MINUTES OF VMD MANAGEMENT BOARD MEETING HELD ON 27 SEPTEMBER 2023

Members
Alison White (Chair)
Timothy Riley
Philippa Hardwick
Abigail Seager – VMD
Gavin Hall - VMD
Mike Griffiths – VMD
Muiz Agbaje – VMD
Sally Randall – Defra (for item 1)
Nicola Charlton – Boardroom Apprentice

Present
Chris Abbott – VMD (note taker)

1. Announcements and apologies for absence

1.1 Alison White welcomed everyone to her first meeting as MB Chair. The new interim Director General of Food, Biosecurity and Trade, Sally Randall, attended the first part of the meeting to meet the members and explain how she sees her role's responsibility for progressing farming, agriculture, animal welfare and EU trade. She recognises that VMD leads on many issues at policy level and is aware that the AMR action plan and vaccine availability are major issues at the moment.

2. Declarations of interest in the matters to be discussed

2.1 No interests were declared.

3. Review of Annual Report and Accounts (as tabled at ARAC) and recommendation to Chief Executive to sign

3.1 The Board were content with the Annual Report and Accounts as reviewed at audit committee, subject to some minor alterations being completed, and recommended them to the Chief Executive for signing.

4. Minutes of the meeting held on 6 July 2023 **VMDMB 23/22**

4.1 The minutes were agreed.

5. Matters Arising/Actions **VMDMB 23/23**

5.1 Members had not yet received the Enforcement team newsletter and the last issue would be sent to them.
ACTION

6. Vaccine Availability

6.1 Gavin Hall explained that VMD has received an increasing number of PQs and Ministers Correspondence, as well increased media around people being unable to vaccinate livestock and companion animals due to a shortage of vaccines and there is a public perception this has been caused by Brexit and that the solution rests with the VMD. VMD's initial view is that it seems to be due to several reasons including e.g.: product specific ad hoc issues with manufacture, QC testing and release of individual products; several of the vaccines having supply issues are only manufactured by one or two MAHs and therefore where there is a problem with manufacture this impacts availability; a lack of manufacturing premises and QC testing sites compounded as companies faced the challenge of setting up new sites in the EU (it is a requirement of the EU that manufacture, QC testing and release takes place in the EU) and a general increase in demand partly due to the move to using vaccines for prevention rather than cure. Additionally Brexit means that batches vaccine (depending on the MA) often are produced as "GB vaccine" or "EU vaccine" and therefore if there is an issue with one or the other there is less resilience with respect to flexibility of supplying the other market.

VMD is engaging with veterinary sectors to investigate the reasons and is setting up a roundtable discussion involving representatives from a range of sectors including Office of Life Sciences, NOAH, Animal Health and Welfare Board – England, veterinary groups, manufacturers and species representative groups to discuss ways of improving the situation and securing a long-term solution to vaccine supply chain resilience. These include better animal husbandry and importing more products depending on suitable products being available in other countries; to also bring together areas of UKG that provide funds in relation to human medicines to see if similar opportunities may be available to incentivise the manufacturers of veterinary vaccines. VMD's drive to encourage vets, and animal sector groups, to use vaccines rather than antibiotics has been successful and a shortage would threaten the progress made. Ministers briefed on the situation. The Office of Life Sciences provides funding to manufacturers of human medicines but not yet for animal medicines. The joint review schemes set up with other regulators in Switzerland, Australia and New Zealand should encourage companies to apply for marketing authorisations across regulatory jurisdictions. VMD has to take a pragmatic approach, but is unable to compromise on product safety, and this could involve granting provisional marketing authorisations with associated data derogations (where there is no authorised vaccine with a full marketing authorisation).

Post-meeting note:

VMD recognise the problem with the vaccine availability:

Short term supply issues are dealt with utilising the Special Import Scheme, supporting the prescribing cascade.

Autogenous Vaccine Authorisations (AVA) available for manufacture of inactivated autogenous vaccines where a suitable authorised vaccine might not be available.

Exceptional marketing authorisation routes (Provisional MA and Limited MA) available and may be granted following submission of a reduced data package where specific data is not available, and the applicant can demonstrate that the benefits of the product outweigh any potential risks.

Recent concerns regarding e.g. availability of sheep vaccines - having liaised closely with one of the main vaccine manufacturers, we understand that the current shortages are a consequence of high demand and manufacturing and logistic challenges.

Longer term supply is a separate issue that needs addressing, VMD is bringing together interested parties from industry, species groups and other government departments to discuss the longer-term picture and solutions.

7. CEO's Report **VMDMB 23/24**

7.1 The CEO's report was presented and reviewed. The Group Corporate Services incentive was being managed and now causing less concern. Members noted that work was continuing on the 2024-2029 AMR national plan and asked if antibiotic residues in livestock at slaughter could be measured. The British Cattle Movement Service is running a consultation and the Livestock Information Service is a good resource which might help effectiveness. VMD noted these suggestions and would consider them further.
ACTION

8. Delivery against the Business Plan 2023/24 **VMDMB 23/25**

8.1 Progress against the Business Plan was noted.

9. Finance report **VMDMB 23/26**

9.1 The finance report provided figures up until the end of August and showed pressure due to IT costs arising from the implementation of VMRs. VMD is meeting with Defra to discuss what underspend is available and is currently content to proceed at risk.

10. Management Board work plan **VMDMB 23/27**

10.1 It was decided to review AMR at the March meeting.

11. Any other business

11.1 VMD has regular meetings with Ministers and NEDs will be invited if needed.

11.2 The NEDs will be invited to VMD's internal information session on AMR when it is arranged.

Veterinary Medicines Directorate
September 2023