Annex 3: Implementation of mandatory VNeeS format for Veterinary regulatory submissions

Updated and adopted by the eSubmission expert group on 18.10.2019

1. Background

The HMA eSubmission Roadmap endorsed by the EU Telematics Management Board and HMA describes the current situation of eSubmissions in the European Union and the issues that will be addressed in the near future. The roadmap includes number of initiatives such as dossier formats, portal solutions and application forms.

This annex describes the steps leading to mandatory use of the VNeeS format for veterinary eSubmissions.

Extract of the EU eSubmission Roadmap:

Area	Objectives	Action	Deliverable	**Timeframe**
Submission format (Veterinary use)	• Streamline the handling of submissions and life cycle management	• Require single electronic formats for applications of medicinal products for veterinary use	• VNeeS only for New MAAs in DCP and CP • VNeeS only for all submissions in EU procedures • VNeeS only for New MAA's in National Procedures • VNeeS only for all submissions in National Procedures	• **Done** • **Done** • **Done** • **Done**

2. VNeeS - General Concerns

Harmonisation in Europe

Harmonisation of technical validation in Europe has been identified as a priority and a proposal for a set of technical validation criteria has been commonly adopted by all Member States and has been taken into account in the updated version of the VNeeS checker tool and any other checker tools. In case of different results between validation reports, the VNeeS validation report should be the reference.[1] In addition, agreement has also been reached on the following proposals made to Member States in a view to harmonise the way validation is handled:

1) Commitment from NCA when acting as RMS (Reference Member State) to validate /review the validation report in "add-info" folder[2]
2) Commitment from NCA when acting as RMS to communicate with applicant when dossiers are not technically valid
3) Commitment from NCAs when acting as RMS to have a statement "technically valid dossier" that can be clearly identified by other MS on the content validation checklist
4) Commitment from NCAs when acting as RMS to put the CESP delivery number (and in case of a re-submission of the same dossier the new CESP number) or the unique reference number,

[1] https://www.anses.fr/en/content/vnees-checker

i.e. a combination of procedure number and submission date, in the validation checklist done by the RMS.

The objective has been achieved, which was to have the above commitments for technical validation in place by all applicants[2] and NCAs beginning of autumn 2015.

Electronic Signatures

Some countries are currently still requesting **wet signature** of application form, cover letter and/or declarations, which prevents electronic only working. A common approach would be highly appreciated with an aim to avoid the need for wet signatures and this is ongoing within the network. Acceptance of submissions through CESP without any parallel wet signatures should preferably be the most effective way to reach an electronic-only way of working and is already implemented by most NCAs.

The CMDv document on "Format and no. of copies of the dossier for new marketing authorisation applications via national, mutual recognition or decentralised procedures" (EMA/CMDv/299619/2011) provides the current submission requirements including the need for wet signatures and/or acceptance of scanned or full electronic signatures.

There is no need to provide wet signed papers for any types of submissions to EMA when submitting via the eSubmission Gateway.

National requirements in addition to VNeeS

There are no specific national technical requirements and other national requirements regarding the content do not impact on the VNeeS format.

ASMF submission

In case of ASMF, additionally to VNeeS, a submission in CTD-based formats is acceptable (in exceptional cases and with a correlation table). For further information please see link below for the ASMF procedure:

Q&A (Q 21 – 21.8):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000059.jsp&mid=WC0b01ac058002d9ad

For further details, please see the document Exceptions to the VNeeS format.

Use of PDF/A format

VNeeS already imposes the use of documents in PDF format in the structured parts, but the VHG has stated it's intent to encourage the use of the PDF/A format specifically, without initially setting any deadline regarding it's mandatory use.

To encourage the adoption, the following actions have been implemented:

- Q&A document has been published on the veterinary eSubmission website to help explain the benefits of the PDF/A format and how to start adopting it in practice http://esubmission.ema.europa.eu/tiges/docs/VHG-QA-PDFA.pdf
- The VNeeS validation report has been modified to provide warnings regarding documents that are not in PDF/A format (clearly indicating that PDF/A is now the preferred format), and to include statistics on the use of the PDF/A format in the submission package.

[2] The applicant is required to add a validation report in the "add-info" folder according to the current guideline on eSubmission

The Veterinary Harmonisation Group (VHG) reached a decision regarding mandatory use of the PDF/A format in VNeeS, starting after the transition period when the CESP dataset module becomes mandatory for all submission types. This dependency towards the CESP dataset module mandatory date allows us to avoid any exceptions on the PDF/A format for the eAF.

3. Key Performance Indicators

To allow a follow-up of the implementation, some statistical key performance indicators should be defined and should be monitored by the VHG.

To monitor the progress after the implementation of milestones achieved, a periodical survey will be initiated by the eSubmission expert group asking the NCAs to track and confirm the formats received for each procedure. With regards to granularity, i.e. whether each NCA counts for example number of dossiers or number of authorisations, it is important that they then keep counting the volumes as they started doing. This way, evolutions over time in the compliance rates can be investigated.

4. Information about implementation

All the milestones have been reached. The VHG is now working towards the implementation of the PDF/A format.

Any need for updates of the current guidelines or validation criteria to facilitate the use of VNeeS format should be reported through https://servicedesk.ema.europa.eu and handled by the eSubmission expert group/Vet Harmonisation Group (VHG).

4.1. Timelines

- ***Mandatory use of VNeeS for new MAA in CP and DCP by Q1 2016***

Mandatory use in place.

- ***Mandatory use of VNeeS for all submissions in European procedures (CP, DCP and MRP) by Q1 2017***

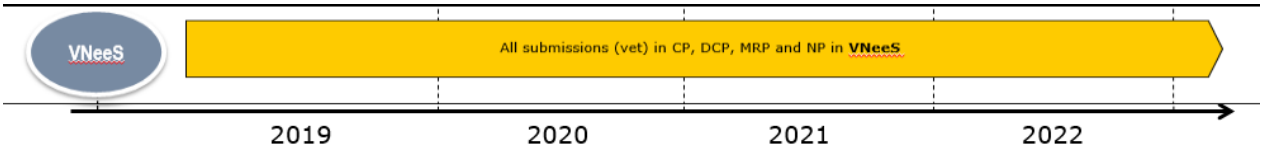
Mandatory use in place.

- ***Mandatory use of VNeeS for new MAA in purely national procedures by Q3 2018***

Mandatory use in place.

- ***Mandatory use of VNeeS for all national procedures by Q1 2019***

Mandatory use in place.



4.2. Guidance Notes, useful links and contacts

All information, including relevant guidance and Q&A documents, is available under: http://esubmission.ema.europa.eu/tiges/vetesub.htm

For any query please contact the EMA IT service desk: https://servicedesk.ema.europa.eu

Please see link to CMDv website: http://www.hma.eu/568.html