Customer Survey 2016 Action Plan

Overall, the results of the 2016 customer survey were extremely positive, with improvement on the high levels of satisfaction seen in 2014. The VMD would like to thank everyone who contributed to the survey: 218 people completed it this years, this represent an 88% increase compared to 2014 participation. These numbers provided a good spectrum of our industry stakeholders and a strong base for analysis. Respondents represented independent consultants (11%), employees of marketing authorisation holders- MAHs (65%), manufacturing authorisation holders (39%) and wholesaler dealer authorisation holders (28%) in broadly similar proportions to 2014.

The survey was conducted in three phases: a first internal phase with a review of the survey questionnaire to update/delete/add questions to reflect new processes and issues; input on current issues and concerns was sought from industry representatives. The revised questionnaire was used for a web based survey phase (the quantitative phase) followed by one to one telephone interviews to explore in-depth with those customers who were not fully satisfied on a number of services and indicated their willingness to take part in this third phase (qualitative phase).

This action plan has been split into the thematic areas where the suggestions for improvement were made. Where we consider that no further action is needed, we have explained why.

Areas where the VMD has made or intend to make improvements following the survey feedback include the following:

- **Joint labelling:** the introduction of the revised mock up procedure on 1 April 2016 and recent enhancements of processes with Ireland should improve overall timescales and the mock-up procedure.
- **Product literature standard (PLS)**: following industry consultation and discussions with Ireland, the PLS has been updated to review the layout and format to make it more user friendly and include mock up procedure changes.
- **Pharmacovigilance (PhV):** Improved communication and guidance, additional training for MAHs has been implemented for pharmacovigilance inspections; processes and team guidance have been reviewed to improve consistency of advice provided on all PhV matters.
- **Batch release:** a new internal process has been implemented and has shown improvements. This process will be further refined in 2017 with the investigation into the feasibility of e-submission for batch release requests.
- **Communication:** we continue to use opportunities when meeting companies (e.g. at company meetings and larger fora such as the NOAH meetings, Pharmaceutical Industry Open Day, etc.) to gain detailed feedback on stakeholders' issues with GOV.UK and explain how they can be resolved as well as implementing technical improvements which are designed to help make searching for specialist information easier (e.g. by 'tagging' GOV.UK documents).

Issue identified in the survey	Proposed Action or explanation why no action is considered necessary	Progress
Licensing Administration Overall level of service excellent. No one had encountered problems that had not been dealt with satisfactorily with 85%+ scoring all parameters as good / excellent.		
a) Speed of response time scored the lowest at 85% which was an improvement on 2014.	The team deals with all enquiries in accordance with the published standards for response of enquiries and will continue to do so. No action required.	N/A
Joint labelling The overall response was similar to 2014 and 73% of respondents gave a score of good or excellent. Clarity of the process scored the highest with 77%, however timescales for the process was lower than 2014 with 68% of respondents scoring a good or excellent in comparison to 74% in 2014.		
a) Improvements seen, although overall trend is similar, however, timescale could be improved.	The introduction of the revised mock up procedure introduced on 1 April 2016 to improve overall timescales and the mock-up procedure.	Following discussions with Ireland in Sept 2016, minor changes to the mock up assessment procedure have been implemented with the aim to gain more consistency between IE and UK assessment of mock ups. The consistency should result in a reduction in the number of times revised mock-ups need to be submitted and faster approval of mock ups.
Product literature standard (PLS) There were notable improvements since the 2014 survey where this was included for the first time and 77% of respondents gave a score of good or excellent for the overall usefulness and ease of navigation of the PLS. Clarity of the guidance scored highest (85%) while the extent to which it is applied a) consistently and b) pragmatically by assessors scored above the 70% line (73% and 72%, respectively).		
a) Would benefit from simplification and also more consistency with other countries in Europe.	We will look to review the Product Literature Standard to include any changes following discussion with Ireland about how the recent changes to the mock ups procedure have been going and we will also take on board the feedback that the guidance is still too wordy.	Following industry consultation and discussions with Ireland, the PLS has been updated to review the layout and format to make it more user friendly and include mock up procedure changes. The revised version is planned to be published in December 2016.

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Product Information Database Rated good or excellent on all parameters by 78% with 53% of respondents finding the PID very useful. 56% of respondents were happy with the search function and required no improvement.		
a) Improved search function was the main suggested improvement, especially for European products.	The number of pre-defined searches has continually increased and we welcome feedback on any other specific areas that would benefit from this. We would also consider enhancing the search facility to accommodate any specific request. It is planned to include details of refused applications within the database. We will also add the name of the RMS to the web entry for each product.	These improvements are underway and they will be implemented in accordance with other priorities.
Pharmacovigilance The overall level of service from the pharmacovigilance team was scored good or excellent by 87% of respondents. All 11 parameters were scored as good or excellent by over 70% of responders. There were notable improvements since 2014 where 4 out of the 11 parameters scored less than 70%. Pharmacovigilance inspections had not previously been covered by the survey and 67% of respondents scored this area as good or excellent and this area was identified for qualitative follow up.		
a) Concern over "one size fits all" approach	a) The purpose of PhV inspections is to ensure Marketing Authorisation Holder (MAH) compliance with the legislation regardless of the product portfolio or size of the MAH. Advice that may be given during inspections is provided as a possible solution to issues identified but it is the MAH's role to assess whether or not the suggested solution would be useful or appropriate for their systems. Inspectors will make it clear when compliance issues are identified and if advice is given, that this is merely a suggestion of one possible solution. MAHs are always welcome to ask questions and seek advice from us, and where possible we will try to assist. We have two email addresses, one for adverse events(adverse.events@vmd.defra.gsi.gov.uk) and one for PSURs (psur.queries@vmd.defra.gsi.gov.uk) which MAHs can contact us on at any time.	The 2 email addresses referred to are already setup and in use.

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b) Lack of advanced detail about the visit.	b) The letter informing MAHs of an inspection and the relevant documents provided has been revised to give more detail of what to expect. They already clearly state that if the MAH has any questions to please contact the lead inspector.	The letter has been reviewed and updated.
c) Wish for a more collaborative and pragmatic approach	c) We have recently provided training on Eudravigilance Vet (EVVet) to smaller MAHs and have also requested that NOAH provides VMD staff with some training and an overview of MAHs so that we have a better understanding of issues from an MAH perspective.	The EVVet training has been provided to 3 groups of MAHs and a further session took place in November 2016. Discussions are underway with NOAH to arrange training for veterinary assessors.
d) Relevance of questions and clarity of issues identified relating to adverse event reports, PSURs and inspections and the consistency of approach between assessors	d) Ensure that all Standard Operating Procedures and desk instructions are updated and all assessors have an understanding of what is required. Peer review assessors questions where appropriate and give clearer explanations for any questions asked. Where possible and appropriate to do so, assessors will telephone rather than email queries. Continue to hold joint meetings with NOAH, where relevant pharmacovigilance issues can be discussed. Record and maintain "lines to take" which the team can use as guidance in order to improve consistency of advice given.	All SOPs and desk instructions have been reviewed and updated as necessary and the assessors responsible for these procedures have been notified of the changes. A record of "lines to take" has been implemented and will be updated when questions arise.
Biologicals (Immunological team) The overall level of service was similar compared with the 2014 results, with 79% of respondents scoring them good or excellent. Speed of response to enquiries had improved with a good/excellent score at 79%. Areas identified for improvement were consistency of approach between assessors and level of pragmatism which scored just 64% and 60% respectively.		
a) Sometimes difficult to identify the correct person to speak to	a) These comments have been taken on board and procedures will be put in place to ensure both telephone and e-mail communications are up to date and include the correct contact information.	Each of the team are aware that if they are unavailable then the phone and e-mail should be updated accordingly. During periods of absence from the office an out of office message should include

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	It should be noted that at the outset VMD validation letters, which are sent to the applicant when an application passes validation, include the name of the assessor together with VMD contact details. Thus this letter contains the relevant information. For centralised applications, applicants are requested to submit all communication by e-mail through the EMA. Contact names for different areas in the VMD are also published in MAVIS.	details directing the enquirer to the switchboard where they can request to speak to an alternative biological assessor.
b) Variation in terms of advice, level of pragmatism and collaborative approach within the assessment team	b) A guideline is already in place which sets out the requirements of company meetings and aspects of this document are shared with companies prior to meetings. Consideration will be given to updating this document to make clear that VMD can advise /comment on the company strategy but cannot offer solutions. Companies have the opportunity to provide feedback on the usefulness of such meetings by completing the feedback questionnaire. Review for consistency and relevance of questions is part of the current approach in that new applications are peer reviewed and/or discussed at the formal Biologicals Committee meetings. Additionally, complicated and/or recurrent issues arising from the assessment of variations are discussed during team meetings to collate input from assessors, share approach and ensure agreement within the team. No action required.	N/A
Batch Release Most parameters were scored good/excellent by 88% of respondents and most had remained similar to 2014 with the exception of timescales which decreased from 100% to 88% but still remains high. However, this could be reflected in the number of responses which had increased from 7 in 2014 to 33.		
a) Timescales: decrease in score but remain high	Consideration will be given to the need to update industry on batch release (what to do and why) and lines of communication to take to request special batch release	A new internal process has been implemented which has shown evidence of improvements.

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	following changes to the groups responsible for batch release within VMD. It is noted that the website makes it clear that: The special import, export, and batch release schemes are all digital services run by a team that only deal with queries by email (please do not ring the VMD about matters in relation to any of these schemes).	
GDP & GMP Inspections All parameters were scored good/excellent by more than 88% of respondents and remained similar to 2014. There were a couple of areas identified as opportunities for improvement including inspector resource and lack of industry knowledge of the Veterinary Medicines Regulations which are addressed below.		
a) Inspector resource levels and training & development to ensure consistency/pragmatism.	a) A recruitment exercise has been carried out for 3 Inspections & Investigations Team (IIT) inspectors. A recruitment exercise was also carried out for 2 GMP Inspection Team (GMPIT) inspectors to take the team back up to full strength (3 full time inspectors). We have a training plan in place for new IIT inspectors and we conduct training at inspectors quarterly meetings We have a training plan in place for new GMPIT inspectors and ongoing training once in post, including joint training with the MHRA. Qualitative assessment and comparison of inspectors' reports has been identified as an area for improvement at IIT's recent internal audit. The Head of the IIT will put in place a plan to regularly review inspectors' reports and start accompanied inspections from September 2016. For consistency, inspections are often conducted by two inspectors, which facilitates learning and knowledge-sharing and GMP inspection reports are peer reviewed before issue to the MAH.	Three inspectors joined the IIT in September and October 2016. They are undertaking the IIT training programme One GMP inspector has been appointed. A recruitment exercise is underway for an additional inspector which should be completed by the end of the year. The Head of the IIT has put in place a plan to regularly review a sample of inspectors' reports; and has begun accompanying inspectors on visits, beginning with the two new inspectors.
b) Training Marketing Authorisation Holders (and wider industry) to help comply	b) IIT regularly conducts training for Suitably Qualified Persons (SQPs) at AMTRA / AHDA meetings and with inspectors from other organisations who carry out	

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with Veterinary Medicines Regulations.	inspections on our behalf. Our inspections include an element of advice and update for the personnel seen The GMPIT has provided training for MAHs in the past and we will consider what other training can be provided in the future. Our GMP inspections include an element of advice and update for the personnel seen.	
Communications There was one main area to follow up on the ease of finding information on GOV.UK with 46% of respondents scoring good/excellent which is a decrease on 2014 of 59%. This has been addressed in the actions set out below.		
a) Dissatisfaction on being able to find information on Gov.uk.	The VMD will continue to provide advice in MAVIS on how to use GOV.UK (e.g. advice on search words to use to locate information first time particularly for newly published information) The VMD's internal Standard Operating Procedure(SOP) on putting material on GOV.UK will stipulate clearly that VMD authors of GOV.UK material to should use key words in the titles and summary of material they create and update to aid users in searching for material on GOV.UK The VMD will continue to use opportunities when meeting companies (e.g. at company meetings and larger fora such as the NOAH licensing meeting, Pharmaceutical Industry Open Day etc.) to gain detailed feedback on stakeholders' issues with GOV.UK and explain how they can be resolved. The VMD's Communications and IT teams are keeping abreast of technical developments on GOV.UK that are being overseen by the Government Digital Service which are designed to help make searching for specialist information easier (e.g. by 'tagging' GOV.UK documents).	The SOP has been updated to require authors to add key words for searching for new items. This is included as part of the checking procedure prior to publishing. A workshop was held on the use of GOV.UK at an Industry meeting in March. The Communications team gave a presentation at the VMD Open Event in September which included VMD content on GOV.UK and tips for effective searching. Two recent searching problems were used as examples of how page titles and content can be amended to facilitate search enquires. A narrated version of the presentation slides will be loaded on the VMD Youtube account which can be accessed through our GOV.UK landing page

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Europe Respondents scored the VMD first in nine out of ten parameters, coming second to Ireland on overall value for money. Results also indicated that companies were likely to use the UK as RMS for pharmaceutical product and immunological products (88% and 75% respectively). Out of those who expressed an opinion, over 90% considered the VMD as a leader in Europe. Some comments on differences between the VMD and agencies in other Members States are addressed below.		
a) Some EU countries do not require assessment of mock ups.	a) VMD has recently introduced a revised mock up procedure which has reduced the requirement for companies to submit mock ups for certain applications. No action required.	N/A
b) EU: Others, Value for money and lower fees	b) Our application fees are based on the average cost of work in assessment; time spent on different applications is monitored via work recording software which feeds directly into the fee calculations. There is sufficient resource to allow companies to submit applications at any time. Our charges are periodically reviewed. No action necessary.	N/A
Pharmaceutical Team The overall level of service remained high and was similar to the 2014 survey with 87% of respondents scoring good or excellent in the overall level of service. The lowest scores which were in excess of 70% were found in the areas set out below.		
a) Consistency of approach between assessors.	a) The three assessor teams within the Pharmaceutical Team hold regular team discussions of applications, peer review assessments, and discuss assessments at meetings involving all the teams. CPD knowledge transfer is also provided on occasions during assessor meetings. Assessors log queries from companies, CROs, consultants, vets, members of the public and members of other governmental departments and their responses to those queries. The efficacy and target animal safety assessors also log any precedents made by the team. The team will start logging precedents for the safety and quality team and remind assessors to log all queries in the correct location, as per the handling enquiries document.	The Quality team have started logging precedents and the Safety team are in the process of doing the same.

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b) Ease of identifying the correct person to speak to in this area	b) Applicants are told 2which assessors will be assigned to each application before the start of the procedure. Contact details of individual assessors are also added to assessment reports. Over periods of leave, applications which are likely to need attending to are transferred to another assessor Regarding queries not related to a specific application, a VMD-wide contact list is used to direct callers to the most appropriate person. No action required.	N/A