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EMA mandates use of electronic forms, eSubmission Gateway for human drugs

by Vibha Sharma

As of 1 July, the European Medicines Agency has made it mandatory for pharmaceutical companies to use electronic application forms for all centralized marketing authorization applications for human and veterinary medicines[1].

As of 1 July, the European Medicines Agency has made it mandatory for pharmaceutical companies to use electronic application forms for all centralized marketing authorization applications for human and veterinary medicines[1].

Also from this date, companies should no longer send their centralized procedure applications for human medicines to individual EU member states on CDs/DVDs or via the Common European Submission Platform (CESP)[2]. Companies should only send such applications to the EMA via its eSubmission Gateway/Web Client and these applications will automatically be made available to all national competent authorities via a common online repository.

Mandatory use of electronic application forms

The EMA says it has made significant improvements to the electronic application forms over the past few years based on stakeholder feedback. The EMA will conduct further testing before releasing the next version of the forms in the coming months.

From January 2016, the use of electronic application forms will also be mandatory for all other EU marketing authorization procedures for human and veterinary medicines, ie the decentralized (DCP), mutual recognition (MRP) procedures and for national submissions.

The EMA explains that the electronic application forms reflect and capture the same content as the previous paper-based versions, "but offer a more structured application process for users". Their use is expected to reduce the administrative burden for both regulatory authorities and companies.

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Use of eSubmission Gateway

The mandatory use of the eSubmission Gateway/Web Client from the July date applies to all human centralized procedure applications in the electronic common technical document (eCTD) format. The CESP remains in use for other procedure types as previously.

The common repository, which will be used to transfer applications submitted via the eSubmission Gateway/Web Client to different member states, has been available since February 2014. The repository enables national competent authorities to safely search, browse and download centralized procedure submissions for human medicines in the eCTD format. The system is expected to accelerate the validation of incoming applications and ensure continuous and immediate access to up-to-date dossiers by all national competent authorities, the EMA said.

References

1. EMA press release, 1 July 2015, *www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/07/news_detail_002359.jsp&mid*

2. EMA press release, 1 July 2015, *www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/07/news_detail_002360.jsp&mid*