

Electronic submission

In accordance with the HMA (Heads of Medicines Agencies) meeting agreement on the 28th of February 2005 in Reykjavik, the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) plans to be ready for the reception, management and review of submissions in the e-CTD format submitted through the national procedure, MRP or DCP by the end of the year 2009. In the process of preparation for the e-CTD only submission the JAZMP will follow further HMA recommendations (www.hma.eu).

For the management of the electronic documentation, the JAZMP will use the Lorenz's docuBridge® software (current version 3.6 SP3) and the Lorenz's docuBridge® Validator (current version 3.0 SP1 HF1).

The Lorenz's docuBridge® Validator is based on the ICH e-CTD specifications and the EU e-CTD Module 1 specifications.

During the transitional period, the JAZMP accepts submissions in paper-based as well as electronic form. Electronic submissions may be in the e-CTD or NeeS (Non e-CTD electronic Submission) format, Module 1 should be additionally submitted in paper form. However, the e-CTD is the format, recommended by the JAZMP.

Detailed instructions regarding the e-CTD and NeeS are available on the following links:

- <http://estri.ich.org/ectd/> »Electronic Common Technical Document Specification V3.2.2 (PDF)«
- <http://esubmission.emea.europa.eu/> »EU eCTD [Module 1 specification v1.4 released](#), august 2009«
- <http://www.hma.eu/225.html> »CMD(h) Best Practice Guide on the use of eCTD in the MRP/DCP (April 2008) «
- <http://esubmission.emea.europa.eu/doc/eCTD%20Guidance%20Document%201.0%20FINAL%20FOR%20PUBLICATION.pdf> »DRAFT FOR TESTING; Guidance for Industry on Providing Regulatory Information in Electronic Format: eCTD electronic Submissions«
- http://esubmission.emea.europa.eu/doc/eGuidance_Document_1.4.pdf »FINAL DRAFT; Guidance for Industry on Providing Regulatory Information in Electronic Format: Non-eCTD electronic Submissions (NeeS)«
- [EU NeeS Validation Criteria](#), august 2009

For further questions or comments, please contact: eCTD@jazmp.si.

The website will be updated when new information becomes available.