MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 94 - APRIL 2015

NEWS

VMD CORPORATE BRANDING CHANGE

The VMD will now show the Government insignia as its sole corporate branding in line with other Government Departments and agencies.

We have been using the old VMD logo alongside the insignia but the logo will now be phased out.

You will therefore notice that our documentation (e.g. forms), site signage, etc. will start to look different. However, our Accredited Internet Retailer Scheme logo will remain the same.

If you display or have website links to any VMD material with the old logo please remove the old logo and change the website link to either our corporate entry on www.gov.uk or to the relevant GOV.UK page as appropriate.

If you have any questions please email: postmaster@vmd.defra.gsi.gov.uk.

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Veterinary Medicines Directorate

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NEWS

VMD ON GOV.UK

In *MAVIS 93* we told you that our website content is now on GOV.UK. All the VMD material you need should be there. We explained that you will find this information using key search words rather than navigating through a menu.

To help you get the most out of GOV.UK we thought it would be helpful to give you some tips based on our experience of using the site.

Searching

The GOV.UK search function works like Google and other search engines. You can also search for VMD material directly on Google.

The GOV.UK search engine will search for the words you have entered that are held in the title of the document or the summary statement underneath. This means that links and attachments (e.g. forms, templates and other websites) cannot be searched for separately.

Not all of the VMD's documents, including our guidance, on GOV.UK are in webpage format and are therefore not easily searchable. We are therefore updating our documents including our guidance so it is in webpage format which will make it more accessible.

Search words

To avoid finding similar information that the Medicines Healthcare Regulatory Agency provides for human health, use "animal" or "veterinary" in your search terms.

Search terms that work in finding key VMD material are:

To find out:	Use the search term:
How to apply for a licence to market an animal medicine	Licence to market animal
How to apply to change a marketing authorisation for an animal medicine	Change a (or variation) marketing authorisation animal
How to find information about controlled drugs: recording, using, storing and disposal	Controlled drugs veterinary
About supply problems with animal medicines	Supply problems animal
How to apply to export a veterinary medicine from the UK	Export veterinary

We have written our website material with the aim of reflecting the words that people use to search for this content. But we are flexible and responsive to change if our content does not match the words used for searching (see contact us opposite).

The VMD's 'home' page

Enter VMD in the search box to find our corporate 'home' page. There are five quick links to our most used material at the top right of the page:

- Product Information Database
- Veterinary Medicines Guidance Notes
- Apply for Special Import
- Report an Adverse Event
- MAVIS

Contact us

Please let us know by emailing postmaster@vmd.defra.gsi.gov.uk if you have any problems finding information and tell us what search words you have used. We will do the following:

- check to see if it is available on GOV.UK
- look at the title and the summary and how it compares to your search words, amending if necessary
- if the information isn't there, see if it is on the archived VMD website
- if it is, discuss internally to see if it should be added to GOV.UK and re-written if necessary
- if it isn't, discuss internally if the information should be provided
- reply to your email within 15 working days at the latest.

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

IMPROVING OUR GUIDANCE ON VETERINARY MEDICINES

We are rewriting our guidance to better meet your needs.

Knowing how to comply with the law, use our services etc. will be easier and quicker to do on GOV.UK.

No procedures are changing (with the exception of the process for applying for export certificates) . We are simply improving the presentation of existing content. If you are looking for our Veterinary Medicines Guidance Notes you will be directed to the new content on GOV.UK.

We have published our first item of revised guidance on GOV.UK - applying for an export certificate. Please look on our GOV.UK home page or sign up to RSS feeds for further announcements about our revised guidance.

We welcome any feedback on how we can continue to improve our guidance to meet your needs. You can send this by email to postmaster@vmd.defra.gsi.gov.uk.

LICENSING

PRODUCTS CONTAINING CONTROLLED DRUGS

All products containing a controlled drug in either Schedule 2 or 3 of the Misuse of Drugs Regulations 2001 should be clearly identified with "CD" either in a triangle (preferable) or a box with the relevant schedule detailed on the labels.

You do not need to submit a variation to the VMD to include this information; we simply ask that you include this information on the labels at the time of the next print run.

If your product is joint-labelled with Ireland, this information should be included in the UK-Only box.

With effect from 30 November 2015, ketamine will be moved from Schedule 4 to 2; therefore, the above will apply to these products and it is your responsibility to make sure the labels are updated and anything QP released on/after this date has on it this information.

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

MOCK-UPS: CHANGES TO ADMINISTRATIVE DETAILS

You no longer need to submit mock-ups in support of the following variations if the **only** change being made is to the name and/or address:

Distributor (A.z)
Local Representative (C.II.6(a))
MA holder details (A.1 – same legal entity)
MA holder details (A.z – new legal entity)

Upon issue, the VMD will send you an annotated copy of the latest authorised mock-ups showing the approved change.

If you wish to make any other changes, you will need to submit mock-ups for assessment under a C.II.6(b) variation category, or as part of a grouped variation involving the other changes.

The guidance on changes to distributors and legal entity has been updated to reflect this.

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

APPLICATIONS FOR BIOPHARMACEUTICAL PRODUCTS OR PRODUCTS CONTAINING A PERSISTENT BIO ACCUMULATIVE AND TOXIC (PBT) SUBSTANCE

Work is currently being undertaken by the Committee for Medicinal Products for Veterinary Use (CVMP) to provide greater clarity on the authorisation of products containing substances designated as persistent bio accumulative and toxic (PBT) to the environment.

The potential for PBT substances to have harmful effects on the environment will form part of the benefit:risk evaluation where the overall need for the product will be considered against potential risks.

The outcome of this evaluation has to be positive for a Marketing Authorisation (MA) to be granted. Therefore, it is important that the PBT aspects of a product are considered early in product development.

During product development, should you discover or have concerns, that a product you are developing contains a PBT substance, we advise you to come in for a company meeting **before** applying for an MA. Likewise for biopharmaceutical products, it would be helpful to meet with you prior to the submission of your application.

Biopharmaceuticals are outside the usual type of application and a meeting beforehand will help the VMD to better understand your product and assign the appropriate assessors.

To arrange a company meeting please contact: Chris Abbott (VMD, email: c.abbott@vmd.defra.gsi.gov.uk, 01932 338353).

VETERINARY MEDICINE PRODUCT SUPPLY PROBLEMS

To find the latest information on supply problems with Veterinary Medicinal Products (VMP) please use the search term "supply problem animal medicines" at www.gov.uk.

To report a VMP supply problem please use the search term "report supply problem" at www.gov.uk.

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

■ TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 JANUARY - 27 MARCH 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	2,176
Greer Allergenic Extract Patient Prescription	Allergens	271
Vet-Goid	Allergens	263
Scabivax***	Contagious Pustular Dermatitis Virus	257
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	143
BioRelease Deslorelin	Deslorelin Acetate	101
Botulism Vaccine	Clostridium botulinum type C toxoid, Clostridium botulinum type D toxoid	73
Staphage Lysate (SPL)	Staphylococcus aureus	72
ACTT Allergy Drops	Allergens	58
Antepsin 1g Tablet	Sucralfate	55

*** *Supply problem with UK authorised product*

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

ENFORCEMENT

A key element in our strategy for assuring the safety, quality and efficacy of veterinary medicines is the action that we take against the illegal marketing and use of unauthorised products and to promote the responsible use of authorised products. This section describes the most significant developments and outcomes in this area.

■ SEIZURE NOTICES

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

Ms Regan Clarke, Camberley, Surrey. Two products were seized as they were not authorised for use in the UK.

■ IMPROVEMENT NOTICES

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

Vetmedsdirect.co.uk, Tranent, Edinburgh. Internet sales of veterinary medicines via vetmedsdirect.co.uk and the Amazon.co.uk marketplace were not prescribed or supplied in accordance with the Veterinary Medicines Regulations 2013. The improvement required is for all orders of POM-VPS and NFA-VPS products to obtain sufficient information to allow proper prescribing/supplying and all supplies must be individually authorised by the veterinary surgeon prior to allocation/supply. Internet site questions also to be updated on all VPS products and SOPs put in place for prescribing and supplying.

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 January to 31 March 2015, the VMD received 1,279 suspected adverse event reports involving animals. Of these, 34 reports related to unauthorised or unidentified products and two reports involved animal trials under Animal Test Certificates (ATCs). Excluding these two categories, the remaining 1,243 suspected adverse event reports were associated with 299 authorised products.

The 1,243 reports were divided by distribution categories as follows:

1120	Prescription Only Medicine - Veterinarian (POM-V)
77	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
25	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
18	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
3	Small Animal Exemption Scheme (N/A)

During the quarter 25 reports of human suspected adverse reactions and one environmental incident were received.

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

PERIODIC SAFETY UPDATE REPORTS (PSURS) – CLAMPING DOWN ON NON-COMPLIANCE

Marketing Authorisation Holders (MAHs) should be aware that it is a requirement of Volume 9B of the Rules Governing Medicinal Products in the European Union that PSURs are submitted within 60 days of the Data Lock Point (DLP). **Failure to submit a PSUR within 60 days of the DLP is recorded as non-compliance**.

Since a considerable amount of staff time is being spent chasing up late PSURs and unfulfilled requests for information (e.g. annual sales figures, electronic line listings etc.) we would like to remind you of a specific requirement for pharmacovigilance in the Veterinary Medicines Regulations.

Schedule 1, paragraph 56(b) states that MAHs must respond to *"…any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product fully and within any time limit imposed by the Secretary of State when the information was requested, including the volume of sales of the veterinary medicinal product concerned…"*

Therefore, where the required information has been omitted from a PSUR, we will request that you provide it within a defined period (usually no longer than two weeks). **Failure to provide this information on time will also be recorded as non-compliance.**

The VMD will address cases of non-compliance with a written warning, as well as increasing the frequency of pharmacovigilance inspections. In repeated cases, we will issue improvement notices which are published on GOV.UK and in MAVIS. Our primary aim is to improve the timeliness of PSUR submissions and therefore efficiency of assessment, so we hope these actions will not be necessary.

For further information please contact: Jennifer Blenkinsop (VMD, email: j.blenkinsop@vmd.defra.gsi.gov.uk, 01932 338396).

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 17 February 2015 at the VMD. The group discussed recent trends in antibiotic resistance in bacteria of importance to human and animal health, including the finding of LA-MRSA in two GB piglets in February 2015.

The VMD updated the DARC group on antimicrobial resistance (AMR) R&D projects which the VMD is funding, and attendees from other lead government agencies shared updates on their AMR research areas. The group discussed the work being conducted under the Pig Health and Welfare Council (PHWC) Antimicrobial Usage Subgroup and the Cattle Health and Welfare Groups (CHAWG).

The next DARC meeting is planned for 2 June 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. We also provide the secretariat for the group. The most recent discussion took place in March 2015. The task force gave an update on the progress achieved by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) on the collection of usage data project; they discussed the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report published in January 2015, which presents possible relationships between the consumption of antimicrobial agents and the occurrence of antimicrobial resistance in humans and food-producing animals. The task force also provided an update on the veterinary medicinal products and medicated feed legislation and presented a draft paper on key elements of what would form a scheme of pathogen surveillance in Europe, as part of a proposed Target Pathogen Surveillance Programme.

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

The 2014 data for the annual Antibiotic Sales Report are currently being collected. The report will be combined with England and Wales data on the antibiotic susceptibility of veterinary and foodborne pathogens to form the joint report named 'UK Veterinary Antibiotic Resistance and Sales Surveillance Report (UKVARSS) 2014'.

The UKVARSS 2013 was published on 18 November 2014. 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 27 January 2015. 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 was published in December 2014. The report sets out the work underway and includes the further measures to be taken over the next four years to respond to the risk of AMR and to promote the responsible use of antibiotics. www.gov.uk/government/publications/progress-report-on-the-uk-five-year-amr-strategy-2014

In order to strengthen surveillance of antimicrobial use in the animal health sector, we 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 we have expanded the UK surveillance programme of resistance in veterinary zoonotic and commensal bacteria, in line with new statutory EU requirements.

We have also published a reference document for keepers of livestock on the responsible use of animal medicines, which reflects the Government position that routine preventative use of antibiotics is not acceptable. www.gov.uk/government/publications/responsible-use-of-animal-medicines-on-the-farm

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 our meetings held since May 2014 are available on our GOV.UK page 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 http://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: n.dorian@vmd.defra.gsi.gov.uk, 01932 338491).

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 and 2015 PROGRAMME

Sampling commenced in January for the majority of species. Details of sample results since the report in *MAVIS 93* are below.

2014 PROGRAMME

Species	Number of Samples Analysed	Number of Non-Compliant Samples	Analyte Detected
Cattle	320	4	Beta-nortestosterone (1) Beta-testosterone (1) Dihydrostreptomycin (1) Taleranol & zeranol (1)
Pigs	389	1	Oxytetracycline (1)
Sheep	328	4	Alpha-boldenone (2) Beta-nortestosterone & alpha-boldenone & beta-boldenone (1) Diazinon (1)
Horses	6	0	
Poultry	148	1	Salinomycin (1)
Game	54	4	Lasalocid (3) Lead (1)
Fish	253	0	
Milk	198	1	Ivermectin (1)
Eggs	141	0	
Honey	4	0	

2015 PROGRAMME

Species	Number of Samples Analysed	Number of Non-Compliant Samples	Analyte Detected
Cattle	1,008	4	Cadmium (1) Ivermectin (1) Oxytetracycline (1) Taleranol (1)
Pigs	740	0	
Sheep	1,148	6	Alpha-boldenone (1) Cadmium (1) Closantel (2) Nitroxynil (1) Oxytetracycline (1)
Horses	20	1	Cadmium (1)
Poultry	1,258	1	Toltrazuril sulfone (1)
Game	42	0	
Fish	235	0	
Milk	437	0	
Eggs	206	1	Lasalocid (1)
Honey	0	0	

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. Samples for the programme were collected from May to November 2014. Details of analyses completed for the entire 2014 programme are set out below.

Sample Type	Number of Analyses Completed	Number of Non-Compliant Samples	Analyte Detected
Farmed Warm Water Crustaceans	233	2	Oxytetracycline (2)
Imported Farmed Fish	252	3	Leucomalachite Green (1) Oxytetracycline (1) Sulfadiazine (1)
Imported Poultry Muscle	268	1	Doxycycline (1)
Imported Raw Beef	487	0	

The Non-statutory Surveillance Scheme ended on 31 December 2014 and this will be the last report on the programme.

For full details of all results, together with information on any action taken please contact Carol Brailsford (VMD, email: c.brailsford@vmd.defra.gsi.gov.uk, 01932 338330.

STAFF CHANGES

The following staff changes took place during this quarter:

New Staff

- Victoria Warnock joined the Pharmacovigilance team on 9 February 2015
- Marie Odile Hendrickx joins as Director of Authorisations on 5 May 2015

Departing Staff

- Jim Adams resigned on 6 March 2015
- Lesley Johnson retired on 15 April 2015
- Robert Harrison resigned on 17 April 2015
- Martha Spagnuolo-Weaver resigned on 30 April 2015

Promotions

- Suzanne Eckford was promoted to Head of the Pharmaceuticals and Feed Additives team on 16 February 2015
- Nina Dorian was temporarily promoted within the Committee and Office Support team on 16 March 2015
- John Millward was temporarily promoted to the Head of the Post Authorisation Surveillance Unit on 23 March 2015
- Christine Paine was temporarily promoted to the Head of the Inspections and Investigations team on 6 April 2015

Transfers

- Dawn Greener temporarily transferred to the Committee and Office Support team on 13 April 2015

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 8 DECEMBER 2014 - 5 MARCH 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Alfamed	17902/4083	Milbeworm 2.5 mg/25 mg Film-Coated Tablets for Small Dogs and Puppies		POM-V
	17902/4081	Milbeworm 4 mg/10 mg Film-Coated Tablets for Small Cats and Kittens	Milbemycin Oxime (A3 and A4) Praziquantel	POM-V
	17902/4082	Milbeworm 12.5 mg/125 mg Film-Coated Tablets for Dogs		POM-V
	17902/4080	Milbeworm 16 mg/40 mg Film-Coated Tablets for Cats		POM-V
Bayer plc	00010/4203	Endectrid 40 mg + 4 mg Spot-on Solution for Small		POM-V
	00010/4204	Endectrid 40 mg + 10 mg Spot-on Solution for Small Dogs		POM-V
	00010/4202	Endectrid 80 mg + 8 mg Spot-on Solution for Large Cats		POM-V
	00010/4200	Endectrid 100 mg + 25 mg Spot-on Solution for Medium Dogs		POM-V
	00010/4201	Endectrid 250 mg + 62.5 mg Spot-on Solution for Large Dogs		POM-V
	00010/4205	Endectrid 400 mg + 100 mg Spot-on Solution for Extra Large Dogs		POM-V
	00010/4191	Prinovox 40 mg + 4 mg Spot-on Solution for Small Cats and Ferrets	Imidacloprid Moxidectin	POM-V
	00010/4192	Prinovox 40 mg + 10 mg Spot-on Solution for Small Dogs		POM-V
	00010/4190	Prinovox 80 mg + 8 mg Spot-on Solution for Large Cats		POM-V
	00010/4188	Prinovox 100 mg + 25 mg Spot-on Solution for Medium Dogs		POM-V
	00010/4193	Prinovox 250 mg + 62.5 mg Spot-on Solution for Large Dogs		POM-V
	00010/4189	Prinovox 400 mg + 100 mg Spot-on Solution for Extra Large Dogs		POM-V
	00010/4206	Quantex 20 mg Spot-on Solution	Praziquantel	AVM-GSL
	00010/4208	Quantex 50 mg Tablets		AVM-GSL
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4053	Quantilex Plus XL Tablets for Dogs	Febantel Praziquantel Pyrantel Embonate Pyrantel	NFA-VPS
Cross Vetpharm Group Ltd	12597/4060	Bilovet 200 mg/ml Solution for Injection for Cattle and	Tylosin	POM-V
	12597/4061	Mastiseal 2.6 g Intramammary Suspension for Cattle,	Bismuth Subnitrate	POM-V
Eurovet Animal Health B.V.	16849/4051	Taf Spray 28.5 mg/g Cutaneous Spray Solution	Thiamphenicol	POM-V
Fish Vet Group Limited	33459/4001	Salmosan Vet Azamethiphos 50%w/w Powder for Suspension for Fish Treatment	Azamethiphos	POM-V
Huvepharma N.V.	30282/4022	Doxx-Sol 500 mg/g Powder for Use in Drinking Water/ Milk Replacer for Pre-ruminant Calves, Pigs and Chickens	Doxycycline Hyclate	POM-V
Intervet UK Ltd	01708/4609	Deltamole 7.5 mg/ml Pour-on Suspension for Cattle	Deltamethrin	POM-VPS

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Krka Dd	01656/4074	Milbactor 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
	01656/4083	Milbactor 12.5 mg/125 mg Tablets for Dogs Weighing at least 5 kg		POM-V
	01656/4073	Milbactor 16 mg/40 mg Film-Coated Tablets for Cats Weighing at least 2 kg		POM-V
	01656/4076	Milprazon 2.5 mg/25.0 mg Tablets for Small Dogs and Puppies Weighing at least 0.5 kg		POM-V
	01656/4075	Milprazon 12.5 mg/125.0 mg Tablets for Dogs Weighing at least 5 kg		POM-V
Le Vet Beheer B.V.	41821/4015	Amoxibactin 50 mg Tablets for Dogs and Cats	Amoxicillin Trihydrate	POM-V
	41821/4014	Amoxibactin 250 mg Tablets for Dogs	Amoxicillin Trihydrate	POM-V
	41821/4016	Amoxibactin 500 mg Tablets for Dogs	Amoxicillin Trihydrate	POM-V
	41821/4018	Finilac 50 microgram/ml Oral Solution for Dogs and Cats	Cabergoline	POM-V
	41821/4020	Furosoral 10 mg Tablets for Cats and Dogs	Furosemide	POM-V
	41821/4021	Furosoral 40 mg Tablets for Cats and Dogs	Furosemide	POM-V
Merial Animal Health Ltd	08327/4263	Omeproshield 370 mg/g Oral Paste for Horses	Omeprazole	POM-V
Norbrook Laboratories Limited	02000/4393	Cefimam DC, 150 mg Intramammary Ointment for Dry Cows	Cefquinome Cefquinome Sulphate	POM-V
Richter Pharma AG	22080/4006	Aurimic Ear Drops and Cutaneous Suspension for Dogs and Cats	Miconazole Nitrate Polymyxin B Sulphate Prednisolone Acetate	POM-V
Sogeval	20749/4043	Modulis 100 mg/ml Oral Solution for Dogs	Ciclosporin A	POM-V
Virbac S.A.	05653/4190	Virbakor 20 mg Film-Coated Tablet for Dogs	Benazepril Hydrochloride	POM-V
Zoetis UK Limited	42058/4019	Starthrin 12.5 mg/ml Pour-On Solution for Sheep	Cypermethrin Cis 80:Trans 20	POM-VPS

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 8 DECEMBER 2014 - 5 MARCH 2015

Company Name	Product Name	Brief Details	Legal Category
Alstoe Ltd (Alstoe Animal Health)	Vetergesic Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats	Change in MAH name from Alstoe Limited to Sogeval UK Limited	POM-V
Animalcare Ltd	Aqupharm 1 0.9% Solution for Infusion		POM-V
	Aqupharm 3 Solution for Infusion		POM-V
	Aqupharm 9 Ringer's Solution for Infusion		POM-V
	Aqupharm 11 Solution for Infusion		POM-V
	Aqupharm 18 Solution for Infusion		POM-V
	Atrocare 600 µg/ml Solution for Injection		POM-V
	Enrocare 25 mg/ml Solution for Injection for Dogs, Cats and Exotic Animals		POM-V
	Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats		POM-V
	Enrocare 100 mg/ml Solution for Injection for Cattle and Pigs		POM-V
	Pentoject Pentobarbitone Sodium 20% w/v Solution for Injection		POM-V
	Buprecare 0.3 mg/ml Solution for Injection for Dogs and Cats		POM-V
	Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats		POM-V
	Vitofyllin 50 mg Film-coated Tablets for Dogs	Change in distributor details	POM-V
	Vitofyllin 100 mg Film-coated Tablets for Dogs		POM-V
	Marbocare 20 mg/ml Solution for Injection for Cattle and Pigs		POM-V
	Marbocare 100 mg/ml Solution for Injection for Cattle and Pigs		POM-V
	Xylacare 2% w/v Solution for Injection		POM-V
	Cephacare Flavour 50 mg Tablets for Cats and Dogs		POM-V
	Cephacare Flavour 250 mg Tablets for Dogs		POM-V
	Cephacare Flavour 500 mg Tablets for Dogs		POM-V
	Oxycare Tablets 50 mg		POM-V
	Oxycare Tablets 100 mg		POM-V
	Oxycare Tablets 250 mg		POM-V
	Sodium Calciumedetate 250 mg/ml Concentrate for Solution for Injection		POM-V
	Prednicare Tablets 1 mg		POM-V
	Prednicare Tablets 5 mg		POM-V
aniMedica GmbH	Torphasol 4 mg/ml Solution for Injection for Dogs and Cats	Shelf-life change	POM-V
Bayer plc	Bayer Praziquantel 20 mg Spot-on Solution	Shelf-life change	AVM-GSL
	Bob Martin Spot-on Solution Dewormer 20 mg		AVM-GSL
	Droncit Spot-on 20 mg Solution		AVM-GSL
	Quantex 20 mg Spot-on Solution		AVM-GSL
Chanelle Animal Health Ltd	Clavucill Tablets 50 mg	Shelf-life change	POM-V
	Clavucill Tablets 250 mg		POM-V
	Zerofen 4% w/w Premix for Medicated Feeding Stuff	Change in the distributor details	POM-VPS
CP Pharma Handelsgesellschaft mbH	Marbosol 20 mg/ml Solution for Injection for Calves and Piglets	Shelf-life change	POM-V
	Marbosol 100 mg/ml Solution for Injection for Cattle and Pigs		POM-V

Company	Product	Brief Details	Legal Category
Dechra Limited	Somulose Solution for Injection	Change of address of the Marketing Authorisation holder 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
	Vetivex 1 (9 mg/ml) Solution for Infusion for Cattle, Horses, Dogs and Cats	Variation to introduce multi-pack sizes	POM-V
	Vetivex 11 Solution for Infusion for Cattle, Horses, Dogs and Cats		POM-V
Dechra Veterinary Products A/S	Fuciderm Gel 0.5% w/w Fusidic acid, 0.1% w/w Betamethasone	Change in the invented name to Trigoderm Gel	POM-V
Dopharma Research B.V.	Dexa-ject 2 mg/ml Solution for Injection for Cattle, Horses, Pigs, Dogs and Cats	Shelf-life change	POM-V
Eurovet Animal Health B.V.	Forthyron 200 Microgram Tablet	Shelf-life change	POM-V
	Forthyron 400 Microgram Tablet		POM-V
	Sedaxylan 20 mg/ml Solution for Injection for Dogs, Horses and Cattle	Change in the distributor details	POM-V
Forum Products Limited	Cephorum 250 mg Film-coated Tablets for Dogs	Change In MAH address from Forum Products Limited, Betchworth House, 57-65 Station Road, Redhill, Surrey RH1 1DL to Forum Products Limited, 2-8 Gloucester Road, Redhill, Surrey, RH1 1FH	POM-V
Krka Dd	Flimabend 100 mg/g Suspension for use in Drinking Water for Chickens and Pigs	Shelf-life change	POM-VPS
	Flimabo 100 mg/g Suspension for Use in Drinking Water for Chickens and Pigs		POM-VPS
Laboratorios Hipra SA	Hiprabovis Pneumos Emulsion for Injection for Cattle	Change in the invented name to Hiprabovis Somni/LKT Emulsion for Injection for Cattle	POM-V
Listow Limited	Combimox Injection Suspension for Injection	Change in legal entity	POM-V
Merial Animal Health Ltd	Frontect Spot-on Solution for Dogs 2-5 kg	Change to Storage Conditions	POM-V
	Frontect Spot-on Solution for Dogs 5-10 kg		POM-V
	Frontect Spot-on Solution for Dogs 10-20 kg		POM-V
	Frontect Spot-on Solution for Dogs 20-40 kg		POM-V
	Frontect Spot-on Solution for Dogs 40-60 kg		POM-V
	Frontline Combo Spot-on Cat	Change in pack size of the finished product	POM-V
	Frontline Combo Spot-on Dog S		POM-V
	Frontline Combo Spot-on Dog M		POM-V
	Frontline Combo Spot-on Dog L		POM-V
	Frontline Combo Spot-on Dog XL		POM-V
Neptune Pharma Limited	Azasure 500 mg/g Powder for Suspension for Fish Treatment	Shelf-life change	POM-V
Norbrook Laboratories Limited	Combisyn 50 mg Tablets for Dogs and Cats	Change in the invented name to Clavapet	POM-V
	Combisyn 250 mg Tablets for Dogs		POM-V
	Combisyn Palatable Tablets 500 mg for Dogs		POM-V
	Combisyn Suspension for Injection		POM-V
	Depidex Pour-on Solution 0.5% w/v	Change in distributor details	POM-VPS
	Duphamox Palatable Drops 50 mg/ml		POM-V
	Duphamox Palatable Tablets 40 mg		POM-V
	Duphamox Palatable Tablets 200 mg		POM-V
	Pestigon 2.5 mg/ml Cutaneous Spray Solution for Cats and Dogs	Change in the invented name to Fiproclear	POM-V

Company	Product	Brief Details	Legal Category
Novartis Animal Health UK Ltd	Adequan 100 mg/ml Solution for Injection	Change of marketing authorisation holder from Novartis Animal Health UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR to Daiichi Sankyo Altkirch SARL, 39, rue de 3-ème Zouaves, BP 60005, 68131	POM-V
	Adequan 250 mg/ml Solution for Injection		POM-V
	Adequan IM 500 mg/5 ml Solution for Injection		POM-V
Orion Corporation	Domitor 1 mg/ml Solution for Injection	Change in distributor details	POM-V
	Domosedan 10 mg/ml Solution for Injection		POM-V
Sogeval	Kesium 625 mg Chewable Tablets for Dogs	Shelf-life change	POM-V
Vetpharma Animal Health, S.L	Nefotek 100 mg/ml Solution for Injection for Cattle, Horses and Pigs	Change in distributor details	POM-V
	Tolcox 50 mg/ml Oral Suspension for Pigs	Addition of new pack size	POM-V
VetPlus Ltd	Switch 4% w/v Pour-on Solution	Change in distributor details	AVM-GSL
Virbac S.A.	Deltanil 10 mg/ml Pour-on Solution for Cattle and Sheep	Shelf-life change	POM-VPS
Zoetis UK Limited	Blackleg Vaccine	Shelf-life change	POM-VPS
	Dysect Sheep Pour-on Alphacypermethrin 12.5 g/l Pour-on Solution		POM-VPS
	Zermasect Sheep Pour-on Alphacypermethrin 12.5 g/l Pour-on Solution		POM-VPS
	Linco-Spectin 100 Soluble Powder, Powder for Oral Solution		POM-V

EUCE AUTHORISATIONS ISSUED BETWEEN 8 DECEMBER 2014 - 5 MARCH 2015

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	EU/2/14/176/001-016	Bovela Lyophilisate and Solvent for Suspension for Injection for Cattle	Bovine viral diarrhoea virus	POM-V
Merial Animal Health Ltd	EU/2/14/177/001-003	Nexgard Spectra 9.375 mg/1.875 mg Chewable Tablets for Dogs	Afoxolaner Milbemycin Oxime (A3 and A4)	POM-V
	EU/2/14/177/004-006	Nexgard Spectra 18.75 mg/3.75 mg Chewable Tablets for Dogs		POM-V
	EU/2/14/177/007-009	Nexgard Spectra 37.5 mg/7.5 mg Chewable Tablets for Dogs		POM-V
	EU/2/14/177/010-012	Nexgard Spectra 75 mg/15 mg Chewable Tablets for Dogs		POM-V
	EU/2/14/177/013-015	Nexgard Spectra 150 mg/30 mg Chewable Tablets for Dogs		POM-V
Pfizer Ltd	EU/2/14/179/001-002	Suvaxyn CSF Marker lyophilisate and Solvent for Suspension for Injection for Pigs	Classical Swine Fever E2 recombinant BVDV	POM-V
Zoetis Belgium	EU/2/14/178/001	Zulvac SBV	Schmallenberg virus	POM-V

EUCE AUTHORISATIONS VARIED BETWEEN 8 DECEMBER 2014 - 5 MARCH 2015

Company	Product Name	Brief Details	Legal Category
Boehringer Ingelheim Vetmedica Gmbh	Pexion 100 mg Tablets for Dogs	Shelf-life Change	POM-V
	Pexion 400 mg Tablets for Dogs		POM-V
	ProZinc 40 IU/ml Suspension for Injection for Cats	Change in the Storage Conditions	POM-V
	ProZinc 40 IU/ml Suspension for Injection for Cats		POM-V
	ProZinc 40 IU/ml Suspension for Injection for Cats		POM-V
Eli Lilly & Company Ltd	Comfortis 90 mg Chewable Tablets for Dogs and Cats	Amendment to MAH address to include Elanco Animal Health in the full address, Eli Lilly and Company Limited, Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, RG24 9NL	POM-V
	Comfortis 140 mg Chewable Tablets for Dogs and Cats		POM-V
	Comfortis 180 mg Chewable Tablets for Dogs and Cats		POM-V
	Comfortis 270 mg Chewable Tablets for Dogs and Cats		POM-V
	Comfortis 425 mg Chewable Tablets for Dogs and Cats		POM-V
	Comfortis 665 mg Chewable Tablets for Dogs		POM-V
	Comfortis 1040 mg Chewable Tablets for Dogs		POM-V
	Comfortis 1620 mg Chewable Tablets for Dogs		POM-V
	Trifexis 270 mg/4.5 mg Chewable Tablets for Dogs		POM-V
	Trifexis 425 mg/7.1 mg Chewable Tablets for Dogs		POM-V
	Trifexis 665 mg/11.1 mg Chewable Tablets for Dogs		POM-V
	Trifexis 1040 mg/17.4 mg Chewable Tablets for Dogs		POM-V
	Trifexis 1620 mg/27.0 mg Chewable Tablets for Dogs		POM-V
IDT BIOLOGIKA GMBH	Ecoporc Shiga Suspension for Injection for Pigs	Shelf-life Change	POM-V
Merial	Btvpur Alsap 1- 8 Suspension for Injection for Sheep and Cattle	Shelf-life Change	POM-V
	Btvpur Alsap 1 Suspension for Injection for Sheep and Cattle		POM-V
	Certifect 134 mg/ 120.6 mg/ 160 mg Spot-on for Dogs 10-20 kg		POM-V
	Certifect 268 mg/ 241.2 mg/ 320 mg Spot-on for Dogs 20-40 kg		POM-V
	Certifect 402 mg/ 361.8 mg/ 480 mg Spot-on for Dogs 40-60 kg		POM-V

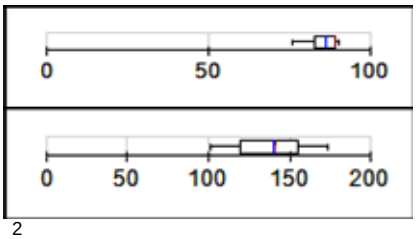
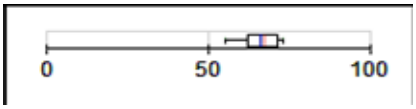
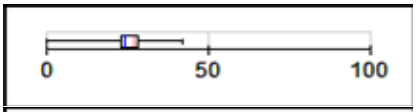
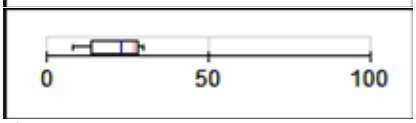
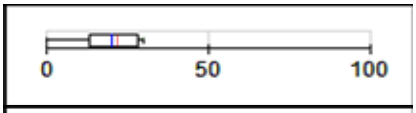
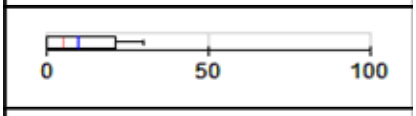
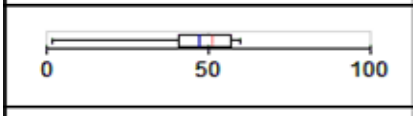
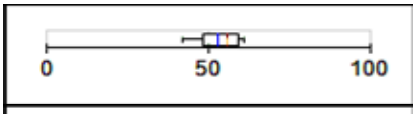
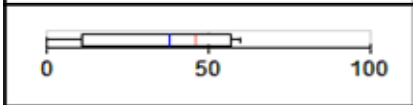
MARKETING AUTHORISATIONS EXPIRED BETWEEN 8 DECEMBER 2014 - 5 MARCH 2015

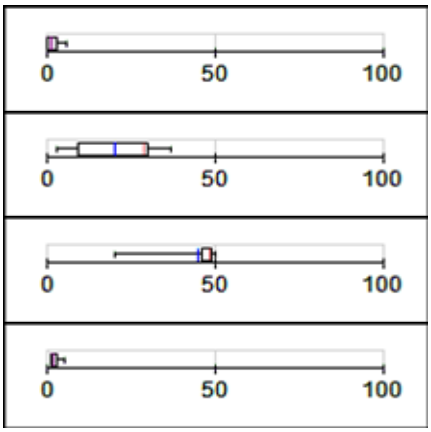
Company	Vm Number	Product Name	Legal Category
Beaphar Ltd	05496/4026	Sherley's Flea Collar for Cats 15% w/w	AVM-GSL
Boehringer Ingelheim Ltd	00015/4071	Bisolvon 3 mg/ml Solution for Injection	POM-V
Dechra Veterinary Products A/S	24883/4002	Sebolyse Shampoo for Dogs and Cats	POM-V
Eli Lilly & Company Ltd	00006/4135	Elanco Scour Formula Powder for Oral Solution	AVM-GSL
	00006/4131	Lectade Powder for Oral Solution	AVM-GSL
	00006/4132	Lectade Small Animal Powder for Oral Solution	AVM-GSL
Intervet UK Ltd	01708/4313	Fertagyl 0.10 mg/ml, Solution for Injection	POM-V
	01708/4284	Nobilis IB H120	POM-VPS
Krka Dd	01656/4024	Marbiflox 20 mg/ml Solution for Injection for Cattle (Calves) and Pigs	POM-V
	01656/4025	Marfloquin 20 mg/ml Solution for Injection for Cattle (Calves) and Pigs	POM-V
Listow Limited	41687/4007	Amoxygen 40 mg Tablets	POM-V
	41687/4006	Amoxygen 200 mg Tablets	POM-V
Virbac S.A.	05653/4000	Canovel Insecticidal Conditioning Collar for Dogs 15% w/w	AVM-GSL
	05653/4085	Catovel 15% w/w Insecticidal Conditioning Collar for Cats	AVM-GSL
	05653/4113	Zolan 100 mg Tablets for Dogs	POM-V
Zoetis Belgium	EU/2/07/071/001-003	Slentrol 5 mg/ml Oral Solution for Dogs	POM-V
	EU/2/11/136/001	Truscient 0.66 mg Kit for Implant for Dogs	POM-V

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 April 2014 to 31 March 2015.

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	**57**	**Excellent**	**90**	**86**	
Sign off (Applications validated >1/4/2011)	**50**	**Excellent**	**180**	**140**	
Sign off and issue (Applications validated <1/4/2011)	**0**		**210**		[2]
MAPIs for MR products & copy-cats					
Initial assessment	**12**	**Excellent**	**75**	**66**	
Sign off	**3**	**Excellent**	**130**	**78**	[2]
Variations					
Type 1A - decision (30 days)	**155**	**Excellent**	**30**	**24**	
Admin - Less than 10 changes	**22**	**Excellent**	**30**	**23**	
Admin - 10 or more changes	**0**		**60**		[2]
Type 1B - initial assessment	**165**	**Excellent**	**30**	**20**	
Type 1B - sign off	**153**	**Excellent**	**30**	**10**	
Type II - initial assessment	**40**	**Excellent**	**60**	**47**	
Type II - sign off	**44**	**Excellent**	**60**	**30**	
Renewals					
Initial assessment	**11**	**Ineffective**	**60**	**53**	
Sign off	**9**	**Excellent**	**60**	**38**	
Batch release (Immunologicals)					
Issue	**2516**	**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	25	Effective	5	1	
Type A and S - sign off	10	Ineffective	30	19	
Type B - sign off	13	Excellent	50	45	
Type A, S and B - issue	22	Excellent	5	2	
Specific Batch Control					
Validation	49	Excellent	3	1	
Initial assessment	48	Excellent	10	2	
Assess response	48	Excellent	10	1	
Issue	47	Excellent	3	1	
Validation/Issue					
Validation	349	Excellent	10	5	
Issue	852	Excellent	10	6	
Pharmacovigilance					
Enter human Pharmacovigilance	125	Excellent	2		
Enter serious animal Pharmacovigilance	3634	Excellent	2		
Enter environmental Pharmacovigilance	26	Ineffective	2		
Enter non-serious Pharmacovigilance	1671	Excellent	10		
Report to Eudravigilance	5027	Excellent	15		
SIC/STC					
Urgent products not previously imported	2	Excellent	5	<1	
Routine products not previously imported	112	Excellent	15	4	
Urgent products previously imported	398	Excellent	2	2	
Routine products previously imported	4906	Excellent	10	4	
On-line instantaneous issue of certificates	14938	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	**41**	**Excellent**			
GDP inspections performed on a risk-basis within 5 years of last inspection	**33**	**Excellent**			
Written deficiency reports sent after GMP and GDP inspection	**71**	**Excellent**	**30**	**22**	
Issue GMP Certificate after last day at site	**38**	**Excellent**	**90**	**83**	
Updated documentation for GDP site issued after last day at site	**31**	**Excellent**	**90**	**71**	
UKPARs					
Make publicly available via the VMD internet & SPC for New MA.	**211**	**Excellent**	**30**	**13**	
Make publicly available via the VMD internet the relevant hyperlink to the EMA website for centralised products within 30 days of issue.	**23**	**Excellent**	**30**	**13**	
Make publicly available via Product Information Database	**121**	**Excellent**	**120**	**102**	
Make publicly available after issue of post-authorisation assessments	**933**	**Excellent**	**60**	**37**	

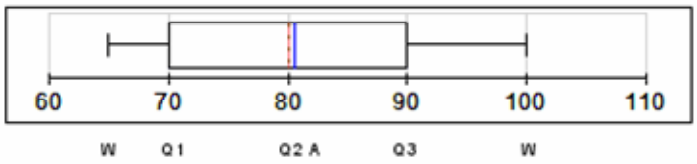
Box-and-Whisker Plots

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, A), 80, 85 (Q3), 90, 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	14	Excellent	100
Mutual Recognition			
RMS			
Production of Final Assessment Report by day 90 (Phase 1)	6	Excellent	90
RMS Circulate the Consolidated List of Questions by day 57	4	Excellent	57
Assessment of Responses by day 70 (Phase 2)	3	Ineffective	70
Procedure completed by day 90 (Phase 2)	4	Excellent	90
CMS			
CMS send any UK comments by day 54 (Phase 2)	13	Excellent	54
Procedure completed by day 90 (Phase 2)	13	Excellent	90
Decentralised			
RMS			
Production of Assessment Report by day 70 (Phase 1)	69	Excellent	70
Production of Assessment Report by day 120 (Phase 1)	53	Excellent	120
RMS Circulate Consolidated List of Questions by day 30 (Phase 2)	43	Excellent	30
Assessment of Responses by 70 days (Phase 2)	68	Excellent	70
RMS send confirmation of acceptance/referral by Day 90 (Phase 2)	68	Excellent	90
CMS			
UK comments sent by 100 days (Phase 1)	34	Excellent	100
CMS Send any UK Comments by day 25 (Phase 2)	40	Excellent	25
UK acceptance/referral sent by 90 days [2nd phase]	46	Excellent	90[210]
European Variations			
Type 1B EUCE Rapp			
Initial Assessment Completed according to EMA timetable	4	Excellent	
Type II EUCE Rapp			
Initial Assessment Completed according to EMA timetable	5	Excellent	
Type II - Mutual Recognition RMS			
PAR circulated by day 40 (Phase 1)	38	Excellent	40
CLOQ or decision circulated by day 59 (Phase 1)	37	Excellent	59
Type IB - Mutual Recognition RMS			
CLOQ or decision circulated by day 30 (Phase 1)	102	Excellent	30
Type IA - Mutual Recognition RMS			
Determined within 30 days	73	Excellent	30
Type II Mutual Recognition CMS			
UK comments sent by day 55 (Phase 1)	69	Excellent	55
UK comments sent by day 80 (Phase 2)	54	Excellent	80
Type IB Mutual Recognition CMS			
UK comments sent by day 20 (Phase 1)	98	Excellent	20
UK comments sent by day 50 (Phase 2)	17	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)	**40**	**Excellent**	**40**
CLOQ circulated by day 59 (Phase 1)	**39**	**Excellent**	**59**
Mutual Recognition CMS			
UK Comments sent by day 55 (Phase 1)	**49**	**Excellent**	**55**
UK Comments sent by day 80 (Phase 2)	**49**	**Excellent**	**80**
Others (Centralised)			
UK as Rapporteur - Complete IA according to EMA timetable	**1**	**Excellent**	
Customer Relations			
Unreturned authorisation documents			
Right first time (Authorisations)	**2484**	**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 5 MAY 2015

Annex 2