

Working Group	Personal Care products and Pharmaceuticals	
Action Plan Initiative	Common Electronic Submission Gateway	
DELIVERABLE OUTCOME	Implementation of a Common Electronic Submission Gateway, using the current US gateway, that allows industry clients the ability to submit large size electronic documents seamlessly to Health Canada and US FDA with a view toward further catalyzing increased review collaboration between the two regulatory agencies, increased efficiency of sovereign decision making, and improve access to introduction to medicine for patients in both countries.	
Task Team Members	HC: Vikesh Srivastava, RMOD Bruce Randall, TPD Barbara Sabourin TPD FDA: Michael Fautleroy, CBER	
Sub-Action Item (as of 2012)	Implementation of the Enabling tool	Permanent collaboration enabled by the ESG mechanism
3-6 months	<p>Outcome: Identification of technical requirements and potential issues.</p> <ul style="list-style-type: none"> Identify the business opportunity, business requirements and product concept. Output is business justification, Capture product need and justification in a Cost-Benefit Analysis document. Develop operational concepts for the submission process between Health Canada and the FDA to confirm the viability of the concepts presented. Capture in an Inter-Agency Concept of Operations for approval. Identify high-level architecture, along with the required hardware and software, so that test environment can be designed and approved. 	<p>Enable cooperation and coordination through information and knowledge sharing to develop joint solutions to technical problems.</p> <p>Enhance learning and build trust. Establish the joint organizational structures to effectively facilitate alignment, allocation of resources, and jointly monitoring progress.</p> <p>Engage industry and the FDA through venues such as the PhRMA ERS WG and the Group on Electronic Regulatory Activities (GERA) to identify other potential collaboration opportunities that the Electronic Submissions Gateway may enable.</p> <p>Leverage existing senior officials' governance structures and international data standards development mechanisms to identify longer term opportunities for collaboration.</p>

	<ul style="list-style-type: none"> • Develop a Proof of Concept document to identify the approach to concept validation and the specific system components that need to be tested prior to a Pilot with Industry. • Develop Health Canada specific Concept of Operations to capture end-to-end business process and interfaces with internal Health Canada systems. • Completion of Proof of Concept with FDA. <p>This group of deliverables will result in the following outcomes:</p> <ul style="list-style-type: none"> • Establish the operational architecture; understand requirements for production environment, validate end-to-end business processes and gather feedback from industry through pilot. <p>Key milestones:</p> <ul style="list-style-type: none"> • Develop a joint plan US FDA for a Health Canada - Electronic Submission Gateway pilot with industry. • Formalize relationship with FDA through an agreement/contract. • Formalize the method by which funds will be received by the FDA from Health Canada to pay for infrastructure changes necessary to support the use of the FDA ESG for Health Canada electronic submissions • Establish the requisite contract modifications to enable ESG's present contract to receive funding in support of the requested/necessary infrastructure changes to support Health Canada's fully electronic submission receipt process. 	<p>Formalize multiyear commitment through the signing of an agreement between the FDA and Health Canada. The agreement would define service descriptions, service levels and payment mechanisms.</p>
--	--	--

	<p>Establish a secure electronic signature policy for the Health Products and Food Branch consistent with Government of Canada and Health Canada policies that supports fully electronic submissions through the gateway.</p> <ul style="list-style-type: none"> Identify Industry Pilot participants based on criteria established in joint Pilot Test Plan. 	
6-12 months	<p>Outcome: Identification of technical requirements and potential issues.</p> <ul style="list-style-type: none"> Begin ESG Pilot with Industry Production environment live. <p>Outcome: Positive impact to industry stakeholders</p> <ul style="list-style-type: none"> Reduce costs Enhanced Productivity Create opportunities for new and modern business models 	
12-18 months	<p>Outcome: Leverage existing partnership to foster innovation</p> <p>Identify opportunities in order to improve business outcomes and streamline business processes through existing senior officials' governance structures and international data standards development mechanisms to enable the following - *:</p> <ul style="list-style-type: none"> Review of FDA and HC electronic drug review processes to identify differences and similarities. 	

	<ul style="list-style-type: none"> • Review differences in each country’s submission data standard requirements for similar product approvals and build a proposal to address those differences. • Identify and study other issues that could be barriers to furthering collaboration toward product approval processes. <p>* - While decision making will remain independent, the outcome of these initiatives will permit closer alignment of business processes and requirements between Health Canada and the FDA, thereby reducing the burden on industry.</p>	
<p>18 months +</p>		<p>Implement on an on-going basis the use of this tool in both institutions so industry can submit to one or both organizations.</p> <p>Building on this tool, identify additional opportunities for collaboration and cooperation on technical solutions, such as developing collaborative efforts for reviews of generic products and exploring post-market collaboration.</p>

Contacts:

HC:

Robin Chiponski

Director General

Resource Management and Operations Directorate Health Products and Food Branch

Tel: 613-957-6690

Email: Robin.Chiponski@hc-sc.gc.ca

Barbara J. Sabourin

Acting Director General

Therapeutic Products Directorate , Health Products and Food Branch

Tel: 613-952-4619

Email: Barabara.J.Sabourin@hc-sc.gc.ca

USFDA

Paul Seligman,

Director, Asia Pacific Office, Office of International Programs,

Tel: (301) 796-2896

Email: paul.seligman@fda.hhs.gov