EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

Electronic Application Forms pilot guidance

Introduction

The electronic application forms (eAF) pilot enables Applicants and Marketing Authorisation Holders to apply for new Marketing Authorisation, make changes to Marketing Authorisations or apply for renewal of Marketing Authorisation using electronic application forms within the centralised procedure for human (eCTD) and veterinary (VNeeS) applications.

Please note that applicants and marketing authorisation holders may also apply using the same electronic application forms at National level through Mutual recognition or Decentralised procedure; please refer to the European Commission website[3].

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 format
- Integration with dynamic lists of controlled terminologies

The European Medicines Agency (EMA) will commence a pilot phase 1[1] on 12th March 2012 and phase 2[2] on 2nd May 2012. The pilot phases are expected to last until late-July 2012. Subject to success criteria, it is anticipated that the forms will become an alternative, recommended format for submitting human (eCTD) and veterinary (VNeeS) applications to the EMA.

The content of the electronic application forms to be published in the pilot phases are based on the current versions of the application forms published by the European Commission in the EudraLex - Volume 2B[3] (human) and Volume 6 (veterinary)[4].

How to participate

If you are interested in participating in the pilot phase of the electronic application forms (eAF), please follow the steps below:

[1] Phase 1 forms: initial marketing authorisation applications for human medicines, and variations and renewal applications for human and veterinary medicines
[2] Phase 2 form: initial marketing authorisation applications for veterinary medicines
[3] Pharmaceutical Legislation Notice to applicants (NTA) and regulatory guidelines medicinal products for human use, as "word" and "pdf" documents (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)
[4] Notice to applicants (NTA) and regulatory guidelines for medicinal products for veterinary use, as "word" and "pdf" documents (http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm)

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An agency of the European Union

- You must have Adobe Reader/Acrobat 8 or later. The security settings of your Adobe Reader/Acrobat must be configured as described in the *eAF Questions and Answers* document that can be found on the electronic application forms (eAF) section of the EMA's eSubmission webpage: http://esubmission.emea.europa.eu/eaf/.

- If you wish to receive urgent alerts and other communications related to the eAF pilot, please send an email with the following details to: eafregistration@ema.europa.eu.

    - Name
    - Job title
    - Organisation or Company name
    - Email address

- When submitting an application using the eAF, please mention this on the cover letter attached to your submission.

Further information can be found in the Questions and Answers document for the electronic application forms. This document, the latest version of all the available forms and other supporting documents may be found on the electronic application forms (eAF) section of the EMA's eSubmission website: http://esubmission.ema.europa.eu/eaf.