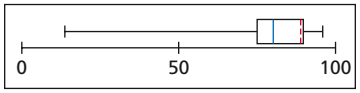
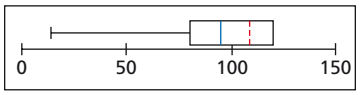
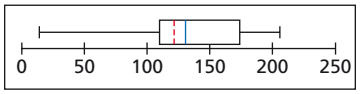
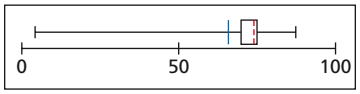
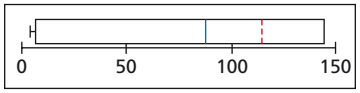
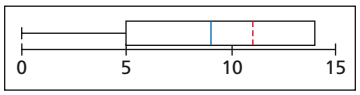
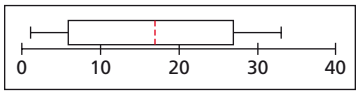
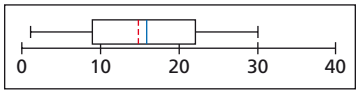
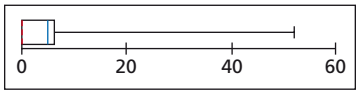
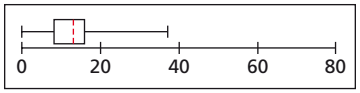
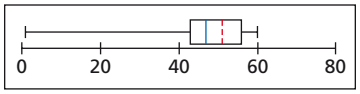
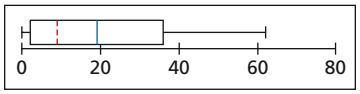
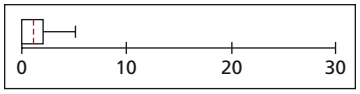
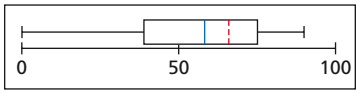
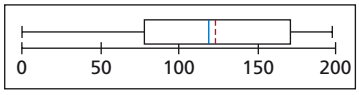
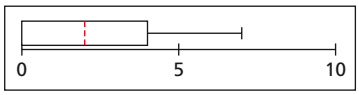
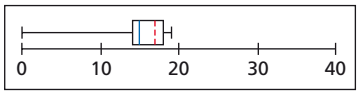
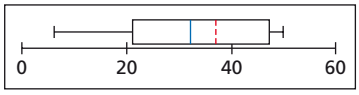
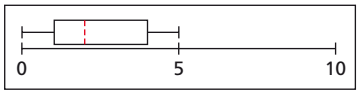
Appendix A

Meeting Our Published Standards – Detailed Results

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 MAs and MAPIs					
Initial assessment	45	EXCELLENT	90	78	
Sign off, VPC or further questions	34	EXCELLENT	120	96	
Sign off and issue	39	EXCELLENT	210	130	
MAPIs for MR products & copy-cats					
Initial assessment	17	EXCELLENT	75	66	
Sign off, VPC or further questions	8	UNACCEPTABLE	120	88	
Sign off and issue	4	EXCELLENT	210	63	[2]
Variations					
Type IA – decision	399	EXCELLENT	14	9	
Type IB admin – issue	73	EXCELLENT	30	17	
Type IB – initial assessment	269	EXCELLENT	30	16	
Type IB – sign off	260	EXCELLENT	30	5	
Harmonisation – sign off	11	EXCELLENT	60	15	
Type II – initial assessment	636	EXCELLENT	60	47	
Type II – sign off	530	EXCELLENT	60	19	
Renewals					
Administrative – sign off	185	EXCELLENT	30	1	
Full and conditional – initial assessment	44	EXCELLENT	90	58	

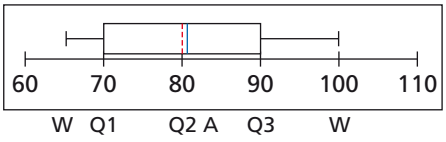
Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: - - - = Median —— = Average
Full and conditional – sign off	110	EXCELLENT	180	118	
ATCs					
Type A and B – validate	41	EXCELLENT	5	2	
Type A – sign off	16	EXCELLENT	30	15	
Type B – sign off	23	EXCELLENT	50	32	
Type A and B – issue	39	EXCELLENT	5	2	
Batch release (Immunologicals)					
Issue	1989	EXCELLENT	15	4	
AVAs and NFABBAs (inc variations)					
Assess	4	EXCELLENT	45	28	
Specific Batch Control					
Validate	44	EXCELLENT	3	<1	
Initial assessment	44	EXCELLENT	10	2	
Assess response	50	EXCELLENT	10	<1	
Issue	49	EXCELLENT	3	<1	
Validation/Issue					
Validate	1373	EXCELLENT	10	4	
Issue	1847	EXCELLENT	10	6	
UKPARs					
Module 1	131	EXCELLENT	30	16	
Module 2	110	EXCELLENT	120	48	
Module 3	142	EXCELLENT	60	36	
Import Certificates[3]					
SIC – urgent/non-urgent	3118	EXCELLENT	2/10	<1	
STC – urgent/non-urgent	3891	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 quantities.

E.g. Application days for 10 applications: 80, 75, 90, 95, 65, 65, 80, 85, 70, 100
65, 65, 70, 75, 80, 80, 85, 90, 95, 100
w Q1 Q2 A Q3 W

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



Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable	Target (days[1])
European Centralised			
Rapp – Initial assessment	1	EXCELLENT	70
Co-Rapp – 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	33	EXCELLENT	90
Assessment of Responses by 2nd 70 days	29	EXCELLENT	70
Procedure completed by 2nd 90 days	28	EXCELLENT	90
CMS			
Procedure completed by 2nd 90 days	17	EXCELLENT	90
Decentralised RMS			
Production of Assessment Report within 70 days	27	EXCELLENT	70
Production of Assessment Report within 120 days	14	EXCELLENT	120
Assessment of Responses by 70 days	10	EXCELLENT	70
Procedure completed by 90 days [210 in total]	9	EXCELLENT	90 [210]
CMS			
UK comments sent by 100 days	35	UNACCEPTABLE	100
Procedure completed [decision made] by 120 days	10	EXCELLENT	120
UK acceptance/referral sent by 90 days [2nd phase] [210 days]	20	EXCELLENT	90 [210]
MRL (No. 6.i)			
Report for CVMP	1	EXCELLENT	120
European Variations Type II – Mutual Recognition RMS			
PAR circulated	57	EXCELLENT	40
CLOQ circulated	55	EXCELLENT	60
Procedure completed	42	EXCELLENT	90
Type IB – Mutual Recognition RMS			
CLOQ circulated	47	EXCELLENT	30
Procedure completed	46	EXCELLENT	60
Type IA – Mutual Recognition RMS			
Determined within 14 days	27	EXCELLENT	14
Type IA – Mutual Recognition CMS			
Determined within 14 days	33	EXCELLENT	14
Type II Mutual Recognition CMS			
UK comments sent by 55 days	39	UNACCEPTABLE	55
UK comments sent by 85 days	21	EXCELLENT	85
Type IB Mutual Recognition CMS			
UK comments sent by 20 days	28	EXCELLENT	20

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable	Target (days[1])
UK comments sent by 50 days	43	EXCELLENT	50
European Renewals Mutual Recognition RMS			
PAR circulated by 40 days	25	EXCELLENT	40
CLOQ circulated by 60 days	31	EXCELLENT	60
Procedure completed by 90 days	21	EXCELLENT	90
Mutual Recognition CMS			
UK Comments sent by 55 days	20	UNACCEPTABLE	55
UK Comments sent by 85 days	33	EXCELLENT	85[5]
Customer Relations Customer Care Visits			
Number of Visits	12	EXCELLENT	
Publishing themes	2006/07	EXCELLENT	
Unreturned authorisation documents			
Right first time (Authorisations)	2,022	EXCELLENT	
Right first time (SIC/STCs Certificates)	5,749	EXCELLENT	
Right first time (Export Certificates)	1,185	EXCELLENT	
SARs			
Enter human SARs	147	EXCELLENT	2
Enter serious animal SARs	1,260	EXCELLENT	2
Enter environmental SARs	44	EXCELLENT	2
Enter non-serious SARs	1,585	EXCELLENT	10
Report to Eudravigilance	417	EFFECTIVE	5
Inspections			
Inspect	26	EXCELLENT	
Prepare report	19	UNACCEPTABLE	60
Issue Certificate	9	EXCELLENT	90
Annual VPC evaluation of Assessment Reports Others			
Evaluation	3	EXCELLENT	

[1] The days are specified as either calendar days or clock days according to the target and as set out in detail in the published standards.
[2] 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.

MA – Marketing Authorisation
MAPI – Marketing Authorisation Parallel Import
MR – Mutual Recognition
ATC – Annual Test Certificate
AVA – Autogenous Vaccine Authorisation
NFABBA – Non-Food Animal Blood Bank Authorisation
UKPAR – United Kingdom Public Assessment Report
SIC – Special Import Certificate
STC – Special Treatment Certificate
RMS – Reference Member State
CMS – Concerned Member State
MRL – Maximum Residue Level
SAR – Suspect Adverse Reaction

Appendix B

Veterinary Products Committee (VPC)

The VPC was established in 1970 under Section 4 of the Medicines Act 1968 (the Act).

On 30 October 2005 the Act was disapplied to veterinary medicines by the Veterinary Medicines Regulations 2005 SI No 2745 (the Regulations). However, whilst the statutory requirement for the VPC was retained in the Regulations, its terms of reference were not. In October, following the recommendation of the Committee, Ministers agreed the following terms of reference for the Committee, effective from 30 October:

"The Veterinary Products Committee is a statutory committee established to:

i) provide the Secretary of State with scientific[†] 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; and

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 publishes a report of its activities and those of its sub-committees."

[†] Scientific advice means all aspects, including risk/benefit analysis, of the safety, quality and efficacy of a veterinary medicinal product apart from regulatory issues.

Medical and Scientific Panel

The Medical and Scientific Panel, a sub-committee of the VPC, was established in 1994 to:

- evaluate research currently available, and in progress, on organophosphorus sheep dip products in relation to possible human exposure;
- advise on any additional work that may be needed to elucidate the potential long-term effects on humans of organophosphorus sheep dip;
- advise on the suitability of any projects submitted for research; and
- report its findings to the VPC, as its sub-committee.

Appraisal Panel on Human SARs

The Appraisal Panel, a sub-committee of the VPC, was established in November 1991 to:

- evaluate all SARs to veterinary medicinal products in humans to:

  i) identify any trends and signals of emergent problems;

  ii) generate hypotheses as to possible causes of these trends;

- monitor the consequences of recommendations for changes in working practices or use; and
- report its findings to the VPC and produce an Annual Report of its findings.

Veterinary Residues Committee (VRC)

The VRC was established in January 2001. Following a review in 2004 it produced revised terms of reference. These are to advise Ministers[A] (where appropriate) and the CEOs of the VMD and the FSA on:

- the incidence and concentrations of residues of veterinary medicines[B] in samples collected under the VMD's surveillance programmes, with particular reference to food safety and observance of withdrawal periods for veterinary medicines[C];
- to assess and advise on the scope and operation of the VMD statutory surveillance programme within the requirements of European Community legislation;
- to formulate an annual non-statutory surveillance programme, advise on the scope and results of relevant FSA surveys and consider the need for further analytical surveys;
- to set up sub-groups as necessary to further the work and objectives of the VRC; and
- to publish an Annual Report on Veterinary Residues Surveillance, and to communicate the VRC's findings and recommendations to Government and stakeholders in a comprehensive, understandable and timely way.

[A] The Ministers referred to are:
The Secretary of State for Environment, Food and Rural Affairs, Ministers of the Scottish Executive, the National Assembly for Wales and the Minister for Agriculture and Rural Development Northern Ireland.

[B] In addition to veterinary medicines, surveillance also covers banned substances, heavy metals (lead and cadmium), malachite green, organochlorines (OCs), organophosphates (OPs) and polychlorinated biphenyls (PCBs).

[C] A withdrawal period is the length of time after end of treatment with a veterinary medicine that must pass so that any residues in edible tissues will have depleted to below the Maximum Residue Limit (MRL).

Appendix C

VMD Publications[31] and Statutory Instruments

Publications 2007/08

Veterinary Medicines Guidance Notes 1-27 (updated versions)

Code of Practice for the responsible use of animal medicines on the farm (updated version)

Code of Practice for Suitably Qualified Persons (SQPs) and guidance for the registration of retail premises (updated version)

Statutory Instruments coming into effect in 2007/08

The Veterinary Medicines Regulations 2007

SI 2007 No 2539

Made: 30 August 2007

Coming into force: 1 October 2007

31. VMD publications can be found at www.vmd.gov.uk under Publications

Appendix D

VMD People Strategy – Our Commitment to Staff

The VMD recognises the diversity of our staff and the role this plays in focusing our performance on our business. We seek to treat everyone fairly and encourage, value and recognise everyone's views and contribution.

The VMD's overall aim is to create a working environment within which good management practice is promoted, recognised and rewarded; and that ensures that each member of staff is:

- treated with respect;
- valued for the differences, skills and experience they bring to work;
- encouraged and enabled to develop their potential in the workplace and to progress;
- free from harassment, bullying and discrimination; and
- able to work without fear of blame.

In developing our policies and services we are open to the views of different stakeholders and customers, and take full account of them.

Appendix E

Audit & Risk Committee Annual Report 2007/08 to the VMD Chief Executive and Accounting Officer

Introduction

The purpose of the VMD's Audit & Risk Committee is to reassure the VMD's Chief Executive Officer and Accounting Officer that effective measures are in place to justify confidence:

- in the accuracy of financial information;
- in the control of risk; and
- in the efficacy of corporate governance, managerial controls and audit procedures.

Membership

The membership of the VMD Audit & Risk Committee during the year was:

Brian Morris (Chairman) – External member of the VMD Management Board

David Skilton – External member of the VMD Management Board

John Preston – External member of the VMD Management Board

Heather Oliver (Secretary) – March-October, VMD, Head of Legislation & Core Services

David Rayner (Secretary) – October-March, VMD, Head of Core Services and Communications

The following persons are normally invited to attend meetings to provide advice to the Committee:

Steve Dean – VMD CEO

Michael Addison – VMD Head of Finance

In addition, representatives from Internal Audit, the National Audit Office and its contracted external auditors all attend meetings of the Committee and contribute to its work.

Meetings

The Committee met formally on four occasions in 2007/08. The frequency and timing of meetings were scheduled to fit in with the stages of the financial year.

Work of the Committee

Overall, the Committee's work through the year included:

1. Tracking and monitoring the annual cycle of processes through which are prepared the Annual Accounts and the Statement of Internal Control.
2. Similarly monitoring the strategy and processes through which internal and external audit and risk management are planned, executed, implemented and appraised.
3. Examining selected areas of the VMD's infrastructure in relation to its governance, audit and potential risks; in particular:
   - enforcement arrangements (June 2007);
   - business continuity (in the context particularly of a recently-experienced site power shutdown in July 2007);
   - arrangements for the prescribing cascade (December 2007); and
   - arrangements for GMP approval and inspection (March 2008).

The Chairman attended the Best Practice for Audit Committee Conference held by HM Treasury on 22 October 2007.

Conclusion

The VMD Audit & Risk Committee concludes that it is reasonable for the VMD Accounting Officer to feel confident in relying on the particular processes that the Committee has reviewed in the course of the year. From these examinations, more general confidence in the VMD's operations, governance and audit seems reasonable, after allowing for the Committee's limited role and resources.

Brian Morris
Chairman