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RCC Agriculture and Food 2 Working Group: Veterinary Drugs Work Plan

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U.S. Leads: Murray Lumpkin, Commissioner's Senior Advisor and Representative for Global Issues, U.S. Food and Drug Administration (FDA)

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.

Description:

The goal of this initiative is to facilitate simultaneous new animal drug submissions in both countries of the same fundamental data set with a view to promote the simultaneous availability of drugs to end users, as well as to further align Maximum Residue Limits (MRLs)/tolerances whenever possible. .

As part of this initiative, simultaneous reviews will be conducted to explore similarities and differences in approach between the two countries, with a view to develop a mechanism that, subject to some acceptability criteria, would allow for simultaneous submissions and collaborative reviews.

In addition, this initiative will see Health Canada and the U.S. Food and Drug Administration continue their close collaboration towards the establishment of comparable

human food safety standards for veterinary drugs.

Building on the high degree of harmonization already achieved with regards to data requirements for veterinary drugs, it is a significant next step towards further alignment of veterinary drugs approvals in Canada and the US.

While maintaining each country's ability to make decisions regarding the availability of a product, this pilot project could be the first step towards more regular simultaneous veterinary drug access on both sides of the border when a drug manufacturer decides to apply at the same time in the USA and in Canada.

- Structure and governance of the working group and task teams.
  - The task team is composed of staff from Health Canada's Veterinary Drugs Directorate (VDD), and the U.S. FDA's Center for Veterinary Medicine (CVM).
  - The task team will build on the practical and proactive CVM-VDD relationship that already exists, so that information is shared on an as-needed basis.

- Description of working group and task team mandate/objectives, meeting frequency and alignment with pre-existing bilateral committees.
  - The frequency of working group meetings will be determined after further discussions between regulators.

- Description of the stakeholder engagement approach and frequency.
  - On the Canadian side, the industry and producers will be kept appraised of the progress of the initiative on an at least bi-yearly basis through the regular CAHPRAC (Canadian Animal Health Products Regulatory Advisory Committee) meetings.
  - Working group updates on initiative progress to be provided on RCC websites.
  - The need for additional stakeholder engagement will be further discussed by regulators as the initiative progresses.

Timelines:

Deliverable outcome	Facilitate simultaneous new animal drug submissions in both countries of the same fundamental data set with a view to promote the simultaneous availability of drugs to end users, as well as to further align Maximum Residue Limits (MRLs)/tolerances whenever possible. As part of this initiative, simultaneous reviews will be conducted to explore similarities and differences in approach between the two countries, with a view to develop a mechanism that, subject to some acceptability criteria, would allow for simultaneous submissions and collaborative reviews.	
Action items	Action Item 1: Complete simultaneous review pilot project for drug submissions made simultaneously in both countries, with a view to develop a mechanism that, subject to some acceptability criteria, would allow for simultaneous submissions and collaborative reviews.	Action Item 2: Through simultaneous review pilot project, continue to build on scientific collaboration in the establishment of comparable human food safety standards, including the further alignment of MRLs/tolerances whenever possible.
Interim Deliverables		
3-6 Months	Identification of potential drug submissions for simultaneous review pilot project.	Identify potential candidate drug submission(s) for simultaneous review of Human Food Safety technical section.

	Develop workplan for simultaneous review. Simultaneous review pilot project initiated for drug submissions.	
6-12 Months	Throughout initiative, ongoing exchange of information as needed between HC and FDA on the pilot submissions. Initiate documentation and discussion of similarities and differences in approaches.	
12-18 Months	Identify opportunities and potential candidates for simultaneous submissions and collaborative review of technical sections. Technical sections include Drug Effectiveness, Target Animal Safety, Chemistry and Manufacturing, and Human Food Safety (including Microbial Safety for antimicrobials). Continued interaction including teleconferences, sharing of documents or in-person meetings, as needed. Gain experience by simultaneously reviewing one drug submission for each technical section.	Ongoing discussion to promote scientific collaboration. Fully participate in VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) activities in the establishment of human food safety data requirements for veterinary drugs. Explore further aligning positions to Codex. Perform analysis of MRLs/tolerances calculation procedures and residue reports to identify key similarities and differences between CVM and VDD.
Beyond 18 Months	Completion of review and readiness for review decision on at least one of the simultaneously and collaboratively reviewed drug submissions by both HC and FDA separately. Through analysis of the experience with simultaneously reviewing drug data submissions, identify similarities and differences in review processes and develop lessons learned.	Maintain ongoing dialogue to keep promoting the further alignment of food safety standards, including Microbial Food Safety, and MRLs/tolerances whenever possible.
	Further to completion of the analysis above and a lessons learned exercise, Health Canada and the U.S. FDA will continue working toward simultaneous and collaborative review of submissions for sponsors interested in applying at Health Canada and the US FDA at the same time by: - Creating a CVM-VDD working group which would establish criteria, considering resource constraints, respective regulatory frameworks and statutory mandates, industry interest, marketing of products in both countries at the same time, and protection of consumers, for eligibility of drugs to a simultaneous submission review process. - Evaluation by the CVM-VDD Working Group of the lessons learned from each major technical section simultaneous review of a veterinary drug application with the goal of comparing regulatory standards and approaches. This includes the approach to the evaluation of human food safety and setting of MRLs/tolerances. - Developing a document outlining criteria for eligibility of veterinary drugs to the simultaneous submission and collaborative review process.	

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