EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Procedural announcements

CHMP meeting 19-22 September 2011

Change in EMA's communication practice on the outcome of extension of indication application

The EMA has, for several years, been publishing a 'Q&A document' or a 'summary of opinion' for positive and negative CHMP opinions on extension of indication applications and for situations where an application for extension of indication is withdrawn.

This practice is being extended now and the EMA will communicate on the outcomes of extension of indication applications where the initial scope of the variation applied for has been changed resulting in a CHMP opinion that does not cover the extension of indication initially applied for.

In these cases the EMA will publish a 'Q&A document' (which will cover the outcome of the assessment of the extension of indication initially applied for). At the time of the Commission Decision, the CHMP assessment report will be published (after deletion of commercially confidential information) and the EPAR will be updated with a description of the initial scope and of the opinion finally granted in the document 'Procedural steps taken and scientific information after the authorisation'.

This is a transparency measure to help ensure that stakeholders are made aware of important CHMP assessments.

Changes in submitting Product Information in eCTD format

Following the new eCTD Technical Validation Criteria and the related TIGes Harmonised eCTD Guidance version 2.0 that has been endorsed across the EU member states, we would like to draw your attention to the EMA's new requirements of submitting 'decision' or otherwise known as 'closing' sequences.

Please refer to the esubmission website under "what's new" and familiarise yourself with the above-mentioned guidance document, more specifically section 4.

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Claim for new active substance status

The Agency would like to remind applicants that every claim made within marketing authorisation applications (MAAs) needs to be duly substantiated. In the context of this requirement, for MAAs submitted in accordance with Article 8(3) of Directive 2001/83/EC and claiming to pertain to a new active substance, applicants will have to substantiate this claim with sufficient evidence and justification as to why their substance should be regarded as new. Reference should be made to the current EU guidance on this subject (Notice to Applicants (NtA), Vol 2A, Chapter 1, Annex 3.).
All arguments underlining the applicant's claim should be provided under the indent "additional data" in Module 1 of the CTD.