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SCIENCE MEDICINES HEALTH

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Electronic Application Forms ready for pilot

For initial marketing authorisation applications (human), variation and renewal applications

From 12th March 2012 it will be possible to use **electronic application forms** (eAF) to submit initial marketing authorisation applications for human medicines, and variations and renewal applications for human and veterinary medicines. The European Commission, the European Medicines Agency and National Competent Authorities have worked together to produce these forms, which can be used for centralised, mutual recognition or decentralised procedures (using the eCTD format for human applications).

The electronic application forms will be published on 12th March 2012. The content is identical to that of the current application forms published by the European Commission in the EudraLex – Volume 2[1]. The electronic application forms will be updated in parallel to any update of EudraLex – Volume 2.

The use of the electronic application forms offers the following benefits:

- Improvements to data quality and consistency during data entry
- Access to the underlying data entered into the forms in an XML[2] format
- Integration with dynamic lists of controlled terminologies

As usual with the introduction of a new service, the electronic application forms will be implemented in the context of a pilot. This pilot will last 4 months until mid-July 2012. There will be two phases of electronic application form publication.

Phase 1: electronic application forms for human and veterinary[3] medicinal products:

- MAA-Human (rev. 9, May 2008)
- Variation-Human and Veterinary (Dec. 2009 version)
- Renewal-Human and Veterinary (Feb. 2007 version)

[1] Pharmaceutical Legislation Notice to applicants (NtA) and regulatory guidelines medicinal products for human use, (volume 6 for Veterinary use), as "word" and "pdf" documents (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)
[2] Extensible Markup Language
[3] Except Initial Marketing Authorisation for Veterinary medicines which will be available in phase 2

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Phase 2: electronic application form for veterinary initial Marketing Authorisation Applications:

- MAA-Vet (rev 7.2, Oct 2008).

During the pilot phase, applicants/Marketing Authorisation Holders intending to apply for Marketing Authorisation (submitting in eCTD format for human applications) using these electronic application forms will be encouraged to register their interest so that they will receive any urgent updates that may need to be communicated.

The pilot exercise is a step towards the use of electronic application forms as the standard way of inputting application data within eCTD submissions for human applications. Further steps in this direction will be announced after the successful completion of the pilot exercise.

To facilitate the use of the electronic forms for Centralised Procedure applications, the EMA will make the following information available:

- An email address where the pilot user group community may register interest and therefore receive alerts, notifications and other communication pertaining to the pilot
- Guidance to organisations on how to participate in the pilot
- Links (URLs) to the forms enabling download of forms from the internet; the links will be accessible via the following eSubmission website: http://esubmission.ema.europa.eu/eaf
- User assistance materials to facilitate the use of the forms
- An email address to contact in case of questions or difficulties