

MAVIS

MARKETING AUTHORISATION VETERINARY INFORMATION SERVICE

EDITION 65 – JANUARY 2008

■ THE VETERINARY MEDICINES REGULATIONS 2008: UPDATE

As part of the annual project to revoke and remake the Veterinary Medicines Regulations, we are currently preparing the documents for the 2008 Regulations, which are due to come into force on 1 October 2008.

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 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.

Further information regarding the Veterinary Medicines Regulations please contact Caroline Povey (VMD, 01932 338319, e-mail: c.povey@vmd.defra.gsi.gov.uk).



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The best available information on the work of the VMD can be found on our on-line MAVIS service www.vmd.gov.uk



INVESTOR IN PEOPLE

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ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

■ VMD CONTRIBUTES TO SUSTAINABLE DEVELOPMENT

The purpose of this article is to tell you that the VMD has produced its second Sustainable Development (SD) Action Plan, covering the period from October 2007 to the end of 2009. We produced our first plan as part of the commitment to the UK Government Sustainable Development Strategy – Securing the Future (March 2005), under which all Government departments and their executive agencies produced focused sustainable development action plans based on the Strategy.

The first plan set out how we contributed to outcomes that are now included under the Sustainable Development banner, by using sound science responsibly and implementing good governance to develop policy and regulate veterinary medicines (our core business since 1990). The second plan builds on these achievements by taking account of lessons we learned during the implementation of the first plan and advice we received from Defra and the Sustainable Development Commission.

The plan includes a number of actions across a range of our activities that we believe will contribute further to the Government's Sustainable Development objectives, as set out in Securing the Future and Defra's Mission to 'live within our environmental means'. It also shows how we are increasingly embedding Sustainable Development principles and priorities in our decision making, whilst also delivering the requirements set down in European and UK legislation for veterinary medicines. The plan can be downloaded from the VMD website www.vmd.gov.uk (under About/Sustainable Action Plan).

Further information about the plan or any other aspects of our approach to Sustainable Development: David Lewsey (VMD, 01932 338332, e-mail: d.lewsey@vmd.defra.gsi.gov.uk).

■ STAFF CHANGES

- Judith Mitchley, Veterinary Research Officer in the Pharmaceuticals & Feed Additives team, commenced full time working from 1 January 2008.
- Sharon Price, Veterinary Research Officer, returned from maternity leave on 1 November 2007.
- Sarah Millard and Karen Hanna were promoted to Higher Scientific Officers in the Quality team on 1 November 2007.
- Janette Rickard, Residues, retired on 31 December 2007.
- Sam Ward was promoted to Executive Officer in the Licensing Services team on 3 December 2007 and Lori Hughes, who was temporarily covering this post, returned to her position as Administrative Officer in Licensing Services on 1 January 2008.
- Sam Fletcher commenced a period of temporary promotion to Senior Scientific Officer in the Safety team on 1 January 2008.
- Ken Stapleton commenced a period of temporary promotion to Higher Scientific Officer in the Safety team on 1 January 2008.
- Aizaz Moin transferred to the Residues Surveillance Unit (initially on a 4 month experience posting) on 7 January 2008.

■ EU REVIEW RESIDUES LEGISLATION

The VMD has created a new area on its website dedicated to informing stakeholders of developments about a review of EU residues legislation.

The Commission started the review of residues legislation in 2003. It found the existing legislation on pharmacologically active substances used in veterinary medicinal products had greatly increased consumer protection. However, the legislation had also contributed to the decreased availability of medicines for use in food producing animals in the EU. The legislation had also led to various problems in international trade related to enforcing laws controlling residues.

Three pieces of EU law are included in the review:

1. **Regulation 2377/90** which is the procedure used to assess pharmacologically active substances for safety and where appropriate, set Maximum Residue Limits. There are four major components:
 - providing a legal base for Codex MRLs to be adopted by the EU without further risk assessment where the science is supported by the EU;
 - making the assessment of the possibilities for extrapolation a part of the scientific assessment when setting MRLs and creating a legal basis for the Commission to set down the principles for applying extrapolation;
 - the complex area of residues of substances not authorised for use in the EU detected in food (particularly imported from non-member states);
 - setting Maximum Residue Limits for those biocides that are used in animal husbandry.
2. **Directive 96/22** which limits the use of hormonal substances and beta-agonists in animals. The main amendments are:
 - banning the remaining (therapeutic) uses of oestradiol-related substances in farm animals;
 - requiring the Commission to gather additional information on other hormonally-active substances and bringing forward any new proposals it thinks are necessary;
 - removing the restrictions on using certain hormonal substances in pets, including allowing non EU countries that authorise certain hormonal substances in pet animals only, to export food to the EU; and
 - removing the prohibition on treating horses with beta-agonists.
3. **Directive 96/23** which requires Member States to undertake surveillance for residues of veterinary medicines and certain other substances.

The Commission have not brought forward formal proposals yet but we expect them to do so during 2008.

Further information on the objectives and progress of the review is on our website www.vmd.gov.uk (under General Information/Veterinary Residues Legislation) or contact David Webb (VMD, 01932 338327, e-mail: d.webb@vmd.defra.gsi.gov.uk).

■ MEDICATED FEEDINGSTUFFS PRESCRIPTIONS (MFSp)

The VMD has reviewed completed prescriptions for in-feed veterinary medicinal products and it is clear that the rules relating to the completion of MFSp are not always being followed correctly. We hope the following advice will help veterinary surgeons when completing MFSp.

The review of completed prescriptions showed a variety of errors or omissions. Examples of the most commonly reported errors include:

- incorrect level of medication
- incorrect feed named
- wrong Vm number
- animal numbers missing
- no, or incorrect number of, withdrawal days
- no feed amount specified.

The information which a veterinary surgeon must include in a MFSp is given in Schedule 5 of the Veterinary Medicines Regulations.

Veterinary Medicines Guidance Note 21 (Medicated Feedingstuffs Prescriptions) also contains details of what must be included on the prescriptions. The Guidance Note can be downloaded from the VMD website www.vmd.gov.uk (under General Information/ Veterinary Medicines Regulations & Guidance/Legislation Documents).

Veterinary surgeons may produce their own prescription form electronically, provided it follows the requirements as listed in the Regulations.

The veterinary surgeon has sole responsibility for the correct completion of an MFSp. He or she may liaise with a feed mill over the completion of a particular prescription but must not accept a request from a mill for a MFSp without first ensuring that there is an actual need for the medicated feed prescription.

The Regulations make it clear that a veterinary surgeon should carry out a clinical assessment of the animal or animals, which must be under his care, before issuing an MFSp. Therefore, if there is any doubt, he or she should discuss the matter with the keeper of the animals and undertake an assessment of the animals.

The veterinary surgeon must also ensure that an MFSp is sufficient for only one course of treatment. Such prescriptions may be valid for up to three months, so, if the length of time of the treatment of the animal will exceed three months, the veterinary surgeon will need to issue a fresh prescription part way through the course of treatment. If the treatment requires the prescription to be valid for a period of longer than one month, the veterinary surgeon should specify on the prescription the amount of medicated feed to be provided each month as the supplier may not provide more than 31 day's supply at any one time. In specifying the quantity of feed prescribed the veterinary surgeon must accurately take into account the number of animals to be treated, the quantity of feed to be fed per day and the duration of the treatment.

When a veterinary surgeon supplies an in-feed veterinary medicinal product to a home-mixer, he or she should also issue an MFSp.

Please check that the feed manufacturer is approved by the VMD before supplying in-feed veterinary medicinal products or writing an MFSp for the manufacture of medicated feeds. Details of approved manufacturers are on the VMD website www.vmd.gov.uk (under Industry/AMI) or contact the Animal Medicines Inspectorate on 024 7684 9260.

■ MEMBERSHIP OF THE VETERINARY RESIDUES COMMITTEE 2009 - 2012

The Chair and Board Appointments Team of the Veterinary Medicines Directorate is inviting applications for terms of office beginning 1 January 2009.

The Veterinary Residues Committee is the independent committee established in 2001 to provide advice to the Veterinary Medicines Directorate and Food Standards Agency on veterinary medicine residues surveillance.

The VRC is seeking candidates who have current, relevant experience in the following areas:

Local authority

A Chartered Environmental Health Practitioner, possessing a strong knowledge of food safety legislation enforcement and practical experience of local authority enforcement of imported food controls, as well as the control of veterinary medicines and similar banned substances in food in a local authority context.

Food Industry

Should combine in-depth experience of working in the food industry with knowledge of the implications of veterinary residues in the production of foodstuffs.

Agriculture Industry

Should have a detailed knowledge of working in the agriculture industry and knowledge of livestock rearing.

Pharmaceutical Industry

Strong understanding of the pharmaceutical industry, complemented by knowledge of the authorisation, manufacture, and distribution processes of veterinary medicines.

Feed Industry

Combining a comprehensive knowledge of the feed industry to an awareness of the usage of feed additives.

Fish Farming

Someone with knowledge and experience in the fish farming industry and of the relevant production methods.

Food Chemical Safety/Risk Assessment

Although expertise in veterinary medicines is not essential for this role, the candidate must have substantial scientific experience of food chemical safety issues and the assessment of risks to consumers.

To be considered for any of these positions, candidates must be a strong communicator and team player who can apply specialist knowledge to develop strategy and policy. They should also have the ability to work independently as well as within a committee structure to arrive at sound, balanced and timely decisions.

The Committee usually holds four meetings a year in January, March, June and October. The October meeting is the Committee's 'open' meeting and although this has previously been held in London, the Committee is considering holding future open meetings at other locations within the UK. All other meetings of the Committee are held at the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS.

Further information

These appointments are not for full-time employment. The VRC pays its members £142 to attend each of these meetings, together with £36 preparation time. The initial appointment will be for a four year term starting on 1 January 2009.

For an information pack and application form please contact Public Appointments at Defra on 0207 270 6166, via e-mail at: publicappts@defra.gsi.gov.uk or by post to: Linda Bailey, Room Area 3c, Whitehall Place West, 3 – 8 Whitehall Place West, London, SW1A 2HH

The application form and information pack are also available online at: www.defra.gov.uk/corporate/appointments/index.htm

Completed application forms must be received by **31 March 2008**.

The UK Government and devolved administrations are committed to improving the diversity of their public bodies and welcome applications irrespective of race, ethnic or national origin, sex, marital status, disability, sexual orientation, religion, religious beliefs or similar philosophical belief, age, gender re-assignment or community background. All public appointments are based on the principle of merit.

Further information on the Veterinary Residues Committee please visit www.vet-residues-committee.gov.uk.

LICENSING

■ UK PUBLIC ASSESSMENT REPORTS, UKPARS

UKPARs published between 8 September 2007 - 28 November 2007

Route of Authorisation	Product	Date published
<u>National</u>		
	Bimagen Forte AS	12 September
	Nemovac	12 September
	Fenflor 300mg/ml Solution for Injection for Cattle	13 September
	Fenflor 300mg/ml Solution for Injection for Pigs	13 September
	Poulvac AE Vac	17 September
	Bovidip 2% w/w Concentrate Dip or Spray Solution	24 September
	Bovidip 0.5% w/w Teat Dip or Spray Solution	24 September
	Johnson's 4 Fleas Protector 10% Spot-On Solution for Cats and Kittens	4 October
	Johnson's 4 Fleas Protector 2% Spot-On for Puppies and Small Dogs	4 October
	Johnson's 4 Fleas Protector 2% Spot-On for Medium Dogs	4 October
	Johnson's 4 Fleas Protector 2% Spot-On for Large Dogs	4 October
	Ripercol 75mg/ml Oral Solution	4 October
	Spirovac for Cattle	4 October
	Enroxil Max Solution for Injection 100mg/ml for Cattle	8 October
	Vetmedin 5.0mg Flavour Tablets	19 October
	Vetmedin 1.25mg Flavour Tablets	19 October
	Norodyl 5% Small Animal Injection for Cats and Dogs	31 October
	Reproval 5% Small Animal Injection for Cats and Dogs	2 November
	Tiamvet Solution 12.5%	2 November
<u>Mutual Recognition</u>		
RMS	Anipryl 2mg Tablets for Dogs	21 September
RMS	Anipryl 5mg Tablets for Dogs	21 September
RMS	Anipryl 10mg Tablets for Dogs	21 September
RMS	Anipryl 15mg Tablets for Dogs	21 September
RMS	Anipryl 30mg Tablets for Dogs	21 September
RMS	Carprogesic 20mg Tablets for Dogs	21 September
RMS	Carprogesic 50mg Tablets for Dogs	21 September
CMS	Poulvac Pabac IV	26 October
CMS	Rimifin 20mg Tablets for Dogs	19 November
CMS	Rimifin 50mg Tablets for Dogs	19 November
CMS	Rimifin 100mg Tablets for Dogs	19 November
CMS	Avinew	22 November
CMS	Sumex Pour-On Solution 0.5%	22 November
<u>Decentralised</u>		
RMS	Gallimune Se+St	12 September
RMS	Duramune Dap	14 September
RMS	Duramune Dap+L	14 September
RMS	Duramune Dap+LC	14 September
<u>Centralised</u>		
	Prilactone 10mg	2 November
	Prilactone 40mg	2 November
	Prilactone 80mg	2 November
	Previcox 8.2mg/g Oral Paste for Horses	8 November

We would appreciate feedback on the UKPAR web pages and product scientific discussions. Please e-mail Iain Jenkins i.jenkins@vmd.defra.gsi.gov.uk with any comments you may have.

■ CLARIFICATION OF SECTIONS 1, 9 AND 11 IN THE SUMMARY OF PRODUCT CHARACTERISTICS (SPCs) FOR NATIONALLY AUTHORISED PRODUCTS ONLY

Recent feedback from Marketing Authorisations Holders has suggested that it is not always clear what information is required in Sections 1, 9 and 11 of the SPC. Therefore, we thought it would be useful to provide some clarification to ensure that a consistent approach is applied across the board.

The following will apply to applications for new MAs and applications where SPC changes are required. It will apply to nationally authorised products only and it will not be applied retrospectively.

Section 1 (Product name)

Pharmaceutical products: Name + strength* + pharmaceutical form. Target species if necessary only.
*[only where there is one active].

Immunological products: Name. Vaccine strain if necessary/relevant only. Target species if necessary/relevant only.

Section 9 (Date of first authorisation/date of the renewal of the authorisation)

The date of first authorisation only should be included in this section.

Section 11 (Further information)

This is a national requirement only. The text 'Section 11' will not be included in the SPC and the VMD (not the applicant) will add 'Section 11', plus the relevant information, in exceptional circumstances only.

The following are examples of what the VMD would consider appropriate:

1. Reference to specific requirements relevant to the PET Travel Scheme.
2. Restrictions to the supply of the product subject to national or EU control measures.

Further information: Lesley Johnson (Head of Pharmaceuticals and Feed Additives), (VMD, 01932 338413, e-mail: l.johnson@vmd.defra.gsi.gov.uk) or Martin Illott (Head of Immunologicals) (VMD, 01932 338331, e-mail: m.illott@vmd.defra.gsi.gov.uk).

■ SMALL ANIMAL EXEMPTION SCHEME

The Small Animal Exemption Scheme permits certain veterinary medicines to be marketed without the need for a Marketing Authorisation. The scheme was fully implemented on 1 November 2007, when the requirements for the labelling and manufacture of products came into force.

We have received a number of enquiries regarding the pack size requirements for aquatic products and therefore wish to clarify the position.

The Regulations state that pack size "must only be sufficient for a single course of treatment, or in the case of a veterinary medicinal product for aquarium fish, sufficient for a single

■ APPLICATIONS & RESPONSES - NUMBER OF PAPER COPIES REQUIRED

As part of the Data Disposal project the Veterinary Medicines Directorate has re-assessed its requirements for the number of copies of supporting data needed for applications. Our intention is to help reduce administrative burdens to the Industry whilst still maintaining an appropriate number of paper copies in order that we can effectively and efficiently carry out our assessment work.

We have identified three areas where we can reduce the number of copies required. With immediate effect the number of copies of data required will be as follows:

- **New Marketing Authorisation:** for Immunological Products: Three (3) copies of the Full dossier (we do not need the extra Part 1 dossiers required for Pharmaceutical products).
- **Written Responses:** Two (2) full copies of response to questions.
- **Mock-ups:** Only One (1) copy of the Mock-ups.

These amendments have been forwarded to the Commission for inclusion in Volume 6A, Chapter 7 of the Notice to Applicants.

An overall summary of the VMD's requirements for copies of submissions can be found on our website, please go to General Information, select Application Page followed by FAQs.

The VMD is aware that a number of companies would be keen to provide electronic copies of the supporting data rather than paper copies. The VMD is committed to being able to accept electronic only copies of dossiers by **no later than** the end of 2009, in accordance with the agreement reached by the European Heads of Medicines Agencies (HMA).

We hope that you will find this helpful, should you require any further information please contact: Becky Young (VMD, 01932 338444, e-mail: b.young@vmd.defra.gsi.gov.uk).

course of treatment of no more than seven administrations to an aquarium of 25,000 litres".

Products to treat an aquarium of more than 25,000 litres are not permitted to be sold. Products may be indicated for a single course of treatment of up to seven administrations. For example a product may be indicated for seven administrations to a 25,000 litre pond, over a period of 14 days, at one dose every other day. Those products labelled or indicated in product literature to treat more than 25,000 litres will be seized.

Further information and advice is available on the VMD website www.vmd.gov.uk (under Industry/SAES) or by contacting Simon Hack (VMD, 01932 338306, e-mail: s.hack@vmd.defra.gsi.gov.uk) or Barry Haycraft (VMD, 01932 338308, e-mail: b.haycraft@vmd.defra.gsi.gov.uk).

■ MEASURES TO HELP REDUCE THE BURDEN ON INDUSTRY WITH REGARD TO THE SUBMISSION AND ASSESSMENT OF MOCK-UPS

The VMD is aware that for some companies the need to send mock-ups to the VMD for approval can prove to be quite a difficult, time consuming and costly process. Despite these difficulties the VMD considers that the provision of mock-ups is very important. Past experience has demonstrated that if the VMD does not examine mock-ups, the labels on the products in the market place in a surprisingly high proportion of cases will not correspond to the authorised SPC. Furthermore, certain aspects can only be checked by examining the mock-ups rather than the proposed text. For example, it is important to ensure that sufficient emphasis is given to important warnings and it is necessary to check labels are not over-crowded and that they are legible.

However, in recognition of the problems that are sometimes created by VMD requests to provide mock-ups the VMD has implemented some measures, over the past couple of years, to try to help reduce the burden on industry with regard to the submission of mock-ups during and/or after an application procedure; some examples of these measures are detailed below.

Previously the VMD required a full set of mock-ups to be submitted as part of the application package for a new national marketing authorisation (MA) in order for the application to be deemed valid. This is no longer the case; however, mock-ups will be required at some point during the assessment process and before the MA is granted. Additionally, the VMD used to request a set of revised mock-ups following grant of a national new or renewal application; now revised mock-ups will only be requested if deemed necessary by the assessor(s).

The VMD no longer requests revised mock-ups to be submitted following the approval of a national variation application; if revised mock-ups are required these will be requested during the assessment process as part of the 'question' letter.

For national and European procedures the VMD will accept and approve text for non-marketed products or pack sizes on the proviso that marketing authorisation holders (MAHs) submit mock-ups for approval before placing the product on the market for sale and supply. In these circumstances mock-ups should be submitted under cover of a Type IB (i) variation in order that they may be formally assessed.

If MAHs submit more than one national application for the same product at the same time the VMD will normally accept one set of mock-ups to cover all applications. The VMD would be grateful if MAHs discussed this with the validating assessor prior to submission to ensure that it is feasible.

The VMD has also collaborated with the Irish Medicines Board to develop a procedure for achieving and maintaining joint labels following an EU application procedure.

A clarification paper about this issue is available on the VMD website at www.vmd.gov.uk

The requirements for the submission of mock-ups for national application procedures are outlined in VMGN No. 18, which is also available on the VMD website. Please note that the VMD has also created a checklist for applicants to use when submitting mock-ups for national and/or EU application procedures. This checklist is annexed to the above guidance note.

For general information about the submission of mock-ups please contact Natalie Shilling (VMD, 01932 338452, email: n.shilling@vmd.defra.gsi.gov.uk). If you wish to discuss mock-ups in relation to a specific application procedure please contact the relevant assessor(s).

■ CHANGE TO THE NAME AND/OR ADDRESS OF THE MARKETING AUTHORISATION HOLDER FOR NATIONALLY AUTHORISED PRODUCTS

The purpose of this article is to clarify the procedure for changing the name and/or address of the Marketing Authorisation Holder (MAH), which is a Type IA(1) variation, and any consequential changes arising from this.

A change to the name and/or address of the MAH will be dealt with administratively.

In order to help reduce the administrative burden on applicants the VMD is happy to process a number of consequential changes at the same time, under a single application, as follows:

- a change to the name and/or address of the distributor; and/or
- a change to the name only of the manufacturer/assembler of the active substance Type IA(4) and/or finished product Type IA(5).

A change to the legal entity of the MAH (national Type IB(c)), with consequential changes to the name and address of the distributor only, will also be dealt with administratively and may be processed together under a single application.

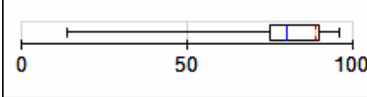
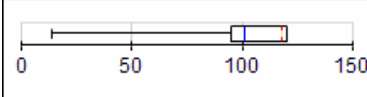
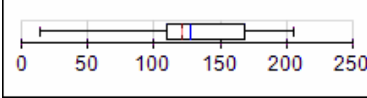
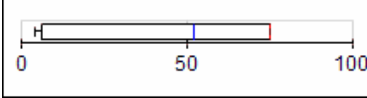



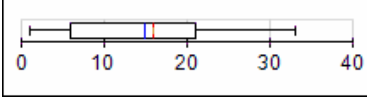
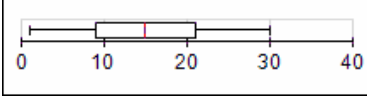
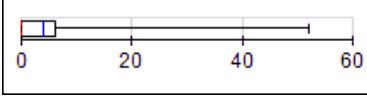
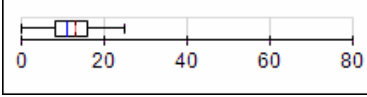
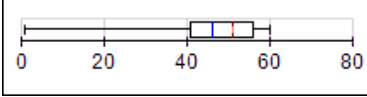
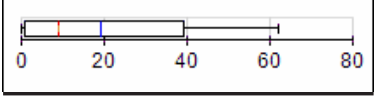
Consequential changes must be applied for at the same time on the same form; if any of these changes are applied for at different times and/or on different forms, they will be processed separately and charged for accordingly.

Please note - Any changes to the address of the manufacturer/assembler of the active substance Type IA(4), and/or finished product Type IA(5), will be dealt with scientifically as per normal variation procedures. These will not be considered consequential to any changes of MAH details.

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

MONTHLY REPORTING AGAINST: VMD PUBLISHED STANDARDS FOR LICENSING WORK 2007/2008

The following summarises the VMD's performance against its published standards for the period 1 July 2007 to 31 December 2007. To be fully understood these summarised results must be read in conjunction with the published standards issued in April 2007.

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days ¹)	Average time in days	Box Whisker Plots Key: ----- = Median — = Average
National MA and MAPIs					
Initial assessment	32	Excellent	90	80	
Sign-off, VPC or further questions	26	Excellent	120	101	
Sign-off and issue	31	Excellent	210	128	
MAPIS for MR products & copy-cats					
Initial assessment	6	Excellent	75	52	
Sign-off, VPC or further questions	3	Excellent	120	43	
Sign-off and issue	3	Excellent	210	44	
Variations					
Type 1A - decision	243	Excellent	14	9	
Type 1B admin - issue	49	Excellent	30	15	
Type 1B - initial assessment	192	Excellent	30	15	
Type 1B - sign off	189	Excellent	30	4	
Harmonisation - sign off	10	Excellent	60	11	
Type II - initial assessment	430	Excellent	60	46	
Type II - sign off	382	Excellent	60	19	

¹ The days are specified as either calendar days or clock days according to the target and as set out in detail in the published standards.

² Box whisker plots have been omitted due to low numbers of applications.

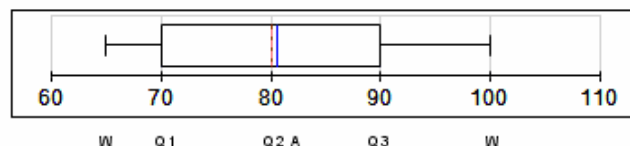
Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days ¹)	Average time in days	Box Whisker Plots
Renewals					
Administrative - sign off	140	Excellent	30	2	
Full and conditional - initial assessment	32	Excellent	90	62	
Full and conditional - sign off	70	Excellent	180	56	
ATCs					
Type A and B - validate	31	Excellent	5	2	
Type A - sign off	13	Excellent	30	15	
Type B - sign off	20	Excellent	50	33	
Type A and B - issue	33	Excellent	5	2	
Batch release (Immunologicals)					
Issue	1488	Excellent	15	5	
AVAS and NFABBA (inc variations)					
Assess	3	Excellent	45	30	
Specific Batch Control					
Validate	35	Excellent	3	< 1	
Initial assessment	35	Excellent	10	2	
Assess response	35	Excellent	10	< 1	
Issue	34	Excellent	3	< 1	
Validation/Issue					
Validate	999	Excellent	10	4	
Issue	1333	Excellent	10	6	
UKPARs					
Module 1	103	Excellent	30	15	
Module 2	86	Excellent	120	47	
Module 3	114	Excellent	60	35	
Import Certificates³					
SIC - urgent/non-urgent	1533	Excellent	2/10	< 1	
STC - urgent/non-urgent	2933	Excellent	2/10	< 1	

Box and Whisker Plots

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

E.g. Application days for 10 applications: 80, 75, 90, 95, 65, 65, 80, 85, 70, 100
 First order the data in numerical order: $\underset{W}{65}, \underset{Q1}{65}, \underset{Q2}{75}, \underset{A}{80}, \underset{Q3}{85}, \underset{W}{95}, 100$

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



³ These are presented for information only - they do not form part of the VMD's formal published standards. They relate to paper based applications. The combined figures are for both the Scientific and Administrative teams.

Category/Application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days ⁴)
European			
Centralised			
Rapp - Initial assessment	1	Excellent	70
Co-Rap - Provide comments on assessment report by 85 days	2	Excellent	85
UK as Member only - LOQ by 100 days	1	Excellent	100
Mutual Recognition			
RMS			
Production of Final Assessment Report by 1st 90 days	26	Excellent	90
Assessment of Responses by 2nd 70 days	20	Excellent	70
Procedure completed by 2nd 90 days	22	Excellent	90
CMS			
Procedure completed by 2nd 90 days	13	Excellent	90
Decentralised			
RMS			
Production of Assessment Report within 70 days	18	Excellent	70
Production of Assessment Report within 120 days	11	Excellent	120
Assessment of Responses by 70 days	4	Excellent	70
Procedure completed by 90 days [210 in total]	4	Excellent	90[210]
CMS			
UK comments sent by 100 days	23 ⁵	Unacceptable	100
	7	Excellent	120
UK acceptance/referral sent by 90 days[2nd phase] [210 days]	15	Excellent	90[210]
MRL (No. 6.i)			
Report for CVMP	1	Excellent	120
European Variations			
Type II - Mutual Recognition RMS			
PAR circulated	40	Excellent	40
CLOQ circulated	26	Excellent	60
Procedure completed	46	Excellent	90
Type IB - Mutual Recognition RMS			
CLOQ circulated	13	Excellent	30
Procedure completed	66	Excellent	60
Type IA - Mutual Recognition RMS			
Determined within 14 days	20	Excellent	14
Type IA - Mutual Recognition CMS			
Determined within 14 days	14	Excellent	14
Type II Mutual Recognition CMS			
UK comments sent by 55 days	33 ⁶	Unacceptable	55
UK comments sent by 85 days	19	Excellent	85
Type IB Mutual Recognition CMS			
UK comments sent by 20 days	24	Excellent	20
UK comments sent by 50 days	31	Excellent	50

⁴ The days are specified as either calendar days or clock days according to the target as set out in detail in the published standards.

⁵ 95.7% within target.

⁶ 97.0% within target.

Category/Application type	Number (of Applications)	Performance level - % (excellent, effective, unacceptable)	Target (days ⁴)
European Renewals			
Mutual Recognition RMS			
PAR circulated by 40 days	16	Excellent	40
CLOQ circulated by 60 days	21	Excellent	60
Procedure completed by 90 days	3	Excellent	90
Mutual Recognition CMS			
UK Comments sent by 55 days	13 ⁷	Unacceptable	55
UK Comments sent by 85 days	23	Excellent	85
Customer Relations			
Customer Care Visits			
Number of Visits	10	Excellent	
Publishing themes	2006/07	Excellent	
Unreturned authorisation documents			
Right first time (Authorisations)	1463	Effective	
Right first time (SIC/STCs Certificates) ³	5349	Excellent	
Right first time (Export Certificates) ³	975	Excellent	
SARs			
Enter human SARs	111	Excellent	2
Enter serious animal SARs	1018	Excellent	2
Enter environmental SARs	42	Excellent	2
Enter non-serious SARs	1211	Excellent	10
Report to Eudravigilance	239 ⁸	Unacceptable	5
Inspections			
Inspect	19	Excellent	
Prepare report	8 ⁸	Unacceptable	60
Issue Certificate	7	Excellent	90

⁷ 61.5% within target.

⁸ 87.4% within target.

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.

■ RECENT PROSECUTIONS

On 1 November 2007 at Grantham Magistrates Court, Mr R W Morris of Brant Broughton, Lincoln, pleaded guilty to three charges under the Veterinary Medicines Regulations 2005. The charges concerned the possession of unauthorised veterinary medicinal products contrary to Regulation 26 of the Veterinary Medicines Regulations 2005. Mr Morris was fined a total of £1,000 and was ordered to pay costs of £1,000.

■ SEIZURE NOTICES

Since the last edition of *MAVIS* three seizure notices have been issued:

- Mrs Valerie Taylor, 200 Holburne Road, Greenwich, SE3 8JG. Six bottles of assorted wormers for sheep and eye drops for cats and dogs were seized on 6 September 2007 because they were not authorised for the UK and had not been lawfully supplied.
- Mrs Charlotte Breese, Poolfield Farm, Hewelsfield, Gloucestershire, GL15 6UW. One bottle of a non-steroidal anti-inflammatory for dogs was seized on 29 October 2007 because it was not authorised for the UK.
- Mr Kris Lovell, Lovell Pets, 1 Bell Lane, Eton Wick, Windsor, Berkshire, SL4 6JP. Eight sachets of an equine wormer and three boxes of an equine endectocide were seized on 30 October 2007 because they had not been lawfully supplied.

■ IMPROVEMENT NOTICES

Since the last edition of *MAVIS* three improvement notices have been issued. The details of these notices are as follows:

- Paul Smith, Crown Chicken Ltd, Green Farm, Edge Green, Kenninghall, Norwich, NR16 2DR. This improvement notice was issued on 11 September 2007 during an inspection of a feed mill. The improvements to be made were to review procedures for receiving prescriptions and implementing directions contained therein, to implement checking procedures to ensure no repetition and for a copy of the revised procedures to be sent to the Animal Medicines Inspectorate. All compliances were made within the required time frame.
- Scats Countryside, 1A Mylem Road, Andover, Hampshire, SP10 35Y. This improvement notice was issued on 25 September 2007 during an inspection of a retailer. The improvement to be made was to apply for the premises to be registered for sale of POM-VPS and NFA-VPS products. All compliances were made within the required time frame.
- David Leak, Hadrian Equine, West House Farm, Bishopton, Near Sedgefield, County Durham, TS21 1LL. This improvement notice was issued on 28 September 2007 during an inspection of a retailer. The improvements to be made were that the owner must register with an appropriate authority to enable the sales of POM-VPS products and that proof must be sent to the Animal Medicines Inspectorate. All compliances were made within the required time frame.

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.

■ SALES DATA REPORT

VMD have collected and collated all the data on sales of veterinary antimicrobials from Pharmaceutical Companies for 2006 and prepared the annual report. The report was published on the VMD website on 20 December 2007. The report for 2006 includes for the first time data on the amounts of antimicrobials imported into the UK for use in animals via the Special Treatment Certificate (STC) and Special Import Certificate (SIC) routes.

Copies of the Reports detailing veterinary antimicrobial sales from 1998 to 2006 can be obtained from the VMD website at www.vmd.gov.uk under Publications/Antibiotic Related tabs, or from Dr Kay Goodyear at the VMD.

■ DARC GROUP MEETING

The Defra Antimicrobial Resistance Coordination (DARC) Group met on 6 November 2007. Items discussed included: a review of Defra's antimicrobial resistance policy, reviewing recently completed R&D, an update on the first meeting of the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI), revision of the AMR Surveillance Strategy Document, *Clostridium difficile* in animals, Extended Spectrum Beta-Lactamase (ESBLs) and Meticillin-Resistant *Staphylococcus aureus* (MRSA) in animals. The next meeting of the Group is planned for February 2008.

Following the DARC Group's review Defra published its revised policy on Antimicrobial Resistance on the VMD website on 20 December 2007. The policy can be viewed at www.vmd.gov.uk (under General Information/DARC Group/Relevant Publications) or a copy obtained from Dr Kay Goodyear at the VMD.

■ ARHAI MEETING

A meeting of the Department of Health's Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) was held on 31 October 2007. The policy can be viewed items discussed included: an update on the work of the DARC Group including formation of an ESBL sub-group, surveillance of health-care associated infections in the UK, the Soil Association report on MRSA in animals, European issues and consultation documents.

Further information about ARHAI can be found at www.advisorybodies.doh.gov.uk/arhai/INDEX.HTM.

■ OTHER ANTIMICROBIAL ISSUES

VMD attended a Food Standards Agency open meeting on 29 November 2007 called Antimicrobial Resistance: To what extent does the food chain contribute to this problem? VMD gave a joint presentation with VLA on Antimicrobial Use and Resistance Issues in Food Animal Production.

VMD represented the UK at a CODEX Interdepartmental Task Force meeting on AMR in October 2007. The Task Force has been set up to develop science based guidance to assess and manage the risks to human health associated with the presence and transmission of AMR micro-organisms and resistance determinants in food and feed. The UK was one of 36 member countries in attendance.

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 2007, the VMD received 745 suspected adverse reaction reports involving animals. Of these, 49 reports related to unauthorised use, 16 involved an unauthorised or unidentified product, and 48 reports were considered unlikely to be product related. There was one report involving animal trials under Animal Test Certificates (ATCs) and 127 reports involved suspected lack of efficacy.

The remaining 504 suspected adverse reaction reports were associated with 196 licensed products.

The 504 reports were divided by marketing categories as follows:

- 463 Prescription Only Medicine (POM)
- 10 Pharmacists and Merchants List (PML)
- 12 Non-Food Animal - Veterinarian, Pharmacist, SQP (NFA-VPS)
- 18 General Sales List (GSL)
- 1 Authorised Veterinary Medicine - General Sales List (AVM).

During the quarter 34 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 2 reports of environmental incidents where there was some impact on the environment were received from the Environment Agency.

The SARSS Bi-monthly Report for September & October 2007 was presented to the meeting in November 2007.

Further information: Denise Burge (VMD, 01932 338427, e-mail 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 scientific¹ 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 Veterinary Products Committee will publish a report of its activities and those of its Sub-Committees.

¹Scientific 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 in November 2007. It reviewed and confirmed the minutes of its September meeting and considered the following matters relating to the authorisation of veterinary medicines:

Applications

The Committee examined evidence relating to an application for a variation to change the legal category of a product for use in cats from Non-Food Animal-Veterinarian, Pharmacist, Suitably Qualified Person (NFA-VPS) to Authorised Veterinary Medicine-General Sales List (AVM-GSL).

Two Members declared personal, non-specific interests and took no part in the discussion except, at the Chairman's discretion, to answer questions. One Member declared a non-personal non-specific interest. The Committee provided advice for consideration by the VMD.

Suspected Adverse Reactions (SARs)

The Committee considered and commented upon the SARSS Report for September and October 2007.

The Committee discussed the incidence of SARs in cats in

connection with the use of a spot-on product authorised for use in dogs, and the possible reasons for the inappropriate off-label use of this product. Members were informed that reports received by the VMD from veterinarians, members of the public and from the Marketing Authorisation (MA) holder were assessed and used for the calculation of the incidence of adverse reactions. The calculation was based upon the number of animals in which reactions were reported and the number of doses sold.

The Committee discussed two reports of anaphylaxis in cattle following the use of a penicillin product indicated for the treatment of mastitis in dairy cows. A member declared a personal non-specific interest and took no part in the discussion except, at the Chairman's discretion, to answer questions. The product was authorised in 2000 but only recently had it been promoted in the UK.

The Committee noted the SARs reports on an inactivated vaccine for use in salmon. A member declared a non-personal non-specific interest. The product had a Provisional MA and the Summary of Product Characteristics (SPC) stated that the efficacy of the vaccine had not been fully evaluated.

Officials agreed to update the Committee on the incidence of suspected lack of efficacy to parvovirus vaccines in the UK.

Members commented on the relatively high number of reports of human SARs involving products recently authorised through the centralised procedure for the treatment of fleas and ticks in dogs and cats.

General

The Committee was advised of the result of the second formal consultation on the recommendations for the cattle vaccines, pig vaccines, dog NSAIDs containing carprofen, sheep anthelmintics, dog and cat anthelmintics, dog anthelmintics and cat anthelmintics which, overall, were supported. However, strong feelings had been expressed against the recommended change for some cattle vaccines, from POM-V to POM-VPS, because it was considered that, due to the complexities of the diseases and clinical syndromes involved, veterinary supervision was required. In response to concerns expressed by Members, Officials explained that it was not uncommon, when carrying out a consultation exercise, to receive similar comments from members of an organisation. In such cases each reply was considered as an individual response and none were ignored. In the light of the comments received, the Committee agreed that the Sub Group should reconsider its recommendations for cattle vaccines.

Members expressed some concern over the role of the Committee as it was possible that its scientific advice could be overruled by VMD Officials, and decisions made based on policy considerations. Members were informed that in order for advice to be given to Ministers, Officials looked to the VPC for scientific advice. If Officials considered that the advice should not be followed they would inform Ministers and give a full explanation for that decision. The Committee was reassured that its role was made clear in its terms of reference.

At a Member's request, articles and readers' letters on scientific methodology published in the Financial Times (26 September, 1 October and 10 October) had been distributed

for discussion, together with an extract of item 8 of the minutes of the VPC meeting of July 2006 when the Committee had concluded that it was not in favour of minority reports being published.

The Committee considered whether to revisit the subject of minority reports but, as there was no clear support for the proposal, the Chairman, at the request of a member, called for a show of hands by those in favour (1), followed by those against (5). The remaining Members (11) abstained. The Chairman concluded that the Committee was against re-opening the issue.

The Committee took note of the annual return of Members' interests. Members' interests are published on the VPC website www.vpc.gov.uk.

The Committee was informed that the British Veterinary Association (BVA) had published a Good Practice Guide on Veterinary Medicines in collaboration with the VMD. The Guide is available only to BVA members.

The Chairman announced that the terms of office of Professor Aw, Mrs Collingborn, Professor Day, Dr Greaves, Dr Thompson and Mr Wall would come to an end on 31 December and thanked them all for their service to the Committee.

Members received the following papers for information, which are publicly available:

- Copies of The Veterinary Record Contents (front page) for editions published since the last meeting [recent articles are available on the website www.bvapublications.com].
- Soil Association Leaflet: Super bugs in farm animals.
- Guidelines for the Vaccination of Dogs and Cats.

Members also received the following papers for information. These papers are not publicly available:

- Report to the VPC on current ATC applications.
- Report to the VPC on current EU applications.
- Report to the VPC on Special Import Certificates/ Special Treatment Authorisations.
- Report to the VPC on new MA applications granted.
- Report from the Scientific Secretariat and the Biological Committee.
- Hotel requirements for 2008.

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 2007

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 Animal Health Agency 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.

Following the outbreaks of Foot and Mouth Disease and Bluetongue in Great Britain in 2007, a high priority was placed on Animal Health Agency staff containing the problems and identifying and tracking affected animals. Officers who would normally collect on-farm samples from cattle, pigs and poultry for the NSS were seconded to work in the disease surveillance zones. To cover the shortfalls for these species, sampling at abattoirs was increased by the corresponding number of samples.

The results of analyses completed between 1 January 2007 and 4 December 2007 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.

* *Maximum Residue Limit (MRL) is the maximum concentration of residue resulting from the use of veterinary medicine that is legally permitted or recognised as acceptable in or on a food.*

■ RED MEAT

Synthetic Steroids and Natural Hormones

Nortestosterone

Sheep

Since the last edition of MAVIS one sample of sheep urine has confirmed non-compliant for residues of nortestosterone at a concentration of 1.1µg/l. Due to the outbreak of Foot and Mouth Disease, officers from the Animal Health Agency were not asked to investigate the cause of this residue, which was likely to be a natural occurrence. Further sampling will be undertaken when sheep from the same farm are presented for slaughter in the future.

Since the last edition of MAVIS the investigation into a residue of nortestosterone at 1µg/l has been completed and is reported below.

Follow-up investigation: Sheep urine Nortestosterone 1.0µg/l

The investigation into the cause of this residue found no reason to suspect the illegal use of hormones on this farm. The ewes lamb in February-April and are fattened on grass with some creep feed and sold by the end of September. Rams are brought in whilst replacement ewes are bred on the farm and those for culling are fattened with the lambs. Medicine records and medicine storage were in accordance with the legal requirements. The animal in question was most likely an old cull ewe and the Veterinary Officer (VO) considered the concentration detected was most likely to be a natural occurrence.

Antimicrobial Screen

Cattle

Since the last edition of MAVIS one sample of cattle kidney has confirmed non-compliant for a residue of tylosin at a concentration of 870µg/kg (MRL 100µg/kg). Officers of the Animal Health Agency have been asked to carry out a follow-up investigation into the cause of this residue. The result will be reported in a later edition of MAVIS.

Pigs

In MAVIS 64 we reported that a sample of pig kidney had confirmed non-compliant for a residue of chlortetracycline/epi-chlortetracycline at a concentration of 1,780µg/kg (MRL 600µg/kg). The follow-up investigation into the cause of this residue has been completed and the result is reported below.

Follow-up investigation: Pig kidney: Chlortetracycline 1,780µg/kg

The follow-up investigation into this residue was unable to establish the exact cause. The pigs in this unit are routinely given medicated feed containing chlortetracycline.

The medicine records and storage were in accordance with the legal requirements. Three of the feed rations are medicated and the farm also feeds finisher and sow pellets. Grower and finisher rations are stored in their own dedicated trailers also used to collect the feed from the feed mill. Weaners, growers and finishers are in separate buildings each with a dedicated feed barrow to take the appropriate feed ration from the appropriate trailer. The VO considered that the residue could have occurred either because the farm procedures broke down or as a result of contamination of finisher ration with chlortetracycline during the manufacturing process at the mill. The Animal Medicines Inspectorate has been asked to inspect the mill.

Sulphonamides

Pigs

Since the last edition of *MAVIS* two further samples of pig's kidney out of 685 analysed by 4 December have confirmed non-compliant for residues of sulfadiazine at concentrations of 940µg/kg and 2,700µg/kg (MRL 100µg/kg). Officers of the Animal Health Agency have been asked to carry out follow-up investigations into the causes of these residues and the results will be reported in a later edition of *MAVIS*.

Cadmium

Cattle

Since the last edition of *MAVIS* a further sample of cattle kidney has confirmed non-compliant for a residue of cadmium at a concentration of 1,160µg/kg. The result of the investigation into the cause of this residue is given below.

Follow-up investigation: Cattle kidney: Cadmium 1,160µg/kg

The follow-up investigation into the cause of this residue was unable to establish the exact cause because there were no identifiable sources of cadmium such as sewage sludge, pollution incidents or industrial activity on or near the farm. The animal sampled was a barren suckler cow which was slaughtered following a caesarean. It is likely that the residue was the result of natural accumulation in the animal over time. The farmer had no medicine records and medicines storage was inadequate. The Veterinary Officer has written to the farmer explaining that he is in breach of the Veterinary Medicines Regulations. The farmer has been given four weeks to take the necessary corrective action and will be subject to a further inspection at the end of this period.

Sheep

Since the last edition of *MAVIS* a further sample of sheep kidney has confirmed non-compliant for a residue of cadmium at a concentration of 2,530µg/kg. Officers of the Animal Health Agency have been asked to carry out a follow-up investigation into the cause of this residue and the result will be reported in a later edition of *MAVIS*.

In *MAVIS*64 we reported that a sample of sheep's kidney had confirmed non-compliant at a concentration of 1,730µg/kg.

The follow-up investigation into the cause of this residue has been completed and the result is given below.

Follow-up investigation: Sheep kidney: Cadmium 1,730µg/kg

The follow-up investigation was unable to establish the exact cause of the residue. There were no obvious sources of cadmium on the farm such as sewage sludge or nearby industrial or mining areas. The animal in question was a ewe over 36 months old which had been bought in by the farmer sometime ago. It is likely that the residue was the result of natural accumulation in the animal over time. Medicine records and storage were in accordance with the legal requirements.

Lead

Sheep

In *MAVIS*63 we reported that a sample of sheep kidney had confirmed non-compliant for a residue of lead at a concentration of 2,040µg/kg. Officers of the Animal Health Agency have completed their investigation into the cause of this residue and the result is reported below.

Follow-up investigation: Sheep kidney: Lead 2,040µg/kg

The follow-up investigation into the cause of this residue established that the medicines records and storage on this lamb fattening unit were in accordance with the legal requirements. In winter the lambs are on pasture but they are brought inside in bad weather. There were no obvious sources of lead in the fields. The building the lambs are kept in does have some flaking paint and contains some painted hurdles so the cause may be contamination via lead paint.

NSAIDs

Phenylbutazone

Cattle

Since the last edition of *MAVIS* a sample of cattle plasma has confirmed non-compliant for a residue of phenylbutazone at a concentration of 6µg/kg. The result of the follow-up investigation into the cause of this residue is given below.

Follow-up investigation: Cattle plasma: Phenylbutazone 6µg/kg

The follow-up investigation into the cause of this residue established that the animal in question had not been treated with a product containing phenylbutazone. However the farmer owns a mare that is receiving treatment twice a day for laminitis. She is normally stabled but has been exercised in the cattle shed. The farm purchases cows as stores in the autumn and sells them for slaughter the next year. The cattle are kept in the shed the night before transport to the slaughterhouse so may have eaten some straw contaminated with urine containing phenylbutazone. The farmer has been advised not to have the mare in the cow shed before the cattle are kept there prior to loading and to ensure that all utensils used for feeding the mare are used exclusively for her.

Horses

Since the last edition of *MAVIS* one sample of horse plasma out of 25 analysed has confirmed non-compliant for a residue of phenylbutazone at a concentration of 2µg/kg. The result of the follow-up investigation into the cause of this residue is given below.

Follow-up investigation: Horse plasma: Phenylbutazone 2µg/kg

The follow-up investigation into the cause of this residue established that no medicine records were being kept.

The owner believed these were not required because this was not a farm producing animals for the food chain (only two horses were kept). Although the horse that was slaughtered had not been treated with a product containing phenylbutazone, a second horse on the premises was being treated. Despite the two horses being fed in separate places, the veterinary officer considered the most likely cause was accidental access to medicated feed intended for the other horse. The owner has been advised to ensure that the passport for the treated horse is marked to ensure it cannot enter the food chain. Officers from the Animal Health Agency will carry out further checks to ensure that the medicines records and passport requirements are complied with.

■ POULTRY

Nicarbazin

Since the last report two further samples of broiler liver have confirmed non-complaint for residues of nicarbazin at concentrations of 350µg/kg and 1,300µg/kg. In accordance with the advice of the Veterinary Residues Committee, the VMD has written to the farmer concerning the residue at 350µg/kg and provided advice on how to avoid such residues in future. The AMI has been asked to carry out a follow-up investigation into the cause of the residue at 1,300µg/kg and the result will be reported in a later edition of MAVIS. The result of the investigation into the residue of 1,200µg/kg reported in MAVIS 64 is given below.

Follow-up investigation: Broiler liver: Nicarbazin 1,200µg/kg

The follow-up investigation considered that the most likely cause of the residue was cross-contamination of the feed on the farm. The house the bird came from has three bins intended for starter crumbs and pellets, rearer and withdrawal feeds and whole wheat. However, the farmer admitted that all the feed for this house was delivered to one bin due to confusion over bin and house numbering, causing cross-contamination of the withdrawal ration.

Ionophores

In MAVIS 64 we reported that a sample of broiler liver had confirmed non-compliant for a residue of lasalocid at a concentration of 740µg/kg. The result of the follow-up investigation into the cause of this residue is given below.

Follow-up investigation: Broiler liver: Lasalocid 740µg/kg

The follow-up investigation into the cause of this residue established that there was no misuse of this substance on this farm and that the medicines records and storage were in accordance with the legal requirements. The most likely cause of the residue was thought to be cross-contamination of feed on the farm. This was either via one of the feed bins not being empty when withdrawal ration was added so the birds could have eaten medicated feed during the withdrawal period or via the small hoppers in the shed where the feed is dispensed to go down the lines into the feeding pans.

The farmer thinks it possible for feed to collect at the edge of these so there could be cross contamination. There was no conclusive evidence from the feed mill investigation that the cause of the residue was contamination during manufacture.

■ EGGS AND FARMED FISH

No further non-compliant samples have been confirmed since the last edition of MAVIS.

■ MILK AND GAME

Sampling began in January and no non-compliant samples had been confirmed up to 4 December.

■ HONEY

Sampling began in May and no further non-compliant samples have been confirmed since the last edition of MAVIS. The result of the investigation into the cause of the residue of naphthalene at 88µg/kg reported in MAVIS 64 is given below.

Follow-up investigation: Honey: Naphthalene 88µg/kg

The investigation into the cause of this residue established that the bee-keeper had been unable to obtain his usual product for treating his supers for wax moth infestation and had therefore used a product with naphthalene as the active ingredient. The contaminated honey has been destroyed and the beekeeper advised on suitable products for the treatment of his supers.

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

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN RED MEAT
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007**

Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Hormones						
Boldenone	Cattle	< 24 months	Urine	182		
	Fattening cattle	> 30 months	Urine	121	2	2, 17
	Fattening cattle/cows	> 30 months	Urine	15		
Methyltestosterone	Pigs		Feed	17		
	Pigs		Urine	71		
	Sheep		Urine	72		
	Cattle		Urine	236		
Nortestosterone	Fattening cattle		Urine	193	13	3, 6, 6, 8, 10, 12, 14, 20, 20, 26, 30, 50, 80
	Sheep		Urine	149	10	0.7, 1, 1, 1, 1, 1.1, 1.2, 2, 2, 4
	Cattle	Male	Serum	219		
Oestradiol	Fattening cattle	Male	Serum	196		
Progesterone	Cattle	Male	Serum	153	4	0.6, 1, 1, 1.5
	Fattening cattle	6 - 24 months Male	Serum	94	1	0.7
Stilbenes	Cattle	> 30 months	Liver	1		
	Cattle	> 30 months	Urine	160		
	Fattening cattle	> 30 months	Urine	94		
	Fattening cattle/cows	> 30 months	Urine	4		
	Pigs		Urine	78		
	Sheep		Urine	76		
	Cattle	> 30 months Female	Serum	236		
Testosterone	Fattening cattle	6 - 24 months Female	Serum	155		
	Fattening cattle/cows	> 30 months Female	Serum	11		
	Cattle	> 30 months	Urine	285		
Trenbolone	Fattening cattle	6 - 24 months	Urine	188		
	Fattening cattle/cows	> 30 months	Urine	9		
	Pigs		Urine	74		
	Sheep		Urine	155		
Zeranol	Cattle	> 30 months	Urine	161	1	0.9
	Fattening cattle	6 - 24 months	Urine	91		
	Fattening cattle/cows	> 30 months	Urine	3		
	Pigs		Urine	149		
	Sheep		Urine	76		
■ 2 Pesticides Including PCBs						
OC/PCBs	Cattle		Kidney fat	55		
	Pigs		Kidney fat	50		
	Sheep		Kidney fat	118		
Organophosphates	Cattle		Kidney fat	170		
	Pigs		Kidney fat	103		
	Sheep		Kidney fat	515		
■ 3 Pyrethroids/Carbamates						
Pyrethroids	Calves	< 6 months	Kidney fat	12		
	Cattle		Kidney fat	53		
	Pigs		Kidney fat	50		
	Sheep		Kidney fat	516		
■ 4 Beta-Agonists						
	Calves	< 6 months	Liver	16		
	Cattle	> 30 months	Liver	474		
	Fattening cattle	> 30 months	Feed	125		
	Fattening cattle	6 - 24 months	Urine	104		
	Fattening cattle/cows	> 30 months	Urine	2		
	Horses		Liver	5		
	Pigs		Feed	37		
	Pigs		Liver	280		
	Sheep		Liver	264		
■ 5 Heavy Metals						
Cadmium	Cattle	> 30 months	Kidney	59	6	1060, 1060, 1150, 1160, 1630, 2420
	Goats		Kidney	4		
	Pigs		Kidney	9		
	Sheep		Kidney	49	4	1730, 2040, 2530, 2990
Lead	Cattle	> 30 months	Kidney	59	1	860
	Goats		Kidney	4		
	Pigs		Kidney	9		
	Sheep		Kidney	49	3	1060, 1720, 2040

Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 6 Sulphonamides	Calves	< 6 months	Kidney	50		
	Cattle		Kidney	133		
	Pigs		Kidney	685	4	130, 330, 940, 2700
	Sheep		Kidney	122		
■ 7 Antimicrobial Screen						
	Calves	< 6 months	Kidney	136	5	1430, 9800, 20000, 20300, 31200
	Cattle	> 30 months	Kidney	1,033	2	870, 20900
	Goats		Kidney	9		
	Horses		Kidney	5		
	Pigs		Kidney	705	1	1780
	Sheep		Kidney	2,584		
■ 8 Florfenicol	Calves	< 6 months	Kidney	88	2	390, 490
■ 9 Annex IV						
Chloramphenicol	Calves	< 6 months	Kidney	16		
	Cattle	< 24 months	Kidney	189		
	Fattening cattle	> 30 months	Feed	114		
	Pigs		Kidney	181		
	Sheep		Kidney	138		
Dimetridazole	Calves	< 6 months	Kidney	8		
	Cattle	< 24 months	Kidney	68		
	Horses		Kidney	5		
	Pigs		Feed	12		
	Pigs		Kidney	172		
Nitrofurans	Sheep		Kidney	92		
	Calves	< 6 months	Kidney	9		
	Cattle	> 30 months	Kidney	157		
	Fattening cattle	> 30 months	Feed	81		
	Pigs		Feed	10		
	Pigs		Kidney	230		
	Sheep	< 6 months	Kidney	217		
■ 10 Anthelmintics						
Avermectins	Cattle		Liver	252		
	Goats		Liver	12		
	Horses		Liver	5		
	Pigs		Liver	138		
	Sheep		Liver	522		
Benzimidazoles	Cattle		Liver	165		
	Pigs		Liver	141		
	Sheep		Liver	533		
Levamisole	Cattle		Liver	174		
	Sheep		Liver	249		
■ 11 Glucocorticoids						
	Cattle	> 30 months	Liver	263		
	Pigs		Liver	34		
	Sheep		Liver	17		
■ 12 Gestagens						
Altrenogest	Pigs		Kidney fat	74		
Gestagens	Cattle	> 30 months	Kidney fat	244		
	Fattening cattle	6 - 24 months	Serum	158		
	Fattening cattle/cows	> 30 months	Serum	8		
	Sheep		Kidney fat	74		
■ 13 NSAIDs						
	Cattle	> 30 months	Kidney	231		
	Pigs		Kidney	28		
	Sheep		Kidney	53		
Phenylbutazone	Cattle	> 30 months	Plasma	206	1	6
	Horses		Plasma	25	1	2
■ 14 Coccidiostats						
Ionophores	Calves	< 6 months	Liver	39		
	Pigs		Liver	79		
	Sheep		Liver	296		
■ 15 Mycotoxins						
Aflatoxins	Cattle		Liver	20		
	Sheep		Liver	10		
Ochratoxin A	Pigs		Liver	45		

Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 16 Carbadox	Pigs		Liver	40		
■ 17 Sedatives						
Carazolol	Pigs		Liver	128		
Sedatives	Cattle		Liver	31		
	Pigs		Liver	128		
	Sheep		Liver	85		
■ 18 Thyrostats						
	Cattle	> 30 months	Urine	141		
	Fattening cattle	6 - 24 months	Serum	94		
	Fattening cattle/cows	> 30 months	Serum	4		
	Pigs		Urine	74		
	Sheep		Urine	74		
Total				19,058	61	

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN POULTRY MEAT RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007

Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Hormones						
Stilbenes	Broilers		Liver	138		
	Ducks		Liver	4		
	Hens		Liver	5		
	Turkeys		Liver	15		
Trenbolone	Broilers		Liver	132		
	Ducks		Liver	4		
	Hens		Liver	10		
	Turkeys		Liver	20		
Zeranol	Broilers		Liver	172		
	Ducks		Liver	7		
	Hens		Liver	9		
	Turkeys		Liver	24		
■ 2 Pesticides Including PCBs						
OC/PCBs	Broilers		Liver	194		
	Ducks		Liver	8		
	Hens		Liver	11		
	Turkeys		Liver	31		
■ 3 Pyrethroids/Carbamates						
Carbamates	Broilers		Liver	53		
	Ducks		Liver	6		
	Hens		Liver	5		
	Turkeys		Liver	21		
Pyrethroids	Broilers		Liver	53		
	Ducks		Liver	6		
	Hens		Liver	5		
	Turkeys		Liver	21		
■ 4 Beta-Agonists						
	Broilers		Feed	132		
	Broilers		Liver	378		
	Ducks		Feed	9		
	Ducks		Liver	15		
	Hens		Feed	7		
	Hens		Liver	18		
	Turkeys		Feed	20		
	Turkeys		Liver	62		
■ 5 Heavy Metals						
Cadmium	Broilers		Liver	19		
	Broilers		Muscle	63		
	Ducks		Muscle	2		
	Hens		Muscle	2		
	Turkeys		Liver	1		
	Turkeys		Muscle	5		

Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg	
Lead	Broilers		Liver	19			
	Broilers		Muscle	63			
	Ducks		Muscle	2			
	Hens		Muscle	2			
	Turkeys		Liver	1			
	Turkeys		Muscle	5			
■6 Sulphonamides	Broilers		Muscle	253			
	Ducks		Muscle	7			
	Hens		Muscle	10			
	Turkeys		Muscle	39			
■7 Antimicrobial Screen	Broilers		Muscle	975	1	350	
	Ducks		Muscle	33			
	Hens		Muscle	42			
	Turkeys		Muscle	144			
■8 Quinolones	Broilers		Muscle	384			
	Ducks		Muscle	11			
	Hens		Muscle	17			
	Turkeys		Muscle	58			
■9 Annex IV Chloramphenicol	Broilers		Muscle	727			
	Ducks		Muscle	28	1	0.4	
Dimetridazole	Hens		Muscle	32			
	Turkeys		Muscle	115			
	Broilers		Feed	131			
	Broilers		Liver	615			
	Ducks		Feed	9			
	Ducks		Liver	24			
	Hens		Feed	10			
	Hens		Liver	31			
	Turkeys		Feed	22			
	Turkeys		Liver	94			
	Nitrofurans	Broilers		Feed	132		
		Broilers		Muscle	703		
Ducks			Feed	8			
Ducks			Muscle	28			
Hens			Feed	7			
Hens			Muscle	32			
Turkeys			Feed	23			
Turkeys			Muscle	104			
■10 Anthelmintics Benzimidazoles		Broilers		Liver	109		
		Ducks		Liver	10		
	Hens		Liver	10			
	Turkeys		Liver	33			
Levamisole	Broilers		Liver	111			
	Ducks		Liver	12			
	Hens		Liver	12			
	Turkeys		Liver	37			
■11 Coccidiostats Ionophores	Broilers		Liver	269	1	740	
	Hens		Liver	10			
	Turkeys		Liver	37			
Nicarbazin	Broilers		Liver	264	15	240, 250, 280, 290, 310, 320, 350, 540, 560, 1200, 1300, 1400, 1400, 1800, 3000	
	Broilers		Muscle	125	1	230	
■12 Mycotoxins Aflatoxins	Broilers		Liver	8			
	Ducks		Liver	1			
	Hens		Liver	1			
	Turkeys		Liver	5			
Total				7,681	19		

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN GAME
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007

Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Hormones Zeranol	Deer	Liver	5		
■ 2 Pesticides Including PCBs OC/PCBs	Deer	Kidney fat	5		
■ 3 Pyrethroids/Carbamates Carbamates	Deer	Liver	5		
■ 4 Beta-Agonists	Deer	Liver	5		
■ 5 Heavy Metals Cadmium	Deer	Muscle	6		
	Partridge	Muscle	3		
	Pheasant	Muscle	2		
	Wild Deer	Muscle	10		
Lead	Deer	Muscle	6		
	Partridge	Muscle	3		
	Pheasant	Muscle	2		
	Wild Deer	Muscle	10		
■ 6 Antimicrobial Screen	Deer	Kidney	21		
■ 7 Annex IV Dimetridazole	Partridge	Muscle	1		
	Pheasant	Muscle	1		
■ 8 Anthelmintics Avermectins	Deer	Liver	4		
Levamisole	Deer	Liver	5		
■ 9 NSAIDs	Deer	Liver	4		
■ 10 Coccidiostats Ionophores	Partridge	Muscle	4		
	Pheasant	Muscle	4		
Total			106		

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN MILK
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007

Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Pesticides Including PCBs OC/PCBs	Cattle	Milk	33		
Organophosphates	Cattle	Milk	15		
■ 2 Heavy Metals Cadmium	Cattle	Milk	27		
Lead	Cattle	Milk	27		
■ 3 Antimicrobial Screen Antimicrobial	Cattle	Milk	521		
■ 4 Quinolones Quinolones	Cattle	Milk	230		
■ 5 Annex IV Chloramphenicol	Cattle	Milk	265		
Dimetridazole	Cattle	Milk	262		
■ 6 Anthelmintics Avermectins	Cattle	Milk	208		
Benzimidazoles	Cattle	Milk	75		
Levamisole	Cattle	Milk	90		
■ 7 NSAIDs Phenylbutazone	Cattle	Milk	161		
■ 8 Mycotoxins Aflatoxins	Cattle	Milk	62		
■ 9 Cephalosporins	Cattle	Milk	292		
Total			2,268		

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN EGGS
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007

Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Pesticides Including PCBs OC/PCBs	Barn	Eggs	3		
	Caged	Eggs	11		
	Free Range	Eggs	19		
■ 2 Pyrethroids/Carbamates Pyrethroids	Free Range	Eggs	15		
■ 3 Antimicrobial Screen	Barn	Eggs	17		
	Caged	Eggs	69		
	Free Range	Eggs	122		
■ 4 Tetracyclines	Barn	Eggs	9		
	Caged	Eggs	36		
	Free Range	Eggs	63		
■ 5 Annex IV Chloramphenicol	Barn	Eggs	9		
	Caged	Eggs	32		
	Free Range	Eggs	61		
Dimetridazole	Barn	Eggs	8		
	Caged	Eggs	37		
	Free Range	Eggs	61		
Nitrofurans	Barn	Eggs	9		
	Caged	Eggs	36		
	Free Range	Eggs	65		
■ 6 Anthelmintics Benzimidazoles	Free Range	Eggs	16		
■ 7 Coccidiostats Ionophores	Barn	Eggs	15		
	Caged	Eggs	75		
	Free Range	Eggs	128		
Nicarbazin	Barn	Eggs	16		
	Caged	Eggs	60		
	Free Range	Eggs	107	2	40, 60
Total			1,099	2	

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN HONEY
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007

Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Pesticides Including PCBs Organochlorines	Bees	Honey	14		
	Bees	Honey	10		
Organophosphates	Bees	Honey	10		
■ 2 Pyrethroids/Carbamates Pyrethroids	Bees	Honey	10		
■ 3 Heavy Metals Cadmium + Lead	Bees	Honey	10		
	Bees	Honey	10		
■ 4 Antimicrobial Screen	Bees	Honey	22		
■ 5 Tetracyclines	Bees	Honey	18		
■ 6 Streptomycin	Bees	Honey	18		
	Bees	Honey	18		
■ 7 Annex IV Chloramphenicol	Bees	Honey	11		
	Bees	Honey	11		
Nitrofurans	Bees	Honey	11		
■ 8 Macrolides	Bees	Honey	14		
■ 9 1,4 dichlorobenzene	Bees	Honey	10		
■ 10 Napthalene	Bees	Honey	10	2	88, 120
Total			158	2	

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN FARMED FISH
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2007 - 4 DECEMBER 2007**

Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	Concentration where sample above MRLµg/kg
■ 1 Pesticides Including PCBs						
OC/PCBs	Salmon		Muscle	8		
	Trout		Muscle	6		
Organophosphates	Salmon		Muscle	30		
■ 2 Pyrethroids/Carbamates						
Pyrethroids	Salmon		Muscle	93		
■ 3 Heavy Metals						
Cadmium	Salmon		Muscle	4		
	Trout		Muscle	3		
Lead	Salmon		Muscle	4		
	Trout		Muscle	3		
Mercury	Salmon		Muscle	7		
	Trout		Muscle	3		
■ 4 Antimicrobial Screen						
	Barramundi		Muscle	1		
	Salmon	Market	Muscle	75		
	Tilapia		Muscle	2		
	Trout	Market	Muscle	7		
■ 5 Florfenicol	Salmon	Market	Muscle	74		
■ 6 Tetracyclines						
	Salmon	Market	Muscle	79		
	Trout	Market	Muscle	7		
■ 7 Quinolones						
	Salmon	Market	Muscle	74		
	Trout	Market	Muscle	7		
■ 8 Annex IV						
Chloramphenicol	Salmon	Young	Muscle	153		
	Trout		Muscle	21		
Dimetridazole	Salmon		Muscle	141		
	Trout		Muscle	19		
Nitrofurans	Salmon		Muscle	80		
	Trout		Muscle	9		
■ 9 Anthelmintics						
	Salmon		Muscle	146		
	Trout		Muscle	6		
Benzimidazoles	Salmon		Muscle	59		
	Trout		Muscle	10		
■ 10 Mycotoxins						
Aflatoxins	Salmon		Muscle	6		
	Trout		Muscle	6		
■ 11 Malachite Green						
Leucomalachite Green	Salmon	Young	Muscle	115	1	10
	Trout	Young	Muscle	94		
Malachite Green	Salmon	Young	Muscle	115		
	Trout	Young	Muscle	94		
Total				1,561	1	

■ 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 2007

Rolling programme

Sample collection and analysis for the 2007 non-statutory rolling programme commenced in April. Port Health Officers, market inspectors and shoppers from a market research company have collected 925 assayable samples of the 1,400 samples in the plan during the period April–November 2007. The Central Science Laboratory (CSL) has completed 2,729 of the analyses due on these samples.

Since the report in MAVIS 64, a further sample has been found to contain residues above the Maximum Residue Limit or Action Level. A summary is given below.

Nitrofurans

Farmed Warm Water Crustaceans

A sample of soft shell crab imported from the United States of America and collected at a Border Inspection Post (BIP) contained residues of the nitrofurazone metabolite semicarbazide (SEM) at a concentration of 2.6 µg/kg.

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 Deputy Chief Veterinary Officer has written to his opposite number in the United States of America to inform them of this result and has asked to be kept informed of the outcome of any action that is taken. This result has also been reported to the Food Standards Agency (FSA). A Rapid Alert was not issued because the product was distributed to a cruise ship which had already left the British Isles and the FSA had no information on the ship's location. Apart from the manufacturer details, there were no best before dates/batch codes etc available making it extremely difficult to trace the affected batch. It was also highly likely that the other crabs in the consignment had already been consumed.

SUMMARY OF PROGRESS SINCE MAVIS 64

In MAVIS 64 we reported on a sample of tilapia, imported from Jamaica and purchased from a retail outlet, which contained residues of crystal violet at a concentration of 0.9 µg/kg.

Following the positive test result the UK supplier carried out an investigation and traced the batch back to a specific pond on a tilapia farm in Jamaica. They were able to provide the supplier with samples of fish from the same pond, mud from the pond floor, fish from several additional sites and feed samples. They were tested at the CSL and the results were all negative.

The farming company senior veterinarian has confirmed in writing that they do not use any form of antifungal or antimicrobial chemicals for preventative or therapeutic treatment.

The UK supplier obtained a list of all the ingredients used in all feeds manufactured by their feed supplier. The feed supplier keeps no inventory of, nor uses any drugs, medications, antibiotics or hormones in their feeds. Therefore there is a very low risk of cross-contamination of their standard feeds.

The manufacturers of the packaging, gel packs, paper towels, soaps and sanitizing agents have also verified that they do not use crystal violet.

The UK supplier advises that the presence of crystal violet rather than leucocrystal violet might indicate post harvest contamination and that it is well known that there are lots of human medical uses. In Jamaica, it is bottled and sold over-the-counter as a liquid by three companies as Gentian Violet. It is used as a dressing for cuts and burns in humans and animals and as a treatment for fungal infections and is easily available.

The company in Jamaica has subsequently explained to their employees the absolute necessity of not using this product and this is now part of their routine training for all employees.

FEEDBACK FROM THE AUTHORITIES IN THE COUNTRIES OF ORIGIN ON ACTION TAKEN ON POSITIVE SAMPLES FOR 2007

There have been no further responses to the CVO's letters from the authorities in the countries of origin of the positive samples.

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

**2007 NON-STATUTORY SURVEILLANCE RESULTS
1 APRIL 2007 - 5 DECEMBER 2007**

Sample	Analysed for	No. of samples analysed	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)
Farmed Warm Water Crustaceans				
	Antimicrobial Screen	198		
	Chloramphenicol	198		
	Nitrofurans	32	1	2.6
Imported Farmed Fish				
	Antimicrobial Screen	193		
	Chloramphenicol	193		
	Crystal Violet	193	2	0.9, 3.7
	Malachite Green	193		
	Nitrofurans	193	2	1.2, 1.8
	Quinolones	193		
Imported Raw Beef				
	Avermectins	174		
	Trenbolone	174		
	Zeranol	174		
Imported Raw Poultry				
	Chloramphenicol	207		
	Nicarbazin	207		
	Nitroimidazoles	207		

**MARKETING AUTHORISATION MA & EUDEs ISSUED UNDER THE VETERINARY
MEDICINAL PRODUCTS REGULATIONS 1994
BETWEEN 29 AUGUST 2007 - 27 NOVEMBER 2007**

Company	Vm Number	Product Name	Legal Category
Alpharma Animal Health BVBA	21766/4005	Aurofac 250 mg/g Granular Premix for Medicated Feeding Stuff	POM-V
Ceva Animal Health Ltd	15052/4028	Tiamvet Solution 12.5 %	POM-V
Dechra Ltd	10434/4008	Prednidale 25 Tablets for Dogs	POM-V
Fort Dodge Animal Health Ltd	01596/4360	Poulvac Pabac IV	POM-V
Intervet UK Ltd	01708/4532	Nobivac Ducat-Chlam	POM-V
Pfizer Ltd	00057/4269	Spirovac for Cattle	POM-V
VetXX A/S	24883/4005	Sebolyse Shampoo for Dogs and Cats	POM-V
Virbac S.A.	05653/4134	Virbacef Sterile Powder For Solution for Injection	POM-V
Chanelle Pharmaceuticals Manufacturing Ltd	08749/4008	Rimifin 100mg tablets for dogs	POM-V
	08749/4006	Rimifin 20mg tablets for dogs	POM-V
	08749/4007	Rimifin 50mg tablets for dogs	POM-V
Chanelle Animal Health Ltd	11990/4039	Sumex Pour-On Solution 0.5%	POM-VPS
Fort Dodge Animal Health Ltd	01596/4364	Poulvac AE Vac	POM-VPS
Janssen-Cilag Ltd	00242/4062	Ripercol 75mg/ml Oral Solution	POM-VPS
Novartis Animal Health UK Ltd	12501/4161	Fasimec Duo S 0.1%/5% Oral Suspension for Sheep	POM-VPS
Alfamed S.A.S.	17902/4012	Johnson's 4 Fleas Protector 10% Spot-On Solution for Cats and Kittens	AVM-GSL
	17902/4010	Johnson's 4 Fleas Protector 2% Spot-On Solution for Large Dogs	AVM-GSL
	17902/4011	Johnson's 4 Fleas Protector 2% Spot-On Solution for Medium Dogs	AVM-GSL
	17902/4013	Johnson's 4 Fleas Protector 2% Spot-On Solution for Puppies and Small Dogs	AVM-GSL

**HOMEOPATHIC REGISTRATIONS ISSUED UNDER THE VETERINARY MEDICINES
REGULATIONS BETWEEN 29 AUGUST 2007 - 27 NOVEMBER 2007**

Company	Vm Number	Product Name	Legal Category
Complements of Scotland Ltd (trading as Freeman's Homeopathic Pharmacy)	27722/9005	Arsenicum Album Tablets 4c-MM	AVM-GSL

**MARKETING AUTHORISATION EUCES VARIED APPROVED UNDER COMMUNITY
AUTHORISATIONS REGULATIONS (EC) NO 726/2004
BETWEEN 29 AUGUST 2007 - 27 NOVEMBER 2007**

Company	Product Name	Brief Details	Legal Category
Intervet International BV	Nobivac Piro	Change to shelf life	POM

**EXPIRED MARKETING AUTHORISATIONS
BETWEEN 29 AUGUST 2007 - 27 NOVEMBER 2007**

Company	Vm Number	Product Name	Legal Category
Chanelle Animal Health Ltd	11990/4027	Synulox Ready To Use Injection	POM
Novartis Animal Health UK Ltd	12501/4027	Utocyl	POM
Dowelhurst Ltd	05662/4000	Equest Oral Gel	PML
	05662/4001	Equest Oral Gel	PML
	05662/4002	Equest Oral Gel	PML
Vetoquinol UK Ltd	08007/4105	Lignadrin 2%	PML
Genitrix Ltd	19886/4000	Genitrix Anti-Flatulance Tablets	GSL
	19886/4001	Genitrix Diarrhoea Tablets	GSL
Harkers Ltd	11245/4001	Spartakon	GSL
Net-Tex Agricultural Ltd	20220/4000	Super Zinc	GSL
Sinclair Animal and Household Care Ltd	16516/4029	Armitage Felt Flea Collar Twin Pack	GSL
Eli Lilly & Company (Elanco Animal Health)	00006/4086	Apralan G20 Premix	MFS

**MARKETING AUTHORISATION, MA AND EUDE VARIED UNDER THE
VETERINARY MEDICINES REGULATIONS 2006
BETWEEN 29 AUGUST 2007 - 27 NOVEMBER 2007**

Company	Product Name	Brief Details	Legal Category
Bayer Plc	Baycox Bovis 50mg/ml Oral Suspension	Additional pack size	POM-V
	Baytril Max 10% Solution for Injection	Change to container size	POM-V
Boehringer Ingelheim Ltd	Vetmedin 1.25mg Flavour Tablets	Change to shelf life	POM-V
Dechra Ltd	Intra-Epicaine 2.0%w/v Solution for Injection	Change to withdrawal period	POM-V
Dopharma Research B.V.	Phenoxyphen 32.5% Water Soluble Powder for Chickens, powder for use in drinking water	Change to packaging	POM-V
Fort Dodge Animal Health Ltd	Poulvac iSE	Additional pack size	POM-V
Intervet UK Ltd	Cephaguard LA 7.5% suspension for injection for cattle	Additional pack size	POM-V
Lohmann Animal Health GmbH & Co KG	AviPro ND C131	Change in pack size	POM-V
Norbrook Laboratories Ltd	Alamycin LA 300	Additional pack sizes	POM-V
	Noroclav Tablets 250mg	Change to product name in France from Taclor 250mg Comprime to Noroclav 250mg Comprime	POM-V
	Noroclav Tablets 50mg	Change to product name in France from Taclor 50mg Comprime to Noroclav 50mg Comprime	POM-V
Novartis Animal Health UK Ltd	FORTEKOR 2.5 mg tablets for dogs and cats	Marketing Authorisation holder address changed to Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR	POM-V
	FORTEKOR 20mg film-coated tablets for dogs	" "	POM-V
	FORTEKOR 5mg film-coated tablets for dogs and cats	" "	POM-V
	Milbemax Film-Coated Tablets for Cats	" "	POM-V
Pfizer Ltd	Spirovac	Change to shelf life	POM-V
Schering-Plough Ltd	Nuflor 40mg/g Premix for Medicated Feeding Stuff for Swine	Change to packaging	POM-V
	Nuflor 40mg/g Premix for Medicated Feeding Stuff for Swine	Change to packaging	POM-V
Boehringer Ingelheim Ltd	Vetmedin 1.25mg Capsules	Change to packaging	POM
Laboratorios Hipra Sa	Hipragumboro G97	Change to shelf life	POM

Company	Product Name	Brief Details	Legal Category
Novartis Animal Health UK Ltd	Atopica 100mg Capsule	Marketing Authorisation holder address changed to Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR	POM
	Atopica 10mg Capsules	" "	POM
	Deposel Multidose	" "	POM
	Rearguard	" "	POM
Oropharma Nv	Amoxicure	Marketing Authorisation holder address changed to Kapellestraat 70, B-9700 Deinze, Belgie	POM
Vetoquinol UK Ltd	Doxyseptin 300	Change to dimension of tablets	POM
Cross Vetpharm Group Ltd	Bimectin 1% w/v Solution for Injection	Change to shelf life	POM-VPS
Janssen-Cilag Ltd	Solubenol 100mg/g Oral Emulsion	Change to shelf life	POM-VPS
Merial Animal Health Ltd	Ivomec Classic Injection for Cattle and Sheep	Change to withdrawal period	POM-VPS
Ballinskelligs Veterinary Products	Veticop Injection	Change to packaging	PML
Cross Vetpharm Group Ltd	Embotape	Change to packaging	PML
Day Son And Hewitt Ltd	Tensolvect	Change to shelf life	PML
Novartis Animal Health UK Ltd	Allverm 4%	Marketing Authorisation holder & distributor address changed to Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR	PML
	Clik 5% Pour-On	Marketing Authorisation holder address changed to Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR	PML
	Crovect Pour-On	" "	PML
Virbac De Portugal Laboratorios Lda	Virbamec Injectable Solution for Cattle, Swine and Sheep	Change to shelf life	PML
Bayer Plc	Bayer Cat Wormer Tablets	Product name changed to Bob Martin All-in-One Cat Dewormer Tablets	NFA-VPS
Sinclair Animal and Household Care Ltd	Canac Cat Flea Collar	Product name changed to Beaphar Soft Cat Flea Collar	AVM-GSL
Johnson's Veterinary Products Ltd	Canac Ear Drops	Product name changed to Beaphar Ear Drops	GSL
Kilco Chemicals Ltd	C Dip	Additional pack size	GSL
Novartis Animal Health UK Ltd	Aurogran 500	Marketing Authorisation holder address changed to Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR	MFS
Novartis Animal Health UK Ltd	Tiamutin 80% Premix	Product name changed to Denagard 80% premix	MFS
Pharmacia Animal Health Ltd	Uniprim 150 Powder	Marketing Authorisation holder name and address changed to Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ	MFS