EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 January 2015

Transitioning to a compulsory usage of the eAFs for Human and Veterinary procedures

1. Status and next steps (Annex to the HMA eSubmission Roadmap detailing the status and next steps of outlined strategy relating to eAFs)

Background

The final adopted version of the HMA eSubmission roadmap was endorsed by the EU Telematics Management Board on the 1st of October 2014, 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 a number of initiatives such as dossier formats, portal solutions and application forms.

This paper provides more details about the implementation of compulsory usage of the electronic application forms.

Same content – New opportunities

The current Word based application forms (AF) are being replaced by electronic application forms (eAF), using PDF technology to capture the information and XML technology to transfer the information. The content of the forms will be the same as today however, new possibilities like electronic data import/export, data population within the form, online access to standardised catalogue terms, built in business rule validation and support for validation of form, etc. have been introduced. This will apply to all the application forms, i.e. initial, renewals and variations and for both human and veterinary submissions.

The ultimate objective and vision is to reduce the administrative burden for Regulatory Authorities and Industry and to support the need for high data quality for the submission of application forms.

A stepwise approach has been developed to deliver the vision, as follows:

- Step 1: 1st of July 2015: Usage of the eAFs is compulsory for Human and Veterinary Centralised Procedures.
- Step 2: 1st of January 2016: The application forms in Word format published by the Commission will no longer be available and the eAFs are to be used for all EU procedures[1]

As a further and later step, the eAFs will be integrated, potentially using a different technology, into a Single Submission Portal[2] by 2018, as described in the eSubmission Roadmap.

We are now preparing for Step 1 and 2, i.e. making the usage of the eAFs compulsory, which is a first and essential step towards the Single Submission Portal with an integrated eAF.

2. Benefits of using the eAFs

- Removal of manual data extraction processes; Re-use of data
- Possibility to import 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
- Validation rules for the forms are in place and publicly available
- Brings Industry and NCAs toward a single application process

3. Availability of forms

- The eAFs are **already available** for Human and Veterinary procedures (Initial MAA, renewal, variations for all procedures including national procedures) through the European Commission (NtA) and the EMA websites, in addition to the Word format AFs. The eAFs are intelligent PDF

[1] The eAF will be the only published version of the AF, i.e. it will also be applicable for national procedures, even if this is not explicitly covered by the EU eSubmission Roadmap
[2] information will be available at: http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html

forms offering functionality which is not available via word forms (XML export/import, form validation, online access to controlled terms, etc.)

- Both the eAFs and the Word format AFs **remain currently available** during the implementation phase but only the eAFs will be accepted for the Centralised Procedures from the 1st of July 2015. From the 1st of January 2016 the eAF will be the only accepted format also for all other EU procedures. After that date, the Word format AFs will no longer be acceptable to use for any procedures and will not be further published by the European Commission.

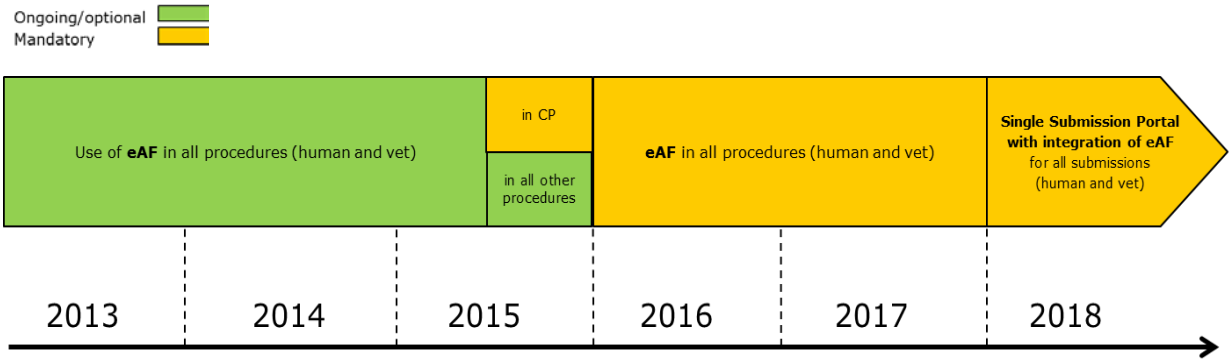
4. Information about implementation

The implementation towards a compulsory usage of the eAFs will be organised by a project team with members from Regulatory Authorities and Industry. The team would be pleased to receive your feedback and/or ideas for the implementation phase (see contact details below).

4.1. Timelines

• **Step 1: 1st of July 2015**: Usage of the eAFs is compulsory for Centralised Procedures (CP).

• **Step 2: 1st of January 2016**: Remove the application forms in Word format published by the Commission and leave only the latest version of the eAFs to be used for all EU procedures.



4.2. Important milestones

Milestone	By
Details about implementation plan available at: http://esubmission.ema.europa.eu/eaf/index.html	End of January 2015
Information campaign 1 (HMA/NCAs/EMA websites, Industry)	February 2015
User Acceptance Test 1 (includes forms for human and veterinary, all procedure types CP, MRP/DCP, national)	February 2015
Final eAF release for CPs	April 2015
Updated Q&As and "work around" documents with focus on CPs	End of April 2015
Updated Guidance Documents	End of May 2015
Information campaign 2 (HMA/NCA/EMA websites,	End of May 2015

Industry)	
Usage of eAFs compulsory for Centralized Procedures	**1st of July 2015**
Updated Guidance Documents for all procedures	End of September 2015
Information campaign 3 (HMA/NCAs/EMA websites, Industry)	End of September 2015
User Acceptance Test 2 (includes forms for human and veterinary, all procedure types CP, MRP/DCP, national)	October 2015
Final eAF release for all procedures	November 2015
Remove Word format AFs from EC website and usage of eAFs compulsory for all EU procedures	**1st of January 2016**

4.3. Guidance Notes, useful links and contacts

All information (direct or linked) will be made available under:
http://esubmission.ema.europa.eu/eaf/index.html

Relevant guidance and documents will be updated / created (user guidance, Q&A, workaround documents, etc…) and made available.

If you have any questions regarding these electronic application forms, or ideas/feedback on the implementation phase, please contact the eAF service desk with your query: eaf@ema.europa.eu