



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

Licensing Customer Survey 2009/10 – Update on Improvements

In the (June 2010) edition of MAVIS the results of the customer survey for 2009/10 were summarised and information was given on some of the immediate steps which had been taken to address some of the areas identified for improvement. This article provides an update on the work that has been done as a direct consequence of the customer survey results:

Area requiring improvement	Action Taken
<p>Lack of clarity on what action companies should take to get an application to pass validation.</p>	<p>The VMD has reviewed the process for deciding whether deficient applications should either be deferred or failed at validation.</p> <p>The VMD's templates for validation deferral and failure letters have been revised so that validation assessors, in addition to saying why an application has not passed validation, will set out what action the company needs to take to secure a validation pass. In addition the letters set out the time period in which the company has to provide the required information.</p> <p>A separate article in MAVIS sets out the changes in more detail.</p>
<p>Delays in the approval of mock-ups.</p>	<p>For labels/leaflets not harmonised with Ireland, mock-ups will now be examined and either approved, or required changes identified, within 20 days of receipt of mock-ups or revised mock-ups.</p> <p>Following discussion with the IMB we are planning to pilot the application of a similar approach to labels/leaflets harmonised with Ireland. The start date of the pilot will be announced.</p> <p>A guideline on checking mock-ups is being developed with IMB and will be shared with industry and the hope is that this will help companies get mock-ups right first time and will help the VMD to be consistent in its approach to checking mock-ups.</p>

<i>Delays in the approval of mock-ups (cont/d.)</i>	A separate article in MAVIS sets out the changes in more detail.
Lack of clarity on the timelines for progressing GMP inspections.	<p>In the letters which are sent to companies setting an inspection date, and the agendas for GMP inspections, information is now included on the expected timescale for the complete process of inspection and follow-up.</p> <p>A separate article in MAVIS will set out the timelines for dealing with applications for Manufacturing Authorisations, GMP Certificates and Wholesale Dealer Authorisations.</p>
Lack of clarity concerning when changes to SPCs, such as withdrawal periods, should be implemented.	<p>Document now published on the VMD website clarifying when changes to SPCs should be implemented</p> <p>http://www.vmd.gov.uk/changes_to_SPCs.pdf)</p>
Inconsistent approach to inclusion of information under “what’s new” on the VMD website.	An internal policy has been finalised which sets out the type of information that should appear under “what’s new”. Unless there are special circumstances notices will only appear under “what’s new” for 4 weeks. Items in this section will also always appear within the relevant page of the website.

Clearly one of the main areas of concern for industry is the time taken to agree mock-ups which delays the issue of the Marketing Authorisation. As the above table illustrates, the VMD is taking a series of steps which we hope will help address this. However, industry also has a part to play to improve the current situation, by ensuring that good mock-ups which reflect the agreed SPC are supplied quickly following the end of a procedure. Companies are asked to aim to get mock-ups to the VMD within **20 days** of a request for these.

The VMD aims to issue Marketing Authorisation official documentation within 10 days of sign-off of a product by assessors. This sign-off by assessors includes the approval of mock-ups where appropriate. In 2009/10 the average time for issue of Marketing Authorisation official documentation was 6.3 days.

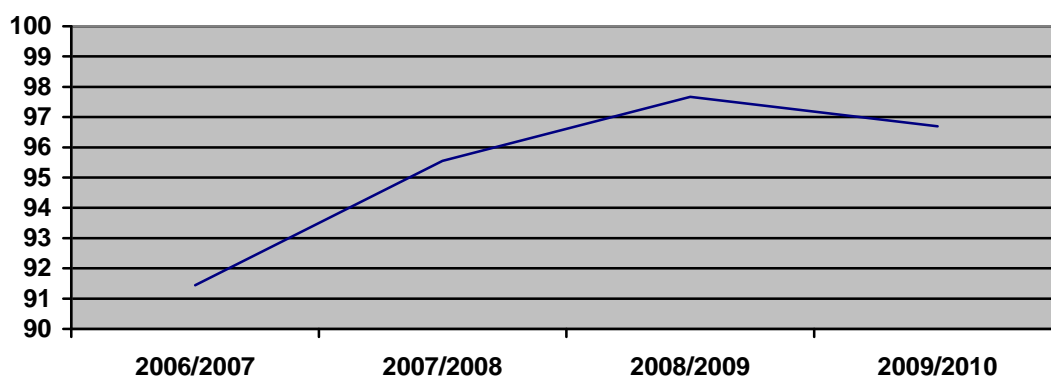
One of issues that was identified during the survey was that companies were not always aware that in most EU procedures the VMD could not influence the timetables. The only situations where the VMD can modify a European timetable are:

- Where the UK is RMS, in the first phase of Mutual Recognition Procedure, the VMD may be able to reduce the time for production of the assessment report subject to availability of suitable resource and an agreement with the applicant.
- Where the UK is RMS and all of the CMS are willing to accept an accelerated timescale. This is rarely possible, except where the number of CMSs involved is very low.

One of the challenges for the VMD is ensuring consistency in approach between assessors and administrators. The VMD's newly introduced Quality System is an important tool to avoid inconsistency, as are the training programmes for new staff and the various peer review processes. Industry can help the VMD tackle inconsistent approaches by contacting the relevant Head of Team whenever they notice this type of discrepancy.

The customer survey highlighted that there may be some misconceptions in terms of VMD performance in some areas. The table and graph below demonstrates that the quality of documentation (which relates to marketing authorisation official documentation) issued by the VMD is now consistently high and for the last three years the number of 'right first time' documents has been above 95%.

Financial Year	No Issued	No of Documents Returned	% of Documentation Correct First Time
2006/2007	1928	165	91.44
2007/2008	2022	90	95.55
2008/2009	2404	56	97.67
2009/2010	1894	63	96.70



There are a small number of areas where the VMD has identified a solution to an identified issue but has not yet put the solution into place. In particular in the area of fees the VMD intends to produce guidance to accompany the fees in the VMRs 2010 and the fees calculator which is intended to help companies identify the relevant fee for any planned application.

For further information please contact Jackie Atkinson:
email: j.atkinson@vmd.defra.gsi.gov.uk or phone: 01932 338387