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RCC Personal Care Products and Pharmaceuticals Working Group: Common Electronic Submissions Gateway (ESG) Work Plan

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Proposal to explore and develop joint proposals to identify on-going systemic alignment mechanisms between the U.S. Food and Drug Administration (FDA) and Health Canada (HC)

A goal of collaboration between HC and the FDA is to better align our regulatory systems, reduce unnecessary duplications and differences, and, to the extent feasible, better leverage resources to help both agencies meet their public health missions within the parameters allowed by prevailing laws and regulations subject to available human and financial resources.

Building on the strong, extensive and long-standing bilateral regulatory cooperation between the agencies, the FDA and HC will explore and develop proposals outlining joint regulatory collaborations in areas of mutual benefit, such as personal care products and pharmaceuticals for human and animal use. These proposals will outline key elements to help facilitate on-going better systemic alignment of regulatory systems, strategies, and practices between HC and FDA. When exploring potential proposals, FDA and HC will:

- Take stock of collaboration and experience gained to date between the FDA and HC;
- Identify mechanisms for possible regulatory alignment and mutual reliance in such areas as product review and inspection of manufacturing facilities, as well as establishing requirements/standards where appropriate; and
- Examine enablers and barriers related to implementation and identify options for addressing barriers (e.g. legislative and administrative barriers).

These proposals will foster the pursuit of real opportunities to further leverage capacity and expertise, as well as the identification and implementation of effective ongoing systems strategies to help better align regulatory requirements and avoid unnecessary duplication in areas of mutual benefit.

Health Canada and FDA will up-date stakeholders, on a regular basis, on progress and developments emanating from the four current HC-FDA RCC initiatives and future developments, as appropriate.

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 improved access to the introduction of medicines for patients in both countries.

Sub-Action Item (as of 2012)	Implementation of the Enabling tool	Permanent collaboration enabled by the ESG mechanism
3-6 months	Outcome: Identification of technical requirements and potential issues. • 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. • 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 captured end-to-end business process and interfaces with internal Health Canada systems. • Completion of Proof of Concept with FDA. This group of deliverables will result in the following outcomes: • Establish the operational architecture; understand requirements for production environment, validate end-to-end business processes and gather feedback from industry through pilot. Key milestones: • Develop a joint plan US FDA for a Health Canada - Electronic Submission Gateway (ESG) pilot with industry. • Formalize FDA-HC arrangements and funding transfer mechanism through a Cooperative Research and Development Agreement (CRADA). • Establish the requisite contract modifications to enable ESG's present contract to receive funding in support of the requested/necessary infrastructure changes	Enable cooperation and coordination through information and knowledge sharing to develop joint solutions to technical problems. Enhance learning and build trust. Establish the joint organizational structures to effectively facilitate alignment, allocation of resources, and jointly monitor progress. Engage industry and the FDA through venues such as the PhRMA (Pharmaceutical Manufacturers Association) ERS Working Group and the Group on Electronic Regulatory Activities (GERA) to identify other potential collaboration opportunities that the Electronic Submissions Gateway may enable. Leverage existing Senior Officials' meeting and governance structures, and international data standards development mechanisms, to report progress, identify longer term strategic opportunities for collaboration to improve business outcomes and streamline regulatory processes.

	to support Health Canada's fully electronic submission receipt process. 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. • Identify Industry Pilot participants based on criteria established in joint Pilot Test Plan.	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.
6-12 months	Outcome: Identification of technical requirements and potential issues. • Begin ESG Pilot with Industry Use results of Pilot with Industry to verify the functionality, reliability and efficiency of the FDA and Health Canada gateway solution. Production environment live. Transaction Partners will be able to submit similar electronic common technical document (eCTD) submissions to Health Canada and the FDA, with some country-specific differences due to current policy or regulatory differences. Outcome: Positive impact to industry stakeholders • Reduce costs • Enhanced Productivity • Create opportunities for new and modern business models Outcome: Convergence of both Electronic Submissions Gateway ESG and Electronic reporting of adverse drug reaction projects. Define a convergence plan for HC/FDA ESG and electronic reporting project for Adverse Drug Reaction (ADR), the goal being alignment to a single solution for electronic regulatory submissions to Health Canada.	
12-18 months	Outcome: Leverage existing partnership to foster innovation Identify opportunities (e.g. Harmonize Orphan Drug and Drug Master File submission content requirements, and simultaneous filing) 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 **- ***:	Health Canada and FDA align to common international data standard requirements (e.g. Regulated Product Submissions) to support two-way communications and submission lifecycle management.

	• Review of FDA and HC electronic drug review processes to identify differences and similarities. • 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. * - 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.	
18 months +		Modernized regulatory and policy frameworks to support future strategic opportunities for cooperation. Implement on an on-going basis the use of this tool in both institutions and continue to align submission requirements through harmonization of international standards so industry can submit to one or both organizations. 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.

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