

To HMA special press release e-submissions:

The HMA notes that not all NCAs are ready to accept an electronic-only submission from 1 January 2010. An electronic-only submission is defined as an application for a marketing authorisation in electronic format without paper copies, except for cover letter, application form or other specific documents mainly for the sake of having a signed document.

From 1 January 2010 nineteen (19) national competent authorities (NCAs) out of the thirty-one responsible for medicinal products for human use are ready to accept electronic-only applications for marketing authorisation. Seven (7) NCAs ask for part of the dossier in paper and five (5) NCAs require full paper dossiers of which two only for national applications and when they act as RMS. An overview on the status is illustrated by a [map](#) (the status for Lithuania is not yet confirmed).

The status on e-readiness will be updated when new information becomes available. HMA will intensify the work on e-submissions and readiness by involving CMDs and TIGes and open up for discussions with industry associations during 2010.

The above information concerns applications for medicinal products for human use. The intention is to also publish the status for veterinary medicinal products when this information is available.