EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2012
Information and Communications Technology
EMA/254406/2012

Electronic Application Form ready for pilot

For initial marketing authorisation applications (vet)

From 2nd May 2012 it will be possible to use an **electronic application form** (eAF) to submit applications for initial (or extensions to) marketing authorisation applications for veterinary medicines. The European Commission services and the European Medicines Agency have worked together to produce this form, which can be used for centralised, mutual recognition or decentralised procedures.

The electronic application form will be published on 2nd May 2012. The electronic application forms will be updated in parallel to any update of EudraLex – Volume 6[1].

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 phase. This pilot phase will last approximately 3 months until late-July 2012, i.e. could be used for submissions of new/extension applications for the recommended submission dates of 2 May, 30 May or 27 June 2012, or in preparation for the 1 August 2012 submission date.

. This is the second of two phases of electronic application form publication.

Phase 1 (released 12th March 2012): electronic application forms for human and veterinary medicinal products:

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

Phase 2 (this release): electronic application form for initial/extension veterinary Marketing Authorisation Applications:

[1] Notice to applicants (NTA) as "word" and "pdf" documents (http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm)
[2] Extensible Markup Language

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- MAA-Vet (rev 7.2, Oct 2008)[3].

During the pilot phase, applicants/marketing authorisation holders intending to apply for Marketing Authorisation 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 phase is a step towards the full use of electronic application forms as the standard way of providing application data for human and veterinary applications. Further steps in this direction will be announced after the completion of the pilot phase.

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 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

[3] This is essentially the same form but with the legal references to Regulation (EC) No. 470/2009 (residues) updated.