1 June 2015

Regulatory information - Transitioning to mandatory use of electronic application forms for all Centralised Procedure applications

As of 1 July 2015 it will be mandatory for companies submitting applications for Centralised Procedures (Human and Veterinary) to use the electronic application form.

The forms are now available from the eAF webpage and can be used at any time for any Centralised Procedure application.

From 1 January 2016 the application forms in Word format published by the European Commission will no longer be available and only the latest version of the electronic application form will be used for all EU procedures, including CP, MRP/DCP and national procedures.

The electronic application forms offer a convenient, online version of the paper versions, which are published and maintained on the European Commission's EudraLex website. These electronic forms are designed to reflect and capture the same content as the paper-based application forms. EMA first made these forms available to companies in July 2012, following a successful pilot phase. Since the initial release, the forms have been significantly improved and further releases based on change requests have been made available in March 2015.

The mandatory use of these forms is expected to reduce the administrative burden for both the regulatory authorities and the industry, while at the same time improving data quality and consistency during data entry.

Further information on the new requirements can be found on the eSubmission website where an information leaflet on the mandatory use of the forms has been published.

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