



Health
Canada

Santé
Canada

Your health and safety...our priority.

Votre santé et votre sécurité... notre priorité.

Helping the people
of Canada maintain and
improve their health

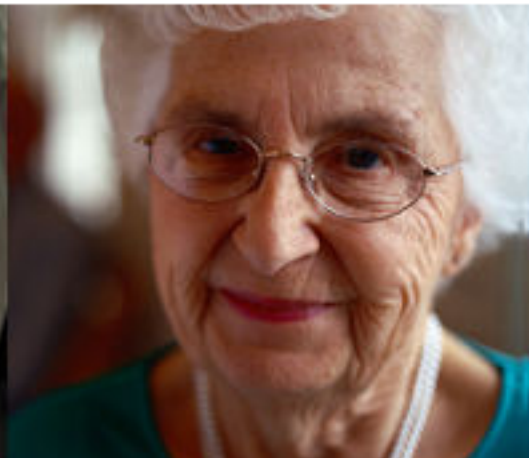
Aider les Canadiens et
les Canadiennes à améliorer
leur état de santé

Antimicrobial Use & Antimicrobial Resistance

Updates from the Veterinary Drugs Directorate

NFAHW Council Meeting

November 25, 2014



Canada

VDD's Contribution to Antimicrobial Stewardship

- Health Canada's ongoing efforts to mitigate AMR risks have more recently focused on two measures (aligning with work and timelines in the U.S.):
 - Voluntary removal of growth promotion and/or production claims of medically-important antimicrobial drugs; and
 - Development of options to strengthen the veterinary oversight of antimicrobial use in food animals

Notice to Stakeholders posted April 10, 2014:

<http://www.hc-sc.gc.ca/dhp-mps/vet/antimicrob/amr-notice-ram-avis-20140410-eng.php>



VDD's Current Initiative: Scope

- The initiative focuses on the medically-important antimicrobials (i.e., those belonging to Categories I , II and III of Health Canada's categorization scheme)
- Medically important antimicrobial products administered via animal feed or drinking water are affected:
 - No Category I antimicrobials authorized by VDD for use in feed or water
 - Category IV drug products (e.g., ionophores) are not affected
 - The affected products include:
 - 61 products with growth promotion/ production claims (AGPs)
 - 143 products with OTC status (including AGPs)



Working Principles & Continued Outreach

- **Working principles for implementing the 2 measures**
 - Collaborative approach (domestic)
 - Level playing field between U.S. and Canada
 - Minimize burden to stakeholders (industry and producers)
 - Ensure continued and timely access to needed products (e.g. no impact on Category IV antimicrobials)
 - **Both proposals need to be integrated for implementation**
- VDD continues to work with stakeholders to prepare for implementing these measures. Ongoing outreach and support from stakeholders is important and needed throughout the implementation phases



VDD Initiative: Implementation Proposals

- **Current thinking on implementation proposals for the two measures :**
 - **Removal of growth promotion claims:**
 - Providing procedural guidance to the drug sponsors to respond
 - Encouraging sponsors to book pre-submission meetings
 - Addition of new claims is also being considered
 - Proposing fixed implementation date for final label changes and NOC issuance
 - Proposing any changes in label claims to be submitted latest by June 1 2015.



VDD Initiative: Implementation Proposals

- **Increasing Veterinary oversight**

- **In-water medications**

- About 70 affected products are approved for sale in drinking water
- In contrast to feed medications where CMIB exists and there are *Feed Regulations* at play, there are limited options available for in-water medication products to increase veterinary oversight
- US FDA is moving OTC in-water medications to Pr status
- Need to work with provinces and other key stakeholders to discuss distribution practices for such products so as to minimize the impact on producers.





- **Increasing Veterinary oversight:**

- **In Feed medications:**

- Working closely with CFIA
- Discussing options available (e.g., prescription-only; Canadian version of US Veterinary Feed Directive)
- Building on experiences in Québec (all medications *Rx*) and the US (VFD)
- To maintain/update CMIB for in-feed antimicrobials for affected products
- Commercial feed manufacturers
 - ❖ efficient manufacturing/production
- On-farm feed manufacturers
 - ❖ ongoing access to drugs including medically important drugs



Next Steps

- **Moving forward**
 - Soliciting stakeholder feedback: Fall 2014 - Winter 2015
 - Completion of the implementation proposals with feedback received
 - Overall objective is to align with the U.S. FDA's December 31, 2016 implementation date.
- **Comments and suggestions** related to implementation challenges and opportunities as it relates to increasing veterinary oversight are welcome :

consultationVDD-DMV@hc-sc.gc.ca



Annex

Products Impacted by 2 Measures

Measure	Number of the Products (Active Ingredient)*			
	Category I	Category II	Category III	Total Number
Measure #1: Growth promotion/ production claims	0	24 (Erythromycin, Penicillin G, Streptomycin, Tylosin, Virginiamycin)	37 (Bacitracin, Chlortetracycline, Neomycin, Oxytetracycline, Sulfonamides)	61
Measure #2: Strengthen veterinary oversight	0	52 (Erythromycin, Lincomycin, Penicillin G, Streptomycin, Tilmicosin, Tylosin, Tylvalosin, Virginiamycin)	91 (Apramycin, Bacitracin, Chlortetracycline, Neomycin, Novobiocin, Oxytetracycline, Spectinomycin, Sulfonamides, Tiamulin)	143

*Used in feed or drinking water.

