



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

Sending electronic submissions (Human) via the eSubmission Gateway - Statement of Intent

The European Medicines Agency hereby announces plans to implement the eSubmission Gateway. The eSubmission Gateway will allow the electronic-only submission of all centralised procedure eCTD applications.

In this context, the European Medicines Agency is pleased to announce that a pilot phase for the eSubmission Gateway is starting on 9th of January 2012.

During the pilot phase the Gateway will be available to a limited number of applicants as a new submission channel through which all types of centralised procedure eCTD applications can be submitted to a limited number of applicants (e.g. new applications, supplementary information, variations and renewals).

The pilot phase will run for three months and the Agency would like to welcome all interested applicants to register for the pilot. To register, please follow the steps described in the Pilot Guidance document.

It is expected that the pilot phase will be followed by full production allowing all applicants, after successful registration, to submit centralised procedure eCTD applications to the Agency via the eSubmission Gateway to the Agency.

The Agency's long-term intention is to use the Gateway as the strongly-recommended channel for eCTD applications and further steps towards this objective will be announced after the successful completion of the pilot.

The Agency is also developing a web-based eSubmission Gateway client which is more suitable for low transmission volumes and which could be used by small and medium-sized pharmaceutical companies. Implementation plans for this web-based client will be communicated during the first quarter of 2012.

The Pilot Guidance document and a question-and-answer (Q&A) document regarding the EMA eSubmission Gateway are available on the eSubmission website¹.

¹ <http://esubmission.ema.europa.eu/esubmission.html>

