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Questions and answers related to the “CESSP Phase 1” project which will replace the MAA eAF

This question and answer document aims to address the commonly-asked questions and provide guidance regarding technical and practical aspects of the project to replace the PDF format electronic Application Forms (eAFs) by a web user interface integrated in CESP.

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

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Document History

Version	Date	Changes applied	Author
1.0	17/10/17	Original – information on the concept of CESSP and the project implementation	CESSP project team

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IMPORTANT INFORMATION

Users should continue to refer to EudraLex Volume 2 (Human) and EudraLex Volume 6 (Veterinary) for detailed guidance on marketing authorisation applications.

In addition, the regulatory USER GUIDE FOR THE ELECTRONIC APPLICATION FORM FOR A MARKETING AUTHORISATION (presently covering the current forms, is available for human medicinal products at CMDh and for veterinary medicinal products at CMDv) should be taken into consideration.

1. General questions on CESSP (H+V)

1.1. What is CESSP?

CESSP is a programme to implement an online authoring tool for application forms and to enhance the current PDF based electronic application forms.

The first phase of this programme called "CESSP Phase 1" will deliver a new format for creation of Marketing Authorisation Applications with the goal to replace the relevant PDF forms with a web based interface. This will cover both, human and veterinary application forms for new marketing authorisations and extension applications.

The programme is part of the eSubmission Roadmap which also describes the concept of a Single Submission Portal which will provide online service for stakeholders and which will eventually integrate the current [Common European Submission Platform \(CESP\)](#) and the [EMA eSubmission Gateway](#). The EU Telematics Management Board has agreed that this single portal shall be built using the current CESP portal. During the development project this system has been referred to as the CESSP but will be implemented within the current CESP as a new module.

1.2. Which procedure types and domains do the CESSP projects cover?

In CESSP Phase 1, the MAA and extension for both, human and veterinary applications for all procedure types (CP, DCP, MRP and NP) will be covered.

The scope of the next projects is under discussion but should include variation and renewal forms for both domains.

1.3. What is a dataset?

The dataset contains the required information of the NtA application forms which can be electronically processed and can be used to generate an online application form.

The dataset will be created in a structured format which is human readable and can also be utilised by IT-systems (e.g. for importing data into NCA-systems).

1.4. How can I create a dataset?

To create and process the dataset an extension of CESP is being implemented and called "CESP Application Dataset Management Module (CESP Dataset Module)".

This module can be accessed via a new menu entry in CESP. Users will need to have a CESP account to gain access to this interface.

1.5. Will the future forms still be called eAF?

Yes, the future output will also be called eAF and will be named with a new major version number.

1.6. Will RMS and OMS data be utilised?

Yes, the "CESP Application Dataset Management Module (CESP Dataset Module)" will provide controlled terminology fields from RMS and OMS (see [EMA SPOR website](#)).

1.7. Can I use my CESP login?

After the go-live the existing CESP will provide a new functionality via the CESP menu-bar.

Current CESP users will continue to log-in to the same system and will still be able to access the same functionality as in current version of CESP, however, this will be extended by the new dataset module to collect all data relevant for e.g. the marketing authorisation application.

1.8. Do I need to have a CESP account to access the "CESP Application Dataset Management Module (CESP Dataset Module)"?

Yes, you will need to be registered with CESP, since the CESP Dataset Module is provided within the CESP system.

1.9. Who will maintain the new "CESP Application Dataset Management Module (CESP Dataset Module)"?

The system will be technically maintained and supported by the current CESP team. A user group, like the existing one for eAF, with representatives from the EU network (NCAs and EMA) will advise on change management and guidance. Requirements raised by industry stakeholders will also be considered.

1.10. If I can't find the value in the referential list (RMS data), how should this issue be handled?

If an expected value is not present in the controlled term list the user should request a new term. Addition of new terms will be handled using the SPOR change control process. See the [EMA SPOR website](#).

1.11. How should issues / suggested features be reported?

Bugs and suggested enhancements should be submitted as per the change control process that will be set up and communicated prior to go live.

1.12. Can multiple users work on the draft dataset?

Yes, but not simultaneously.

1.13. Is there any requirement for a particular browser? Are there any specific browser settings required?

The current limitations applicable to CESP will also apply to the new "CESP Application Dataset Management Module (CESP Dataset Module)".

1.14. Can dataset be exported for re-use in a future dataset?

Yes, but subject to future version management and compatibility.

1.15. Is it possible to author the dataset offline?

No, you will need to be connected to the internet and logon to CESP in order to process the dataset.

1.16. How complex will it be to access the different parts of the system?

The system has been designed using standard web controls and navigation patterns to ensure familiarity for the CESP users. We have already received feedback from the first UAT that the system is user friendly and intuitive.

1.17. Can applicants author test datasets?

Once you have an account, you can create as many datasets as you wish.

1.18. Will signatures, digital or other, be required?

There will be an equivalent of the signature panel, which is used to lock the eAF in PDF format.

2. Specific questions on the dataset module (H+V)

2.1. Where can I find guidance to complete the dataset?

Guidance on how to correctly fill in a dataset from a regulatory point of view is published by the CMDh and CMDv and will be updated to cover also the CESP application dataset module. This continues to be the best way for users to ensure that the content of the forms adheres to legislation and business requirements. Technical guidance documents with detailed information will also be available as for the current eAF.

Field level help will be available within the CESP dataset module and is accessed by moving the mouse pointer over each field in the interface; these are called 'tooltips'. If you hover on the particular field/term you can see the field description/full term name description as a tooltip.

2.2. Will there be training guides?

There will be help online and on-screen tooltips within the system. Additional training will be provided.

2.3. Can I submit the dataset independently within the system and if so, do applicants still need to include this data within the eCTD, NeeS or VNeS submission?

The current submission process doesn't change.

The eAF is not intended to be submitted as a stand-alone submission. The current CESP system that enables applicants to send dossiers to NCAs will continue to be used to submit all regulatory information to the authorities. The users will generate the eAF from the system and place it inside an eCTD, NeeS or VNeS dossier which should be sent to the relevant agencies via CESP or eSubmission Gateway as applicable in the usual way.

2.4. Is 'the person authorised on behalf of the applicant' only allowed to submit dataset via the system, or can another representative do this?

The current submission process doesn't change.

As the eAF is submitted inside an eCTD or VNeS submission, anyone with current CESP rights to dispatch submissions to agencies can submit. Similar process applies for the Centralised Procedure submissions via the eSubmission Gateway. This does not change due to the use of the CESP dataset module.

2.5. Does the eAF have to be submitted on the same day as the rest of the dossier via the EMA gateway, and on what basis will the dossier be officially accepted by the EMA/NCAs?

The current submission process doesn't change. The eAF should never be sent as a stand-alone submission but should be included in an eCTD, NeS or VNeS submission.

2.6. Will the future eAF have the same information as the current eAF, or will it be different?

The future eAF will contain and display the information according to the latest version required by Notice to Applicants (NtA). In addition the XML backbone will contain additional metadata to facilitate regulatory activities.

2.7. Will the dataset be compliant with ISO-IDMP?

The CESSP programme is taking an iterative approach to the implementation of ISO-IDMP in agreement with CMDh, CMDV and NtA. The intention is to be compliant to ISO-IDMP in accordance with the EU implementation guide.

2.8. If CESP goes offline the same day as an MAH deadline, will the deadline be extended?

It is planned that the service level for CESP is in line with other EU network services. It's recommended to prepare the application well in time before critical deadlines.

2.9. After submitting the eAF as part of the dossier, will the EMA/NCAs be performing any technical validation check on this?

The applicant needs to ensure the technical and content validity of the dossier before sending it. The EMA and/or NCAs will continue to perform the current technical validation of the dossier (eCTD, NeS or VNeS) and content/business validation.

It is under discussion to introduce validation rules for the eAF as part of the eCTD/NeS/VNeS validation rules.

2.10. How will industry be notified of version updates and changes to the CESP dataset module? Will there be a transition period between using new versions, or will the user be automatically pushed to the updated version?

Changes will be managed in the same way as for the current eAF, where new versions are announced on the eSubmission website, and, where possible, there is a transition period between the old version and new version.

2.11. Can I import data from current eAFs into the CESP application dataset management module?

No, due to the change in the technology it will not be possible to import the eAF xml into the CESP dataset module.

2.12. The current schedule says that the dataset will be for initial and extension applications only. Will the variation and renewals forms also be added to the new system?

This is planned in a next development phase which is currently not defined. Any available information will be provided on the eSubmission website.