

**GUIDANCE ON SUBMISSION OF MARKETING AUTHORISATION, VARIATION, RENEWAL
APPLICATIONS AND ASMF DEPOSIT (Revision of 7 May 2019)**

Please be informed that AIFA adheres to the **eSubmission Roadmap** adopted by the HMA and, therefore, in accordance with Annex 2 of the HMA eSubmission Roadmap, starting from 1 January 2019, the obligation to use the electronic Common Technical Document (**eCTD**) extends to all regulatory activities concerning marketing authorizations granted through national procedure. For further information on the timing concerning the mandatory use of eCTD, Electronic Application Forms (eAF), please refer to the eSubmission portal:

<http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html>

For detailed information on specific issues concerning national, mutual recognition and decentralised procedures, please refer to the eSubmission section of the CMDh website:

<http://www.hma.eu/277.html>

In order to facilitate the shift to the eCTD format, different formats may be accepted for the variations / renewals of national marketing authorizations, provided that the application is accompanied by a commitment to re-submit the documentation in eCTD format, as integration of the variation / renewal, by 30th June 2019.

With regard to the use of the Common European Submission Portal (CESP) and the provisions in force for the different types of applications submitted to the Marketing Authorisation Office and Post Authorization Office, it is noted the following.

As also indicated on the CESP website, in the "Contacts" section (<https://cesportal.hma.eu/Public/Contacts>), the submission of all applications as well as any subsequent response document through CESP shall be considered only supportive and not as an official submission. However, AIFA is working on adapting its systems for full integration with the CESP portal.

New MA / Line Extension applications submitted through national, mutual recognition, repeat use and decentralized procedure, including any subsequent response document.

the application must be sent by mail on digital medium containing the entire eCTD dossier accompanied by Cover letter and Application form:

- in electronic format with digital signature or signed and submitted together with a copy of the identity document;

or

- in paper format with wet signature;

All the above shall also apply to all documents that require a signature and submitted in national and mutual recognition / decentralised procedures in which Italy acts as a Reference Member State (RMS); certifications issued by other public bodies belonging to the European Economic Area (EEA) must be submitted as original document or in certified true copy. A revenue stamp must be attached to the Cover letter. The obligation to provide the "Circolare 9" for national procedures remains unaffected.

Applications for variation and renewal of the marketing authorization including any subsequent (response) document:

the applications must be submitted respectively on the AIFA variations portal and on the AIFA renewal portal (<https://servizionline.aifa.gov.it/>), accompanied by Cover letter and Application form:

- in electronic format with digital signature or signed and submitted together with a copy of the identity document;

or

- in paper format with wet signature;

All the above shall also apply to all documents that require a signature and submitted in national and mutual recognition / decentralised procedures in which Italy acts as a Reference Member State (RMS); certifications issued by other public bodies belonging to the European Economic Area (EEA) must be submitted as original document or in certified true copy. For renewal and type II variation (included WS), a revenue stamp must be attached to the Cover letter. The obligation to provide the "Circolare 9" for national procedures remains unaffected.

Active Substance Master File (ASMF), including all subsequent additions:

The ASMF must be submitted on digital medium accompanied by Submission letter and Letter of Access originally signed (in electronic format with digital signature or in paper format with original signature).