EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmissions update

Update on Developments, e-Application Form, Progress on Harmonization with MSs

2016 European Medicines Agency/IFAH-Europe Info Day

Presented by Dorota Stark on 18 Mar 2016
Veterinary Regulatory and Organisational Support

An agency of the European Union

E-submissions update

Update on developments

- Gateway for veterinary submissions
- Roll-out plan

E-Application Form (eAF)

- eAF mandatory for all procedures from 1 January 2016
- New eAF release planned for 15 April 2016 – v. 01.20

Progress on harmonization with MSs

- 1 January 2016 – new milestone for VNeeS format
- Harmonisation of technical validation in Europe
- New VNeeS Guideline and validation criteria v. 2.4

Gateway for veterinary submissions

Gateway improvements for veterinary submissions in 2016 - intention to mandate Gateway for veterinary submissions as of 1 January 2017

- Gains:
  - Improved user experience for Applicants:
    - User-friendly interface
    - Vet Industry representatives involved in early design stages (Gateway Advisory Group)
    - First “look and feel” of the improved Gateway planned in July 2016 at the latest
  - Possibilities for automation of submission handling
  - Readiness towards the Single Submission Portal

Gateway for vet submissions

Gateway improvements for veterinary submissions in 2016 - intention to mandate Gateway for veterinary submissions as of 1 January 2017

- Challenges:
  - Common Repository does not currently accept veterinary submissions format
  - 5 out of 30 NCAs involved in VMP assessment are not signed up to CESP (submission on CD/DVD)
  - Industry would need to use at least two different submission channels for CAPS (Gateway + CD/DVD; Gateway + CESP + CD/DVD) for a single procedure
  - EMA no longer has resource to support multiple submission channels
  - Gateway must be developed to accommodate for future Single Submission Portal

Gateway for veterinary submissions

Current use of Gateway

- Use of Gateway / Web Client extended to all veterinary submissions since 1 April 2014
- Current interim allowance for submission by alternative routes than Gateway (CD/DVD Eudralink)
- The use of Gateway for Initial MAA and MRL applications in 2015 just under 50%

Focus in 2016

- Extensive consultations with Industry representatives during 2016 via Gateway Advisory Group
- Readiness to meet and discuss any specific concerns in addition
- Training/webinars provided as required when new release of Gateway goes live

Roll-out plan

1st production release* by May 2016 – key dates:

- End of System Test of the solution: 29/03/16
- Start EMA UAT overall solution: 30/03/16
- End EMA UAT overall solution: 14/04/16
- **Start Industry/NCA UAT: 18/04/16**
- **End Industry/NCA UAT 11/05/16**
- Go Live v03.05: 23/05/16

E-Application Form (eAF)

eAF mandatory for all procedures from 1 January 2016

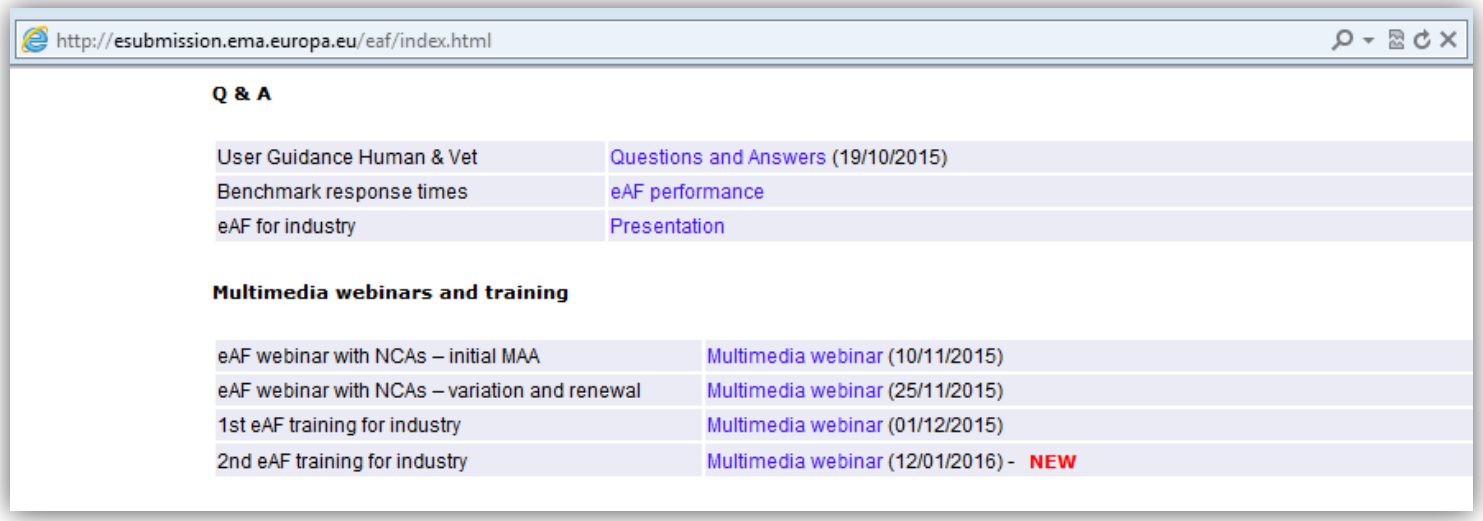
- Final change from Word to PDF
- Communication campaigns to industry representatives September 2015 - January 2016
- User Acceptance Testing of the eAF done by Industry prior to mandatory use: 28/09/15 to 02/10/15
  - Lessons learnt: small participation = more undetected defects = emergency hotfixes
- Currently applicable version of the eAFs*
  - Variations: 1.19.0.2 (from 23 February 2016)
  - Initial MAA Veterinary Renewal: 1.19.0.1 and 1.19.0.2

Always check http://esubmission.ema.europa.eu/tiges/index.htm for latest status and news.

E-Application Form (eAF)

eAF mandatory for <u>all procedures</u> from 1 January 2016

- Training webinars for industry on use of eAF (human and vet)
  - 1 Dec 2015
  - 11 Jan 2016



E-Application Form (eAF)

New eAF release planned for 15 April 2016 – v. 01.20

- Version 01.19 withdrawn from website 1 May 2016
- Replacement of eAF 01.19 by 01.20 on 1 June 2016
- Last release!
- Major change of Variation eAF – section 2 (products concerned) – Annex A and B obsolete

User Acceptance Testing of the last version:

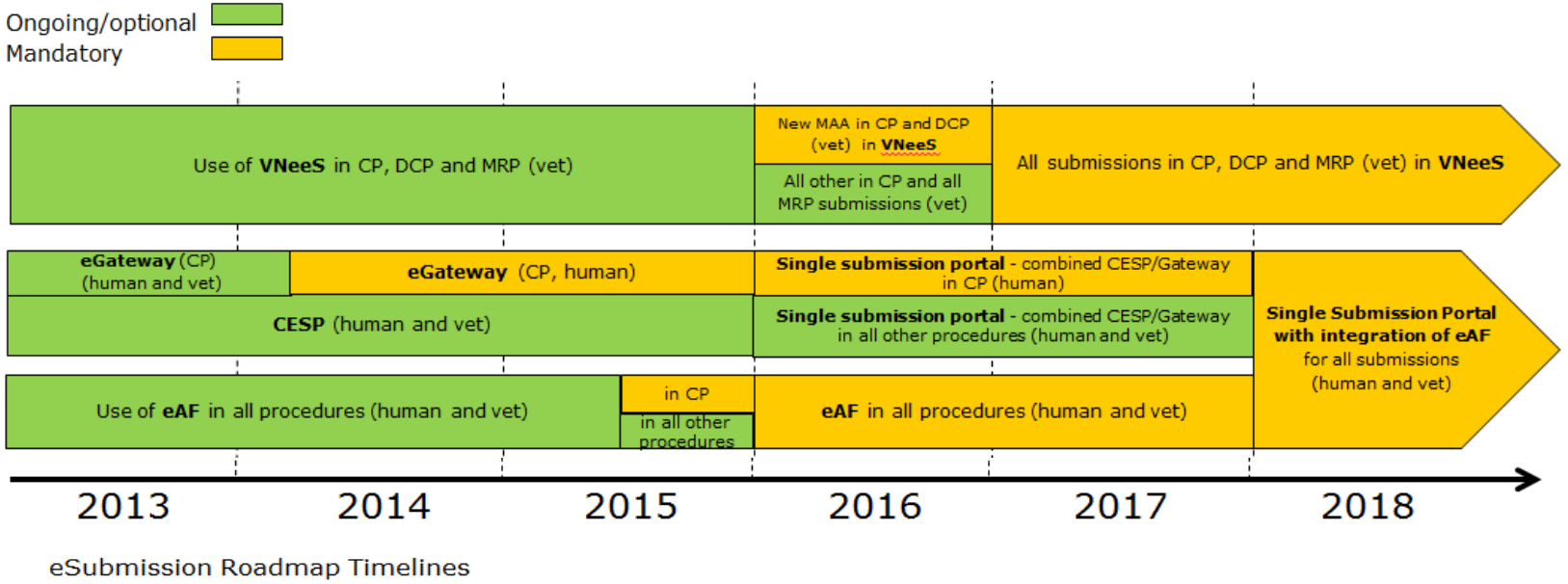
UAT done by Industry: from Mon 21/03/16 to Thu 24/03/16

UAT done by NCAs: from Tue 29/03/16 to Fri 01/04/16

You are vital! (turi.salami@ext.ema.europa.eu)

Progress on harmonization with MSs

1 January 2016 – new milestone for VNeeS format - VNeeS mandatory for new MAA in CP and DCP



Progress on harmonization with MSs

1 January 2016 - VNeeS format mandatory for new MAA in CP and DCP

VHG survey among MSs December – March 2016: VNeeS Questionnaire

- Does your agency comply with EU published guidance for applicants on submission of veterinary Marketing Authorisation *applications* in electronic format?
- Statistics on applications received electronically and complying with VNeeS format

Progress on harmonization with MSs

Harmonisation of technical validation in Europe

VNeeS Guideline and Validation Criteria v. 2.3

- Applicable from 1 October 2016
- **Valid**/**Invalid** outcome of the VNeeS checker (v. 2.3.b)

VHG survey among MSs December – March 2016: RMS validation using VNeeS checker

- Are you, as RMS, checking in the add-info folder that the VNeeS report is present and that it says “technically valid”? – If you are not checking, what is the reason why?
- Have you had any cases of “technically invalid” submission and how did you handle them?
- Are you including the results of technical validation in your content validation checklists?

Progress on harmonization with MSs

New VNeeS Guideline and Validation Criteria v. 2.4

- Acceptability of CTD Module 2 and 3 in veterinary dossiers
- Step-wise implementation of VICH Guideline 53 (PDF/A document format)

Webinar: Introduction to VNeeS 2.4 - 24 February 2016

- The rationale of the VNeeS 2.4 update of the guideline, the validation criteria
- What the changes are
- The impact on applicants
- Know how to produce technically valid dossiers

EMA Veterinary eSubmissions Webinar in planning: http://esubmission.ema.europa.eu/tiges/vetesub.htm

Thank you for your attention

Further information

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

Queries on Gateway: eCTD@ema.europa.eu; VNeeS: eSubmission@ema.europa.eu;
eAF: EMA Service Desk portal (https://servicedesk.ema.europa.eu)

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