MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 98 - APRIL 2016

2016 PHARMACEUTICAL INDUSTRY CUSTOMER SATISFACTION SURVEY – THE RESULTS ARE IN

We would like to say a big thank you to everyone who responded to our survey. 218 people responded (an 88% increase on the last survey in 2014). We received responses from a cross-section of the veterinary pharmaceutical industry, including NOAH and non-NOAH companies, a range of different sized companies in the UK and overseas, with people from manufacturing and wholesaler sites and regulatory offices responding. The wide range of evidence and views is invaluable to us in understanding our customers' needs and expectations.

We are delighted that the 2016 survey shows we have maintained and, in many areas, improved on the very high levels of customer satisfaction shown in the last survey.

We will be presenting the findings of the survey to you at our Industry Information Day on 1 July 2016. In the meantime we wanted to give you some of the highlights:

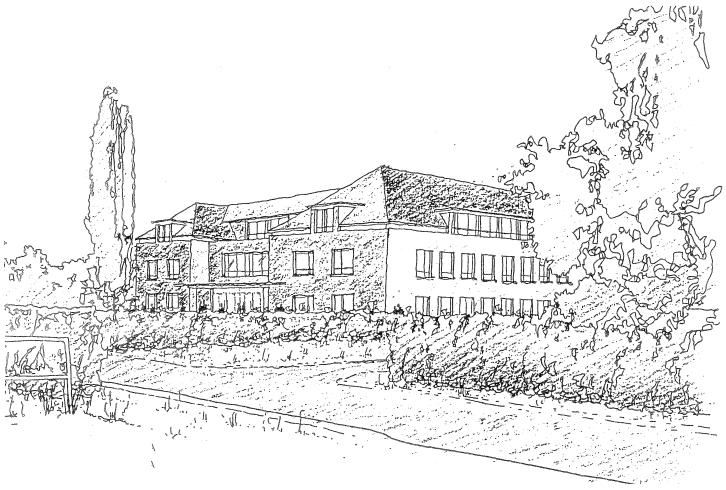
- 87% of you scored our overall level of service across all our activities as Good or Excellent
- Three quarters of you rated us as Good or Excellent compared to the five large agencies in the EU
- You ranked us the best on all but one of the survey's parameters compared to the five large agencies in the EU

But we are not complacent. We are analysing the findings and identifying areas where we need to take action to further improve our services to you.

We will give you details of the actions we plan to take at the Industry Information Day. We will publish our action plan in the next edition of *MAVIS* along with full details of the survey's findings.

The survey was carried out by Mo Gannon Associates Ltd. We optimised the survey (content and process) based on previous results and it consisted of two phases - a first quantitative phase involving a web based survey followed by one to one telephone interviews to explore in-depth with those customers who were not fully satisfied with a number of services and had indicated their willingness to take part in this second qualitative phase.

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



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Veterinary Medicines Directorate

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Tel: +44 (0)1932 336911 Search for VMD on GOV.UK
Email: postmaster@vmd.defra.gsi.gov.uk

NEWS

THE VMD PHARMACEUTICAL INDUSTRY INFORMATION EVENT ON FRIDAY 1 JULY 2016

The VMD will be holding an Information Event for the Pharmaceutical Industry on Friday 1 July 2016. We are currently developing the schedule for the day and we are inviting your suggestions on areas you would like to see covered. The results of our Pharmaceutical Industry Customer survey will be included in the program of the event.

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, email: n.burge@vmd.defra.gsi.gov.uk, 01932 338349).

CHANGES TO VMD BANK DETAILS

Please keep a note of the following changes when making a bank transfer to the VMD.

Our bank account details changed on 18 January 2016.

The account details are as follows:

- account name: DEFRA - VMD
- account number: 10001867
- sort code: 60-70-80
- swift code: NWBKGB2L
- IBAN: GB84NWBK60708010001867

National Westminster Bank
RBS, London Corporate Service Centre, 2nd Floor
280 Bishopsgate
London
EC2M 4RB

Send remittance details to:

Accounts Payable
VMD
Woodham Lane,
New Haw, Addlestone
Surrey, KT15 3LS

or email details to: ***finance@vmd.defra.gsi.gov.uk***.

CHANGES TO THE ACCREDITED INTERNET RETAILER SCHEME (AIRS)

The Accredited Internet Retailer Scheme (AIRS) has been running for nearly three years and we consider it to have been a great success. With 35 accredited websites it's been very effective in improving overall practice in the supply of veterinary medicines via the internet. It has also benefitted consumers by providing reassurance that AIRS members take their responsibilities as animal health professionals and retailers seriously and are complying with the law.

However, we're always looking for ways to improve the scheme. A recent audit of our procedures for processing AIRS applications found that assessing them took up a considerable amount of VMD staff time due to:

- Some websites being very large with a wide range of products that are time-consuming to navigate
- Having to check non-medicinal products are not making medicinal claims. Preparing detailed feedback on each application and reviewing and following-up responses.

In light of the audit's findings, the voluntary status of the scheme and that accreditation is free, we do not consider the scheme is sustainable in its current form.

We've therefore carried out a review of AIRS to simplify the accreditation process whilst maintaining appropriate controls on the supply of veterinary medicines by internet retailers.

We would welcome your views and comments. If you would like to see and comment on our proposals, please email the team at ***inspections@vmd.defra.gsi.gov.uk***.

We would like to introduce changes to the scheme in the summer so we would be grateful for your responses by 20 May 2016. We are of course, happy to receive other feedback about the scheme at any time.

Please send comments or feedback to inspections@vmd.defra.gsi.gov.uk.

LICENSING

CHANGES TO THE WAY MOCK-UPS ARE DEALT WITH:

GUIDANCE FOR MARKETING AUTHORISATION HOLDERS (MAH)

We are changing the way we deal with mock-ups from 1 April 2016. This applies to all Marketing Authorisation (MA) and veterinary homeopathic remedy (VHR) applications NOT dealt with via the centralised application procedure.

At the moment, you are asked to provide revised mock-ups for assessment for all applications that affect them. From 1 April 2016, you will only have to provide revised mock-ups in some cases.

When will we want to see revised mock-ups

- For all new MA and VHR applications
- For all variation-extension applications
- For renewal and variation applications where the number and/or type of change being proposed means it would be easier to see revised mock-ups rather than annotating the changes ourselves
- For any application on a product where we do not currently hold electronic versions of the mock-ups

Where mock-ups are not requested, we will annotate the agreed changes onto the latest authorised versions and issue these to you.

All mock-ups will be assessed by the same team during a separate mock-up phase; this will help ensure consistency of approach.

Mock-ups should reflect the agreed Quality Review of Documentation (QRD), and we will be placing more emphasis on the assessment and maintenance of QRD text from 1 April 2016.

All mutually recognised products have agreed QRD text, but most nationally authorised products do not. To help us get QRD text for all nationally authorised products and to facilitate mock-up procedures for these products, please see 'Getting QRD text for national products' on GOV.UK.

Revised guidance on GOV.UK

See SPCs and Product Literature on GOV.UK for more information. This provides updated guidance on the production and submission of SPCs, QRD text and mock-ups from 1 April 2016.

Transition Period

National applications that pass validation on/after 1 April 2016 will be subject to the new procedures. Any application that is already in the system and passes validation before 1 April 2016 will be subject to current mock-up procedures.

EU applications that have already entered the national phase will be subject to current mock-up procedures.

Getting QRD text for national products

Please submit QRD text for review against the latest authorised mock-ups and SPC by 31 July 2017**;** no fee will apply. Please use this form when submitting your QRD for review.

Please note, if your product is due for renewal, you can submit QRD text for approval as part of the renewal process instead.

We will check your QRD text and aim to issue the agreed version back to you within 90 days of receipt. Once QRD text has been agreed, please submit a revised version with all future applications that affect it.

If you wish to submit revised QRD text and mock-ups for assessment, i.e. to update the QRD using the latest template, please do so under cover of a Type IB variation (C.II.6(b)), which will be dealt with as per normal variation procedures.

Other changes

We will no longer identify non-marketed pack sizes on the memorandum document.

When submitting mock-ups for assessment, please use the category C.II.6(b), not C.I.z.

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

SUBMISSION OF MOCK-UP CHANGES VIA NOTIFICATION

Any change to mock-ups that does not affect approved text or legibility (e.g. font size, layout) may be introduced via a notification.

If you wish for any changes to be considered as a notification, submit an email request to ***notification@vmd.defra.gsi.gov.uk*** and include the following information:

- Detail all proposed change(s) in comparison to the current authorised mock up(s).
- Confirm that all other text remains unchanged (to include wording and font size).

If you choose to provide mock ups these will be used to help define the proposed changes but will NOT be assessed.

If you cannot make this change by way of notification, you will need to submit a variation in the usual way.

For joint labelled products, you will also need to consult directly with the HPRA.

There is no fee for a notification.

Search 'mock up notification' on GOV.UK.

For further information please email: notification@vmd.defra.gsi.gov.uk.

CHANGES TO FEES CHARGED FOR NATIONAL WORKSHARE VARIATIONS

The VMD has reviewed the fee charged for national workshare variations when the UK role is 'other' (Paragraph 18, Schedule 7 of the Veterinary Medicines Regulations (VMR)).

We are pleased to announce this fee will be administratively reduced from **1 April 2016** from £12,060 to £6,030**.** An administrative reduction is one that can be made without the need to amend the VMR.

This revised fee will apply to applications that pass validation on/after 1 April 2016.

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

TOP TEN IMPORTED VETERINARY MEDICINES QUARTERLY REPORT FROM 1 JANUARY TO 31 MARCH 2016

The VMD provides a list on a quarterly basis of the ten products for which most Special Import and Special Treatment Certificates (SIC and STC) have been granted. This list contains details of the product, the active ingredient and the number of certificates issued. Where appropriate it will also indicate those imported products where a UK product is now authorised and available; no further imports of these products will be permitted.

We hope the pharmaceutical industry find this list helpful in considering where there might be a need for a UK authorised product.

Product	Active Ingredient	No. of Certificates Issued
Artuvetrin® Therapy, suspension for subcutaneous injection in dogs	Allergens	2,459
Vet-Goid	Allergens	302
Spectrum Hyposensitisation Vaccine - Injectable Solution	Allergens	201
Pneumabort-K +1b **	Equine Rhinopneumonitis Virus	200
Botulism Vaccine	Clostridium botulinum type C toxoid Clostridium botulinum type D toxoid	182
Greer Allergenic Extract Patient Prescription	Allergens	176
Antepsin **	Sucralfate	90
Staphage Lysate (SPL)	Staphylococcus aureus	68
Artuvetrin® Test, injection fluid for intracutaneous use in dogs.	Allergens	62
Oncept (Canine Melanoma Vaccine)	Canine Melanoma DNA	61

***Supply problem with UK 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* one seizure notice has been published.

Oldfield Lodge Vets/AA Rescue, Chelmsford, Essex. The following products were seized as they are not authorised for use in the UK:

2 x 30 tablets Zyloric 300 mg Alopurinol
3 x 30 tablets Alopurinol Mundogen
5 x 5ml ampoules Glucantime 300 mg/ml

IMPROVEMENT NOTICES

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

Paynes Southdown Bee Farm, Hassocks, West Sussex. Apiguard was being presented for sale in 3 kg tubs which are not authorised for use in the UK, and unauthorised veterinary products were being presented for sale with claims to treat or prevent disease. These are offences under Regulation 4 (Placing a veterinary medicinal product on the market) of the Veterinary Medicines Regulations.

The improvements are to:

- Cease marketing and sale of the 3 kg Apiguard tubs on the UK market.
- Remove all medicinal claims presenting products to treat or prevent disease from the Paynes Bee Farm website and from any other Paynes Bee Farm marketing material. This includes publicity via social media, leaflets, in store advertising, product descriptions and customer testimonials.

Horsebridge Veterinary Practice, High Street, Hailsham, East Sussex. Medicines such as Carprieve 100 mg have been supplied to customers labelled as Rimadyl and incorrect records kept of the actual medicines supplied.

This is a breach of Regulation 23 (Records of the receipt or supply of prescription products) and Schedule 3 paragraph 12(3) (Labelling at the time of retail supply) of the Veterinary Medicines Regulations.

The improvements are for Horsebridge Veterinary Practice to ensure that all medicines are labelled correctly at the time of dispensing, and to ensure that it keeps full and correct records of medicines obtained and supplied.

Parklands Veterinary Clinic, Cookstown, County Tyrone. Supplies of an unauthorised veterinary medicine, namely Botulism vaccine, to veterinary practices without a special treatment certificate (STC) in place.

Improvements are to update procedures and to retrain staff on the supply of Botulism vaccines and STCs and not to supply the product until the premises is in possession of a valid STC for the product.

Please report any information you have about suspected illegal medicines or breaches of the Veterinary Medicines Regulations to enforcement@vmd.defra.gsi.gov.uk.

If it is regarding a non medicinal product (product making unauthorised claims etc.) please submit an 'Unauthorised Product Complaint Reporting Form' which is available on GOV.UK.

All information will be treated confidentially.

PHARMACOVIGILANCE

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

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

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

QUARTERLY REPORT

During the period 1 January to 31 March 2016, the VMD received 1,276 suspected adverse event reports involving animals. Of these, 40 reports related to unauthorised or unidentified products, four reports involved animal trials under Animal Test Certificates (ATCs) and seven further reports were from studies not requiring ATCs.

Excluding these three categories, the remaining 1,225 suspected adverse event reports were associated with 349 authorised products in the following distribution categories:

1,088	Prescription Only Medicine - Veterinarian (POM-V)
80	Prescription Only Medicine - Veterinarian, Pharmacist, SQP (POM-VPS)
16	Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
33	Authorised Veterinary Medicine - General Sales List (AVM-GSL)
8	Products sold under the Exemption for Small Pet Animals (N/A)

During the quarter 40 reports of human suspected adverse reactions and no environmental incident reports were received.

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

ANTIMICROBIAL RESISTANCE

Concerns about the impact of antimicrobial resistance has led to increasing consideration about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. A cross-Government AMR Strategy has been developed to address this issue. The Veterinary Medicines Directorate is responsible for delivering the animal health aspects of this Strategy. The following articles describe the most recent actions that we have taken.

DARC GROUP UPDATE

The most recent meeting of the Defra Antimicrobial Resistance Co-ordination (DARC) group was on 9 February 2016. Recent trends in antibiotic resistance in bacteria of importance to human and animal health were discussed; significant discussion was given to colistin resistance in the UK. The group also discussed preliminary results from a Livestock-Associated Methicillin Resistant *Staphylococcus aureus* (LA-MRSA) survey in people, as well as the harmonisation of antibiotic sensitivity testing (AST) in veterinary laboratories across the UK. The next DARC meeting is scheduled for 1 June 2016.

Additionally, a joint DARC/ARHAI (Antimicrobial Resistance and Healthcare Associated Infections) 'Colistin Workshop' was hosted at Richmond House after the DARC meeting. The workshop was attended by human health colleagues from the Department of Health (DH) and Public Health England (PHE) as well as representatives from the pig and poultry industry. The group exchanged knowledge on colistin use and resistance in human and veterinary medicine and sought to identify current evidence on and knowledge gaps surrounding the issue. Presentations on colistin use and resistance were received from PHE, the Animal and Plant Health Agency (APHA), the VMD, the British Poultry Council (BPC) and the Pig Veterinary Society (PVS).

SALES DATA REPORT AND ANTIBIOTIC RESISTANCE SURVEILLANCE REPORT

The 2014 UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report was published on 18 November 2015. The report presents 2014 antibiotic sales data as collected from UK Marketing Authorisation Holders alongside antibiotic resistance data generated by the VMD's AMR surveillance programme. Additionally, a high level summary report was also published alongside the main report. This report and previous reports can be found at:

https://www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2014

Collation of sales and resistance data for inclusion in the 2015 UK-VARSS Report will begin in the next few weeks.

EUROPEAN SURVEILLANCE OF ANTIMICROBIAL CONSUMPTION (ESVAC)

The ESVAC annual network meeting was held at the European Medicines Agency (EMA) on 1 and 2 March 2016. Preliminary analysis of 2014 antibiotic sales data across the EU was presented and discussed. Other agenda items included the draft ESVAC strategy 2016-2020, the development of protocols for the collection of consumption data by species and the development of technical units to analyse these data.

UK AMR SUMMIT

Gathering key representatives from across different animal sectors and government the VMD hosted its second Antibiotic Resistance Summit on the 29 February 2016. The morning consisted of presentations from the pig, poultry and small animal sectors outlining case studies where new initiatives and interventions had resulted in a reduction in the need for antibiotics. Farm Animals Initiatives gave a presentation on applying the '3Rs' in Antimicrobial Stewardship and updates were received from the Devolved Administrations along with a speech from the Minister of State for Farming, Food and the Marine Environment.

In the afternoon discussion groups addressed key questions regarding antibiotic stewardship and exchanged suggestions on approaches to achieve shared aims. The meeting was successful in highlighting key barriers for implementing alternative practices to antibiotic use, and discussing further actions to devise a stewardship plan for each sector. Thank you to all those who gave up their time to attend.

HEADS OF MEDICINES AGENCY (VETERINARY) (HMA-V) UPDATE

The VMD chairs the Heads of Medicines Agencies – Veterinary (HMA-V) group, 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 most recent HMA-V meeting was held on 12 January 2016. Topics discussed included plans for collection of antimicrobial consumption data and plasmid mediated colistin resistance.

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 February 2016. Summary minutes of the meetings held since May 2014 are available on GOV.UK at www.gov.uk/government/organisations/veterinary-products-committee/about/membership.

Minutes of meetings held between 2009 and May 2014 are available on the National Archives website at webarchive.nationalarchives.gov.uk/20140909095305/http:/www.vmd.defra.gov.uk/vpc/.

Comments or requests for further information on the summary minutes should be sent to Lea Stott (VMD, email: l.stott@vmd.defra.gsi.gov.uk, 01932 338490).

RESIDUES CONTROLS AND MONITORING

The VMD operates the National Surveillance Scheme (NSS) which implements EU legislation and therefore has a statutory basis. This programme monitors the use of veterinary medicines and unauthorised substances in UK food producing animals and is funded by the industry sectors in accordance with EU legislation.

■ RESULTS OF STATUTORY SURVEILLANCE

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

For further information please contact: Carol Brailsford (VMD, email: c.brailsford@vmd.defra.gsi.gov.uk, 01932 338330).

STAFF CHANGES

The following staff changes took place during this quarter:

New Staff

- Stacey Brown joined the Antimicrobial Resistance Control and Surveillance team on 10 February 2016
- Tahira Kauser joined the Committee and Office Support team on 16 March 2016
- Jan Horn joined the Pharmaceuticals and Feed Additives team on 4 April 2016
- Fraser Broadfoot joined the Antimicrobial Resistance Control and Surveillance team on 25 April 2016
- Mike Griffiths will join us as Head of the Business Support team on 9 May 2016

Departing Staff

- Nick Renn retired on 29 January 2016
- Amarinder Singh resigned on 2 March 2016
- Jo Cawthorne left on 10 March 2016
- Aline Goult resigned on 29 March 2016
- Lesley Theofanous retired on 31 March 2016
- Brian Timms resigned on 15 April 2016
- David Rayner retired on 18 April 2016

Promotions

- Robin Bedford was temporarily promoted within the IT team on 25 January 2016
- Claire Stratford was promoted within the Pharmaceuticals and Feed Additives team on 1 February 2016
- Lea Reynolds, Lee Grist, Anna Burrows and Denise Burge were temporarily promoted within the Legislation team on 1 February 2016
- Alison Jones was temporarily promoted and transferred to the Residues team on 8 February 2016
- David Steer was temporarily promoted and transferred to the IT team on 15 February 2016
- Ken Stapleton was promoted within the Pharmaceuticals and Feed Additives team on 29 February 2016
- David Webb was promoted within the Inspection and Investigations team on 1 April 2016
- David Lewsey was temporarily promoted within the Core Services team on 11 April 2016

Transfers

- Paul Dolton transferred to the Directors Support team on a part-time basis on 21 March 2016
- Giles Davis will transfer to Head of the Legislation team on 16 May 2016

MARKETING AUTHORISATIONS

MARKETING AUTHORISATIONS ISSUED BETWEEN 24 NOVEMBER 2015 - 10 MARCH 2016

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Avimedical B.V.	43564/4001	Orniflox 25 mg/ml Concentrate for Oral Solution for Pet Rabbits, Rodents, Ornamental Birds and Reptiles	Enrofloxacin	POM-V
C&H Generics Ltd	40162/4017	Extrontel Plus XL Tablets for Dogs	Febantel, Praziquantel, Pyrantel	NFA-VPS
	40162/4018	Ezi-Wormer Plus XL Tablets for Dogs		NFA-VPS
	40162/4019	Ridaworm Plus XL Tablets for Dogs		NFA-VPS
	40162/4020	VetUK Plus XL Dog Wormer Tablets		NFA-VPS
Ceva Animal Health Ltd	15052/4077	Strectis 68 mg/34 mg Spot-on Solution for Cats 0.5-5 kg	(S)-Methoprene, Fipronil	POM-V
	15052/4076	Tildren 500 mg Lyophilisate for Solution for Infusion for Horses	Tiludronic Acid	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4059	Epromec 5 mg/ml Pour-on Solution for Beef and Dairy Cattle	Eprinomectin	POM-VPS
	08749/4061	Zepromec 5 mg/ml Pour-on Solution for Beef and Dairy Cattle		POM-VPS
	08749/4060	Zeromectin 5 mg/ml Pour-on Solution for Beef and Dairy Cattle		POM-VPS
Cross Vetpharm Group Ltd	12597/4065	Tetroxy Vet 200 mg/ml Solution for Injection for Cattle, Sheep and Pigs	Oxytetracycline, Oxytetracycline Dihydrate	POM-V
Desitin Arzneimittel GmbH	14040/4000	Epirepress 60 mg Tablets for Dogs	Phenobarbital	POM-V
Eurovet Animal Health B.V.	16849/4053	CTC Spray 78.6 mg/g Cutaneous Spray, Suspension for Pigs, Sheep and Cattle	Chlortetracycline Hydrochloride, Chlortetracycline	POM-V
	16849/4054	Phenocillin 800 mg/g Powder for Use in Drinking Water for Chickens	Phenoxymethylpenicillin Potassium	POM-V
Global Vet Health S.L.	36167/4004	AMOXICILLIN GLOBAL VET HEALTH 500 mg/g Powder for Use in Drinking Water for Chickens, Turkeys, Ducks and Pigs	Amoxicillin Trihydrate, Amoxicillin	POM-V
Huvepharma N.V.	30282/4021	Gutal 1000 mg/g Premix for Medicated Feeding Stuff for Piglets	Zinc Oxide	POM-V
IDT BIOLOGIKA GMBH	26750/4010	Salmovac 440 Lyophilisate for Use in Drinking Water	Salmonella enteritidis	POM-V
Industrial Veterinaria, S.A.	36547/4006	Sedecalm 1 mg/ml Solution for Injection for Dogs and Cats	Medetomidine Hydrochloride	POM-V
Kernfarm B.V.	43877/4002	Rotavec Corona Emulsion for Injection for Cattle	Bovine coronavirus, Bovine rotavirus, Escherichia coli	POM-VPS

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Krka d.d., Novo Mesto	01656/4092	Ataxxa 500 mg/100 mg Spot-on Solution for Dogs Over 4 kg up to 10 kg	Imidacloprid, Permethrin (Cis:Trans 40:60)	POM-V
	01656/4094	Ataxxa 2000 mg/400 mg Spot-on Solution for Dogs Over 25 kg		POM-V
Le Vet Beheer B.V.	41821/4026	Enrobactin 25 mg/ml Concentrate for Oral Solution for Pet Rabbits, Rodents, Ornamental Birds and Reptiles	Enrofloxacin	POM-V
	41821/4029	Metrobactin 250 mg Tablets for Dogs and Cats	Metronidazole	POM-V
	41821/4030	Metrobactin 500 mg Tablets for Dogs and Cats		POM-V
Merial Animal Health Ltd	08327/4264	Eurican Lmulti Suspension for Injection	Leptospira canicola Leptospira grippotyphosa Leptospira icterohaemorrhagiae	POM-V
	08327/4273	Bovalto Respi 3 Suspension for Injection for Cattle	Bovine parainfluenza virus 3, Bovine respiratory syncytial virus, Mannheimia haemolytica	POM-V
	08327/4274	Bovalto Respi 4 Suspension for Injection for Cattle		POM-V
	08327/4265	Gallivac IB88 NEO Effervescent Tablet for Suspension for Nebulisation for Chickens	Infectious bronchitis virus	POM-V
Norbrook Laboratories Ltd	02000/4395	Meloxaid 0.5 mg/ml Oral Suspension for Cats	Meloxicam	POM-V
	02000/4396	Meloxaid 1.5 mg/ml Oral Suspension for Dogs		POM-V
	02000/4397	Meloxaid 5 mg/ml Solution for Injection for Dogs and Cats		POM-V
Pharmanovo GmbH	43588/4000	Novomate 277.8 mg/ml Powder and Solvent for Suspension for Injection for Cattle	Penethamate Hydriodide, micronised	POM-V
Pharmaq AS	21714/4005	ALPHA JECT Micro 1 PD Emulsion for Injection, Vaccine for Atlantic Salmon	Salmon pancreas disease virus	POM-V
Tulivin Laboratories Ltd	11810/4011	Tramazole 100 mg/ml SC Oral Suspension for Cattle and Sheep	Albendazole	POM-VPS
Univet Ltd	05150/4004	Curofen 50 mg/g Oral Powder for Pigs	Fenbendazole	POM-VPS
Vetoquinol UK Ltd	08007/4141	Cefaseptin 75 mg Tablets for Dogs	Fenbendazole	POM-V
	08007/4142	Cefaseptin 300 mg Tablets for Dogs		POM-V
	08007/4143	Cefaseptin 750 mg Tablets for Dogs		POM-V
Vetpharma Animal Health, S.L	32509/4020	Vetpril 20 mg Film-coated Tablets for Dogs	Benazepril	POM-V
Virbac	05653/4199	Effipro Duo 50 mg/60 mg Spot-on Solution for Cats	Fipronil, Pyriproxyfen	POM-V
	05653/4195	Effipro Duo 67 mg/20 mg Spot-on Solution for Small Dogs		POM-V
	05653/4200	Effipro Duo 100 mg/120 mg Spot-on Solution for Very Large Cats		POM-V
	05653/4196	Effipro Duo 134 mg/40 mg Spot-on Solution for Medium Dogs		POM-V
	05653/4197	Effipro Duo 268 mg/80 mg Spot-on Solution for Large Dogs		POM-V
	05653/4198	Effipro Duo 402 mg/120 mg Spot-on Solution for Very Large Dogs		POM-V
Zoetis UK Limited	42058/4189	Lutalyse 12.5 mg/ml Solution for Injection for Cattle	Dinoprost Trometamol, Dinoprost	POM-V
	42058/4194	Versiguard Rabies	Rabies virus	POM-V

ALL MARKETING AUTHORISATIONS VARIED BY THE VMD BETWEEN 24 NOVEMBER 2015 - 10 MARCH 2016

Company Name	Product Name	Brief Details	Legal Category
Bayer plc	Advantage 40 Spot-on Solution for Dogs	Addition of secondary packaging site and addition of a pack size	NFA-VPS
	Advantage 100 Spot-on Solution for Dogs		NFA-VPS
	Advantage 250 Spot-on Solution for Dogs		NFA-VPS
	Advantage 400 Spot-on Solution for Dogs		NFA-VPS
Bob Martin (UK) Ltd	Bob Martin Clear Wormer 20 mg Spot-on Solution for Cats and Kittens	Shelf life change	AVM-GSL
Boehringer Ingelheim Ltd	Ingelvac MycoFlex Suspension for Injection for Pigs	Shelf life change	POM-V
	Vetmedin Chew 1.25 mg Chewable Tablets for Dogs	Change of distributor	POM-V
	Vetmedin Chew 5 mg Chewable Tablets for Dogs		POM-V
	Vetmedin Chew 10 mg Chewable Tablets for Dogs		POM-V
C&H Generics Ltd	Dinelix Plus Tablets for Dogs	Change of name from Dinelix Plus to Ridaworm Plus	NFA-VPS
	Target Wormer 230/20 Film-coated Tablets for Cats	Change of name from Target Wormer to Ridaworm	NFA-VPS
Chanelle Pharmaceuticals Manufacturing Ltd	Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	Change of distributor	POM-V
	Fenoflox 100 mg/ml Solution for Injection for Cattle and Pigs		POM-V
	RidaWorm 20 mg Spot-on Solution Cats and Kittens	Shelf life change	AVM-GSL
Dechra Limited	HY-50 Vet 17 mg/ml Solution for Injection	Change in the address of the MAH	POM-V
	Hypertonic 7.2% w/v Solution for Infusion	Change of legal entity	POM-V
	Vetivex 18 (Sodium Chloride 0.18% w/v and Glucose 4% w/v Intravenous Infusion B.P. (Vet))		POM-V
	Pardale-V Oral Tablets	Change in the address of the MAH	NFA-VPS
	Vetivex 1 (9 mg/ml) Solution for Infusion for Cattle, Horses, Dogs and Cats	Change of legal entity	POM-V
	Vetivex 11 (Hartmann's) Solution for Infusion for Cattle, Horses, Dogs and Cats		POM-V
Desitin Arzneimittel GmbH	Epirepress 60 mg Tablets for Dogs	Shelf life change	POM-V
Eurovet Animal Health B.V.	Vomend 5 mg/ml Solution for Injection for Dogs and Cats	Change of distributor	POM-V
Forte Healthcare Ltd	Bovigen Scour Emulsion for Injection for Cattle	Shelf life change	POM-VPS
Forum Products Ltd	Cephorum 250 mg Film-coated Tablets for Dogs	Storage condition changed from 'Do not store above 30°C' to 'Do not store above 25°C'	POM-V
	Cephorum 500 mg Film-coated Tablets for Dogs	Change in pack size of the finished product	POM-V
	Cephorum 500 mg Film-coated Tablets for Dogs	To add a new storage condition 'Do not store above 25°C'.	POM-V
	Cephorum Film Coated Tablets 500 mg	Change of name from Cephorum film-coated tablets 500 mg to Cephorum 500 mg film-coated tablets for dogs	POM-V
HCS bvba	Fipronil + S-methoprene HCS 50 mg/60 mg Spot-on Solution for Cats and Ferrets	Change of name from Fipronil + S-Methoprene HCS to Fypermid	POM-V
	Fipronil + S-methoprene HCS 67 mg/60.3 mg Spot-on Solution for Small Dogs		POM-V
	Fipronil + S-methoprene HCS 134 mg/120.6 mg Spot-on Solution for Medium Dogs		POM-V
	Fipronil + S-methoprene HCS 268 mg/241.2 mg Spot-on Solution for Large Dogs		POM-V
	Fipronil + S-methoprene HCS 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs		POM-V

Company	Product Name	Brief Details	Legal Category
Intervet UK Ltd	Caninsulin 40 IU/ml Suspension for Injection	Change in storage conditions	POM-V
	Leptavoid – H Suspension for Injection for Cattle	Addition of a new presentation (100 ml)	POM-VPS
Laboratoire TVM	Vitamin K1 Laboratoire TVM 50 mg Film-Coated Tablets for Dogs	Shelf life change	NFA-VPS
Le Vet Beheer B.V.	Amoxibactin 50 mg Tablets for Dogs and Cats	Shelf life change	POM-V
	Amoxibactin 250 mg Tablets for Dogs		POM-V
	Amoxibactin 500 mg Tablets for Dogs		POM-V
	Carprodolor 50mg/ml Solution for Injection for Cattle	Change of distributor	POM-V
	Synthadon 5 mg/ml Solution for Injection for Cats and Dogs	Shelf life change	POM-V
	Synthadon 10 mg/ml Solution for Injection for Cats and Dogs		POM-V
Merial Animal Health Ltd	Frontline Comboline Spot-on Cat	Change of name from Frontline Comboline to Frontline Plus	POM-V
	Frontline Comboline Spot-on Dog S		POM-V
	Frontline Comboline Spot-on Dog M		POM-V
	Frontline Comboline Spot-on Dog L		POM-V
	Frontline Comboline Spot-on Dog XL		POM-V
Neptune Pharma Ltd	Azasure 500 mg/g Powder for Suspension for Fish Treatment	Shelf life change	POM-V
Norbrook Laboratories Limited	Aloquan, 18.7 mg/g + 140.3 mg/g Oral Paste for Horses	Change of distributor	POM-VPS
Novartis Animal Health UK Ltd	ACP Injection 2 mg/ml Solution for Injection	Change of distributor	POM-V
	ACP Tablets 10 mg		POM-V
	ACP Injection 10 mg/ml Solution for Injection		POM-V
	Bovidec		POM-V
	Corvental D 100 mg Hard Capsules		POM-V
	Corvental D 200 mg Hard Capsules		POM-V
	Corvental D 500 mg Hard Capsules		POM-V
	Crovect 1.25% w/v Pour-on Solution for Sheep		POM-V
	Program Tablets 67.8 mg		POM-V
	Program Oral Suspension for Small Cats and Kittens 133 mg		POM-V
	Program Oral Suspension for Large Cats 266 mg		POM-V
	Program Plus Film-coated Tablets 2.3 mg/46 mg		POM-V
	Program Plus Film-coated Tablets 5.75 mg/115 mg		POM-V
	Program Plus Film-coated Tablets 11.5 mg/230 mg		POM-V
	Program Plus Film-coated Tablets 23 mg/460 mg		POM-V
	Program Tablets 204.9 mg		POM-V
	Program Tablets 409.8 mg		POM-V
	Zobuxa 50 mg Tablets for Cats and Dogs		POM-V
	Vetrazin 6% w/v Pour-on Solution		POM-V
	Zobuxa 15 mg Tablets for Cats and Small Dogs		POM-V
	Zobuxa 100 mg Tablets for Dogs		POM-V
	Zobuxa 150 mg Tablets for Dogs		POM-V
	ACP Injection 2 mg/ml Solution for Injection	Change of legal entity	POM-V
	ACP Injection 10 mg/ml Solution for Injection		POM-V
	ACP Tablets 10 mg		POM-V
	Bovidec		POM-V
	Corvental D 100 mg Hard Capsules		POM-V
	Corvental D 200 mg Hard Capsules		POM-V
	Corvental D 500 mg Hard Capsules		POM-V
	Crovect 1.25% w/v Pour-on Solution for Sheep		POM-V

Company	Product Name	Brief Details	Legal Category
Novartis Animal Health UK Ltd Cont/d	Program Tablets 67.8 mg	Change of legal entity	POM-V
	Program Oral Suspension for Small Cats and Kittens 133 mg		POM-V
	Program Oral Suspension for Large Cats 266 mg		POM-V
	Program Plus Film-coated Tablets 2.3 mg/46 mg		POM-V
	Program Plus Film-coated Tablets 5.75 mg/115 mg		POM-V
	Program Plus Film-coated Tablets 11.5 mg/230 mg		POM-V
	Program Plus Film-coated Tablets 23 mg/460 mg		POM-V
	Program Tablets 204.9 mg		POM-V
	Program Tablets 409.8 mg		POM-V
	Zobuxa 50 mg Tablets for Cats and Dogs		POM-V
	Vetrazin 6% w/v Pour-on Solution		POM-V
	Zobuxa 15 mg Tablets for Cats and Small Dogs		POM-V
	Zobuxa 100 mg Tablets for Dogs		POM-V
	Zobuxa 150 mg Tablets for Dogs		POM-V
	Fasinex 10% Oral Suspension for Cattle	Change of distributor	POM-VPS
	Fasinex 100 10% (w/v) Oral Suspension for Cattle and Sheep		POM-VPS
	Fasinex 240, 24% w/v Oral Suspension for Cattle		POM-VPS
	Fasinex 5% w/v Oral Suspension		POM-VPS
	Flypor 4% w/v Pour-on Solution		POM-VPS
	Rycoben SC 2.50% w/v Oral Suspension for Sheep		POM-VPS
	Rearguard 6% w/v Cutaneous Solution		POM-VPS
	Fasinex 10% Oral Suspension for Cattle	Change of legal entity	POM-VPS
	Fasinex 100 10% (w/v) Oral Suspension for Cattle and Sheep		POM-VPS
	Fasinex 240, 24% w/v Oral Suspension for Cattle		POM-VPS
	Fasinex 5% w/v Oral Suspension		POM-VPS
	Flypor 4% w/v Pour-on Solution		POM-VPS
	Rearguard 6% w/v Cutaneous Solution		POM-VPS
	Rycoben SC 2.50% w/v Oral Suspension for Sheep		POM-VPS
Sogeval	Amoxival 500 mg/g Oral Powder for Pigs and Chickens	Change of distributor	POM-V
	Efex 10 mg Chewable Tablets for Cats and Dogs	Shelf life change	POM-V
	Efex 40 mg Chewable Tablets for Dogs		POM-V
	Efex 100 mg Chewable Tablets for Dogs		POM-V
Vetcare Limited	Detogesic 10 mg/ml Solution for Injection for Horses	Change of distributor	POM-V
Virbac S.A.	Effipro combo 50 mg/60 mg Spot-on Solution for cats	Change of name from Effipro Combo to Effipro Duo	POM-V
	Effipro combo 67 mg/20 mg Spot-on Solution for Small Dogs		POM-V
	Effipro combo 100 mg/120 mg Spot-on Solution for Very Large Cats		POM-V
	Effipro combo 134 mg/40 mg Spot-on Solution for Medium Dogs		POM-V
	Effipro combo 268 mg/80 mg Spot-on Solution for Large Dogs		POM-V
	Effipro combo 402 mg/120 mg Spot-on Solution for Very Large Dogs		POM-V
	Neoprinil Pour-on 5 mg/ml Pour-on Solution for Cattle	Shelf life change	POM-VPS
Virbac Tierarzneimittel GmbH	Stabox 1000 mg/g Powder for Use in Drinking Water for Chickens, Ducks, Turkeys	Change of legal entity	POM-V
Zoetis UK Limited	Lincocin Forte S Intramammary Solution	Change of distributor	POM-V
	Lincocin Forte S Intramammary Solution	Change in legal entity	POM-V
	Rispoval 4	Harmonisation of vial size of the 5 dose presentation	POM-V

EUCE AUTHORISATIONS ISSUED
BETWEEN 24 NOVEMBER 2015 - 10 MARCH 2016

Company	Vm Number	Product Name	Active Ingredient(s)	Legal Category
Ceva Sante Animale	EU/2/15/192/001-004	Velactis 1.12 mg/ml Solution for Injection for Cattle	Cabergoline	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	EU/2/11/134/021	Inflacam, Granules in a Sachet for Horses	Meloxicam	POM-V
Eli Lilly and Company Ltd	EU/2/15/193/001-003	Imrestor		POM-V
Merial	EU/2/08/082/001-007	Zactran 150 mg/ml Solution for Injection for Pigs	Gamithromycin	POM-V
Zoetis Belgium	EU/2/15/191/001-003	Simparica 5 mg Tablets for Oral use in Dogs	Sarolaner	POM-V
	EU/2/15/191/004-006	Simparica 10 mg Tablets for Oral use in Dogs		POM-V
	EU/2/15/191/007-009	Simparica 20 mg Tablets for Oral use in Dogs		POM-V
	EU/2/15/191/010-012	Simparica 40 mg Tablets for Oral use in Dogs		POM-V
	EU/2/15/191/013-015	Simparica 80 mg Tablets for Oral use in Dogs		POM-V
	EU/2/15/191/016-018	Simparica 120 mg Tablets for Oral use in Dogs		POM-V

EUCE AUTHORISATIONS VARIED
BETWEEN 24 NOVEMBER 2015 - 10 MARCH 2016

Company	Product Name	Brief Details	Legal Category
Bayer Animal Health GmbH	Profender Spot-on Solution for Small Cats	Variation to update the safety information	POM-V
Boehringer Ingelheim Vetmedica Gmbh	Pexion 100 mg Tablets for Dogs	Change(s) in the SPC, labelling or package leaflet further to a veterinary PSUR	POM-V
	Pexion 400 mg Tablets for Dogs		POM-V
Ceva Sante Animale	Vectra 3D Spot-on Solution for Dogs > 40 kg	Variation to amend the adverse reactions section of the SPC and package leaflet.	POM-V
	Vectra 3D Spot-on Solution for Dogs 1.5 - 4 kg		POM-V
	Vectra 3D Spot-on Solution for Dogs 4 - 10 kg		POM-V
	Vectra 3D Spot-on Solution for Dogs 10 - 25 kg		POM-V
	Vectra 3D Spot-on solution for Dogs 25 - 40 kg		POM-V
Prevtec Microbia GmbH	Coliprotec F4 Lyophilized Live Non-Pathogenic Escherichia Coli Vaccine for Oral Use in Swine	Shelf life change	POM-V
Virbac	Rabigen SAG2 Oral Suspension, for Red Foxes and Raccoon Dogs	Variation to amend the sections on adverse reactions in the SPC and product information in accordance with the recommendations made by the CVMP following the latest PSUR	POM-V
Zoetis Belgium	Equip WNV – Emulsion for Injection for Horses	Change in pack size of the finished product	POM-V
	Equip WNV – Emulsion for Injection for Horses	Shelf life change	POM-V
	Simparica 5mg Tablets for Oral use in Dogs		POM-V
	Simparica 10mg Tablets for Oral use in Dogs		POM-V
	Simparica 20mg Tablets for Oral use in Dogs		POM-V
	Simparica 40mg Tablets for Oral use in Dogs		POM-V
	Simparica 80mg Tablets for Oral use in Dogs		POM-V
	Simparica 120mg Tablets for Oral use in Dogs		POM-V

MARKETING AUTHORISATIONS EXPIRED BETWEEN 24 NOVEMBER 2015 - 10 MARCH 2016

Company	Vm Number	Product Name	Legal Category
Alstoe Ltd (Alstoe Animal Health)	14094/4001	Imposil 10% w/v Solution for Injection	POM-VPS
Boehringer Ingelheim Ltd	00015/4064	Ingelvac PRRS KV Emulsion for Injection for Pigs (Sows and Gilts)	POM-V
Ceva Animal Health Ltd	15052/4036	Cevaxel 50 mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs	POM-V
CP Pharma Handelsgesellschaft mbH	20916/4011	Carprosol 50 mg/ml Solution for Injection for Cattle	POM-V
	20916/4012	Ketosol 100 mg/ml Solution for Injection for Horses, Cattle and Pigs	POM-V
Ecuphar NV	32742/4004	Acticam 1mg Chewable Tablets for Dogs	POM-V
	32742/4003	Acticam 2.5mg Chewable Tablets for Dogs	POM-V
Evans Vanodine International Plc	03940/4100	Masocare Elite 0.54% w/v Ready To Use Teat Dip and Spray Solution	AVM-GSL
	03940/4084	Venture Satinex 0.436% w/v Ready to Use Teat Dip and Teat Spray Solution	AVM-GSL
Intervet International BV	06376/4031	Equilis Resequin Suspension for Injection for Horses	POM-V
	06376/4050	Nobivac Forcat	POM-V
Intervet UK Ltd	01708/4235	Nobilis TRT Live	POM-V
Norbrook Laboratories Ltd	02000/4276	Closivet Solution for Injection for Cattle	POM-VPS
Triveritas Ltd	21759/4001	Forakef Film Coated Tablets 250 mg	POM-V
Vetoquinol UK Ltd	08007/4133	The Blue Cross – Dog Wormer for Large Dogs	NFA-VPS
	08007/4132	The Blue Cross – Dog Wormer for Medium Dogs	NFA-VPS
	08007/4131	The Blue Cross – Dog Wormer for Small Dogs	NFA-VPS
Virbac Ltd	11188/4009	Isoflurane Virbac 100% w/w Inhalation Vapour, Liquid	POM-V
Zoetis UK Limited	42058/4111	Poulvac Pabac IV	POM-VPS

MARKETING AUTHORISATIONS FOR PARALLEL IMPORTS GRANTED BY THE VMD BETWEEN 24 NOVEMBER 2015 - 10 MARCH 2016

Company	Vm Number	Product Name	Legal Category
Kernfarm B.V.	43877/4003	Buscopan Compositum Solution for Injection	POM-V

QUARTERLY REPORTING AGAINST VMD PUBLISHED STANDARDS FOR LICENSING WORK UP TO 31 MARCH 2016

Annex I

Our published standards are on GOV.UK

Key: Dark Green *Excellent 100%* | Light Green *Excellent, but some targets missed* | Amber *Effective* | Red *Ineffective*

Published Standard – No. 1 – Quality of Documentation

	App Type	Total No.	Performance
1	Authorisation Documentation	2,209	97.5%

Published Standard – No. 2 – European Applications

	App Type	No. of Apps	Performance
2	Centralised: New MAs / Extensions	11	100%
3	Centralised – UK as Rapp: Variations	15	100%
4	Centralised – UK as Rapp: Renewals	3	100%
5	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 70)	48	100%
6	DCP – UK as RMS: New MAs / Extensions (Phase 1 – Day 120)	63	100%
7	DCP – UK as RMS: New MAs / Extensions (Phase 2)	67	100%
8	DCP – UK as CMS: New MAs / Extensions (Phase 1)	48	100%
9	DCP – UK as CMS: New MAs / Extensions (Phase 2)	37	100%
10	MRP – UK as RMS: New MAs / Extensions (Phase 1)	10	100%
11	MRP – UK as RMS: New MAs / Extensions (Phase 2)	9	100%
12	MRP – UK as CMS: New MAs / Extensions (Phase 2)	27	100%
13	MRP – UK as RMS: Type IA Variations	95	100%
14	MRP – UK as RMS: Type IB & II Variations (Phase 1)	126	100%
15	MRP – UK as CMS: Type IB & II Variations (Phase 1)	180	100%
16	MRP – UK as CMS: Type IB & II Variations (Phase 2)	84	100%
17	MRP – UK as RMS: Renewals (Phase 1)	40	100%
18	MRP – UK as CMS: Renewals (Phase 1)	78	100%
19	MRP – UK as CMS: Renewals (Phase 2)	62	100%

Published Standard – No. 2 – National Applications

	App Type	No of Apps	Performance	Target Days	Average Days
20	New MAs / Extensions: Initial Assessment	**28**	100%	-	-
	75 Day Clock	4		75	36.5
	90 Day Clock	24		90	82
21	New MAs / Extensions: Sign-Off	**35**	97.1%	-	-
	130 Day Clock	4		130	116
	180 Day Clock	31		180	126
22	New Homeopathic	**0**	0%	50	0
23	Type IA Variations	**170**	99.4%	30	23.6
24	Admin Variations	**34**	100%	-	-
	< 10 Changes	34		30	13.5
	> 10 Changes	0		60	0
25	Type IB / II Variations: Initial Assessment	**235**	97.9%	-	-
	Type IB	178		30	21.4
	Type II	57		60	49.9
26	Type IB / II Variations: Sign-Off	**150**	98.7%	-	-
	Type IB	118		30	15.9
	Type II	32		60	34.2
27	Renewals: Initial Assessment	**9**	100%	60	55.2
28	Renewals: Sign-Off	**9**	100%	60	23.1
29	Batch Release	**2,729**	99.6%	10	2.2
30	AVA, NFABBA & ESCCA	**11**	100%	45	News: 15.7 Vars: 18.1
31	ATCs	**44**	97.7%	-	-
	Type A/S	22		30	13.5
	Type B	9		50	28.7
	Variations / Renewals	13		30	6.7
32	Specific Batch Control	**31**	100%	20	1.4
33	Validation of applications	**996**	100%	-	-
34	Mock-Ups (post New MA)	**177**	100%	-	-
35	Mock-Ups (post EU Variations / Renewals)	**619**	99.0%	-	-
36	Issue of authorisation documentation	**1,309**	100%	-	-

Published Standard – No. 3 – Import and Export Certificates

	App Type	No. of Apps	Performance	Target Days	Average Days
37	STC / SIC Requiring Assessment – New products	**129**	100%	15	4
38	STC / SIC Requiring Assessment – other products	**6,398**	99.9%	-	-
	Urgent	393		2	1
	Non-Urgent	6,005		10	2
39	WDIC – not previously assessed	**9**	100%	15	3
40	WDIC – other applications	**131**	100%	-	-
	Urgent	6		2	1
	Non-Urgent	125		10	2
41	Export	**692**	100%	10	5.8

Published Standard – No. 4 – Public Assessment Reports

	App Type	No. of Apps	Performance	Target Days	Average Days
42	Make publicly available via GOV.UK the SPC for New MAs	**188**	99.5%	-	-
	SPC for MAs	170		30	14
	Link to EMA	18		30	14
43	Make publicly available via GOV.UK the PAR for New MAs	**123**	100%	120	99
44	Make publicly available via GOV.UK the post authorisation assessment	**785**	99.9%	60	39

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
45	Human & Animal AERs	**6,005**	99.5%
46	Human & Animal AERs – Follow Up	**3,120**	99.4%
47	Environmental SAR	**1**	100%
48	Inspections	**25**	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
49	GMP Inspections within 3 years of last inspection	**50**	100%	-	-
50	GDP inspections within 5 years of last inspection	**56**	100%	-	-
51	Send deficiency or post inspections letter	**96**	97.9%	30	
	GMP	50			24
	GDP	46			23
52	Issue GMP Certificates and final inspection reports	**50**	100%	90	83
53	Send final inspection report to wholesaler site	**45**	100%	90	80

ORGANOGRAM APRIL 2016

Annex 2