

## **RCC Working Group Work Plan**

Canada Lead(s) – Daniel Chaput, Director General, Veterinary Drugs Directorate

USA Lead(s) - Steven Vaughn, Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine

### **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 apprised 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.
  - The need for additional stakeholder engagement will be further discussed by regulators as the initiative progresses.

### **Timelines :**

Initiatives appearing in the list of opportunities should be imported and interim deliverables established for each one.

<b>Working Group</b>	Agriculture & Food #2
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Action Plan Initiative	Veterinary Drugs	
<b>Deliverable outcome</b>	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.	
<b>Task team members</b>	VDD: Mary-Jane Ireland, Marc Legrand; CVM: Steven Vaughn, Brandi Robinson, Michael Oehlsen	
<b>Action items</b>	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		
<b>3-6 Months</b>	<p>Identification of potential drug submissions for simultaneous review pilot project.</p> <p>Develop workplan for simultaneous review.</p> <p>Simultaneous review pilot project initiated for drug submissions.</p>	Identify potential candidate drug submission(s) for simultaneous review of Human Food Safety technical section.
<b>6-12 Months</b>	<p>Throughout initiative, ongoing exchange of information as needed between HC and FDA on the pilot submissions.</p> <p>Initiate documentation and discussion of similarities and differences in approaches.</p>	
<b>12-18 Months</b>	<p>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).</p> <p>Continued interaction including teleconferences, sharing of documents or in-person meetings, as needed.</p> <p>Gain experience by simultaneously reviewing one drug submission for each technical section.</p>	<p>Ongoing discussion to promote scientific collaboration.</p> <p>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.</p> <p>Perform analysis of MRLs/tolerances calculation procedures and residue reports to identify key similarities and differences between CVM and VDD.</p>

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<b>Beyond 18 Months</b>	<p>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.</p> <p>Through analysis of the experience with simultaneously reviewing drug data submissions, identify similarities and differences in review processes and develop lessons learned.</p>	Maintain ongoing dialogue to keep promoting the further alignment of food safety standards and MRLs/tolerances whenever possible.
	<p>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:</p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- 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.</li> <li>- Developing a document outlining criteria for eligibility of veterinary drugs to the simultaneous submission review process.</li> </ul>	

Canadian and U.S Working Group and Task Teams Leads contacts

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