EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

E-Submission Roadmap

Veterinary perspective

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An agency of the European Union

Agenda

- Update of progress along the road
- Where we are on the map
- Progress on harmonisation with Member States

Update of progress along the road

The following points have been identified as your expectations (from EU Telematics Strategy presentation):

- e-submission shall be fully sufficient and Member States should not require any paper documents in addition.
- A single format (i.e. currently VNeeS) should apply likewise to all veterinary applications.
- A single European Submission Portal for the purpose of e-submission should be in place.
- The Common Repository should be available for the veterinary sector as well.
- Global alignment needed (e.g. VICH), where relevant.

Single format - VNeeS

- **Annex to eSubmission roadmap** on implementation of VNeeS endorsed – should be published on eSubmission website (http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html)
- **Timelines**: -) VNeeS only for New MAAs in CP and DCP by Q1 2016

  -) VNeeS only for all submissions in EU procedures by Q1 2017
- **eSubmission questionnaire to NCAs**: To monitor progress towards each date of the implementation plan, periodically survey will be initiated asking NCAs to track and confirm formats received for each procedure.
- The esubmission survey of 2013 shows a very large readiness of regulatory authorities and applicants for mandatory VNeeS for all procedures (both initials/variations) in Q1 2016 (respectively 90 and 80 %).
- Draft veterinary regulation addresses mandatory esubmissions in Europe.
- Timeline for **full implementation of VNeeS according to roadmap is very realistic**.

Single Submission Portal

- Current situation:
  - Submission to the Agency : EMA Gateway / Web Client (preferred option), CD/DVD, Eudralink (post-authorisation only)
  - Submission to NCAs: Common European Submission Portal (CESP), CD/DVD, Eudralink

  => Problem: too many submission channels, different submission requirements for one application procedure
- Ultimate goal of Single Submission Portal for 2018 but intermediate steps, milestones needed
- Compulsory use of the eAF as a first and essential step towards Single Submission Portal with integrated eAF

Compulsory use of the eAF

01/07/15 for the centralised procedure / 01/01/16 for all EU procedures

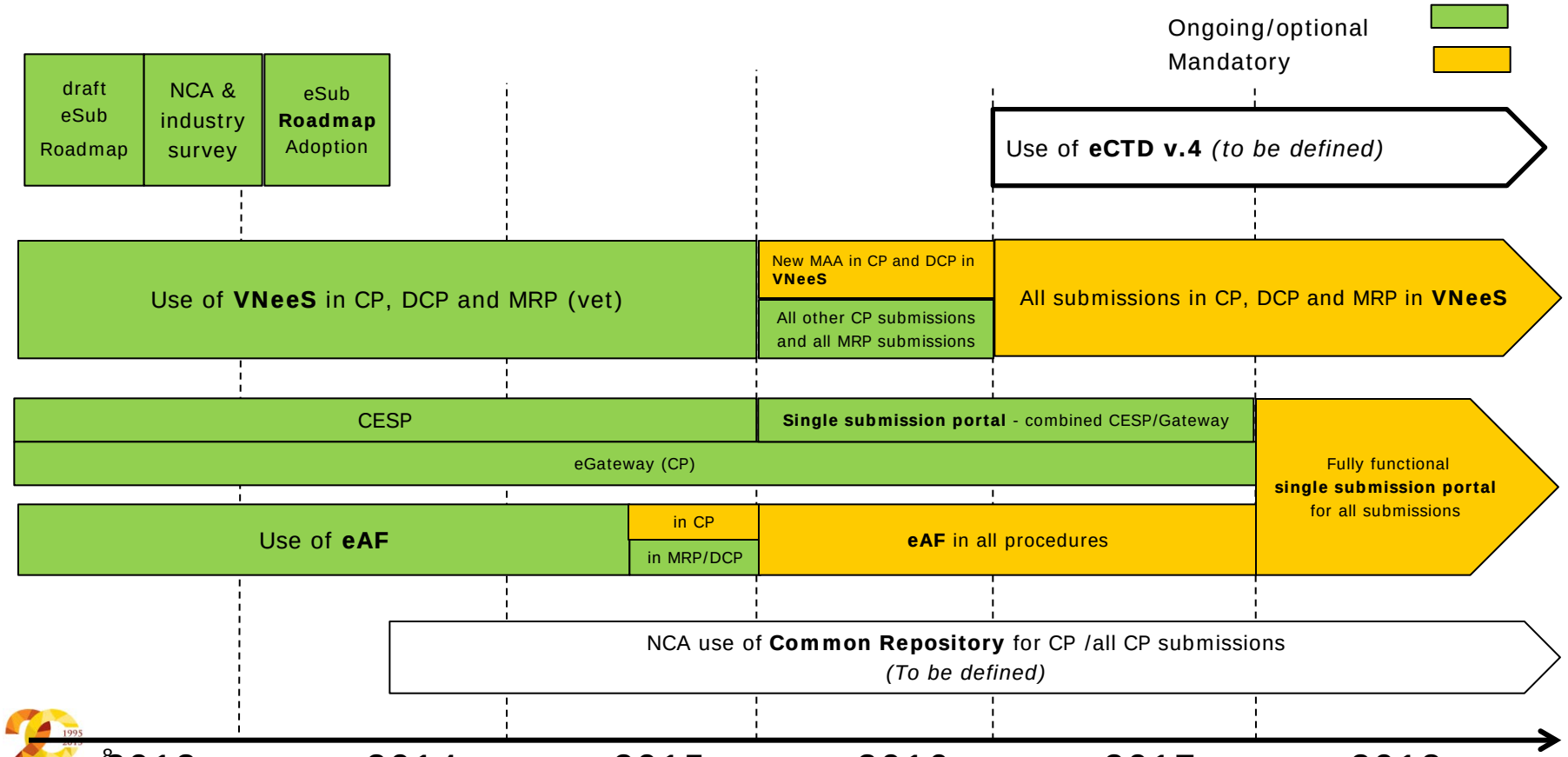
- Benefits of using the eAF
  - Possibility of removal of manual data extraction process, re-use / import of data into databases
  - Higher data quality due to more structured data entry and usage of controlled terms
  - Built in business validation rules guide the applicants to fill in the forms correctly
  - Brings Industry and NCAs towards a single application process
- User acceptance testing performed
- Implementation team and information campaign to Industry and NCAs
- Guidance documents to be updated / created

Common Repository

- Current situation: available only for dossiers in eCTD format
- Need to open Common Repository to all formats (including VNeeS) which has been recognised as a high priority for the Vet Industry and Regulatory Authorities.

Global alignment needed, e.g. VICH

- VICH Guideline 53 on Electronic Exchange of Documents Electronic File Format
- To be signed off by the VICH Steering Committee at step 6 for implementation at step 7
- Important VICH criteria are likely to be implemented in further VNeeS Pass/Fail and Best Practice criteria, like sustainable and correct inter-document hyperlinks and font embedding
- Those Best Practice validation criteria included in the technical validation criteria document and consequently VNeeS checker version 2.3 updated accordingly.


Ongoing/optional
Mandatory
draft eSub Roadmap
NCA & industry survey
eSub **Roadmap** Adoption
Use of **eCTD v.4** *(to be defined)*
Use of **VNeeS** in CP, DCP and MRP (vet)
New MAA in CP and DCP in **VNeeS**
All other CP submissions and all MRP submissions
All submissions in CP, DCP and MRP in **VNeeS**
CESP
Single submission portal - combined CESP/Gateway
eGateway (CP)
Fully functional **single submission portal** for all submissions
Use of **eAF**
in CP
in MRP/DCP
eAF in all procedures
NCA use of **Common Repository** for CP /all CP submissions
(To be defined)
2013
2014
2015
2016
2017
2018

Progress on harmonisation with Member States (MS)

Technical validation of dossier:

- Following workshop, no specific national technical requirements identified.
- Majority of MS ready to apply proposed reduced set of validation criteria, even those that are currently not validating dossiers.
- A proposal for a set of technical validation criteria has been commonly adopted by all MS and will be taken into account in the technical validation criteria document and consequently VNeeS checker tool version 2.3 updated accordingly.
- In addition, agreement reached on the following proposals made to MS in a view to harmonise the way technical validation is handled:

- To have a validation tool stating on validation report "**technically valid / technically invalid**"
- Commitment from NCA when acting as RMS (Reference Member State) to review validation report in "add-info" folder
- Commitment from NCA when acting as RMS to communicate with applicant when dossier non technically valid
- Commitment from NCA when acting as RMS to have a statement "technically valid dossier" that can be clearly identified by other MS on the content validation checklist
- Commitment from NCA when acting as RMS to put the unique reference number in validation checklist

Objective is to have this in place (for applicants and NCAs) by beginning of autumn 2015.

Relevant guidance and tools (eSubmission Guideline, validation criteria, VNeeS checker) updated accordingly.

Conclusions

- Ongoing projects on eSubmission => keep momentum going!
- Industry needs / expectations identified
- Involvement of Industry at early stage as much as possible (VHG, CMB,...)
- Harmonisation when possible through various initiatives (workshops with NCAs, etc..)

Thank you for your attention

Further information

http://esubmission.ema.europa.eu/tiges/vetesub.htm

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