



Making Medicines Affordable

ASMF

**Beata Stepniewska, EGA
Regulatory Affairs Director**

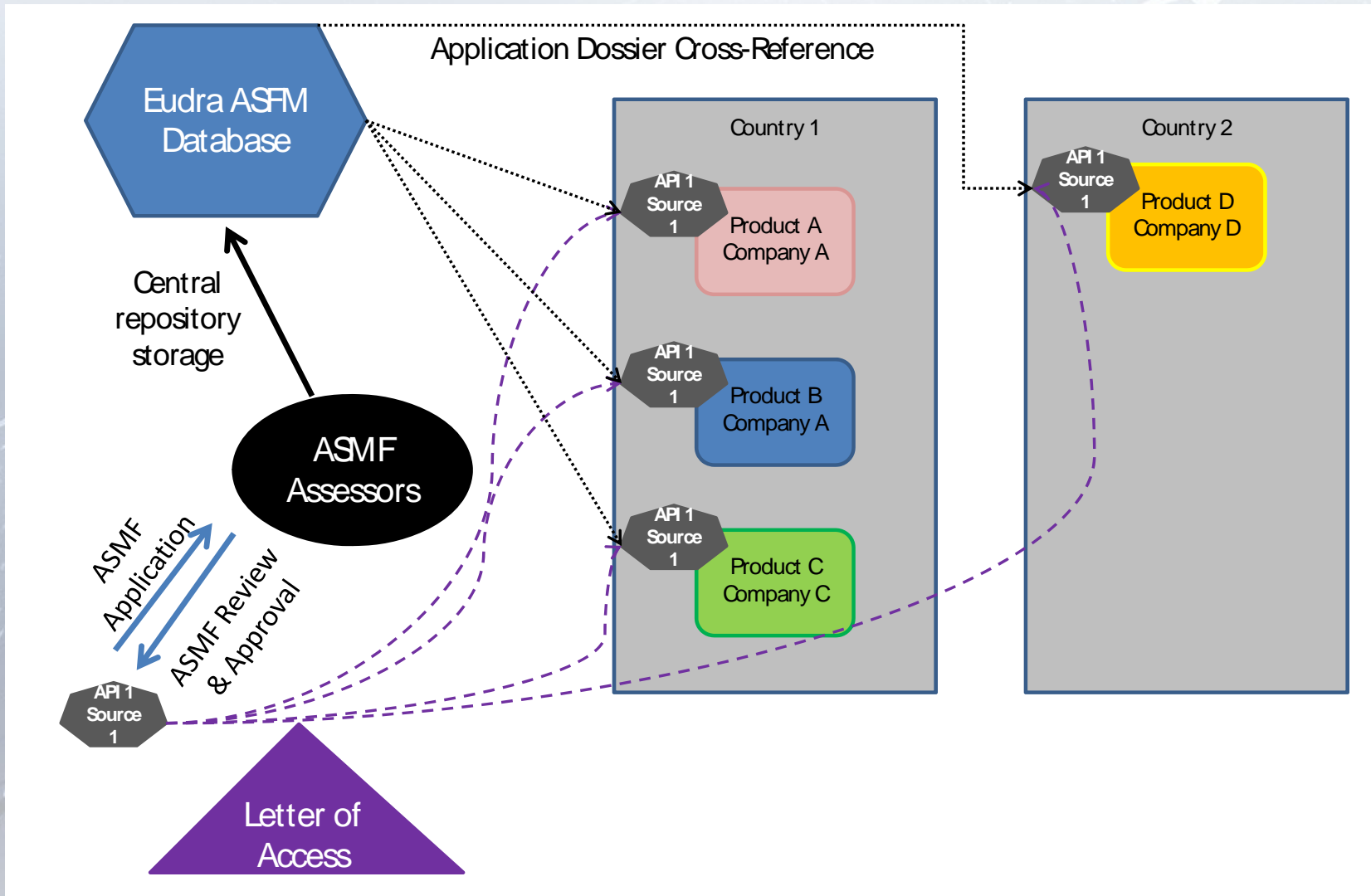
London, 15 November 2010

Optimisation of the ASMF assessment

- Optimisation of the ASMF assessment as a part of the EGA Vision 2015.
 - central ASMF assessment system : an approved ASMF can be accepted by all authorities without the need to re-assess the documentation
 - based on the model provided by the CEP procedure



EGA Proposal for Optimisation of ASMF Assessment



Details of Concept to be Discussed

- Appropriate moment of assessment without delaying the further MA application for Finished Product (FP)
 - Impact on timelines:
 - Competition between MA applicants should not be influenced
 - First MA applicant should not be “punished” by delay of its application
 - Life cycle management of AMSF and FP
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