EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

EMA eSubmission Gateway pilot guidance

Introduction

The 'EMA eSubmission Gateway' will allow the Pharmaceutical Industry to submit all eCTD format Centralised Procedure applications related to the authorisation and maintenance of medicinal products, e.g. new marketing authorisations, variations, renewals, PSURs, active substance master files (ASMF) and Plasma Master Files (PMF) directly to the EMA via the Internet. The submission is entirely electronic and no physical media (paper, CD, DVD) will be required. The applicant will receive an automatic electronic acknowledgement upon receipt of the submission. This acknowledgement receipt will not confirm technical validation. The transmission of the eCTD files is fully encrypted and secure.

How to participate

If you are interested in participating in the Pilot, please follow the steps below:

- Please check if you have access to the ESTRI[1] gateway software and hardware required for the setup of the eSubmission Gateway. Further technical details regarding the gateway can be found in the 'How to connect to eSubmission Gateway' document.
- Please send an email to esubregistration@ema.europa.eu to register your interest in participating. The number of participants in the pilot phase will be limited. Interested companies who cannot be considered for the pilot phase will be the first companies to be connected at the start of the production phase.
- As soon as you have received confirmation that you can participate in the pilot phase, please follow the step by step instructions from the 'How to register for EMA eSubmission Gateway' document.
- At the end of the registration process your request will be automatically forwarded to the technical Gateway support team, who will assist you in the process to configure your access to the gateway. The process itself is described in the 'How to connect to eSubmission Gateway' document.

Further information on EMA eSubmission Gateway can be found in the Q&A document for the EMA eSubmission Gateway.

You will find the latest version of all the documents mentioned above on the eSubmission website under http://esubmission.ema.europa.eu/esubmission.html

[1] Electronic Standards For the Transfer of Regulatory Information

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