

# United States Food and Drug Administration and Health Canada

## Regulatory Partnership Statement

The United States Food and Drug Administration (FDA) and Health Canada (HC) intend to continue regulatory cooperation activities under the Canada-United States Regulatory Cooperation Council's (RCC) [Joint Forward Plan](#).

The following is a general description of how FDA and HC will work together to identify areas of mutual interest and benefit. These discussions are not consultations that occur as part of established national consultation processes related to rule making or regulatory decision-making. Instead, these discussions are ongoing regular discussions that will seek opportunities for possible convergence of regulatory systems in the short-, medium- and long-terms while respecting the sovereignty of each country to make independent regulatory decisions.

The RCC *Joint Forward Plan* sets out commitments for Canadian and U.S. regulatory departments and agencies to establish high-level governance structures; opportunities for stakeholders to provide input, inform strategies, identify priorities and discuss progress on the implementation of initiatives as appropriate; and a mechanism for annual reviews of work plans to consider adjustments and provide status updates on progress.

FDA and HC will leverage a [2003 confidentiality commitment](#), which allows each agency to legally share non-public information regarding products they regulate as part of their cooperative enforcement or cooperative regulatory activities, in order to further support effective communication and collaboration under RCC.

### **GOVERNANCE**

The Commissioner of FDA and Deputy Minister of HC are the Agency leads responsible for the RCC initiative. The Commissioner and Deputy Minister, or their designate, and supported by senior technical managers will use an existing senior officials meeting that is held annually on the margins of the Summit of Heads of Medicines Regulatory Agencies Meeting to discuss the progress of each RCC work plan and to identify short, medium and long term bilateral and multilateral priorities, as appropriate.

These discussions will identify areas for regulatory cooperation over a period of approximately 3 years. As additional opportunities are mutually agreed upon, the senior technical managers will revise the existing work plans to capture any new activities in support of the RCC initiative.

### **STAKEHOLDERS**

Stakeholders will have opportunities to provide input through binational processes and to engage with FDA and HC leadership and senior technical managers. In cases where there are established effective binational structures, such as the joint U.S.-Canada public consultation meeting on International Conference on Harmonisation guidelines, they will be used to engage stakeholders and advance regulators work, as appropriate. In addition, stakeholders will be able to provide input to FDA and HC through existing fora such as the International Medical Devices Regulators Forum Stakeholders meetings, and public events such as the Drug Information

Association annual meetings and the RCC annual stakeholder consultation. In most instances, stakeholders should expect appropriate notification in advance of the meetings. These meetings may also be used by the stakeholders to give comments to the regulators.

For the purposes of medium- and long-term planning, including identification of priorities, stakeholders can provide information on significant industry and consumer trends and associated implications for regulatory systems, such as changes to supply chains and trade partners, the emergence of new technologies, new applications for existing technologies, new manufacturing processes, etc. Stakeholder input on work planning priorities should be specific and include ideas for how work plans could be most effectively implemented.

### **ANNUAL WORK PLANS**

FDA and HC have established an annual work-planning process, led by senior officials to review work plans and engage in priority setting with the aim of achieving mutual regulatory goals. Where we have already put in place appropriate binational structures that can undertake work planning in a particular area, such as an existing multilateral forum (e.g. International Medical Device Regulators Forum), those existing structures will be used to plan and advance work consistent with our RCC objectives.

Currently, we collaborate under the RCC Joint Forward Plan to advance work in the following commitment areas:

1) **Pharmaceuticals and Biologics**

Health Canada and the U.S. Food and Drug Administration will continue to work closely together to harmonize and align their pre and post marketing surveillance requirements and standards (including pharmacovigilance issues) through the work of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, the International Pharmaceutical Regulators Forum and the International Coalition of Medicines Regulatory Authorities. Regulators will continue to share inspection schedules bilaterally and through the Pharmaceutical Inspection Co-operation Scheme and to promote leveraging of inspectional resources to maximize inspection coverage. Regulators will also continue to expand the Common Electronic Submission Gateway for the biological and pharmaceutical industry, where appropriate.

2) **Over the Counter Drug Products**

Health Canada and the U.S. Food and Drug Administration will coordinate and adjust their respective OTC monographs development processes for OTC drugs to reduce the regulatory burden on stakeholders.

3) **Medical Devices**

Health Canada and the U.S. Food and Drug Administration will continue to work closely together on pre and post market regulatory convergence topics, including in particular, through the International Medical Devices Regulators Forum (IMDRF). IMDRF aims to accelerate international medical device regulatory harmonization and convergence for regulators and stakeholders worldwide.

4) Veterinary Drugs

Health Canada and the U.S. Food and Drug Administration will coordinate their respective veterinary drug marketing application submission and review processes to enable simultaneous product reviews. They will coordinate standards development as appropriate and assessment activities pertaining to the pre-market evaluation of veterinary drugs. Further work in this area will also explore the availability of electronic templates that could be used to submit veterinary drug applications.

Work plans will be reviewed annually and uploaded on the Health Canada and U.S. RCC websites at <http://www.hc-sc.gc.ca/index-eng.php> and <http://www.trade.gov/rcc>.