EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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.

Since 2014, PDF/A is also a recommended ICH file format for regulatory information exchange (ICH M2 Expert Working Group Recommendation, v1.0, 02 June 2014).

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 VNeeS 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 VNeeS 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 VNeeS validation criteria, but the font embedding test can now be skipped for PDF/A-compliant files as these files already fulfil this criterion.

With VNeeS 2.6 implemented on 1 January 2018 the VNeeS Best Practice criterion VNeeS_BP006 on PDF/A was added. Based on this criterion the VNeeS checker displayed a warning in case PDF files had not been created and saved as PDF/A-conforming files. In parallel to the establishment of this warning, awareness was raised by further communication like this implementation plan or publication of Q&As on PDF/A.

Since the beginning of 2019, the average PDF/A percentage of documents submitted in the VNeeS format is monitored through the yearly EU electronic submission questionnaire filled by Competent Authorities in the EU.

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The next steps will be the following:

Milestone	Timeline	Comment
Mandatory use of PDF/A: Revise validation criteria to add VNeeS Pass/Fail criterion on PDF/A	To be determined	The current PDF eAF, owing to technical reasons, is not in conformance with the PDF/A standard. Mandatory use of PDF/A will be implemented after the successor eAF webforms have been established. Monitoring the readiness for PDF/A format will be continued.

Related information

- VICH GL 53
- Veterinary eSubmission