

# MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 61 – JANUARY 2007

## ■ APPOINTMENT OF DIRECTOR OF LICENSING

Jackie Atkinson has been appointed to the permanent position of Director of Licensing and took up her post on 8 January 2007.

Lesley Johnson and Martin Ilott were temporarily sharing the responsibility of the Director of Licensing post after John O'Brien's early retirement on 31 May 2006. Both Lesley and Martin have now reverted back to their original positions at the VMD of managing the Pharmaceuticals and Feed Additives and Immunological Products teams respectively.

Bryan Ward has replaced Jackie as Senior Pharmaceutical assessor.



## CONTENTS

News	2
Licensing	5
Antimicrobial Resistance	8
Suspected Adverse Reaction Surveillance Scheme	9
Veterinary Products Committee	9
Residues Controls and Monitoring	11
Marketing Authorisations	24

The best available information on the work of the VMD can be found on our on-line *MAVIS* service [www.vmd.gov.uk](http://www.vmd.gov.uk)



INVESTOR IN PEOPLE

The Veterinary Medicines Directorate  
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS  
Tel: (01932) 336911 Fax: (01932) 336618  
web: [www.vmd.gov.uk](http://www.vmd.gov.uk)  
e-mail: [postmaster@vmd.defra.gsi.gov.uk](mailto:postmaster@vmd.defra.gsi.gov.uk)



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES

## ■ THE VETERINARY MEDICINES REGULATIONS 2007: UPDATE

As part of the annual project to revoke and remake the Veterinary Medicines Regulations, we are currently preparing documents for the 2007 Regulations. These Regulations will come into force on 1 October 2007.

We will publish, on our website, a formal public consultation in early March which will consist of the proposed amendments to the legislation, the accompanying updated Veterinary Medicines Guidance (VMG) Notes and a draft Regulatory Impact Assessment. The consultation will run for 12 weeks. If you have any comments or suggestions on how the current regulations could be changed please let us have them as soon as possible.

*For any questions regarding the Veterinary Medicines Regulations please contact Suzanne McGiven (VMD, 01932 338319, e-mail: [s.mcgiven@vmd.defra.gsi.gov.uk](mailto:s.mcgiven@vmd.defra.gsi.gov.uk)).*

## ■ SINGLE INTEGRATED NATIONAL CONTROL PLAN FOR THE UNITED KINGDOM FROM JANUARY 2007 IN ACCORDANCE WITH (EC) REGULATION 882/2004

The UK's first National Control Plan (NCP) was published on 14 December 2006.

The NCP covers the official control systems in place in the UK in respect of 'feed law' (as defined for the purposes of EU Regulation 882/2004). In accordance with this regulation, each Member State is required to prepare a multi-annual (between three and five years) NCP describing the national official feed and food, and animal health and welfare control arrangements and setting out the objectives and priorities for control activities during the period of the plan.

The plan has been prepared jointly by the Food Standards Agency (FSA), the Department for Environment, Food and Rural Affairs (Defra), the Scottish Executive Environment and Rural Affairs Department (SEERAD), the Welsh Assembly Government Environment, Planning and Countryside Department (EPC) and the Department of Agriculture and Rural Development (DARD) in Northern Ireland.

Copies of the plan may be downloaded from the FSA website at: [www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk](http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk)

*For further information: Janis McDonald (VMD, 01932 338307, e-mail: [j.mcdonald@vmd.defra.gsi.gov.uk](mailto:j.mcdonald@vmd.defra.gsi.gov.uk) or Maggie Green (VMD, 01932 338324, e-mail: [m.green@vmd.defra.gsi.gov.uk](mailto:m.green@vmd.defra.gsi.gov.uk)).*

## ■ BLOOD BANKS FOR COMPANION ANIMALS

Blood transfusion in small animal veterinary medicine is becoming increasingly used in the management and treatment of certain diseases associated with anaemia and blood loss.

A number of veterinary institutions operate blood donor programmes in the UK with varying quality controls in place. Also many veterinary practices have access to donors for emergency supplies of blood, but often these donors are untyped, unscreened and cross-matches are not necessarily performed.

The Veterinary Medicines Regulation 2005 introduced the formal provision for the authorisation of blood banks for companion animals for commercial enterprises who wished to collect and store blood and for placing the blood on the UK market.

The VMD has been advising interested parties on the requirements and procedures that would need to be followed for authorising a UK veterinary blood bank. The criteria and ethics for selecting donor animals should be carefully addressed to limit the risk of transferring pathogens to recipient animals and the manufacturing process should ensure the blood products are not contaminated. Veterinary surgeons using any such products in recipient patients should keep batch records to ensure traceability.

The manufacturing site(s) are subject to inspection and must meet appropriate standards of quality assurance and quality control. Personnel should be sufficiently qualified to carry out all the tasks and the premises should be located, designed, constructed and maintained to suit the operations to be performed. The procedures should be documented appropriately and there should be a complaints and product recall procedure for potentially defective products. All blood products that are produced should be labelled according to UK requirements and records on the production and collection kept for five years.

Veterinary Medicines Guidance Note 17 (Authorisations for Specific Manufacturers – Autogenous Vaccines, Non-Food Animal Blood Banks and Products for Administration Under the "Cascade") provides the requirements for applicants wishing to collect and store blood for use in companion animals. Any company interested in making an application is encouraged to contact the VMD for advice before submitting a formal application.

*The initial contact should be made to Martin Illott (VMD, 01932 338421, e-mail: [m.illott@vmd.defra.gsi.gov.uk](mailto:m.illott@vmd.defra.gsi.gov.uk)).*

## ■ VRC OPEN MEETING

The Veterinary Residues Committee held its 3<sup>rd</sup> Open Meeting on 18 October 2006, at the Fishmongers' Hall, London.

In the morning session attendees were able to see the Committee discuss some of its normal business, including reports on the latest positives from the VMD's surveillance schemes.

In the afternoon session attendees received presentations from the Committee, contractors and the VMD. These explained the way the National Surveillance Scheme worked: from the initial planning through to the follow-up action taken when residues above specific concentrations are found, including the role of the Committee in giving advice to the VMD. There was also a discussion on whether the VRC should consult on the surveillance plans for imports it recommends to the VMD.

After both morning and afternoon sessions there was an opportunity for the attendees to put questions to the Committee and express their views.

A note of the meeting, including the questions put to the Committee is available on the VRC website [www.vet-residues-committee.gov.uk](http://www.vet-residues-committee.gov.uk)

*Further information: David Webb (VMD, 01932 338327, e-mail: [d.webb@vmd.defra.gsi.gov.uk](mailto:d.webb@vmd.defra.gsi.gov.uk)).*

## ■ COMMISSION REGULATION (EC) NO 1950/2006 – LIST OF SUBSTANCES ESSENTIAL FOR THE TREATMENT OF HORSES

European Regulation (EC) No 1950/2006 establishing a list of substances considered essential for the treatment of equidae was published by the European Commission on 22 December 2006 and came into force on 25 December. It directly applies throughout the EU and therefore in the United Kingdom. The text of the Regulation is available on our website [www.vmd.gov.uk](http://www.vmd.gov.uk) under "Product Information/ Authorised Medicines/Veterinary Medicinal Products" for use in horses.

It is important that the use of these substances complies with the Veterinary Medicines Regulations and the Horse Passport legislation. The VMD will prepare a guidance note on the use of horse medicines in conjunction with British Equine Veterinary Association (BEVA).

*For more information on this legislation or medicines please contact Suzanne McGiven (VMD, 01932 338319, e-mail [s.mcgiven@vmd.defra.gsi.gov.uk](mailto:s.mcgiven@vmd.defra.gsi.gov.uk)).*

*For more information specifically on horse passports visit the Defra website at: [www.defra.gov.uk/animalh/tracing/horses/horses\\_index.htm](http://www.defra.gov.uk/animalh/tracing/horses/horses_index.htm) or contact the Defra help line on 08459 335577.*

## ■ COMMISSION DIRECTIVE 2006/130/EC ESTABLISHING CRITERIA FOR EXEMPTING CERTAIN VETERINARY MEDICINAL PRODUCTS FOR FOOD PRODUCING ANIMALS FROM THE REQUIREMENT OF A VETERINARY PRESCRIPTION

This EU Directive was published by the European Commission on the 12 December and came into force on the 1 January 2007. The text of the Decision is available on website: [www.eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_349/l\\_34920061212en00150016.pdf](http://www.eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_349/l_34920061212en00150016.pdf).

We currently expect to implement this Directive by means of the Veterinary Medicines Regulations 2007. A formal consultation on these draft Regulations and related documents is expected to be published in March.

*For more information on this Directive or veterinary medicines legislation please contact Suzanne McGiven (VMD, 01932 338319, e-mail: [s.mcgiven@vmd.defra.gsi.gov.uk](mailto:s.mcgiven@vmd.defra.gsi.gov.uk)).*

## ■ STAFF CHANGES

- Fran Brooks transferred to core Defra on 4 December. Her post is being covered temporarily by Ravinder Sagoo and Hazel Gregory. Paula Huckle is covering the post vacated by Ravinder in the Feed Additives and Sheep Dip policy team and Hazel's post is being covered by a temporary member of staff within Typing and Design Services.
- Lea Stott reverted to her role within the Licensing Team and Vivienne Saville reverted to her post in Licensing Services.
- David Lewsey returned from long-term jury service and is responsible for the overall line management of Core Services and Training & Liaison Unit. Janet Squire and Andrea Ford's period of temporary promotion has come to an end. Janet will continue to work in the Training & Liaison Team and Andrea Ford took responsibility for the line management of Core Services.
- Dan Finn commenced a period of temporary promotion within the Information Management Team on 4 December and Becky Young returned to New Licensing Team. Jenny Cass's temporary transfer to Post Licensing became substantive on 9 November.
- Alison Pearce has commenced a period of temporary promotion in the SARSS Admin team, her post in IT will be covered by a temporary member of staff.
- Annabel Hatch was successful in a recent interview and will be promoted to the UKPAR team on 19 February 2007.

## ■ UK PUBLIC ASSESSMENT REPORTS, UKPARS

Directive 2001/82/EC as amended by Directive 2004/28/EC requires public assessment reports to be made available for products authorised on or after 30 October 2005.

The VMD has created web pages for the UK Public Assessment Reports (UKPARs). Every product authorised after 30 October 2005 is listed on the UKPAR web page with a product profile and three modules. Module 1 is the Summary of Product Characteristics (SPC), Module 2 is the scientific discussion and a summary of the assessment report, and Module 3 is a list of post-authorisation actions such as variations and renewals.

The VMD has set targets of:

- 30 days from MA issue to publish the product profile and SPC (Module 1).
- 120 days from MA issue to publish the scientific discussion (Module 2).

For all products, with the exception of those authorised centrally, the VMD creates Module 1 of the UKPAR. We produce scientific discussions for all nationally authorised products except MAs for parallel import and products authorised by “informed consent”. We produce public assessment reports on mutually recognised and decentrally authorised products when we are Reference Member State only. It is intended that the Heads of Medicines Agency (veterinary) will publish all European Decentralised/ Mutual Recognition Public Assessment Reports (PuARs) on their website when this is up and running. In the meantime all scientific discussions drafted by the VMD will be published on the VMD website. Products authorised via the European Centralised procedure will have public assessment reports published on the European Medicines Agency website [www.emea.europa.eu](http://www.emea.europa.eu)

To date 93 products have been published on the VMD website all with product profiles and SPCs (Module 1). Of these 58 qualify for a UK drafted scientific discussion (Module 2). The most recently published products are listed in the table below.

### Products published online between 11 September 2006 and 20 December 2006

Product	Route of authorisation	Date published
Aquavac ERM Oral	National MA	19 October 2006
Aquavac Furovac	Mutual Recognition. UK = RMS	04 December 2006
Aquavac RELERA	Provisional MA	29 November 2006
Bayvarol Strips	Mutual Recognition. UK = RMS	18 December 2006
Benazecare 20	National MA	09 November 2006
Benazecare 5	National MA	09 November 2006
Canidryl 100mg tablets for dogs	Mutual Recognition. UK = CMS	14 December 2006
Canidryl 20mg tablets for dogs	Mutual Recognition. UK = CMS	14 December 2006
Canidryl 50mg tablets for dogs	Mutual Recognition. UK = CMS	14 December 2006
Closamectin Injection	National MA	30 October 2006
Combisyn Palatable Tablets 500mg	National MA	12 September 2006
Cyclix Porcine Solution for Injection	Mutual Recognition. UK = CMS	11 September 2006
Cyclo Spray	National MA	13 November 2006
Domidine	Mutual Recognition. UK = CMS	11 December 2006
Hipracox Broilers	National MA	20 September 2006
Kenostart SD 3000ppm Teat Spray/Dip Solution	National MA	20 November 2006
Nisamox Palatable Tablets 500mg	National MA	12 September 2006
Nobilis Tri OR Inac	National MA	06 December 2006
Norodyl 20mg Tablet for Dogs	National MA	08 December 2006
Norodyl 50 mg Tablet for Dogs	National MA	08 December 2006
Phenoxyphen 32.5% water Soluble Powder	Mutual Recognition. UK = CMS	20 December 2006
Procyon Dog Lepto	National MA	29 November 2006
Procyon Dog Parvo	National MA	27 November 2006
Resflor Injectable Solution	Mutual Recognition. UK = CMS	24 October 2006
Rispoval RS+Pi3Intranasal	Mutual Recognition. UK = RMS	29 November 2006

**We would appreciate feedback on the UKPAR web pages and product scientific discussions. Please e-mail Abigail Seager [a.seager@vmd.defra.gsi.gov.uk](mailto:a.seager@vmd.defra.gsi.gov.uk) with any comments you may have.**

# LICENSING

## ■ **MARKETING AUTHORISATIONS – LEGISLATIVE UPDATES TO SPCs AND PRODUCT LITERATURE FOR PHARMACEUTICAL PRODUCTS, AND HARMONISATION OF SPC AND PRODUCT LITERATURE WITH IRELAND**

The purpose of this article is to encourage Marketing Authorisation Holders (MAH) to start submitting the appropriate variations to bring their SPCs and labels in line with new UK legislation as soon as possible because all changes resulting from the new UK legislation must be made to all products by 30 October 2008.

The Veterinary Medicines Regulations 2005 introduced changes to the content and layout of the SPC and product literature. Veterinary Medicine Guidance Note (VMGN) No 26 outlines the requirements for SPCs and product literature in light of the legislation and explains what MAHs need to do to bring SPCs and product literature, for nationally authorised products, in line with the legislation.

In order to facilitate this process the VMD decided to assess, and approve, these changes by way of a variation to ensure that SPCs and product literature meet the requirements of the legislation. This applies to nationally authorised products only. MAH are required to submit one Type IB (f) variation (per product) including an SPC and (clean) mock-ups incorporating all the proposed changes, which will attract the normal fee. However, the variation will be assessed in accordance with a Type II timetable due to the fact that a number of disciplines will be involved in the assessment of the variation.

In order to meet the deadline of 30 October 2008 all variations must be approved by 30 April 2008, which gives MAHs six months to make the changes to their SPCs and product literature by the above date. However, as at the end of November 2006, only 10% of pharmaceutical products have been varied, which causes us some concern (logistically) because we might not have the resources to carry out the bulk of the work in such a short period of time.

To ease the burden on industry those MAH who may wish to have a single set of authorised labels and package leaflets for products intended for sale in the UK and Ireland, may submit the SPC/label variation and harmonisation variation simultaneously, with a covering

letter, accompanied by one set of product literature including the UK approved SPC/labels; Irish approved SPC/labels and proposed joint versions in the new format. They should also provide a list highlighting the differences between the UK and Irish versions. The applications will run together on the SPC/label timetable and each variation will attract a fee.

The harmonisation variation should also be submitted in Ireland at the same time as it is submitted in the UK. Please note that MAHs cannot harmonise their SPC/labels with Ireland until they are in the new format, so we will not accept independent harmonisation variations until the SPC/label variation is completed.

Further information about this issue is available in VMGN No 26 - Legislative updates to SPCs and product literature, which is available on the VMD website.

**Further Information: Validating Assessors (contact via the main switchboard on 01932 336911) or Natalie Shilling (VMD, 01932 338452, e-mail: n.shilling@vmd.defra.gsi.gov.uk)**

## ■ **CARBON SAVING INITIATIVE – REDUCTION IN COPIES OF AUTHORISATION DOCUMENTS**

The VMD would like to introduce an initiative to reduce the number of pages of the memorandum document (memo-doc) issued following the conclusion of a variation application procedure (national and European).

At the moment we issue a full memo-doc following all application procedures (including Type IA variations) regardless of whether or not the content of the memo-doc has been changed. Sometimes the only section to be changed is the table, which lists all application procedures conducted on that product since a specific date.

We are proposing to update and issue the last page only for applications, which do not affect the rest of the memo-doc; therefore, marketing authorisation holders (MAH) will have an up-to-date record of all application procedures and can simply replace the last page with the new version. Please note that it is estimated that the VMD is currently photocopying 300/400 pages unnecessarily every week by re-issuing unchanged memo-docs.

A full memo-doc will continue to be issued for all new and renewal applications, and for variations which affect the main body of the memo-doc. *NB.* Please note that the Control Test Appendix (CTA) forms part of the memo-doc (as an appendix) for Immunological products; therefore, when we refer to the main content of the memo-doc we are including the CTA as well.

The VMD welcomes MAHs' comments on this proposal by Thursday, 1 March 2007.

**Further information: Natalie Shilling (VMD, 01932 338452, e-mail n.shilling@vmd.defra.gsi.gov.uk).**

## ■ HARMONISATION OF SPCS AND PRODUCT LITERATURE, FOR NATIONALLY AUTHORISED PRODUCTS, BETWEEN THE UK AND IRELAND (IE)

The purpose of this article is to clarify the joint VMD and IMB harmonisation initiative, which was originally implemented in October 2000, for pharmaceutical and immunological products. Please note that this procedure should not be confused with the joint labelling initiative used following an EU procedure, or the alignment procedure which is applicable to a small number of immunological products only (refer to the clarification paper entitled, "The alignment of Immunological products between the UK and IE", available on the VMD website).

The purpose of the initiative was to introduce a simplified procedure for harmonising the SPC and product literature of nationally authorised products, so that products could be marketed using the same label and, if applicable, leaflet (a "dual label/leaflet") in the UK and IE. This initiative was instigated at the request of industry; the main benefit being the more efficient and cost effective production of packaging.

Marketing Authorisation Holders (MAHs) may apply, at any time, for any class of product, to harmonise their SPCs and product literature by way of a variation. This variation is not intended to update SPCs and/or product literature, but to simply harmonise them. If any changes to parts of the SPC require data to be assessed to bring them into line then this will be dealt with by means of a separate variation. The harmonisation variation cannot be progressed until all other applications have been completed.

Applicants should submit the harmonisation variation in both countries simultaneously. Upon receipt of an application the UK and IE will liaise with each other to confirm that (a) each country has received the variation, and (b) decide who will take the lead on the variation (known as the "lead country"). Harmonisation variations run on a 60-day clock in the UK, and the clock may start/stop a number of times during this period whilst the two countries discuss any issues and/or seek further information from the MAH, if required. Once the procedure is completed, and approved, the SPC and product literature will be classed as harmonised.

A clarification paper about this issue is currently being prepared by the VMD and IMB, and will soon be available on the VMD website under industry information/applications page/guidance documents.

Please note that MAHs may harmonise their SPCs and product literature at the same time as bringing their SPC/ labels in line with new legislation. Please refer to the article entitled, "Marketing Authorisations – Legislative updates to SPCs and product literature for Pharmaceutical Products, and harmonisation of SPC and product literature with Ireland".

**Further Information please contact: Natalie Shilling (VMD, 01932 338452 , e-mail: [n.shilling@vmd.defra.gsi.gov.uk](mailto:n.shilling@vmd.defra.gsi.gov.uk)**

## ■ NUMBERS OF ATCs RECEIVED AND DETERMINED BETWEEN 1 JULY 2006 AND 31 DECEMBER 2006

No. valid ATCs Received	4
No. ATCs Issued	8
Stopped at End Quarter	0
No. Withdrawn during Assessment	0
No. Refused at Validation	1

### Time taken for Initial Assessment of Issued ATCs

Range of Days	0-15	16-31	32+
No. of Applications	3	3	2

Average Days = 21

### Time during which these issued applications were with the company dealing with outstanding questions

Range of Days	0-30	31-96	97+
No. of Applications	4	3	1

Average Days = 43

### Total time from validation to determination

Range of Days	0-30	31-63	63+
No. of Applications	5	2	1

Average Days = 33

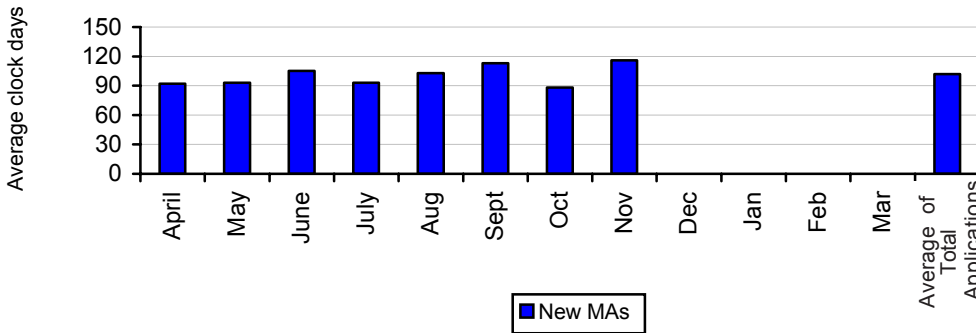
# LICENSING BUSINESS PERFORMANCE AGAINST TARGETS

The Licensing Business is committed to providing information on our performance and to allow stakeholders to monitor our performance against targets throughout the year, rather than once a year in the VMD Annual Report. The attached charts represent this aim and depict, on a monthly basis, the average number of days taken to complete the target defined in the legend to each figure. The last column on the right of each figure represents the overall average achieved during the financial year and the text to the right represents the average day target. We would be grateful for feedback from readers as to how easy they find these charts to understand and if they contain useful information. Suggestions on how they might be improved will be welcome and we will amend the charts in light of comments received.

Further information on figures and charts: *Lea Stott (VMD, 01932 338432, e-mail: l.stott@vmd.defra.gsi.gov.uk)*. For information in relation to licensing business performance contact *Jackie Atkinson (VMD, 01932 338387, e-mail: j.atkinson@vmd.defra.gsi.gov.uk)*.

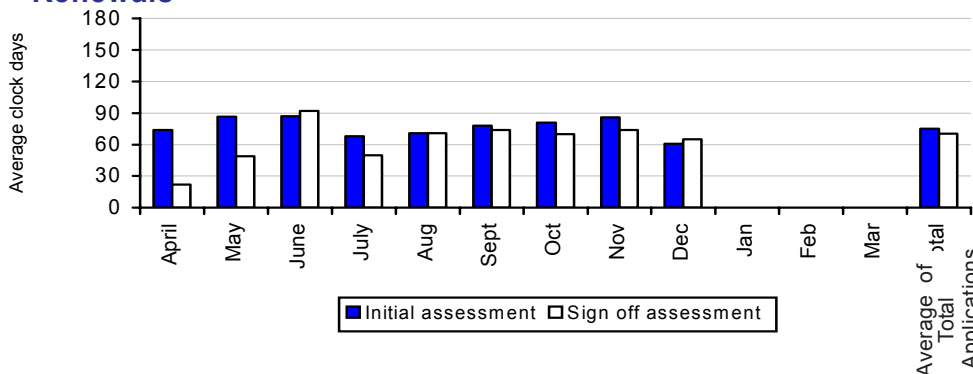
## New Marketing Authorisations

**TARGETS**  
(average clock days)



Signed off or referred to VPC within 120 days

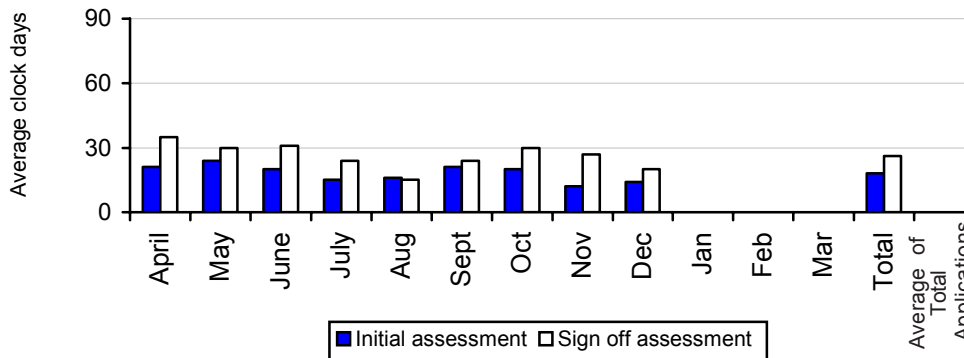
## Renewals



Sign off assessment within 180 days

Initial assessment within 90 days

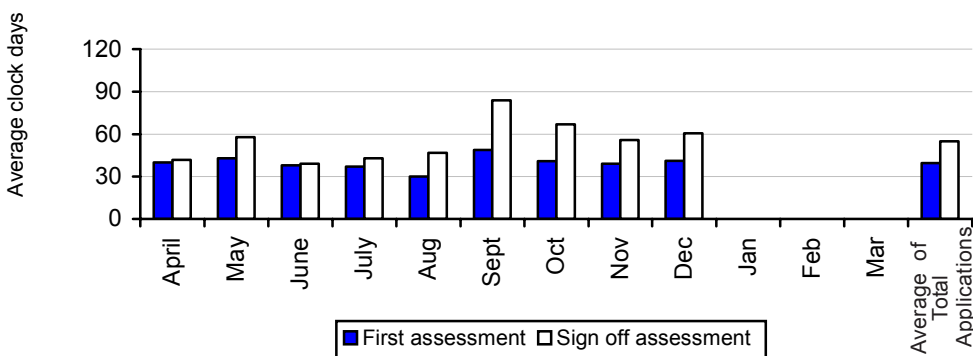
## National Type I Variations



Sign off assessment within 60 days

Initial assessment within 30 days

## National Type II Variations



Sign off assessment within <120 days

Initial assessment within <60 days

# ANTIMICROBIAL RESISTANCE

*Antimicrobial resistance is a serious problem in human and veterinary medicines, resulting in increasing concerns about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. A Government Strategy has been developed to address this issue. The Veterinary Medicines Directorate is responsible for delivering key elements of this strategy, including the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK and providing a secretariat to the Defra Antimicrobial Resistance Coordination (DARC) Group. The following articles describe the most recent actions that the VMD has taken to progress this strategy.*

## ■ DARC GROUP MEETING

The Defra Antimicrobial Resistance Coordination (DARC) Group met on 9 November 2006. Items discussed included: the Overarching Antimicrobial Resistance Report, Consultation for the Zoonoses (Monitoring) Regulations 2006, the UK Antimicrobial Resistance Surveillance Data, Extended Spectrum Beta-Lactamase (ESBLs), Antimicrobial Sales Data Report for 2005 and MRSA in animals.

## ■ SALES DATA REPORT

This year the VMD have had to contact all Pharmaceutical Companies to check the accuracy of the data provided in previous years as some previous data had been found to have been incorrectly provided by a Pharmaceutical Company. As a result some antimicrobial sales data have had to be restated. The report for 2005 was cleared by the Veterinary Products Committee in December 2006 and the report subsequently published in December 2006. Copies of the report are available from the VMD website at [www.vmd.gov.uk](http://www.vmd.gov.uk) under "Publications/Antibiotic Related" tabs, or from Dr Kay Goodyear at the VMD.

Copies of the Reports detailing veterinary antimicrobial sales from 1998 to 2004 can be obtained from the VMD website [www.vmd.gov.uk](http://www.vmd.gov.uk) under "Publications/Antibiotic Related" tabs, or from Dr Kay Goodyear at the VMD.

## ■ OVERARCHING ANTIMICROBIAL RESISTANCE REPORT FOR THE UK

The draft report will be presented to Ministers towards the end of this year ahead of publication early in 2007. Development of the report is cross-departmental and cross-agency and includes staff from VMD, Veterinary Laboratories Agency (VLA), Health Protection Agency (HPA), Food Standards Agency (FSA), Defra, Health Protection Scotland (HPS), Department of Health (DH), Department for Agricultural and Rural Development (DARD) in Northern Ireland and the Scottish Executive Environment and Rural Affairs Department (SEERAD).

## ■ SACAR MEETING

The Specialist Advisory Committee on Antimicrobial Resistance (SACAR) met on 27 November 2006. Items discussed included: the Overarching Antimicrobial Resistance Report, Extended Spectrum Beta-Lactamase (ESBLs), updates from the SACAR sub-groups and the veterinary Antimicrobial Sales Data Report for 2005.

## ■ OTHER ANTIMICROBIAL ISSUES

The Antimicrobial Resistance (AMR) web pages can be accessed through the VMD website [www.vmd.gov.uk](http://www.vmd.gov.uk). Further information about completed AMR related R&D projects has been added to the web pages along with updates to the DARC Group information.

# SUSPECTED ADVERSE REACTION SURVEILLANCE SCHEME

*The definition of a Suspected Adverse Reaction (SAR) is taken from article 1, paragraph 10, of the Directive 2001/82/EC: "adverse reaction means a reaction which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or the modifications of physiological function". The definition of a human adverse reaction is taken from article 1, paragraph 11, of Directive 2001/82/EC "... means a reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine." In addition to this, the UK also include reports of suspected lack of expected efficacy, reports of off-label use of veterinary medicines, reports of environmental incidents and reported violations of approved maximum residue limits arising from the use of a veterinary medicinal product.*

## ■ QUARTERLY REPORT

During the period 1 October to 31 December 2006, the VMD received 625 suspected adverse reaction reports involving animals. Of these, 72 reports related to unauthorised use, 22 involved an unauthorised or unidentified product, and 25 reports were considered unlikely to be product related. There were 2 reports involving animal trials under Animal Test Certificates (ATCs) and 46 reports involved suspected lack of efficacy.

The remaining 458 suspected adverse reaction reports were associated with 149 licensed products.

The 458 reports were divided by marketing categories as follows:

- 412 Prescription Only Medicine (POM)
- 11 Pharmacists and Merchants List (PML)
- 15 Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)
- 1 Medicated Feedingstuff (MFS)
- 16 General Sales List (GSL)
- 3 Authorised Veterinary Medicine – General Sales List (AVM-GSL)

During the quarter 33 reports of human suspected adverse reactions were received. All serious human incidents are considered by the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines. The information thus accrued is analysed to identify any trends or signals that need attention.

During the quarter seven reports of environmental incidents where there was some impact on the environment were received from the Environment Agency. All seven of the incidents occurred in 2006 and occurred in the aquatic environment.

The SARSS Bi-monthly Reports for September and October 2006 and November and December 2006 will be presented to the Veterinary Products Committee (VPC) at the meeting in January 2007.

**Further information: Denise Burge (VMD, 01932 338427, e-mail: [d.burge@vmd.defra.gsi.gov.uk](mailto:d.burge@vmd.defra.gsi.gov.uk)).**

# VETERINARY PRODUCTS COMMITTEE

*The Veterinary Products Committee (VPC) is a statutory committee established to:*

- i) provide the Secretary of State with scientific<sup>1</sup> 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;*
- 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 Veterinary Products Committee will publish a report of its activities and those of its Sub-Committees.*

*<sup>1</sup>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 Veterinary Products Committee met on 21 September 2006. It reviewed and confirmed the minutes of its July meeting and considered the following matters relating to the authorisation of veterinary medicines. All conclusions reached are subject to review and confirmation at the July meeting.

## Applications

The Committee examined evidence relating to applications to change the legal distribution category of five Marketing Authorisations for the prevention and control of flea infestation, from Prescription Only Medicine–Veterinarian (POM-V) to Authorised Veterinary Medicine–General Sales List (AVM-GSL).

Three Members declared non-personal, non-specific interests.

The Committee provided advice for consideration by the VMD.

### Suspected Adverse Reactions

The Committee considered and commented upon the SARSS Reports for July and August 2006. It discussed the increasing incidence of parvovirus infection in the UK. There was anecdotal evidence that only 30% of dogs in the country were vaccinated. VMD was asked to take a proactive role and highlight to the public the importance of vaccination, despite the very low risk of adverse reactions. The VMD informed the Committee that practical advice informing the general public about parvovirus infection and vaccination had already been placed on its website. The SARSS team was carrying out a survey to ascertain the efficacy of parvovirus vaccines currently authorised in the UK and a report would be presented to the Committee at its next meeting.

The Committee was informed that, in response to concerns expressed by Members at a previous meeting, about the incidence of pyrethroid toxicity in cats the VMD would send an article to the veterinary press emphasising the need to follow the manufacturers' instructions when prescribing and dispensing enrofloxacin for cats. The VMD agreed to present a report at the next meeting.

The Committee reviewed a summary of human adverse reactions involving bronchial and lung disorders and noted that the overall incidence was very low. Members were reminded of an earlier investigation carried out by the SARSS team into products authorised for topical use which had shown that certain products with high application volumes were associated with more frequent SAR reports. Details of the investigation are available in the Annual Report for 2004 of the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines.

### General

The Committee considered the VMD's review of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) preliminary report for the reconsideration of approvals of the active constituent Diazinon, registrations of products containing Diazinon, and approval of their associated labels.

The VMD had prepared a response and the VPC was asked to comment on the review, the VMD's response and the responses from the Medical and Scientific Panel (MSP). The Committee agreed with the analysis provided by VMD and agreed that it should be sent to the APVMA in time to meet its deadline of 29 September.

The Chairman of the MSP agreed that the MSP would:

- consider whether the current advice on the risk assessments from exposure to OPs and the toxicology kinetics of Diazinon needed to be revised, and
- reconsider the VPC's earlier advice on the use of showers and jetties.

### Information Papers

The Committee also received the following papers for information, which are publicly available by request from the website or the VPC Secretariat.

- Copies of The Veterinary Record Contents (front page) "This Week's Issue" for editions published since the last meeting (recent articles are available on the website [www.vetrecord.co.uk](http://www.vetrecord.co.uk)).
- Joint VMD/VPC Open Meeting 2006.
- Statement from John Verrall re Food Ethics Council.

Additionally it received the following papers which are not available for publication.

- Report to the VPC on current ATC applications.
- Report to the VPC on current EU applications.
- Report to the VPC on Marketing Authorisations which have been Granted.
- Report to the VPC on Applications for Special Import Certificates and Special Treatment Certificates.
- Report to the VPC from the Sub-Group to review the Distribution Categories.
- Report from the Scientific Secretariat and the Biological Committee.

Corrected VPC Summary Minutes for the meetings of 19 and 20 July 2006 are available on the VPC website or by request from the VPC Secretariat.

The next regular meeting of the Committee will be held on Thursday 25 January 2007.

## ■ INVITATION TO APPLY FOR MEMBERSHIP OF THE VPC AND ITS SUB-COMMITTEES

The VMD is inviting nominations/applications, for membership of the VPC, the Medical and Scientific Panel (MSP), and the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines (AP), for a four year term starting on 1 January 2008. These appointments are not for full-time employment.

We are seeking candidates with expertise in the following areas; Clinical Toxicology, Occupational Health/Hygiene, Veterinary Immunology, Veterinary Surgeon (fish medicine), Veterinary Surgeon (mixed practice/small animal clinician) and a Working Farmer for the VPC; Toxicology and Neurology for the MSP, and Toxicology for the AP.

The closing date for receipt of completed application forms is 16 March 2007.

The UK Government and devolved administrations are committed to improving the diversity of the boards of their public bodies and welcome, in particular, applications from members of currently under-represented groups including women, people from ethnic backgrounds and disabled people. All public appointments are based on the principle of merit.

**Information packs and application forms are available from Becci Langdon, Defra, HRSD, Government Buildings, Block A, Whittington Road, Worcester, WR5 2LQ (01905 768839, e-mail [publicappts@defra.gsi.gov.uk](mailto:publicappts@defra.gsi.gov.uk)) and at: [www.defra.gov.uk/corporate/appointments/index.htm](http://www.defra.gov.uk/corporate/appointments/index.htm)**

# RESIDUES CONTROLS & 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 products where the presence of banned substances are most likely to be found. The programme is funded by Defra.*

*The independent Veterinary Residues Committee scrutinises and advises on the content of the VMD's (and FSA's) surveillance work.*

## ■ STATUTORY SURVEILLANCE IN 2006

The National Surveillance Scheme (NSS) operates in accordance with the requirements of Annexes I-IV of Council Directive 96/23/EC and Commission Decision 97/747/EC. All countries in the European Union must carry out targeted surveillance for residues of veterinary medicines in a range of animals and animal products, including red meat, poultry, farmed fish (salmon and trout), milk, eggs, honey and wild and farmed game.

Authorised officers collect samples from farms, slaughterhouses and egg packing stations. Where confirmed residues of authorised substances are found above the Maximum Residue Limit (MRL), a veterinary officer of the State Veterinary Service (SVS) carries out an investigation at the farm of origin to establish the source of the residue. For residues detected in fish an officer from the Centre for Environment, Fisheries and Aquaculture Science in England and Wales or the Fisheries Research Services in Scotland will undertake the follow-up investigation

Where unauthorised substances or high concentrations of authorised substances are detected, an Investigation Officer from the Department for Environment, Food and Rural Affairs (Defra) Legal Division will undertake an investigation.

The results of analyses completed between 1 January 2006 and 7 December 2006 are given in the accompanying tables, including the concentrations of the positive residues. Details of samples that have tested positive and any follow-up investigations that have been completed since the last edition of MAVIS are outlined in the text below.

## ■ RED MEAT

### **Synthetic Steroids and Natural Hormones**

Since the last edition of MAVIS, three further samples of urine/serum have tested positive above the Action Level for residues of hormones. Natural hormone concentrations vary with the metabolic or physiological status of the animal. As a result it is not possible to tell by confirmatory analysis of the sample whether the presence of the residue is a result of abuse or a naturally occurring elevated concentration. The SVS follow-up investigation includes examination of the animals for evidence of abuse of these substances and further sampling of animals on the farm in question.

### **Nortestosterone**

#### **Cattle**

One sample of cattle urine has confirmed positive for a residue of nortestosterone at a concentration of 10µg/l. The sample was collected from a pregnant animal two days before it calved. Research has shown that elevated levels of nortestosterone occur in cattle during pregnancy. This residue is therefore a natural occurrence and no follow-up action is being taken in respect of this result.

#### **Sheep**

One further sample of sheep urine has confirmed positive for a residue of nortestosterone at a concentration of 1.3µg/l. The SVS will investigate the cause of this residue and the result of their findings will be reported in a future edition of MAVIS.

None of the on-farm investigations into the presence of nortestosterone residues carried out by the SVS over the last 12 months has found any evidence of the abuse of nortestosterone. Research into the natural concentrations that can occur in untreated animals has been commissioned.

#### **Follow-up investigations: Nortestosterone in sheep urine – 3 samples at 1.0µg/l**

The follow-up investigations into the results showed no evidence of the abuse of this substance on the rearing farms. The medicines records and medicine storage were in accordance with the legal requirements. In all three cases the lambs were entire males aged between 3 and 4 months old. The most likely cause for these residues is that the concentrations detected in the urine were natural levels that might be found in rams that had not been castrated.

### **Progesterone**

#### **Cattle**

One further sample of cattle serum has confirmed positive for a residue of progesterone at a concentration of 0.8µg/l. The SVS will undertake a follow-up investigation into the cause of this residue and the result will be reported in a future edition of MAVIS.

#### **Follow-up investigation: Progesterone in cattle serum 1µg/l**

The follow-up investigation into the cause of this residue found no evidence of the illegal use of this substance on this farm. The medicines records and storage were in accordance with the legal requirements. The farm mainly

concentrates on fattening cattle which are purchased at 12-14 months of age and finished at about 24 months. Six further samples taken as part of the follow-up investigation tested negative.

## Antimicrobial Screen

### Calves

One further sample of calf kidney has confirmed positive for a residue of chlortetracycline at a concentration of 1,670µg/kg (MRL 600µg/kg). The outcome of the SVS follow-up investigation into the cause of this residue will be reported in a future edition of *MAVIS*.

### Pigs

One sample of pig kidney has confirmed positive for a residue of chlortetracycline at a concentration of 3,750µg/kg (MRL 600µg/kg). The SVS is continuing its investigation into the cause of this residue.

## Sulphonamides

### Pigs

A further sample of pig kidney has confirmed positive for a residue of sulphadiazine at a concentration of 260µg/kg (MRL 100µg/kg). The results of the follow-up investigation into the cause of this residue and the one reported in *MAVIS 60* are given below.

#### Follow-up investigation: Sulphadiazine in pig kidney 260µg/kg

The follow-up investigation into the cause of this residue established that the medicines records and storage were in accordance with the legal requirements. Products containing sulphonamides had been used on this farm but only for two weeks of a 10-15 week finishing period. Feed is delivered weekly. The most likely cause of this residue is cross-contamination of the feed because one feed bin is used for both medicated and non-medicated feed. Feed bins are not cleaned between deliveries. This residue has been extensively discussed with the farmer, his veterinary surgeon and the company involved.

#### Follow-up investigation: Sulphadiazine in pig kidney 260µg/kg

The follow-up investigation into the cause of this residue established that the medicines records and storage were in accordance with the legal requirements. This is a finisher unit with three buildings and six batches of pigs, each kept in one half of the building which is then cleaned out. Each batch has its own feed bin. Medicated feed is used in the starter ration. The VO considered that the most likely cause of this residue was cross-contamination of the feed. Medicated feed for a new batch of pigs was delivered into the feed bin being used to feed a batch that had not yet left the farm. Due to the bin design the pigs due for slaughter were likely to have had some of the medicated feed.

## ■ NSAIDs

### Horses

One sample of horse plasma has confirmed positive for a residue of phenylbutazone at a concentration of 25µg/kg.

This result has been investigated by the SVS and a summary of the report is given below.

#### Follow-up investigation: Phenylbutazone in horse plasma 25µg/kg

The follow-up investigation into the cause of this positive established that the horse had been out at grazing all summer and not been given any other feed. The owner stated the horse had not been treated with phenylbutazone and had not had access to feed containing this substance. However, a pony on the premises had been treated for laminitis and phenylbutazone has been prescribed for other horses on this farm. The owner was not aware that the animal would 'go for human consumption' when it was sent to the abattoir. Passports for all of the horses on these premises which have been treated with phenylbutazone have been returned to Defra so that the database can be updated to show that they must not go for human consumption.

## Cadmium and Lead

### Cattle

One further sample of cattle kidney has confirmed positive for a residue of cadmium at a concentration of 1,570µg/kg (MRL 1,000µg/kg). The SVS will be carrying out a follow-up investigation into the cause of this residue and the result will be reported in a future edition of *MAVIS*.

### Sheep

#### Cadmium

One sample of sheep kidney out of 45 analysed has confirmed positive at a concentration of 1,210µg/kg (MRL 1,000µg/kg). The results of the follow-up investigation into the cause of this residue are given below:

#### Follow-up investigation: Cadmium in sheep kidney 1,210µg/kg

The follow-up investigation was unable to establish the exact cause of this residue because it was not possible to accurately identify the farm of origin.

## ■ POULTRY

### Antimicrobials

The result of the follow-up investigation into the residue of chlortetracycline in duck muscle reported in the last edition of *MAVIS* is given below.

#### Follow-up investigation: Chlortetracycline in duck muscle 150µg/kg

The ducks are contract reared and this batch had been prescribed medication to reduce mortality and reject levels, which had been causing concern. The last medicated feed was fed 21 days before slaughter (the withdrawal period is 4 days). This result appears to have been due to cross-contamination or ducks finding some spilled medicated feed in the litter whilst being starved prior to slaughter. There is a single bin system using old bins with inaccessible inspection hatches. Farm procedure is that medicated feed is emptied out before plain food is put into the bin. The VO has recommended that the bin is also banged at this

stage in future to ensure bins are empty. In addition, as the young ducks are messy feeders, a considerable amount of feed spillage occurs around the feeders, as well as spills at the corners of the feeder system. As new straw is added each day, feed that has been spilled is likely to be covered, and only once feed is withdrawn before slaughter are the ducks likely to then find and eat this material.

### **Nicarbazin**

Nine further samples of broiler liver have been found to contain residues of nicarbazin above the JECFA MRL of 200µg/kg at concentrations of 260µg/kg, 280µg/kg, 330µg/kg, 350µg/kg, 400µg/kg, 400µg/kg, 880µg/kg, 920µg/kg and 3,100µg/kg. The muscle sample associated with the residue of 3,100µg/kg also confirmed positive at a concentration of 210µg/kg. In accordance with the VRC policy, farmers whose samples contain concentrations below 1,000µg/kg have been written to with guidance on how to avoid such residues in the future. The result of the follow-up investigation into the cause of the residue at 3,100µg/kg is given below.

#### **Follow-up investigation: Broiler liver Nicarbazin 3,100µg/kg and muscle 210µg/kg**

The follow-up investigation into the cause of the residue established that the birds had been sent to slaughter before the end of the withdrawal period. The company concerned admitted responsibility for this. Birds are normally on nicarbazin until 28 days with thinnings slaughtered at 35 days. This batch of birds were slaughtered at 32 days on welfare grounds due to excessive heat at the time. In addition, the withdrawal ration was only delivered one day before the batch of birds was slaughtered. Since this is not the first example where the withdrawal period has not been observed the farm's produce is being targeted at the slaughterhouse.

## **■ EGGS**

### **Antimicrobials**

One sample from caged production has confirmed positive for a residue of chlortetracycline at a concentration of 380µg/kg (MRL 200µg/kg). The result of the follow-up investigation into the cause of this residue is given below.

#### **Follow-up investigation: Chlortetracycline in caged egg 380µg/kg**

The follow-up investigation into the cause of this residue established that the most likely cause of this residue was that the withdrawal period had not been observed. The birds were being treated with Aurofac 100 and the withdrawal period for eggs had recently been changed from zero to four days. The veterinary surgeon who prescribed the medication has been advised of the change to the withdrawal period.

### **Ionophores**

Two samples from free-range production have confirmed positive for residues of the ionophore lasalocid at concentrations of 190µg/kg and 360µg/kg. The result of the follow-up investigation into the residue of 190µg/kg is given below. An investigation into the second positive has

not yet been completed and will be reported in a future edition of MAVIS.

#### **Follow-up investigation: Lasalocid in free-range egg 190µg/kg**

The follow-up investigation into the cause of this residue suggested that the most likely cause was contamination at the feed mill. The only treatment the birds receive is a powder for mite infestation. They come onto the farm at point of lay and are fed layer pellets from 25kg bags which are purchased from a local feed merchant. Any remaining bags are used up before those from a new delivery. Two egg samples taken at the time of the follow-up visit confirmed negative. The result of the analysis of one feed sample taken as part of this investigation is still awaited. The other feed sample confirmed negative. The Animal Medicines Inspectorate (AMI) will carry out an investigation at the feed mill involved.

#### **Follow-up investigation: Caged eggs lasalocid 260µg/kg and 270µg/kg**

These two samples were taken on the same day from eggs from the same farm. No medicines are used on the farm. Birds are purchased at point of lay and kept until about 80 weeks of age. Feed is delivered from the mill every ten days and supplied to three bins – each of which supplies one house. The most likely cause of the residue was felt to be feed contamination at the mill or during transport. An officer from the AMI visited the mill concerned. Four egg and two feed samples taken at the time of the visit tested negative. The report on the mill suggests that there were several areas where cross-contamination could have occurred. The AMI are writing to the mill about these issues.

### **Nicarbazin**

One sample from free-range production has confirmed positive for a residue of nicarbazin at a concentration of 40µg/kg (no MRL). The result of the follow-up investigation into this positive is given below.

#### **Follow-up investigation: Free-range egg Nicarbazin 40µg/kg**

The follow-up investigation into the cause of this residue established that there was no known use of nicarbazin on the farm. The only medicine used is a wormer supplied as a premix from the feed supplier. Each house has one feed bin cleaned at the end of each crop with surplus feed put into the chicken run. The most likely cause of this residue was felt to be cross contamination at the mill. The AMI follow-up investigation at the feed mill did not provide any conclusive evidence that there was an issue at the mill.

## **■ FARMED FISH**

One sample of trout muscle has confirmed positive for a residue of leucomalachite green at a concentration of 500µg/kg (Minimum Required Performance Limit (MRPL) 2µg/kg). Officers from CEFAS have carried out a follow-up investigation on the farm concerned including further sampling from all ponds on the site. Restriction notices

have been placed on the site concerned. The results of the follow-up investigation will be reported in a future edition of *MAVIS*.

## ■ MILK

### **Antimicrobials**

One sample has confirmed positive for a residue of Penicillin G at a concentration of 10µg/kg (MRL 4µg/kg). The result of the follow-up investigation into this residue is given below.

#### **Follow-up investigation: Antimicrobial in milk Penicillin G 10µg/kg**

The follow-up investigation was unable to establish its exact cause. The medicines records and storage were of a high standard. Two products containing antimicrobials were used on the farm but there was no conclusive evidence as to how the residue got into the bulk milk tank. The VO felt that there were two possible causes, a) one of the cattle had been treated without the treatment being recorded, b) cross-contamination had occurred in the milking parlour when a cow was treated for mastitis three days before the sample was taken. A sample taken at the time of the visit tested negative.

### **Aflatoxins**

One sample has confirmed positive for a residue of aflatoxin M1 at a concentration in excess of 0.05µg/kg (MRL 0.05µg/kg). The SVS will be carrying out an investigation into the cause of this residue and the result will be reported in a future edition of *MAVIS*.

## ■ HONEY AND WILD AND FARMED GAME

Sampling for honey commenced in late May and sampling for wild and farmed game commenced in June. No positives have been confirmed.

**Further information: Janet Rubidge (VMD, 01932 338328, e-mail: [j.rubidge@vmd.defra.gsi.gov.uk](mailto:j.rubidge@vmd.defra.gsi.gov.uk)).**

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN RED MEAT  
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006**

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg	
■ 0 Aflatoxins	Cattle		Liver	38			
	Pigs		Liver	51			
	Sheep		Liver	44			
■ 1 Hormones	Methyltestosterone	Pigs	Feed	21			
		Pigs	Urine	84			
		Sheep	Urine	92			
	Nortestosterone	Cattle	Male	Urine	447	1	10
		Sheep		Urine	170	9	0.6, 0.9, 1, 1, 1, 1, 1.3, 2, 2
	Oestradiol	Cattle	Male	Serum	334		
	Progesterone	Cattle	Male	Serum	397	17	0.5, 0.5, 0.6, 0.6, 0.7, 0.7, 0.7, 0.8, 0.8, 0.9, 0.9, 1, 1, 1, 2, 2, 3
	Stilbenes	Cattle	> 30 months	Urine	304		
		Pigs		Urine	86		
		Sheep		Urine	73		
	Testosterone	Cattle	> 30 months	Female Serum	460		
		Trenbolone	Cattle	> 30 months	Liver	1	
	Zeranol	Cattle	> 30 months	Urine	532		
Pigs			Urine	83			
Sheep			Urine	159			
■ 2 Pesticides Including PCBs	OC/PCBs	Cattle	Kidney fat	53			
		Pigs	Kidney fat	52			
		Sheep	Kidney fat	104			
Organophosphates	Cattle		Kidney fat	163			
	Pigs		Kidney fat	117			
	Sheep		Kidney fat	478			
■ 3 Pyrethroids/Carbamates	Calves	< 6 months	Kidney fat	15			
	Calves	< 6 months	Liver	5			
	Cattle		Kidney fat	20			
	Cattle		Liver	7			
	Pigs		Kidney fat	57			
	Sheep		Kidney fat	521			
■ 4 Beta-Agonists	Calves	< 6 months	Liver	25			
	Cattle	> 36 months	Feed	187			
	Cattle	> 30 months	Liver	445			
	Cattle	> 36 months	Urine	163			
	Horses		Liver	11			
	Pigs		Feed	37			
	Pigs		Liver	289			
	Sheep		Liver	272			
■ 5 Heavy Metals	Cadmium	Cattle	> 36 months	Kidney	72	4	1320, 1570, 1610, 1980
		Goats		Kidney	3		
		Horses		Muscle	10		
		Pigs		Kidney	11		
		Sheep		Kidney	45	1	1210
	Lead	Cattle	> 30 months	Kidney	72		
		Goats		Kidney	3		
		Horses		Muscle	10		
		Pigs		Kidney	11		
		Sheep		Kidney	45	2	840, 10070
	■ 6 Sulphonamides	Calves	< 6 months	Kidney	69		
		Cattle		Kidney	134		
Pigs			Kidney	694	2	260, 260	
Sheep			Kidney	126			
■ 7 Antimicrobial Screen	Calves	< 6 months	Kidney	188	3	1380, 1670, 2235	
	Cattle	> 30 months	Kidney	1,083			
	Goats		Kidney	11			
	Horses		Kidney	10			
	Pigs		Kidney	693	1	3750	
Sheep		Kidney	2,574				

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 8 Quinolones	Calves	< 6 months	Kidney	127		
■ 9 Annex IV						
Chloramphenicol	Calves	< 6 months	Kidney	23		
	Cattle	> 36 months	Feed	140		
	Cattle	> 30 months	Kidney	209		
	Pigs		Kidney	206		
	Sheep		Kidney	148		
Dimetridazole	Calves	< 6 months	Kidney	13		
	Cattle	< 24 months	Kidney	78		
	Horses		Kidney	10		
	Pigs		Feed	17		
	Pigs		Kidney	187		
	Sheep		Kidney	101		
Nitrofurans	Calves	< 6 months	Kidney	13		
	Cattle	> 30 months	Feed	106		
	Cattle	> 30 months	Kidney	147		
	Pigs		Feed	6		
	Pigs		Kidney	256		
	Sheep	< 6 months	Kidney	279		
■ 10 Anthelmintics						
Avermectins	Cattle		Liver	247		
	Goats		Liver	11		
	Horses		Liver	9		
	Pigs		Liver	161		
	Sheep		Liver	547	1	180
Benzimidazoles	Cattle		Liver	243		
	Horses		Liver	10		
	Pigs		Liver	152		
	Sheep		Liver	523		
Levamisole	Cattle		Liver	244		
	Horses		Liver	10		
	Sheep		Liver	251		
■ 11 Glucocorticoids	Cattle	> 30 months	Liver	269		
	Pigs		Liver	34		
	Sheep		Liver	18		
■ 12 Gestagens						
Altrenogest	Pigs		Kidney fat	75		
Boldenone	Cattle	> 30 months	Urine	396		
Gestagens	Cattle	< 24 months	Kidney fat	229		
	Cattle	> 30 months	Serum	235		
	Sheep		Kidney fat	82		
■ 13 NSAIDs	Cattle	> 30 months	Kidney	230		
	Pigs		Kidney	29		
	Sheep		Kidney	52		
Phenylbutazone	Cattle	> 36 months	Plasma	224		
	Horses		Plasma	38	1	25
■ 14 Coccidiostats						
Ionophores	Calves	< 6 months	Liver	46		
	Pigs		Liver	91		
	Sheep		Liver	317		
■ 15 Carbadox	Pigs		Liver	40		
■ 16 Sedatives						
Carazolol	Pigs		Liver	139		
Sedatives	Cattle		Liver	33		
	Pigs		Liver	139		
	Sheep		Liver	92		
■ 17 Thyrostats	Cattle	> 30 months	Serum	124		
	Cattle	> 30 months	Urine	154		
	Pigs		Urine	79		
	Sheep		Urine	70		
<b>Total</b>					<b>20,483</b>	<b>43</b>

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN POULTRY MEAT  
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006**

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRL $\mu$ g/kg	
<b>■ 0 Aflatoxins</b>	Broilers		Liver	28			
	Ducks		Liver	2			
	Hens		Liver	2			
	Turkeys		Liver	10			
<b>■ 1 Hormones</b>	Stilbenes	Broilers	Liver	130			
		Ducks	Liver	7			
		Hens	Liver	15			
		Turkeys	Liver	28			
	Trenbolone	Broilers		Liver	132		
		Ducks		Liver	4		
		Hens		Liver	6		
		Turkeys		Liver	26		
	Zeranol	Broilers		Liver	130		
		Ducks		Liver	14		
		Hens		Liver	24		
		Turkeys		Liver	73		
<b>■ 2 Pesticides Including PCBs</b>	OC/PCBs	Broilers	Liver	203			
		Ducks	Liver	2			
		Hens	Liver	2			
		Turkeys	Liver	27			
<b>■ 3 Pyrethroids/Carbamates</b>	Carbamates	Broilers	Liver	55			
		Ducks	Liver	6			
		Hens	Liver	5			
		Turkeys	Liver	20			
	Pyrethroids	Broilers		Liver	55		
		Ducks		Liver	6		
		Hens		Liver	5		
		Turkeys		Liver	20		
<b>■ 4 Beta-Agonists</b>	Broilers		Feed	177			
	Broilers		Liver	376			
	Ducks		Feed	6			
	Ducks		Liver	12			
	Hens		Feed	9			
	Hens		Liver	18			
	Turkeys		Feed	31			
	Turkeys		Liver	66			
<b>■ 5 Heavy Metals</b>	Cadmium	Broilers	Liver	3			
		Broilers	Muscle	20			
		Ducks	Liver	1			
		Ducks	Muscle	3			
		Hens	Liver	1			
		Hens	Muscle	5			
		Turkeys	Liver	5			
		Turkeys	Muscle	12			
	Lead	Broilers		Liver	3		
		Broilers		Muscle	20		
		Ducks		Liver	1		
		Ducks		Muscle	3		
		Hens		Liver	2		
		Hens		Muscle	5		
		Turkeys		Liver	5		
		Turkeys		Muscle	12		
<b>■ 6 Sulphonamides</b>	Broilers		Muscle	255			
	Ducks		Muscle	9			
	Hens		Muscle	14			
	Turkeys		Muscle	28			

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 7 Antimicrobial Screen	Broilers		Muscle	956		
	Ducks		Muscle	30	1	150
	Hens		Muscle	42		
	Turkeys		Muscle	241		
■ 8 Quinolones	Broilers		Muscle	413		
	Ducks		Muscle	12		
	Geese		Muscle	2		
	Hens		Muscle	14		
	Turkeys		Muscle	43		
■ 9 Annex IV	Chloramphenicol	Broilers	Muscle	744		
		Ducks	Muscle	24		
		Hens	Muscle	29		
		Turkeys	Muscle	125		
	Dimetridazole	Broilers	Feed	168		
		Broilers	Liver	681		
		Ducks	Feed	7		
		Ducks	Liver	19		
		Hens	Feed	10		
		Hens	Liver	23		
		Turkeys	Feed	32		
		Turkeys	Liver	103		
	Nitrofurans	Broilers	Feed	171		
		Broilers	Muscle	741		
		Ducks	Feed	4		
		Ducks	Muscle	23		
		Hens	Feed	3		
		Hens	Muscle	29		
		Turkeys	Feed	35		
		Turkeys	Muscle	124		
■ 10 Anthelmintics	Benzimidazoles	Broilers	Liver	110		
		Ducks	Liver	10		
		Hens	Liver	10		
		Turkeys	Liver	38		
	Levamisole	Broilers	Liver	107		
		Ducks	Liver	13		
		Hens	Liver	13		
		Turkeys	Liver	39		
■ 11 Coccidiostats	Ionophores	Broilers	Liver	270		
		Hens	Liver	9		
		Turkeys	Liver	60		
	Nicarbazin	Broilers	Liver	249	24	210, 230, 230, 240, 250, 260, 280, 330, 350, 350, 380, 400, 400, 480, 490, 680, 690, 780, 880, 920, 980, 1700, 2000, 3100
		Broilers	Muscle	58	1	210
<b>Total</b>				<b>7,973</b>	<b>26</b>	

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN EGGS**  
**RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRL $\mu\text{g}/\text{kg}$
<b>■ 1 Pesticides Including PCBs</b>					
OC/PCBs	Barn	Eggs	2		
	Caged	Eggs	11		
	Free Range	Eggs	19		
<b>■ 2 Pyrethroids/Carbamates</b>					
Pyrethroids	Free Range	Eggs	16		
<b>■ 3 Antimicrobial Screen</b>					
	Barn	Eggs	12		
	Caged	Eggs	93	1	380
	Free Range	Eggs	126		
<b>■ 4 Tetracyclines</b>					
	Barn	Eggs	4		
	Caged	Eggs	32		
	Free Range	Eggs	43		
<b>■ 5 Annex IV</b>					
Chloramphenicol	Barn	Eggs	4		
	Caged	Eggs	31		
	Free Range	Eggs	42		
Dimetridazole	Barn	Eggs	7		
	Caged	Eggs	58		
	Free Range	Eggs	80		
Nitrofurans	Barn	Eggs	4		
	Caged	Eggs	32		
	Free Range	Eggs	46		
<b>■ 6 Anthelmintics</b>					
Benzimidazoles	Free Range	Eggs	16		
<b>■ 7 Coccidiostats</b>					
Ionophores	Barn	Eggs	10		
	Caged	Eggs	85	2	260, 270
	Free Range	Eggs	113	2	190, 360
Nicarbazin	Barn	Eggs	9		
	Caged	Eggs	72		
	Free Range	Eggs	97	1	40
<b>Total</b>			<b>1,064</b>	<b>6</b>	

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN MILK**  
**RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRL $\mu\text{g}/\text{kg}$
<b>■ 0 Aflatoxins</b>	Cattle	Milk	83	1	0.05
<b>■ 1 Pesticides Including PCBs</b>					
OC/PCBs	Cattle	Milk	38		
Organophosphates	Cattle	Milk	25		
<b>■ 2 Heavy Metals</b>					
Cadmium	Cattle	Milk	33		
Lead	Cattle	Milk	33		
<b>■ 3 Antimicrobial Screen</b>	Cattle	Milk	590	1	10
<b>■ 4 Quinolones</b>	Cattle	Milk	253		
<b>■ 5 Annex IV</b>					
Chloramphenicol	Cattle	Milk	277		
Dimetridazole	Cattle	Milk	292		
<b>■ 6 Anthelmintics</b>					
Avermectins	Cattle	Milk	263		
Benzimidazoles	Cattle	Milk	93		
Levamisole	Cattle	Milk	100		
<b>■ 7 NSAIDs</b>					
Phenylbutazone	Cattle	Milk	176		
<b>■ 8 Cephalosporins</b>	Cattle	Milk	328		
<b>Total</b>			<b>2,584</b>	<b>2</b>	

**RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006  
NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN FARMED FISH**

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRL $\mu$ g/kg	
■ 0 Aflatoxins	Salmon		Muscle	3			
	Trout		Muscle	5			
■ 1 Pesticides Including PCBs	OC/PCBs	Salmon	Muscle	6			
		Trout	Muscle	5			
	Organophosphates	Salmon	Muscle	25			
■ 2 Pyrethroids/Carbamates							
Pyrethroids	Salmon		Muscle	90			
■ 3 Heavy Metals	Cadmium	Salmon	Muscle	3			
		Trout	Muscle	3			
	Lead	Salmon	Muscle	3			
		Trout	Muscle	3			
	Mercury	Salmon	Muscle	3			
		Trout	Muscle	3			
■ 4 Antimicrobial Screen	Salmon	Market	Muscle	85			
	Trout	Market	Muscle	9			
■ 5 Tetracyclines	Salmon	Market	Muscle	50			
	Trout	Market	Muscle	9			
■ 6 Quinolones	Salmon	Market	Muscle	53			
	Trout	Market	Muscle	8			
■ 7 Annex IV	Chloramphenicol	Salmon	Young	Muscle	165		
		Trout		Muscle	20		
	Dimetridazole	Salmon		Muscle	160		
		Trout		Muscle	19		
	Nitrofurans	Salmon		Muscle	92		
		Trout		Muscle	15		
■ 8 Anthelmintics	Avermectins	Salmon	Muscle	143			
		Trout	Muscle	6			
	Benzimidazoles	Salmon	Muscle	63			
		Trout	Muscle	9			
■ 9 Malachite Green	Leucomalachite Green	Salmon	Young	Muscle	119		
		Trout	Market	Muscle	87	1	500
	Malachite Green	Salmon	Young	Muscle	119		
		Trout	Market	Muscle	87		
<b>Total</b>				<b>1,470</b>	<b>1</b>		

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN GAME  
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006**

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRL $\mu$ g/kg
■ 1 Hormones	Zeranol	Deer	Liver	3		
■ 2 Pesticides Including PCBs						
OC/PCBs	Deer		Kidney fat	3		
■ 3 Pyrethroids/Carbamates						
Carbamates	Deer		Liver	2		
■ 4 Beta-Agonists	Deer		Liver	6		
■ 5 Heavy Metals						
Cadmium	Deer		Muscle	5		
	Partridge		Muscle	3		
	Pheasant		Muscle	4		
	Wild Deer		Muscle	15		
Lead	Deer		Muscle	5		
	Partridge		Muscle	3		
	Pheasant		Muscle	4		
	Wild Deer		Muscle	15		
■ 6 Antimicrobial Screen						
	Deer		Kidney	10		
	Partridge		Muscle	3		
	Pheasant		Muscle	3		
	Quail		Muscle	4		
■ 7 Annex IV						
Dimetridazole	Partridge		Muscle	5		
	Pheasant		Muscle	6		
	Quail		Muscle	8		
■ 8 Anthelmintics						
Avermectins	Deer		Liver	3		
Benzimidazoles	Quail		Muscle	4		
Levamisole	Deer		Liver	3		
■ 9 NSAIDs	Deer		Liver	1		
■ 10 Coccidiostats						
Ionophores	Partridge		Muscle	2		
	Pheasant		Muscle	3		
■ 11 Sedatives	Deer		Liver	2		
<b>Total</b>				<b>125</b>		

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN HONEY  
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY - 7 DECEMBER 2006**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRL $\mu$ g/kg
■ 1 Pesticides Including PCBs					
Organochlorines	Bees	Honey	16		
Organophosphates	Bees	Honey	9		
■ 2 Pyrethroids/Carbamates					
Pyrethroids	Bees	Honey	10		
■ 3 Heavy Metals					
Cadmium + Lead	Bees	Honey	10		
■ 4 Antimicrobial Screen	Bees	Honey	22		
■ 5 Tetracyclines	Bees	Honey	20		
■ 6 Streptomycin	Bees	Honey	21		
■ 7 Annex IV					
Chloramphenicol	Bees	Honey	15		
Nitrofurans	Bees	Honey	15		
■ 8 Macrolides	Bees	Honey	15		
■ 9 1,4 dichlorobenzene	Bees	Honey	5		
■ 10 Napthalene	Bees	Honey	5		
<b>TOTAL</b>			<b>163</b>		

## ■ RESULTS OF NON-STATUTORY SURVEILLANCE

The non-statutory veterinary medicine residue surveillance programme covers mainly imported produce and some home-produced foods that are not part of the National Surveillance Scheme (NSS). The programme can also carry out short surveys for areas of potential concern based on intelligence received.

### Non-statutory Surveillance 2006

#### Rolling programme

Sample collection and analysis for the 2006 non-statutory rolling programme commenced in April. The original plan was to carry out 3,500 analyses on 1,400 samples collected between April and December. However, the plan has been revised to include 1,000 additional analyses to be carried out on 260 additional samples. To accommodate this change, sample collection has been extended into January and February 2007. Analyses on these samples will be completed in March 2007. Port Health Inspectors and shoppers from a market research company collected 1,233 assayable samples of the 1,660 samples in the plan during the period April–November 2006. The Central Science Laboratory has completed 2,684 of the analyses due on the samples.

Since the report in *MAVIS 60*, a further nine samples have been found to contain residues above the Maximum Residue Limit or Action Level. A summary of these results is given below.

#### Nitrofurans

##### Farmed Warm Water Crustaceans

Three samples of farmed warm water crustaceans imported from Bangladesh (2) and India (1) contained residues of nitrofurans metabolites. All of the samples were collected at a Border Inspection Post (BIP) and contained residues of the nitrofurazone metabolite semicarbazide (SEM) at concentrations between 2.2 µg/kg and 3.9 µg/kg.

The remaining stock has been withdrawn from sale for these consignments of crustaceans.

##### Imported Farmed Fish

A sample of tilapia imported from China and collected at a BIP contained residues of the furazolidone metabolite AOZ at a concentration of 1.4 µg/kg.

The local authority has been notified of this result and withdrawal of the product has been recommended. The remaining stock has been quarantined and further sampling undertaken by the supplier as the test results from China were satisfactory.

Nitrofurans are in Annex IV of EC Council Regulation 2377/90. Their use in food producing species in the EU and in produce exported to the EU is prohibited.

The Chief Veterinary Officer (CVO) has written to her opposite numbers in the respective countries to inform them of these results and has asked to be kept informed of the outcome of any action that is taken. The results have also been reported to the Food Standards Agency (FSA) and the European Commission has issued Rapid Alerts.

#### 1,4-Dichlorobenzene

##### Imported Honey

A sample of honey imported from Australia contained residues of 1,4-dichlorobenzene at a concentration of 19 µg/kg. This sample was collected at a BIP. Although this sample was labelled as being produce of Australia and New Zealand the importation documents make no reference to any manufacture in New Zealand. The authorities in New Zealand are contacting Australia about the origin of this sample and its claimed link with New Zealand and investigating the certification history of this consignment.

1,4-dichlorobenzene is a hive fumigant used to clear wax moth infestations. Its use is not authorised in the EU. The CVO has written to her opposite numbers in Australia and New Zealand asking to be kept informed of the outcome of any action that is taken. This result has also been reported to the FSA who will ask the Commission to issue a Rapid Alert.

The FSA has advised that the results of counter analyses carried out by the Australian exporter and UK importer appear to be satisfactory. The retailer of this product has put the remaining stock from the implicated batch on hold and is also carrying out counter analyses. Results are expected shortly.

#### Macrolides

##### Imported Honey

Two samples of honey imported from Argentina and collected at BIPs contained residues of the antibiotic tylosin at concentrations of 2 µg/kg and 2.1 µg/kg. Tylosin is not authorised for use in bees and should not be present in honey imported into the EU. The CVO has written to her opposite number in Argentina asking to be kept informed of the outcome of any action that is taken. The results have also been reported to the FSA and a Rapid Alert has been issued for the sample found to contain 2 µg/kg.

No withdrawal of these products has been instigated as the residues did not pose a risk to health at the concentrations detected. Industry has been informed of these residues and is undertaking investigations.

#### Fluoroquinolones

##### Imported Farmed Fish

A sample of tilapia imported from Thailand and collected at a BIP contained residues of the fluoroquinolone enrofloxacin at a concentration of 830 µg/kg. The EU Maximum Residue Limit for enrofloxacin in fish muscle is 100 µg/kg. Although the toxicological advice is that there is no concern regarding potential effects for consumer health at the concentration detected, the presence of this residue in farmed fish being imported into the EU is still a matter of concern. The CVO has written to her opposite number in Thailand asking to be kept informed of the outcome of any action that is taken. This result has also been reported to the FSA.

Distribution details have been received for this sample and the FSA are awaiting feedback from the local authority on actions taken by some customers prior to preparing a Rapid Alert to send to the Commission.

## Crystal Violet

### Imported Farmed Fish

A sample of frozen salmon farmed in Chile, processed in Thailand and purchased from a retail outlet contained residues of crystal violet at a concentration of 1.8µg/kg.

Crystal violet is not authorised for use in food producing species and should not be present in aquaculture. The CVO will be writing to the Chilean authorities asking to be kept informed of the outcome of any action that is taken. A Rapid Alert has been issued by the Commission.

Following notification of this result the retailers concerned carried out a product withdrawal from all of their branches. The brand owners then carried out a product recall as a precautionary measure and a Food Alert was issued by the FSA for information.

## SUMMARY OF PROGRESS SINCE MAVIS 60

### Nitrofurans

In MAVIS 60 we reported on a sample of crustaceans imported from Bangladesh and found to contain residues of SEM at a concentration of 7.5µg/kg. The local authority was notified of this result and withdrawal of the product was recommended.

A Rapid Alert will be prepared by the FSA following receipt of information from the supplier on the distribution of the product.

We also reported on a sample of crustaceans imported from India and found to contain residues of the furazolidone metabolite AOZ at a concentration of 1.7µg/kg. The remaining stock for this product was disposed of and a Rapid Alert was issued by the European Commission.

## FEEDBACK FROM COUNTRIES OF ORIGIN ON ACTION TAKEN ON POSITIVE SAMPLES

### 1,4-Dichlorobenzene

In MAVIS 60 we reported that the New Zealand Food Safety Authority had advised that they would be introducing further risk mitigation steps as appropriate following the detection of 1,4-dichlorobenzene in samples of honey imported from New Zealand. Formal export requirements relating to 1,4-dichlorobenzene came into effect from 1 September 2006.

*Further information: Dawn Greener (VMD, 01932 338325, e-mail: d.greener@vmd.defra.gsi.gov.uk).*

## 2006 NON-STATUTORY SURVEILLANCE RESULTS 1 APRIL - 4 DECEMBER 2006

Sample	Analysed for	No. of samples analysed	MRL/MRPL/ Action Level µg/kg	No. of samples above the MRL/MRPL/ Action Level	Concentration detected where samples above the MRL or at/above the MRPL/Action Level µg/kg
<b>Farmed Warm Water Crustaceans</b>	Antimicrobial Screen	36			
	Nitrofurans	192		19	1,1.2,1.5,1.7,2.2,2.3,2.9,3.3,3.3,3.9,4.6,5.5,5.9,6.2,6.3,7.4,7.5,22
	Quinolones	36			
<b>Imported Cheese</b>	Chloramphenicol	81			
<b>Imported Cooked Poultry</b>	Nitrofurans	228			
<b>Imported Farmed Fish</b>	Antimicrobial Screen	28			
	Chloramphenicol	185			
	Crystal Violet	186		1	1.8
	Malachite green	186			
	Nitrofurans	186		2	1.4, 1.5
Quinolones	186		1	830	
<b>Imported Honey</b>	1,4-dichlorobenzene	84		2	19, 44
	Macrolides	84		2	2, 2.1
	Naphthalene	84			
	Organophosphates	84			
<b>Imported Raw Poultry</b>	Ionophores	76			
	Lasalocid	222			
	Maduramycin	222			
	Nicarbazin	76			
	Nitroimidazoles	222			

**MARKETING AUTHORISATION EUCEs ISSUED UNDER COMMUNITY AUTHORISATIONS  
REGULATION (EC) NO 726/2004  
BETWEEN 22 AUGUST 2006 - 29 NOVEMBER 2006**

Company	Vm Number	Product Name	Legal Category
Fort Dodge Animal Health Ltd	EU/V/06/060/001	Poulvac Flufend i AI H5N3 RG Vaccine	POM-V
Janssen Animal Health Bvba	EU/2/06/063/001-3	Yarvitan	POM-V
Novartis Sanidad Animal S.L.	EU/2/06/066/001-12	Prac-Tic Spot-On Solution for Dogs	POM-V
Pfizer Ltd	EU/2/06/062/001-5	Cerenia	POM-V

**MARKETING AUTHORISATION, MRP & DCPs ISSUED UNDER THE  
VETERINARY MEDICINES REGULATIONS 2006  
BETWEEN 22 AUGUST - 29 NOVEMBER 2006**

Company	Vm Number	Product Name	Legal Category
Animalcare Ltd	10347/4022	Benazecare 20	POM-V
Animalcare Ltd	10347/4021	Benazecare 5	POM-V
Ceva Animal Health Ltd	15052/4030	Cevac Transmune	POM-V
	15052/4032	Lapinject VHD	POM-V
Cid Lines NV	22136/4001	Kenostart SD 3000ppm Teat Spray/Dip Solution	AVM-GSL
Intervet UK Ltd	01708/4522	Cephaguard IV IM 4.5%	POM-V
	01708/4504	Nobilis Tri-OR inac	POM-V
Jurox (UK) Plc	25296/4000	Alfaxan 10mg/ml Solution for Injection	POM-V
Norbrook Laboratories Ltd	02000/4265	Norodyl 20mg Tablets for Dogs	POM-V
	02000/4266	Norodyl 50mg Tablets for Dogs	POM-V
	02000/4263	Paramectin Drench 0.8% w/v Oral Solution	POM-VPS
Schering-Plough Ltd	00201/4224	AquaVac RELERA	POM-V
	00201/4223	Procyon Dog Lepto	POM-V
	00201/4222	Procyon Dog Parvo	POM-V
	00201/4227	Resflor Injectable Solution	POM-V

The following tables list authorised variations which may affect the use of the product:

**MARKETING AUTHORISATION EUCEs VARIED  
COMMUNITY AUTHORISATIONS REGULATION (EC) NO 726/2004  
BETWEEN 22 AUGUST - 29 NOVEMBER 2006**

Company	Product Name	Brief Details
Boehringer Ingelheim Vetmedica Gmbh	Metacam 1.0mg Chewable Tablets for Dogs	Change of pack size
Boehringer Ingelheim Vetmedica Gmbh	Metacam 1.0mg Chewable Tablets for Dogs	Shelf life of the finished product extended
Eco Animal Health Ltd	Aivlosin Oral Powder	Change of pack size

**MARKETING AUTHORISATION MA, MRP & DCPs VARIED UNDER THE  
VETERINARY MEDICINES REGULATIONS 2006  
BETWEEN 22 AUGUST - 29 NOVEMBER 2006**

<b>Company</b>	<b>Product Name</b>	<b>Brief Details</b>
<b>Alfamed S.A.S.</b>	Friskies Flea And Tick Shampoo For Dogs	Change of medicinal product name from Friskies Flea and Tick Shampoo for Dogs to Canovel Insecticidal Shampoo and Conditioner.
<b>Animax Ltd</b>	Copinox Cattle	Change of Distributor from Bayer PLC to Animax Ltd.
<b>aniMedica GmbH</b>	Buserelin aniMedica 0.004 mg/ml - Solution for Injection	Change of medicinal product name to Generhal 0.004mg/ml - solution for injection for cattle, horses and rabbits
<b>Arnolds Veterinary Products Ltd</b>	Equipalazone Injection	Change of Marketing Authorisation Holder from Arnolds Veterinary Products Ltd. to Dechra Ltd.
	Equipalazone Paste E-PP	Change of Marketing Authorisation Holder from Arnolds Veterinary Products Ltd. to Dechra Ltd.
	Equipalazone Powder	Change of Marketing Authorisation Holder from Arnolds Veterinary Products Ltd. to Dechra Ltd.
	Intra-Epicaine	Change of Marketing Authorisation Holder from Arnolds Veterinary Products Ltd. to Dechra Ltd.
	Ovuplant	Change of Distributor from Arnolds Veterinary Products Ltd. to Dechra Ltd.
	Prednidale 5	Change of Marketing Authorisation Holder from Arnolds Veterinary Products Ltd. to Dechra Ltd.
	Somulose	Change of Marketing Authorisation Holder from Arnolds Veterinary Products Ltd. to Dechra Ltd.
<b>Braun B Melsungen Ag</b>	Gelofusine Veterinary	Change of Marketing Authorisation Holder from Braun B Melsungen Ag to B.Braun Vet Care GmbH
	Gelofusine Veterinary	Change of Distributor from B.Braun Medical Ltd. to Arnolds Veterinary Products Ltd.
<b>Cross Vetpharm Group Ltd</b>	Bimectin	Shelf life of the finished product extended
<b>DEC International (NZ) Ltd</b>	Eazi Breed Cidr Cattle Device Eazi Breed Cidr Cattle Device	Change of Withdrawal period Change of Marketing Authorisation Holder from DEC International (NZ) Ltd. to Pfizer Ltd.
<b>Dechra Ltd</b>	Equipalazone Paste E-PP	Change of medicinal product name from Equipalazone Paste E-PP to Equipalazone Paste
	Urilin Syrup	Change in pack size
<b>Delaval International AB</b>	QuarterMate	Change in pack size
<b>Ecolab Ltd</b>	Farmcare Concentrated Teat Dip	Change in pack size
<b>Ecolab Ltd (Trading as Adams Healthcare)</b>	Dipal Concentrate	Change in pack size
	Farmcare RTU Teat Dip	Change in pack size
<b>Emprasan (chemical) Ltd</b>	Chlorhexidine Rtu Teat Dip Or Spray	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco.
	Emprasan Lanolin Teat Dip Concentrate	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco
	Emprasan Sovereign	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco
	High Emollient Ready To Use Teat Dip Or Spray	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco
	K Dip	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco

<b>Company</b>	<b>Product Name</b>	<b>Brief Details</b>
	RTU Teat Dip or Spray	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco
	Super Concentrated Teat Dip	Change of Marketing Authorisation Holder from Emprasan (Chemical) Ltd. to Kilco
<b>Eurovet Animal Health BV</b>	Dexamethasone 0.2% Injection	Change of Distributor from Eurovet Animal Health BV to Ceva Animal Health Ltd.
<b>Fort Dodge Animal Health Ltd</b>	Dopram V Drops Equest Pramox Oral Gel	Change in packaging material Shelf life of the finished product extended
<b>Intervet UK Ltd</b>	Cephaguard LA 7.5% Levacur SC 3% Nobilis Diluent CA	Shelf life of the finished product extended Change of Distributor address Shelf life of the finished product extended
<b>Janssen-Cilag Ltd</b>	Mebadown Super Supaverm Vecoxan 2.5mg/ml Oral Suspension	Change in packaging material Change in packaging material  Change in pack size
<b>Norbrook Laboratories Ltd</b>	Lincoject Ovidown SC	Change of Withdrawal period Change of Distributor to Norbrook Laboratories (GB) Ltd. on behalf of Downland Marketing Ltd.
<b>Novartis Animal Health UK Ltd</b>	Tiamutin 12.5% Solution  Tiamutin 2% Premix	Change of medicinal product name from Tiamutin 12.5% Solution to Denagard 12.5% Oral Solution Change of medicinal product name from Tiamutin 2% Premix to Denagard 2% Premix
<b>Pharmacia Animal Health Ltd</b>	Vetalar V	Change of Marketing Authorisation Holder from Pharmacia Animal Health Ltd. to Pfizer Ltd.
<b>Schering Plough Ltd</b>	M+PAC	Change of Marketing Authorisation Holder from Schering-Plough Ltd. to Schering-Plough A/S
<b>The Bob Martin Co</b>	Bob Martin Flea Shampoo For Dogs And Puppies  Bob Martin Flea Shampoo For Dogs And Puppies  Bob Martin Flea Shampoo For Dogs And Puppies  Bob Martin Flea Shampoo For Dogs And Puppies	Change in container  Change in packaging material  Change of Marketing Authorisation Holder from The Bob Martin Co to Bob Martin (UK) Ltd. Change of packaging material
<b>VetCom-Pharma Ltd</b>	Reprocine	Change of Marketing Authorisation Holder's address

**EXPIRED MARKETING AUTHORISATIONS BETWEEN  
22 AUGUST 2006 - 29 NOVEMBER 2006**

<b>Company</b>	<b>Vm Number</b>	<b>Product Name</b>
<b>Chanelle Animal Health Ltd</b>	11990/4003	Chanazole Sc
<b>Dales Pharmaceuticals Ltd</b>	00123/4118	Peridale Paste
<b>Intervet Uk Ltd</b>	01708/4479	Rotakor K99
<b>Merial Animal Health Ltd</b>	08327/4181	Panomec Paste For Horses
<b>Norbrook Laboratories Ltd</b>	02000/4250	Battles Lignocaine and Adrenaline Injection
	02000/4251	Dunlop's Local Anaesthetic
	02000/4252	Loconil
	02000/4171	Willows Dry Cow
<b>Pharmacia Animal Health Ltd</b>	04188/4078	Pancrex Vet Powder
<b>Schering Plough Ltd</b>	00201/4122	Systemex 2.265% Worm Drench
<b>Virbac S.A.</b>	05653/4121	Good Girl Junior Flea Collar
	05653/4114	Goodboy Junior Flea and Tick Collar for Puppies