VMD Audit & Risk Assurance Committee

Minutes of meeting held on 24 September 2020

Members

David Corner (Chair) Julia Drown David Catlow

Present

Abigail Seager - VMD Mike Griffiths - VMD Linda Simmons – VMD John Millward - VMD Gillian Diesel - VMD Nick Stokell – Defra GIAA Peter Morland - NAO Emma Parkinson – NAO Chris Abbott – VMD (note taker)

1. Announcements and apologies for absence

1.1 The meeting was held by video conference. Apologies were received from Peter Borriello, Paul Green, David Kennedy and Christine Middlemiss.

2. Declarations of interest in the matters to be discussed

21 None.

3. Minutes of the meeting held on 3 July 2020

VMDARAC 20/36

3.1 The minutes of the last meeting were agreed.

4. **Matters Arising/Actions**

- **VMDARAC 20/37** 4.1 VMD had submitted a CSR bid for a tenant friending relationship with DDTS in order to work collaboratively and resolve the ongoing electronic communication problems with Defra. The Forestry Commission had also submitted a bid. The result should be known by January and, if successful, the new relationship will be established in the next financial year.
- 4.2 In regards to providing a single 24 hour point of contact for travellers to use in an emergency, VMD reported that they are still looking into options and checking what measures other agencies are using, and will report back at the next meeting.
- 4.3 The MoU with the RCVS for veterinary practice inspections has been redrafted and agreed and is ready to be signed off. The revisions have been orientated to improve VMD's involvement and allow for distant assessments, more work shadowing and better follow-up of non-compliance findings.
- 4.4 The Communications Strategy review had been delayed due to other priorities but it would be completed in time for the December meeting.

5. Pharmacovigilance and the management of risk

5.1 VMD's head of pharmacovigilance, Gillian Diesel, gave a presentation on how her team manages risk. The team, consisting of 12 vets, scientists and admin staff, receives around 10,000 reports of adverse events (unfavourable and unintended effects, including a suspected lack of efficacy, observed after use of VMPs) per year from animal owners, vets and MA holders. Reports are received in a number of different ways and MA holders can upload them directly into the VMD's public dashboard on Gov.uk which also shows all the adverse events which have been

reported by product. There is no legal requirement for companies to report events but it is considered good practice by Industry. All reports are assessed and this work is peer reviewed when appropriate and signal (risk) detection meetings are held every month. This helps identify risks arising from the use of authorised medicines and they are then managed using the 'four Ts' approach: Terminate (eg. suspension of product), Treat (eg. change of warnings on packaging), Transfer (communicate the concern) and Tolerate (accept the risks due to the benefits outweighing the risks). This approach resulted in fifty changes to products being actioned last year. As acute adverse events are easier to identify than chronic ones, the team looks at professional literature reports, for example from universities, for evidence of these. It has also recently formed links with the Small Animal Veterinary Surveillance Network (SAVSNET).

- 5.2 The team also assesses MA holders' pharmacovigilance systems and carries out around 25 inspections of these every year. Communication is given a high priority and the team engages with the fish, pigs and poultry sectors in particular as well as regularly attending publicity events and publishing articles in the veterinary press to raise awareness. Some work is carried out jointly with universities, veterinary associations, the RCVS and SQPs.
- 5.3 After the end of the transition period the UK will no longer have access to the EU's pharmacovigilance databases but new legislation will be introduced by 2022 which will give VMD access to reports raised outside the UK and it is hoped that new relationships and data sharing will be achieved with a number of countries.

Financial Year 2019/20

6. Final Audit Completion report

6.1 The external auditor explained that the outstanding areas in the audit completion report for 2019/20 and in the letter of representation that had required completion before certification had now been resolved and the report had been signed off in July. Members noted that one of its recommendations was for the requirement for greater segregation of duties in the Finance team and VMD reported that a new senior member of staff had been recruited to help with this and a review of the whole structure would be complete by the end of the year. It was noted that the notional recharge by DDTS had been resolved following challenge by VMD and NAO.

Financial Year 2020/21

7. Internal audit report

- 7.1 The committee reviewed the audit report on Equality, Diversity and Inclusion which gave moderate assurance and raised four recommendations. Members noted that VMD is performing well in recruiting BAME employees but less well for people with disabilities, although the low number was to be expected due to the relatively low total number of staff. VMD has now established an EDI group and champion who is communicating with other Defra departments. The committee noted the moderate opinion and that an action plan is now in place and the opinion could be changed to substantial at the annual review.
- 7.2 The internal auditor gave an update on progress against the Internal Audit Plan 2020-21 and said that Covid-19 and changes to the VMD timetable had caused some delays but the AMR reference centre and Business IT Enhancement programme audit should be completed in time for the December committee meeting.

8. External audit report

VMDARAC 20/40

VMDARAC 20/38 & 20/39

8.1 The external auditor said that their audit planning report would be delivered at the December meeting. They did not anticipate any difficulties carrying out auditing work remotely.

9. VMD Finance/Other

- 9.1 Implementation of auditors' previous recommendations
 - 9.1.1 The Committee noted the good progress made implementing auditors' previous recommendations. It was noted that a new Grade 7 had been recruited to the Corporate Services Team and would be taking on contract management, and a new inspections app is being developed which will reduce the time it takes to carry out inspections.

Audit & Risk Committee Procedural Items

10. Papers circulated to the Committee since the last meeting

10.1 The Transition and Trade report for August had been circulated.

11. Risk and Assurance

11.1 Risk Register

11.1.1 The Committee reviewed the Risk Register and noted that the Northern Ireland Protocol was the outstanding risk at this time, and there was a lack of information from the EU and EMA about future access to databases. It was noted that remote working due to Covid-19 was continuing to go well.

12. Update on data handling, fraud and corruption issues

- 12.1 Members noted that two direct debits had been set up in error by third parties against the VMD bank account. Both amounts have been recovered through indemnity claims.
- 12.2 It was noted that there had been no changes to the Defra Anti-Fraud policy which the VMD uses during the last year.

13. ARAC annual report

13.1 VMD ARAC has not previously produced an annual report but it was noted that it was Defra policy to do so and it was agreed that the Committee would from now on produce a one page annual report addressed to the Management Board. ACTION

14. Audit Committee Workplan

14.1 It was agreed to ask the AMR team if a representative could attend the December meeting to explain how they manage risk. ACTION

15. Any Other Business

15.1 There was no other business.

16. Dates of future meetings

16.1 8 December 2020.

VMDARAC 20/42

VMDARAC 20/43

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VMDARAC 20/44

VMDARAC 20/41