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Veterinary Medicines Division

Stepwise implementation of VICH GL53 on Electronic exchange of documents: electronic file format – Statement of Intent

The scope of the VICH guideline 53 covers the electronic file format specifications for individual documents and collections of multiple related documents that do not need subsequent modification during the regulatory procedure and are utilised for electronic exchange between industry and regulatory authorities in the context of regulatory approval of veterinary medicinal products.

The VICH guideline 53 introduced the use of the ISO standardised PDF/A format for PDF files as an interchange format for electronic transfer of documents. PDF/A optimises a PDF file for exchange and long-term reproducibility of the content, therefore a separate archiving format for long-term archiving of e-dossiers is no longer needed.

Meanwhile, PDF/A is also a recommended file format from the ICH guideline (ICH M8 Expert Working Group Specification for Submission Formats for eCTD, v1.1, November 10, 2016).

The VICH guideline came into effect in February 2016. In order to implement it, a stepwise approach should be designed. This is the purpose of this document.

Stepwise implementation

With VNeS 2.3 implemented on 1 Oct 2015 a best practice criterion on font embedding was established anticipating requirements related to the upcoming VICH guidance.

With VNeS 2.4 implemented on 1 July 2016 PDF/A was added as the recommended default file format. PDF/A at this stage has not been included into VNeS validation criteria, but the font embedding test can now be skipped for PDF/A-compliant files as these files already fulfil this criterion.

The next steps will be the following:

Milestone	Timeline	Comment
Recommended use of PDF/A: Revise validation criteria to add VNeS Best Practice criterion VNeS_BP006 on PDF/A (version 2.5.b of validation checklist)	Q2 2017	During this period it will be recommended that applicants start switching to the new PDF/A file format at their earliest convenience.



Milestone	Timeline	Comment
Publish revised validation criteria on Vet eSubmission website	Q2 2017	
Include revised validation criteria in the next checker version	Q2 2017	The current checker message "File PDF version is PDF/A (information only)" when file is in PDF/A will turn into "VNeS_BP006 File PDF version is not PDF/A (warning only)" when file is not in PDF/A.
Communication awareness campaign, including survey and training on creating and using PDF/A technology	Q3 2017	Information on available training and other relevant material will be provided on the vet eSubmission website.
Monitor use of PDF/A in applications received	6 months after publication of revised validation criteria	For applicants this would not add any new requirements beyond making non-PDF/A compliance more obvious and by this raising awareness.
Mandatory use of PDF/A: Revise validation criteria to add VNeS Pass/Fail criterion on PDF/A	To be determined	For the time being there would be no defined deadline as this will depend on further monitoring the readiness for PDF/A format.

Related information

- [VICH GL 53](#)
- [Veterinary eSubmission](#)