Replacement of electronic Application Forms by Common European Single Submission Portal (CESSP)

Statement of intent

The electronic Application Forms (eAFs) were first launched in February 2012 and the use of the forms became mandatory for Centralised Procedure in July 2015 and for all European procedures in January 2016. The electronic Application Forms replaced the MS Word format forms provided by the Notice to Applicants (NtA) group, however the content of the eAFs is continued to be managed by the NtA. The forms are used for all marketing authorisation, variation and renewal applications for human and veterinary medicinal products in Europe.

As outlined in the eSubmission Roadmap, the current Common European Submission Platform (CESP) and the EMA eSubmission Gateway will eventually be integrated into a Single Submission Portal. The EU Telematics Management Board has agreed that this single portal shall be built on the current CESP. This future system is meanwhile referred to as the Common European Single Submission Portal (CESSP).

As detailed in the eSubmission Roadmap but independent of the integration of EMA Gateway and CESP, CESSP is also envisaged to integrate the current content of the eAFs. The application content (further on referred to as the application datasets) will be integrated into this new web based solution with a stepwise approach.

The first implementation project step, CESSP Phase 1, will deliver integrated human and veterinary Marketing Authorisation Application datasets for new marketing authorisation and extension applications. It is expected that the first version of the system will be available for use by Q1 2018. This will be followed by the delivery of the Variation and Renewal form datasets into the CESSP. The current eAFs will be withdrawn after a transitional period and the use of the new, integrated application dataset within the portal will become mandatory at a future date which will be communicated at a later stage.

The CESSP will make it possible to reuse the application datasets. Applicants will also be able to use preregistered organisation data and controlled vocabulary terms provided by EMA SPOR (Substances, Products, Organisations, Referentials) data services.

Detailed announcements of the change milestones, training and any additional support information will be provided on the eSubmission website. Once this is available, Applicants and National Competent Authorities are encouraged to regularly consult the website to prepare for the change.

Related information

- [electronic Application Forms](#)
- [CESP](#)
- [eSubmission Website](#)
- [eSubmission Roadmap](#)
- [Master data SPOR](#)