

## Annex 4 to the HMA eSubmission Roadmap: Replacement of the current PDF electronic application forms (eAFs) with the CESP Application Dataset Management Module (CESP Dataset Module)

Adopted by the eSubmission expert group on 15.06.2018

## 1. Background

The [HMA eSubmission Roadmap](#) published on the EMA website describes the current situation of eSubmission procedures for human and veterinary medicines in the European Medicines Regulatory Network (EMRN) and the initiatives that will be addressed in the near future. The roadmap includes many schemes concerning dossier formats, integrated portal solutions, electronic application forms, common repositories and use of master data (SPOR).

CESSP Phase 1 is the first project towards the implementation of the Common European Single Submission Portal (CESSP).

The first phase will deliver a new implementation for creation of Marketing Authorisation Application forms with the goal to replace the relevant PDF forms with a web based interface. This will cover human and veterinary application forms for new marketing authorisations and extension applications. The system was earlier referred to as the CESSP but will be implemented within the current CESP as a new module called "CESP Application Dataset Management Module (CESP Dataset Module). However, the project is referred to as CESSP Phase 1.

This annex provides an update on the replacement of the current PDF electronic Application Forms (eAFs) with the future CESP Application Dataset Management Module (CESP Dataset Module).

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.

### Scope

The current electronic application forms (eAF) are being replaced by a more advanced and modern technology providing a web user interface (CESP Dataset Module) to enter application data. This future module, built as a part of the Common European Submission Platform (CESP) will continue to capture the information as per the Notice to Applicants (NtA) forms. The useful online access to standardised catalogue terms (RMS) and organisation data from OMS as well as the built-in validation business rules will remain. To ensure compatibility with current processes the CESP Dataset Module will produce a human readable form in PDF-format including an XML-attachment.

The data structure of the XML-attachment is defined by the Data Exchange Structure (DES) and will be mostly compatible with the DES version defined for eAF version 1.23. More information about this standard can be found on the relevant [eAF-website](#).

Using this new technology could offer additional opportunities in the future (e.g. re-using information for the formatted table template, the cover letter and the CESP delivery file). Also, a major benefit is expected for variations and renewals forms due to the possibility to pre-populate application forms with data coming from SPOR/PMS.

A detailed Q&A document about the CESP Dataset Module can be found [here](#).

### Implementation roadmap

The replacement will apply to all the application forms and will be deployed in a stepwise approach, starting with phase 1 of the project (so called CESSP Phase 1), which is currently ongoing. The project CESSP Phase 1 will deliver the human and veterinary initial MAA forms.

Starting in 2015 the digitalisation of the application forms is being achieved throughout the following steps:

- Step 1: 1 July 2015: Use of the eAFs is mandatory for Human and Veterinary Centralised Procedures.
- Step 2: 1 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<sup>1</sup>
- Step 3: Q1/2019: Go-live of the CESP Dataset Module. Detailed information will be provided about this transition scenario [here](#).
- Step 4 and following: 2020 (tbc): Extension of the CESP Dataset Module to replace the current variation and renewal forms.

## 2. Benefits of the digitalisation

- Digital data import into application forms
- Removal of manual data extraction processes; Re-use of data for e.g. automatised import data into databases
- Higher data quality due to more structured data entry and mandatory usage of controlled terms (SPOR/RMS)
- Higher data quality due to using master data from SPOR/OMS, SPOR/SMS and at a later stage SPOR/PMS
- Built in business validation rules to guide the applicants to fill in the forms correctly
- Brings Industry and NCAs toward a single application process

## 3. Information about implementation

The implementation towards a mandatory use of the CESP Dataset Module will be organised by a project team with members from Regulatory Authorities and Industry stakeholders. Information will be available on the [CESSP webpage](#), including information about User Acceptance Testing (UAT).

### 3.1. Timelines

- Step 3: Q1/2019

GO-Live and after a 6 month transition phase, the current eAFs MAA (human and veterinary) for all new procedures will be replaced by the mandatory use of the CESP Dataset Module.

- Step 4: Plan and dates to be confirmed

GO-Live and after a transition phase, the current eAFs variation and renewal forms will be replaced by the mandatory use of the CESP Dataset Module

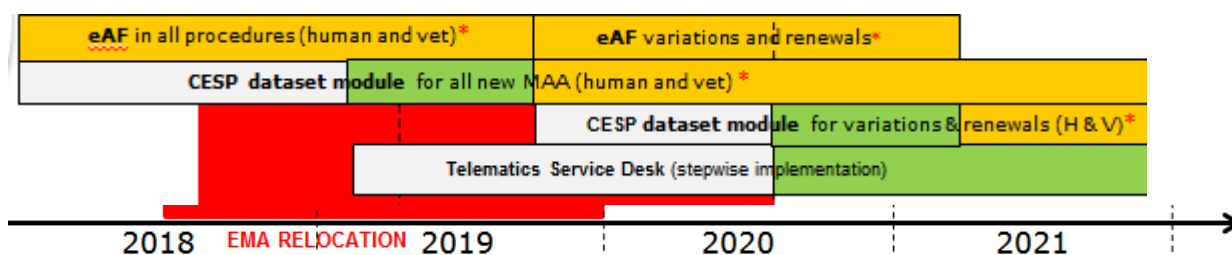
- Step 5: Plan and date to be confirmed

Introduction of a combined Telematics Service Desk to optimise telematics support for telematics IT systems used by industry.

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<sup>1</sup> 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

Ongoing/optional ■  
Mandatory ■



### 3.2. Next steps

Milestone	By
Go-Live CESP Dataset Module to replace the current initial MAA application form (human and veterinary)	Q1/2019
Mandatory use of the CESP Dataset Module, replacement of the eAF MA in the current PDF-technology	Q1/2019 plus 6 months
Extension of the CESP Dataset Module to replace the current variation and renewal forms	tbc
Mandatory use of the CESP Dataset Module, replacement of the eAF variation, renewal in the current PDF-technology	tbc
Introduction of a combined helpdesk handling support for telematics eSubmission systems (especially eAF, CESP, EMA Gateway, ...)	tbc

### 3.3. Guidance Notes, useful links and contacts

All information, including relevant guidance, Q&A and workaround documents, is available under:

<http://esubmission.ema.europa.eu/eaf/index.html>

<http://esubmission.ema.europa.eu/cessp/cessp.htm>

<http://esubmission.ema.europa.eu/CESP/index.html>

For any query please contact the EMA IT service desk: <https://servicedesk.ema.europa.eu> or [cesspproject@hma.eu](mailto:cesspproject@hma.eu)