for Dogs		POM-V
	Nelio 20 mg Tablet for Dogs		POM-V
	Zodon 25 mg/ml Oral Solution for Cats and Dogs	To change the distributor in the UK from Sogeval, 200 Avenue de Mayenne, ZI des touches, 53000 Laval, France to Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB	POM-V
Triveritas Ltd	Linco-Spectin SP 100 mg/g Powder for Oral Solution	Change to MAH and Distributor from Triveritas Ltd to Zoetis UK Limited	POM-V
Vetoquinol UK Ltd	Ceftiocyl 50 mg/ml, Suspension for Injection for Cattle and Pigs	Shelf-life change	POM-V
Vetpharma Animal Health, S.L	Doraflox 100 mg/ml Solution for Injection for Cattle and Pigs	Variation to change the MAH from Vetpharma Animal Health, S.L. Les Corts, 23, 08028 Barcelona, Spain to Dopharma Research B.V., Zalmweq 24, 4941 VX Raamsdonksveer, The Netherlands	POM-V
	VETPRIL 5 mg film-coated tablet for Dogs and Cats	Change in distributor from Bimeda to Lintbells Ltd	POM-V
Virbac S.A.	Canixin DHPPi/L	Shelf-life change	POM-V
	Deltacert 10 mg/ml Pour-on Solution		POM-VPS
	Deltacert 10 mg/ml Pour-on Solution		POM-VPS
	Deltanil 10 mg/ml Pour-on Solution for Cattle and Sheep		POM-VPS
	Deltanil 100 mg Spot-on Solution for Cattle		POM-VPS
	Ivermectin and Clorsulon Solution for Injection for Cattle Virbac	Change to the invented name of the medicinal product from Ivermectin and Clorsulon Solution for Injection for Cattle Virbac to Virbamec Super 10 mg/ml, 100 mg/ml Solution for Injection	POM-VPS

Company Name	Product Name	Brief Details	Legal Category
Virbac S.A. cont'd	Virbamec Super 10 mg/ml, 100 mg/ml Solution for Injection	To change the distributor from Virbac S.A., 1ère avenue – 2065 m – L.I.D., 06516 Carros Cedex, France to Virbac Ltd, Woolpit Business Park, Windmill Avenue, Woolpit, Bury St. Edmunds, Suffolk, IP30 9UP	POM-VPS
Vita (Europe) Ltd	Apistan 10.3% w/w Bee Hive Strip	Change to the storage conditions of the finished product	AVM-GSL
Zoetis UK Limited	Aurofac Granular 250 mg/g Premix for Medicated Feeding Stuff	Shelf-life change	POM-V
	Colombovac PMV/Pox		POM-VPS
	Colombovac PMV		POM-VPS
	Suvaxyn MH-One Emulsion for Injection for Pigs		POM-V
	Suvaxyn MH-One Emulsion for Injection for Pigs	Deletion of 50 dose pack size of the finished product	POM-V

EUCE AUTHORISATIONS ISSUED BETWEEN 8 SEPTEMBER - 9 DECEMBER 2014

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Intervet International BV	EU/2/14/174/001-004	Nobilis IB Primo QX	Infectious bronchitis virus	POM-V
	EU/2/14/175/001-010	Porcilis PCV M Hyo Emulsion for Injection for Pigs	Mycoplasma hyopneumoniae Porcine circovirus-2	POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 8 SEPTEMBER - 9 DECEMBER 2014

Company	Product Name	Brief Details	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	Ingelvac CircoFlex Suspension for Injection for Pigs	Variation to make editorial changes in the text, i.e. re-phrasing and addition of details aiming to improve the conduct of the identity/ potency test. There is no change either in the procedure or in the impurities limit, the analytical method remains the same	POM-V
Zoetis Belgium	Apoquel 3.6 mg Film-coated Tablet for Dogs	Variation to add a new presentation of 50 tablets for each strength (three new presentations altogether) to the existing presentations of 20 and 100 tablets	POM-V
	Apoquel 5.4 mg Film-coated Tablet for Dogs		POM-V
	Apoquel 16 mg Film-coated Tablet for Dogs		POM-V

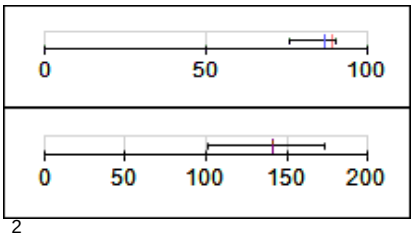
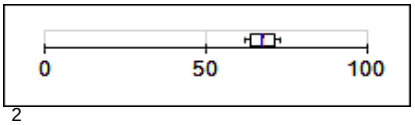
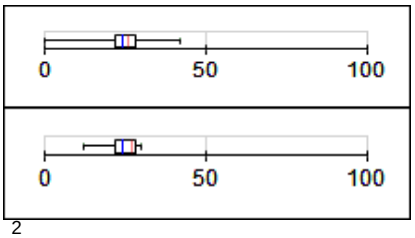
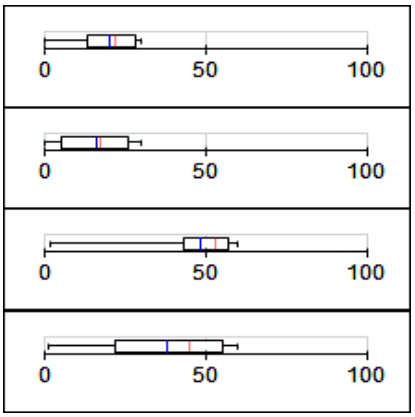
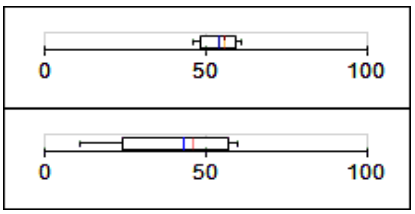
MARKETING AUTHORISATIONS EXPIRED BETWEEN 8 SEPTEMBER - 9 DECEMBER 2014

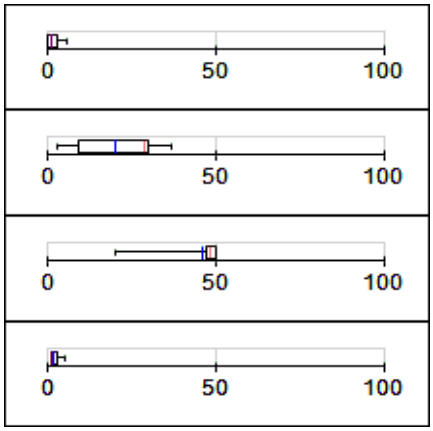
Company	Vm Number	Product Name	Legal Category
Bayer plc	00010/4169	Baytril Flavour Tablets 250 mg	POM-V
Boehringer Ingelheim Ltd	00015/4043	Monzaldon 100 mg/ml Solution for Injection	POM-V
	00015/4077	Vetmedin 1.25 mg Flavour Tablets	POM-V
	00015/4076	Vetmedin 5 mg Flavour Tablets	POM-V
Cross Vetpharm Group Ltd	12597/4010	Ampicaps 250 mg Hard Capsule	POM-V
Dechra Limited	10434/4042	Walpole's Buffer Irrigation Solution	POM-V
Forum Products Limited	05928/4000	Diaproof K Powder for Oral Solution	AVM-GSL
Intervet UK Ltd	01708/4542	Diluvac Forte	POM-V
	01708/4269	Unisolve	POM-VPS
Krka Dd	01656/4054	Ubiflox Cattle 100 mg/ml Solution for Injection for Cattle	POM-V
Virbac Ltd	11188/4012	Virbamec Super Solution for Injection	POM-VPS

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK 2014/2015

Annex I

The following is a summary of VMD's performance against its published standards for 1 October to 31 December 2014.

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: ------- = Median _____ = Average
National					
MA and MAPIs					
Initial assessment	45	Excellent	90	87	 [2]
Sign off (Applications validated >1/4/2011)	30	Excellent	180	141	
Sign off and issue (Applications validated <1/4/2011)	0		210		
MAPIs for MR products & copy-cats					
Initial assessment	10	Excellent	75	67	 [2]
Sign off	1	Excellent	130	79	
Variations					
Type 1A - decision (30 days)	116	Excellent	30	24	 [2]
Admin - Less than 10 changes	15	Excellent	30	24	
Admin - 10 or more changes	0		60		
Type 1B - initial assessment	128	Excellent	30	20	
Type 1B - sign off	78	Excellent	30	16	
Type II - initial assessment	36	Excellent	60	48	
Type II - sign off	29	Excellent	60	38	
Renewals					
Initial assessment	8	Ineffective	60	54	
Sign off	8	Excellent	60	43	
Batch release (Immunologicals)					
Issue	1875	Excellent	15	2	

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: ------- = Median _____ = Average
AVAS and NFABBA (inc variations)					
Assess	2	Excellent	45	41	
ATCs					
Type A, S and B - validate	24	Effective	5	1	
Type A and S - sign off	10	Ineffective	30	20	
Type B - sign off	11	Excellent	50	46	
Type A, S and B - issue	20	Excellent	5	2	
Specific Batch Control					
Validation	41	Excellent	3	1	
Initial assessment	40	Excellent	10	2	
Assess response	40	Excellent	10	1	
Issue	40	Excellent	3	1	
Validation/Issue					
Validation	260	Excellent	10	5	
Issue	667	Excellent	10	7	
Pharmacovigilance					
Enter human Pharmacovigilance	100	Excellent	2		
Enter serious animal Pharmacovigilance	2825	Excellent	2		
Enter environmental Pharmacovigilance	25	Ineffective	2		
Enter non-serious Pharmacovigilance	1238	Excellent	10		
Report to Eudravigilance	3835	Excellent	15		
SIC/STC					
Urgent products not previously imported	2	Excellent	5	<1	
Routine products not previously imported	62	Excellent	15	3	
Urgent products previously imported	342	Excellent	2	2	
Routine products previously imported	3658	Excellent	10	3	
On-line instantaneous issue of certificates	11676	Excellent	-		

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: ------- = Median _____ = Average
Inspections					
GMP inspections performed on a risk-basis within 3 yrs of last inspection	**30**	**Excellent**			
GDP inspections performed on a risk-basis within 5 years of last inspection	**20**	**Excellent**			
Written deficiency reports sent after GMP and GDP inspection	**53**	**Excellent**	**30**	**21**	
Issue GMP Certificate after last day at site	**30**	**Excellent**	**90**	**82**	
Updated documentation for GDP site issued after last day at site	**24**	**Excellent**	**90**	**73**	
UKPARs					
Make publicly available via the VMD internet & SPC for New MA.	**173**	**Excellent**	**30**	**14**	
Make publicly available via the VMD internet the relevant hyperlink to the EMA website for centralised products within 30 days of issue.	**20**	**Excellent**	**30**	**12**	
Make publicly available via Product Information Database	**90**	**Excellent**	**120**	**105**	
Make publicly available after issue of post-authorisation assessments	**778**	**Excellent**	**60**	**37**	

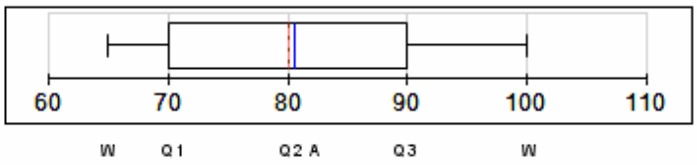
Box-and-Whisker Plots

Box-and-whisker plots are helpful in interpreting the distribution of days an application may take. The median of a set of data separates the data into two equal parts and data can then be further separated into quartiles.

E.g. Application days for 10 applications: 80, 75, 90, 95, 65, 65, 80, 85, 70, 100

First order the data in numerical order: 65[W], 65, 70[Q1], 75, 80[Q2], 80[A], 85, 90[Q3], 95, 100[W]

[Q1] The 1st quartile is the median of the lower part of the data.
[Q2] The 2nd quartile is the median of the entire set.
[Q3] The 3rd quartile is the median of the upper part of the data
[W] The whiskers represent the smallest and largest value.
[A] The average number of days



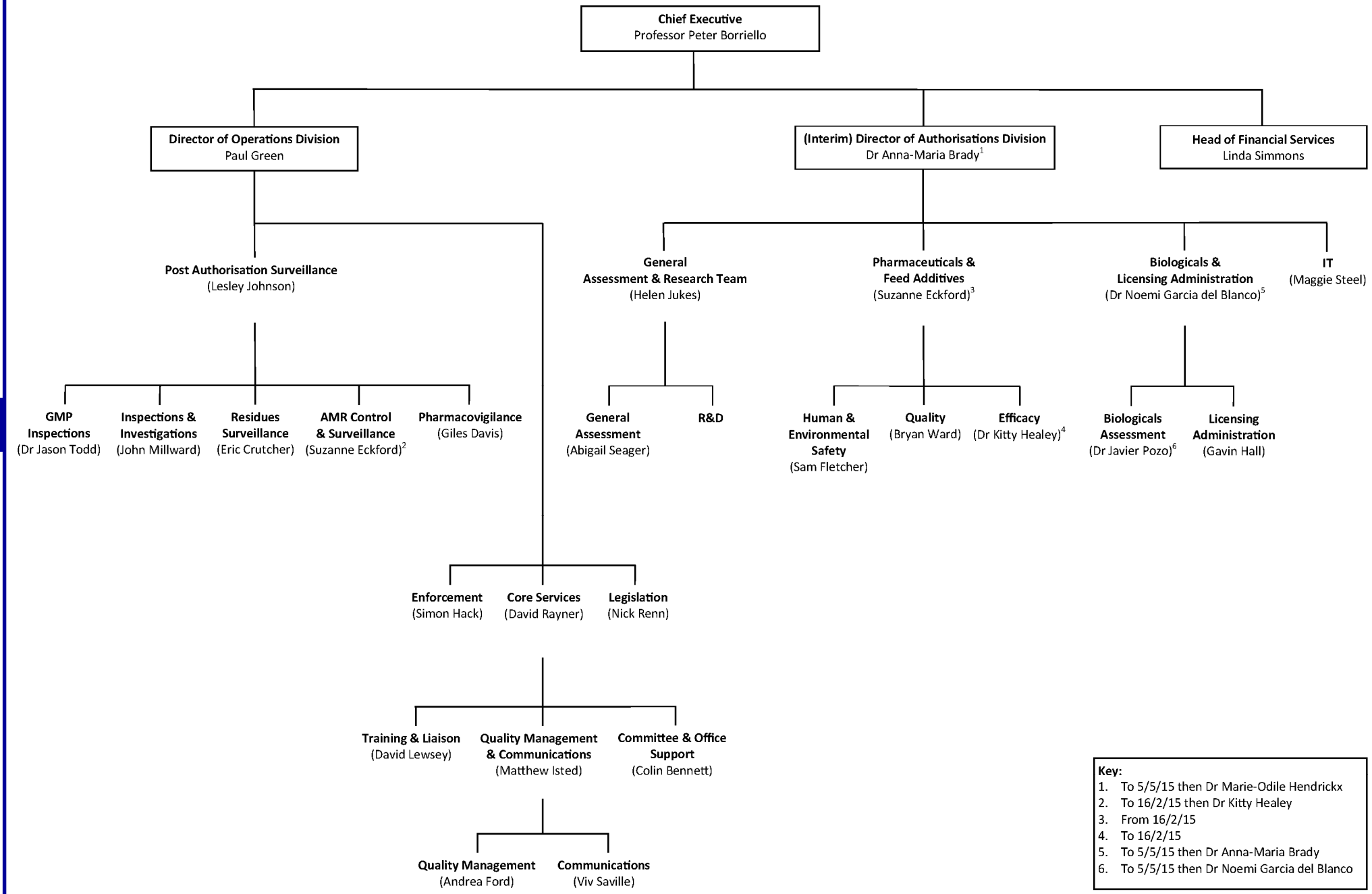
Category/application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days[1])
European			
Centralised			
Rapp - Initial assessment by 70 days	4	Excellent	70
Co-Rapp - Provide comments on assessment report by 85 days	0	Excellent	85
UK as Member only - LOQ by 100 days	9	Excellent	100
Mutual Recognition			
RMS			
Production of Final Assessment Report by day 90 (Phase 1)	5	Excellent	90
RMS Circulate the Consolidated List of Questions by day 57	3	Excellent	57
Assessment of Responses by day 70 (Phase 2)	1	Ineffective	70
Procedure completed by day 90 (Phase 2)	2	Excellent	90
CMS			
CMS send any UK comments by day 54 (Phase 2)	8	Excellent	54
Procedure completed by day 90 (Phase 2)	8	Excellent	90
Decentralised			
RMS			
Production of Assessment Report by day 70 (Phase 1)	51	Excellent	70
Production of Assessment Report by day 120 (Phase 1)	35	Excellent	120
RMS Circulate Consolidated List of Questions by day 30 (Phase 2)	40	Excellent	30
Assessment of Responses by 70 days (Phase 2)	56	Excellent	70
RMS send confirmation of acceptance/referral by Day 90 (Phase 2)	56	Excellent	90
CMS			
UK comments sent by 100 days (Phase 1)	24	Excellent	100
CMS Send any UK Comments by day 25 (Phase 2)	27	Excellent	25
UK acceptance/referral sent by 90 days [2nd phase]	38	Excellent	90[210]
European Variations			
Type 1B EUCE Rapp			
Initial Assessment Completed according to EMA timetable	2	Excellent	
Type II EUCE Rapp			
Initial Assessment Completed according to EMA timetable	4	Excellent	
Type II - Mutual Recognition RMS			
PAR circulated by day 40 (Phase 1)	27	Excellent	40
CLOQ or decision circulated by day 59 (Phase 1)	26	Excellent	59
Type IB - Mutual Recognition RMS			
CLOQ or decision circulated by day 30 (Phase 1)	84	Excellent	30
Type IA - Mutual Recognition RMS			
Determined within 30 days	57	Excellent	30
Type II Mutual Recognition CMS			
UK comments sent by day 55 (Phase 1)	48	Excellent	55
UK comments sent by day 80 (Phase 2)	42	Excellent	80
Type IB Mutual Recognition CMS			
UK comments sent by day 20 (Phase 1)	63	Effective	20
UK comments sent by day 50 (Phase 2)	11	Excellent	50

Category/application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days[1])
European Renewals			
Mutual Recognition RMS			
PAR circulated by day 40 (Phase 1)	**33**	**Excellent**	**40**
CLOQ circulated by day 59 (Phase 1)	**31**	**Excellent**	**59**
Mutual Recognition CMS			
UK Comments sent by day 55 (Phase 1)	**35**	**Excellent**	**55**
UK Comments sent by day 80 (Phase 2)	**34**	**Excellent**	**80**
Others (Centralised)			
UK as Rapporteur - Complete IA according to EMA timetable	**1**	**Excellent**	
Customer Relations			
Unreturned authorisation documents			
Right first time (Authorisations)	**1942**	**Excellent**	

1 The days are specified as either calendar days or clock days according to the target and as set out in detail in the published standards.
2 Box whisker plots have been omitted due to low numbers of applications.

ORGANOGRAM FOR JANUARY 2015

Annex 2



Key:

1. To 5/5/15 then Dr Marie-Odile Hendrickx
2. To 16/2/15 then Dr Kitty Healey
3. From 16/2/15
4. To 16/2/15
5. To 5/5/15 then Dr Anna-Maria Brady
6. To 5/5/15 then Dr Noemi Garcia del Blanco