



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Management Division

## Statement of Intent

# Integration and replacement of Formatted Letter Template with eSubmission Web UI functionality

The EMA's strategy for the electronic submission of applications aims to improve efficiency and streamline processes for all stakeholders.

The use of the Formatted Letter Template will become obsolete as of 1<sup>st</sup> January 2019. This will concern all EMA Human and Veterinary submission (including PSUSA procedures) and companies should then no longer use the Formatted Template as a part of the Cover Letter in Module 1 of eCTD sequences or Part 1 of VNeS dossier.

From 1 January 2019, the Formatted Letter Template will not be maintained by EMA and the document and references will be removed from EMA corporate website.

Users are required to fill in all the submissions attributes correctly through eSubmission Web UI by creating .xml delivery file, since all attributes in the .xml delivery file are used to support important searches in Common Repository. The use of .xml will also support EMA internal processes by significantly reduce the time required for receiving, processing and validating incoming applications and ensures continuous and immediate access to up-to-date dossiers.

Please note, that the [template letter](#) for National Products included in Workshare Procedure will be still be maintained by EMA and is mandatory to use where applicable (Human only).

Please also note that incorrect submissions might lead to procedural delays of incoming applications.



**Related information**

- [User guide to the XML delivery file creation](#)
- [Formatted Letter Template](#)
- [eSubmission Gateway and Web Client](#)