EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 2017

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

Status and next steps

1. Background

The updated version 2.0 of the HMA eSubmission Roadmap was endorsed by the EU Telematics Management Board on the 24th of February 2017, and describes the current situation of eSubmission 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 requirements that have to be fulfilled in order to use and accomplish the following deliverables:

- VNeeS only for New MAAs* in DCP and CP - Done
- VNeeS only for all submissions in EU procedures - Done
- VNeeS only for New MAAs in National Procedures by Q3 2018
- VNeeS only for all submissions in National Procedures by Q1 2019

*Possibilities for exemptions concerning Repeat-use applications and/or Duplicate applications should be further clarified by the CMDv and the eSubmission Change Management Board (CMB).

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** • **2018 Q3** • **2019 Q1**

2. VNeeS - General Concerns

Harmonisation in Europe

Harmonisation of technical validation in Europe has been identified as a priority and a aproposal 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, since 2014. 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) The common EU validation tool (VNeeS Checker[1]) will from the next version be stating on top of the validation report "technically valid/ technically invalid"
2) Commitment from NCA when acting as RMS (Reference Member State) to validate/review the validation report in "add-info" folder[2]

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

3) Commitment from NCA when acting as RMS to communicate with applicant when dossiers are non technically valid

4) 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

5) 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, 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.

The CMDv best practice guidance on "Format and no. of copies of the dossier for new marketing authorisation applications via national, mutual recognition or decentralised procedures" (EMA/CMDv/51626/2013) provides the current submission requirements including the need for wet signatures and/or acceptance of scanned or full electronic signatures.

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

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 Veterinary Harmonisation Group (VHG).

The roadmap has strict milestones for the mandatory use. To monitor the progress towards each date of the implementation plan, a periodically survey will be initiated by the eSubmission CMB 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.

An example of updated questionnaire is attached to this document, in particular questions 11-13.

[2] The commitment from applicant would be to add a validation report in the "add-info" folder according to the revised guideline on eSubmission version 2.3

4. Information about implementation

The implementation towards the mandatory use of VNeeS will be organised via existing change management activity ongoing within the EMA with close collaboration with the NCAs. 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 CMB/Vet Harmonisation Group (VHG).

4.1. Timelines

- ***Use of VNeeS for new MAA in CP by Q1 2016***

Mandatory use in place.

- ***Use of VNeeS for new MAA in DCP by Q1 2016***

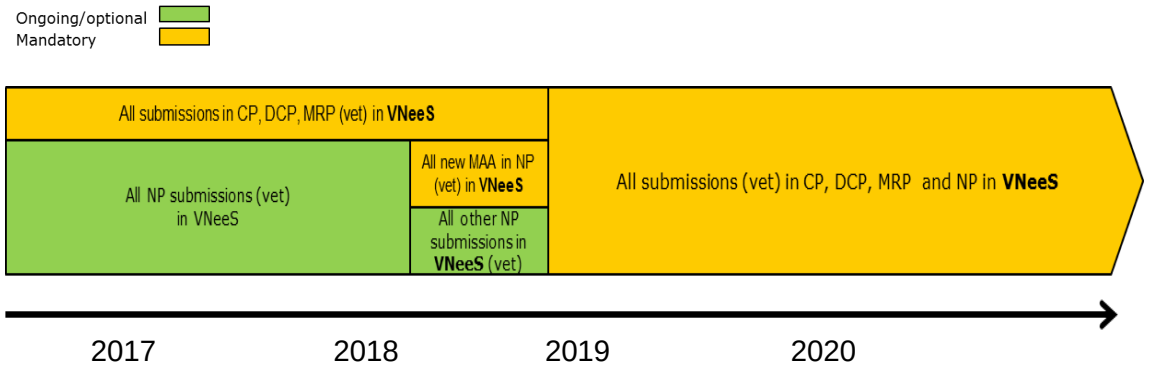
Mandatory use in place.

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

Mandatory use in place.

- ***VNeeS for purely national procedures***

The mandatory use of the VNeeS format is foreseen for National Procedures by Q1 2019.



4.2. Important milestones

Milestone	By
• Use of VNeeS for new MAA in CP / DCP	Done
• Use of VNeeS for all submissions in European procedures (CP, DCP and MRP)	Done
• Use of VNeeS for new MAA in National Procedures	Q3 2018
• Use of VNeeS only for all submissions in National Procedures	Q1 2019

4.3. Guidance Notes, useful links and contacts

All information (direct or linked) will be made available under:
http://esubmission.ema.europa.eu/tiges/vetesub.htm

Relevant guidance and documents will be updated / created (user guidance, Q&A, etc…) and made available. If you have any questions regarding VNeeS, please contact the EMA with your query: https://servicedesk.ema.europa.eu

Format and no. of copies of the dossier for new marketing authorisation applications via national, mutual recognition or decentralised procedures can be found under the CMDv website, following the document EMA/CMDv/51626/2013.