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Press Office

Procedural announcements

CHMP meeting 12-15 March 2012

Electronic Application Forms ready for pilot

It is now possible to use electronic application forms (eAF) to submit initial marketing authorisation applications for human medicines, and variations and renewal applications for human and veterinary medicines. The European Commission, the European Medicines Agency and National Competent Authorities have worked together to produce these forms, which can be used for centralised, mutual recognition or decentralised procedures (using the eCTD format for human applications).

The content is identical to that of the current application forms published by the European Commission in the EudraLex – Volume 2[1]. The electronic application forms will be updated in parallel to any update of EudraLex – Volume 2.

The pilot exercise is a step towards the use of electronic application forms as the standard way of inputting application data within eCTD submissions for human applications. Further steps in this direction will be announced after the successful completion of the pilot exercise.

For more information please refer to the eSubmission website

eSubmission Gateway status update

The European Medicines Agency launched a pilot of its eSubmission Gateway on the 9th of January 2012 and following the largely positive experience from the pilot so far, the agency would like to encourage the use of the eSubmission gateway which is expected to eventually become the recommended channel to submit applications to the agency.

The registration process remains open and all applicants are encouraged to start the registration process in view of the full production phase following the pilot.

The Agency is also working towards a web-based submission client for low-transmission volumes, which may be more suitable for smaller companies. Plans for this client will be published before the end of the pilot phase.

[1] Pharmaceutical Legislation Notice to applicants (NtA) and regulatory guidelines medicinal products for human use, (volume 6 for Veterinary use), as “word” and “pdf” documents (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)

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The applicants are reminded that there is no need to follow the Gateway submissions with a hardcopy (CD/DVD).

For more information please refer to the eSubmission website and updated Questions and Answers document.

A reminder of the changes made to processing of type IA variation applications (single or grouped) from 1 January 2012

The Agency reminds marketing authorisation holders (MAHs) that as of 1 January 2012, fees for type IA variations become due at the start of the 30-day procedure. The start of a type IA procedure is defined as the date of receipt of the notification from the MAH.

There is no change to the invoicing and payments process – MAHs should continue to pay fees on receipt of the Agency's invoice. Fees are charged based on what has been declared in the application form regardless of the outcome (i.e. fees apply equally for accepted and rejected scopes).

The above means that, once submitted to the Agency, modifications such as addition or deletion of type IA variation scopes are not possible. Please refer to the news item published on the Agency's website on 2 December 2011.

By way of example when two type IA scopes are included in the application form, the MAH will receive an invoice from the Agency for two type IA variation fees.

As a consequence of adopting this approach, the Agency is no longer in a position to request a revised application form to change the type or number of scopes applied for as part of the Request for Supplementary Information for Type IA variations.

The Agency will notify the MAH of the result of its review of their Type IA application (single or grouped). A negative outcome will be given for scopes that do not adequately address the changes applied for and the reasons for this will be provided.

In case of a negative outcome on a type IA variation (or group of type IA variations) the MAH should cease to apply the change(s) and should submit a consolidating eCTD sequence to correct the dossier for the product within 2 weeks (see also Questions 3.9, 3.10, 3.12 and 4.8 of "eCTD Variations Q&A document").

In order to implement change(s) whose notification resulted in a negative outcome (for example the incorrect scope was applied for), an additional variation notification should be submitted.

MAHs are also advised to use the pre-notification checklist published on the Agency's website to ensure that the type IA and type IA_{IN} notifications are complete and correct before submission.

Revision of the Guideline on the Processing of Renewals in the Centralised Procedure (EMEA/CHMP/2990/00 rev.4)

In view of the entry into force of the new Pharmacovigilance legislation, applicable as of 2 of July 2012, the Guideline on the Processing of Renewals in the Centralised Procedure has been revised in order to reflect the new provisions as well as other aspects based on the experience gained.

The revised Guideline which has been adopted during the March meeting of the Committee for Medicinal Products for Human Use (CHMP) will be published shortly on the website of the European Medicines Agency for public consultation.

Comments should be addressed until the **13th of April 2012,** using the template provided on the Agency's website.