Common Electronic Submission Gateway (CESG)

Presentation to RCC Stakeholder Dialogue Session
June 20, 2013

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Overview of the initiative

- As one of the initiatives of the Regulatory Cooperation Council (RCC), the Common Electronic Submission Gateway (CESG) will make it easier for American and Canadian firms to do business on both sides of the border through greater regulatory alignment.

- The goal is to provide an automated international standards-based IT environment for exchange, review, and management of information supporting the regulatory services throughout the product lifecycle.

- When in place, the CESG will allow companies to make online submissions for approval of pharmaceutical products to Health Canada as they currently can to the Food and Drug Administration.

- The CESG is the foundation to allow for increased collaboration on the review of these products by the US and Canada.

Progress update

- A joint implementation plan has been agreed upon.
- The technical infrastructure has been established and is being procured/delivered for the current build
- FDA and Health Canada have begun connectivity testing of the end-to-end process
- Health Canada is in process of creating bilingual (French/English) help pages to assist industry

Next steps and key issues

- In order for CESG to be successful, require Industry participation in pilot testing the CESG in both the pre-production and production environments to provide essential feedback on the usability of the CESG.
  - Pilot testing will involve volunteers from GERA and PhRMA/BIO sending test submissions and collection of feedback
  - Stakeholder communication has been ongoing through GERA **starting June 21, 2012.**
  - PhRMA/BIO testers will be solicited by the end of July

- The two Industry test cycles are planned for:
  - Pre-production: **Aug 16 – Sep 12**
  - Production: **Sep 13 – Sep 24**

- Project end date is planned for on **Sep 27, 2013**
  - Health Canada will employ a gradual on-boarding of industry partners.

Process for the next three months for ongoing alignment work

- Explore options to leverage other existing tools (e.g. US FDA eSubmitter) across other regulatory business areas and improve the utility of the ESG

- Establish a joint working group to identify opportunities for further harmonization of submission content (e.g. Common EMEA/FDA Application for Orphan Medicinal Product Designation)

- Explore additional opportunities for collaboration and cooperation on technical solutions, such as exploring collaborative efforts in the post-market.

** Please note: these items should be considered "pre-decisional" and exploratory at this time*

Questions