

## STAKEHOLDERS' INFORMATION

### STRATEGIC HMA WORKSHOP ON e-READINESS AT THE EUROPEAN MEDICINES NETWORK

**12 April 2010 in Sevilla, Spain**

A Strategic workshop on e-readiness at the European Medicines Agencies Network was organised during the HMA meeting in Seville last 12 April under the Spanish Presidency.

The organisation of this workshop was decided during the January HMA meeting in Madrid in which HMA made a commitment to participate and also to promote the attendance of the relevant staff from each national agency. Representatives from 40 National Agencies (veterinary and human medicines agencies) participated in the workshop.

During the first part of the workshop both the benefits of e-submissions and the different systems being used by the Agencies to work in an electronic-only context were identified. There was a very fruitful exchange on practices implemented at the different Agencies and the willingness of the network to exchange experience and solutions as well as to constitute a framework for training was made clear.

It was noted that most human medicines agencies are ready and all will be ready within a very close deadline to accept electronic dossiers. Good progress has also been seen amongst veterinary medicines agencies.

The second part of the workshop was focused on the extent to which industry are submitting e-submissions where this possibility already exists. HMA looked into statistics in this area and it was made clear that once Agencies have moved to the electronic-only model, it will be important that industry also makes the change to electronic-only submissions.




HMA expects to receive only electronic dossiers within a very short timeframe and therefore there is a need to promote and ensure the e-readiness of industry. HMA discussed strategies to promote e-submission as well as the possible setting of an e-only target for industry.

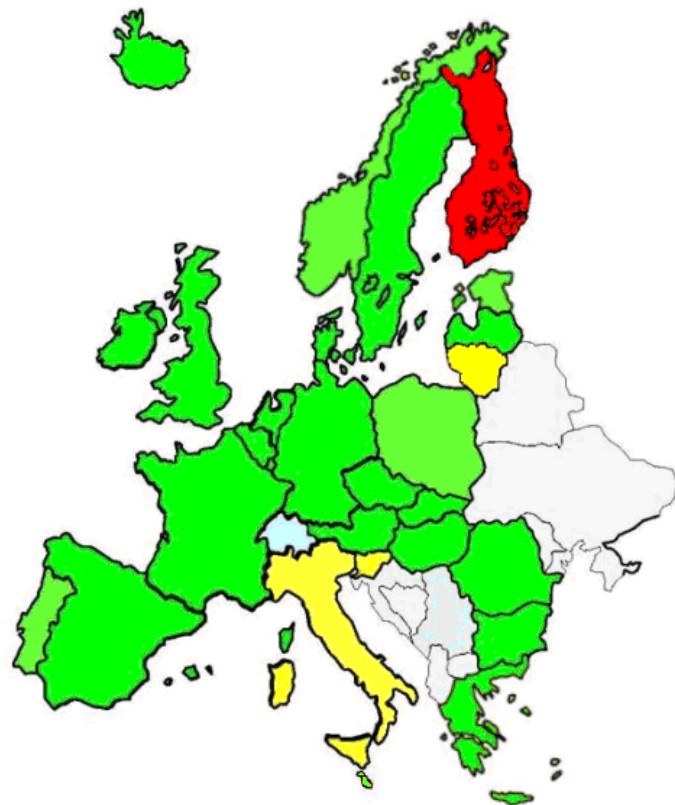
The need to improve the quality of electronic dossiers was highlighted as were the clear advantages of eCTD submissions for human medicines.

It was decided to organise within 2010 an HMA workshop with the industry in order to deal with the immediate industry e-readiness as well as long term IT strategy.

Finally HMA approved the publication of the enclosed updated maps which illustrate the e-readiness status for Human and Veterinary Agencies.

## Dossier requirements in MRP/DCP and national procedures for medicinal products for human use

-  Electronic-only dossier (optional or mandatory)
-  Mixed electronic/paper dossier (only some modules needed in paper)
-  Complete paper dossier



-  Finland (Green July 2010)
  -  Italy (Green Sept 2010)
  -  Lithuania (Green January 2011)
  -  Slovenia (Green January 2011)
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-  Austria
  -  Belgium
  -  Bulgaria
  -  Cyprus
  -  Czech Republic
  -  Denmark
  -  Estonia
  -  France
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-  Germany BfArM
  -  Germany PEI
  -  Greece
  -  Hungary
  -  Iceland
  -  Ireland
  -  Latvia
  -  Liechtenstein
  -  Luxembourg
  -  Malta
  -  Netherlands
  -  Norway
  -  Poland
  -  Portugal
  -  Romania
  -  Slovak Republic
  -  Spain
  -  Sweden
  -  UK

## Dossier requirements in veterinary MRP/DCP and national procedures

- Ready for Electronic Only dossier (Optional or mandatory)
- Partly ready
- Not ready for e-submission without paper – or no response

