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Report from the
Workshop on e-submission in the Veterinary Sector
held on 7 May 2009 at the EMEA

The Workshop was chaired by Dr C. Philippe-Reversat (IFAH Europe) and Dr P. Helboe (Danish Medicines Agency and Chair of the Telematics Implementation sub-group on E-submission in the Veterinary Sector (TIGesVet)) and was well attended by industry and regulator representatives.

Amongst the items discussed were the key aspects of e-submission in the veterinary sector, the results from the Industry and Member State surveys on readiness for e-submission and a proposal from the Veterinary Medicines Directorate (VMD) in the UK for structures for electronic dossiers applications, to be developed in the future. Practical experience of e-submission was presented by Germany and Spain.

The VMD proposal was welcomed as it encompassed two different systems using the same structure: Annex to Directive 2001/82/EC with differing levels of granularity: an electronic Notice to Applicants (e-NTA) (3 levels of granularity, with a Table of Contents (TOC) generated by a bespoke software using an XML backbone and providing tools for product life cycle management) or an Non e-NTA electronic submission (Nees-Vet) (2 levels of granularity without XML TOC, which correspond more or less to the current system).

In addition to the above topics, breakout sessions on Harmonisation of Requirements, Validation Criteria, Previous and Current Experience of E-submission and Assistance to Industry were held.

The following points were highlighted:

Harmonisation of Requirements

- The importance of harmonisation, including possibly other regions (FDA...)
- The need for commitment from all Member States
- More detailed guidance to be added to existing guideline
- Support for the VMD proposal
- The need for a pilot to be tried.

The role of the TIGes Vet Group was stressed and the need for the group to provide information to all stakeholders was highlighted.

Validation criteria

- Harmonisation process needed for all Member States to agree on information to be validated.
- Criteria of validation:
 - Mandatory – e.g. harmonised naming of files.
 - Optional



- Structure of files:
 - Name of file
 - PDF version
 - Different kinds of file protection
 - File size
 - Table of contents
- Feedback to Industry on the quality of the submission

Previous experience of e-Submission

- Password protection to be discussed
- Recommend:
 - Standardised structure
 - Easy navigation
 - Flexibility.

Assistance to Industry

- Lack of resources was stressed for small companies therefore clear guidance and simple structures will reduce the burden of preparation
- Archiving – need for a central repository
- Electronic signatures and the need for a legal copy of the application need to be resolved
- National specificities to be included in the guidance
- Example of a dossier on the web site would be helpful.

Actions:

- The current e-submission guideline would be revised to include the proposals from the VMD and would be released for 2 months public consultation, followed by possible adoption as final at the September TIGesVet group.

Industry would work on a dummy e-dossier to allow a practical demonstration of the creation of a dossier for electronic submission, which could be used ultimately as an example to follow for dossier creation.

- Further highlighting to Heads of Medicines Agencies of the need for readiness to accept electronic submissions.
- A further workshop was proposed for 25 November 2009 (*date to be confirmed*) when the dummy application dossier would be one of the main topics for discussion.

Presentations:

Copies of the presentations given at the Workshop are available on the veterinary section of the e-submission website (<http://esubmission.emea.europa.eu/tiges/vetesub.htm>).