1 August 2014

Electronic Application Forms are now fully available for use

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

The European Medicines Agency hereby announces that the electronic application forms (eAF) for marketing authorisation applications are available following successful completion of the pilot phase.

The electronic application forms allow Applicants and Marketing Authorisation Holders to apply for initial marketing authorisation, variation or renewal applications for both human and veterinary medicinal products using interactive PDF forms. The European Commission, the European Medicines Agency and National Competent Authorities have worked together to produce these forms. The European Medicines Agency recommends using the forms for relevant centralised procedure applications for human and veterinary products.

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 format
- Integration with dynamic lists of controlled terms

Applicants who wish to use the electronic application forms must ensure that they download the latest version directly from the European Medicine Agency's eSubmission website[1] or via the European Commission's Eudralex website [2(human) 3(vet)].

It is not necessary to register before using the electronic application forms. To be kept informed of new releases of the electronic application forms the European Medicines Agency recommends subscribing to the RSS news feed[4] that has been added to the eSubmission website[5].

If you have any questions regarding the electronic application forms, please refer in the first instance to the website: http://esubmission.emea.europa.eu/eaf/. If this does not answer your query please contact the eAF service desk: eaf@ema.europa.eu.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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[1] Latest versions of the electronic application forms can be downloaded from the eSubmission website (http://esubmission.ema.europa.eu/eaf/index.html).

[2] Pharmaceutical Legislation Notice to applicants (NtA) and regulatory guidelines medicinal products for human use (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm - under section "Notice to Applicants, Volume 2B - Electronic Common Technical Document (eCTD)")

[3] Pharmaceutical Legislation Notice to applicants (NtA) and regulatory guidelines medicinal products volume 6 for veterinary use (http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm - under section "Volume 6 - Electronic Submission")

[4] RSS feeds allow you to stay up to date with the latest news about a website. Once subscribed to a feed new content is automatically delivered to your news reader. To learn more about RSS and news readers, read our RSS guide: (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/general/general_content_000332.jsp&mid=WC0b01ac05800b6f02).

[5] The eSubmission website (http://esubmission.ema.europa.eu/eaf/index.html).