VMD: STATEMENT OF OBJECTIVITY AND IMPARTIALITY

The VMD is an executive agency of Defra, a major Government Department, and as such discharges its duties based on evidence without fear or favour. Integrity, impartiality and objectivity, which we take very seriously, are cornerstones underpinning all the VMD's activities at all levels. The following paragraphs provide an insight into how objectivity and impartiality are built into our culture, supported within our legal obligations, and is also a key principle underpinning our scientific work.

To ensure the VMD's objectivity and impartiality we:

1. Adhere to the Civil Service Code
2. Staff are required to complete an annual declaration of interests
3. Assess according to processes set in European legislation
4. Ensure all assessments are peer-reviewed and agreed by committee procedures
5. Provide the independent Veterinary Products Committee with a selection of assessments for its views.

A key inbuilt guarantee of impartiality and objectivity is that we have nothing to gain by conducting our business in any other way. For example, if a company wants to be able to sell medicine in this country it has to have its product reviewed by us, irrespective of the company's views of us. Another way a company can have its products sold legally in the UK, is to have it reviewed for sale across the whole of the European Union. In this case, the company again has no control on which country leads on this review, as the arrangements are the responsibility of the European Medicines Agency. Likewise, for inspections of manufacturers and medicines distributors, those being inspected have no choice in who carries out the inspections.

All of this is one of the benefits of the VMD being an independent National Competent Authority It means there is nothing to be gained by trying to "curry favour" with companies, and everything to lose; predominantly our reputation. Under Treasury rules, the VMD, may only recover the costs involved in actually undertaking the work for the fees it charges.

<u>Culturally</u>

The VMD is part of the machinery of Government and is staffed by Civil Servants. The VMD has a dedicated work-force which upholds the Civil Service Code. You can access this code at the following link http://resources.civilservice.gov.uk/wp-content/uploads/2011/09/civil-service-code-2010.pdf. The code sets out the values and behaviours expected from all Civil Servants – honesty, integrity and objectivity are of paramount importance. The code also forbids our staff from accepting gifts, hospitality or other benefits which may compromise personal judgement or integrity.

At the VMD, all staff are required to complete an annual declaration of interest statement, which is independently reviewed by the VMA Audit and Risk Committee. The declaration records details of financial interests that employees, or close members of their families, may have in any of the business regulated by VMD and details of any previous employment within those businesses. Staff have an obligation to update this declaration as circumstances change. Declarations of interest are used to determine the constraints placed on individuals in conducting our regulatory functions. Should any direct interest exist, individuals would not be permitted to work on conflicted areas, and this in certain areas extends to 5 years after the conflict ceases. Furthermore, during any discussions that relate to such work, the individual may be requested to leave the room until that discussion has concluded, or only contribute if formally asked to do so by the Chair of the meeting.

Whilst staffing levels fluctuate, the actual number of VMD staff at any given time with active conflicts of interest is very low; with respect to any of the business conducted by VMD.

Whilst the VMD manages its potential conflicts of interest, members of staff with experience of working in the industry bring wider benefits to the VMD and the regulatory functions we undertake. Also when staff leave the VMD and move to work in industry there is a required process that is followed to ensure continued impartiality. This is in relation to both the VMD and the industry itself.

Each year all VMD employees are required to undertake training in data handling, fraud and corruption (there is additional training material for information asset owners, senior managers etc.). There is an exam at the end, which people are required to pass with a mark of at least 80%.

VMD staff are often invited to speak at conferences organised by associations or event companies. This has a mutual benefit in that industry hears directly from the Regulator and that the Regulator can share key messages with the industry. The VMD does not, however, accept invitations to conferences which are organised by a single pharmaceutical company or where the speaker is industry sponsored.

Embedded within the VMD is a quality management system. Standard Operating Procedures exist which are followed, and which ensure a consistent approach to process management and ensure that due diligence is demonstrable in the VMD's decision making. A series of audits of key areas and processes are regularly undertaken in order to provide assurances to the senior management team that duties are being effectively and consistently discharged; this includes objectivity.

Finally, there is control on Civil Servants accepting gifts. In instances where the gift is of low value staff may accept them, and particularly for certain cultures it is offensive to the hosts to refuse. In such cases staff have a responsibility to enter details in the VMD's register of gifts and hospitality. Where, in the course of business VMD staff receive any corporate hospitality e.g. meals or paid hotel accommodation, these must also be recorded in the register of gifts and hospitality.

Legally

In addition to the culture of objectivity embedded throughout the VMD, our legal obligations reinforce this position. Much of the work of the VMD has a European dimension and as such legislation is set in either a Directive (which is then implemented into UK law) or via a Regulation which has direct force. Legislation effectively sets out a robust framework over what we can and cannot do and also on what we should and should not do. In the case of authorisations for veterinary medicinal products, there is a legal annex to the Directive that sets out the type of data and requirements which must be met by the applicants within the data dossiers used in support of applications. EU wide standards provide more detailed advice and guidance to applicants (discussed below).

There are other sources of assurance that the VMD is meeting its many legal obligations. The VMD's accounts are audited and cleared by the National Audit Office; a programme of audits of key processes is undertaken by an external and independent company; and the Commission's Food and Veterinary Office (FVO) undertake periodic audits. The FVO will publish the outcomes of its missions and the VMD also publishes its annual review.

Finally, although not directly a legal obligation, the European Medicines Agency (EMA) operates a conflicts of interest policy – this is separate from, and in addition to, anything internal to the VMD. All VMD personnel involved with any business involving the EMA are required to complete an annual declarations form. The EMA will not permit individuals to be involved with centralised applications, or any procedures which are facilitated in part by the EMA, unless a declaration form has been completed. The type of work they can be involved in may then be restricted in view of any interest declared. There are also assurances of objectivity with regard to our residues business. The surveillance programmes are overseen by the independent Veterinary Residues Committee and any residues violations are investigated by other Government Agencies.

Scientifically

Perhaps most significantly, a number of measures are in place to ensure that the scientific evaluation and assessment process is based on evidence, is robust and revolves around the consideration of a positive benefit: risk outcome.

All applications for new marketing authorisations, whether submitted nationally, under mutual recognition or decentralised procedure are subject to a formal peer review process which is carried out at two levels. The assessment of the data for each application is carried out by an assessor with the appropriate scientific expertise (usually one assessor for immunological products and one for each of quality, safety and efficacy for pharmaceuticals). The assessment is then peer reviewed by a colleague within the same discipline. All assessment reports for pharmaceutical products are peer reviewed at the monthly meeting of the Scientific Secretariat. All VMD assessors of pharmaceutical products attend and there is a standing invitation to representatives of a number of other government departments including the Food Standards Agency, Public Health England and the Environment Agency. A similar meeting is held for immunological products, known as the Biologicals Committee. Applications, and the VMD assessment of the data, are presented at the meetings. Attendees then have the right, and obligation, to add comment, to challenge the assessment and to discuss any contentious issues. Ultimately it is the Scientific Secretariat and the Biologicals Committee that reach a decision on the questions and outstanding issues which are sent to the applicant to address – this is not the decision of any one, or small group of, assessors.

Also, as mentioned above, much of the explanation of the technical annex to the Directive on Veterinary Medicinal Products and more specific scientific requirements are detailed in guidance. This guidance is discussed, prepared and agreed at a European level involving all Member States. Adherence to these guidelines provides a level of consistency to the industry and also sets a robust scientific standard. Assessments are therefore conducted within the framework of legislation, within the scope of the relevant EU wide agreed guidelines and peer reviewed within the UK. Not only that the majority of applications now involve other Member States. In such cases the scientific assessment of the UK is peer reviewed by the other Member States involved. This effectively moves the decision from one made solely by the VMD to one that is supported by other Member States.

Furthermore, the scientific rigour of the VMD assessments is also tested by the Veterinary Products Committee (VPC). The VPC is a panel of independent experts appointed for their expertise across a whole range of disciplines. Annually a sample of VMD assessment reports is selected by the VPC for their independent review. Even once a product is authorised, impartiality continues to be assured since the VPC also oversees the work of our Pharmacovigilance Unit, who monitor reports of adverse reactions and suspected lack of efficacy to veterinary medicines in order to identify and act upon emerging problems.

And finally

The VMD has a wider role than just industry funded activities. There are a number of areas, such as developing Government policy for veterinary medicines and the associated enforcement activities, which are funded directly by Government. As with any other Government Department, the VMD is accountable for the way in which it uses public money. The Chief Executive Officer is the accounting officer for the VMD and has to sign an annual statement confirming that internal controls and governance are robust.

To conclude, statutory fees which industry is obliged to pay do fund elements of the VMD business. This, however, has no influence on, or over, its impartiality and objectivity. The VMD has committed people covered by the Civil Service Code; who work within the constraints of legislation; and whose scientific evaluation and advice is evidence based, independently peer reviewed and within standards set by EU guidelines.