MANDATORY USE OF CESP PORTAL FOR DELIVERY OF MUTUAL RECOGNITION AND DECENTRALISED PROCEDURE SUBMISSIONS

Please be informed that, in accordance with the **eSubmission Roadmap** adopted by the HMA to which AIFA adheres, the use of **Common European Submission Portal (CESP)** for delivery of mutual recognition and decentralised procedure submissions will be mandatory by 1 July 2019:
(http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html)

Until a full integration of AIFA IT system with CESP portal is achieved, submissions should continue to be delivered also in accordance with usual methods. Please refer to the Communication dated 20 December 2018 concerning **"Guidance on Submission of Marketing Authorisation, Variation, Renewal Applications and ASMF Deposit"** and subsequent amendments
(http://www.agenziafarmaco.gov.it/content/aggiornamento-modalit%C3%A0-di-presentazione-delle-domande-di-autorizzazione-all%E2%80%99immissione-comme) for further information on this regard; for ease of reference an extract of the communication may be found below.
It should be reminded that, for submission delivered through the Variation and Renewal Portals, CD/DVD should be sent only when the size of the package does not allow the upload on the portals.

GUIDANCE ON SUBMISSION OF MARKETING AUTHORISATION, VARIATION, RENEWAL APPLICATIONS AND ASMF DEPOSIT

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).