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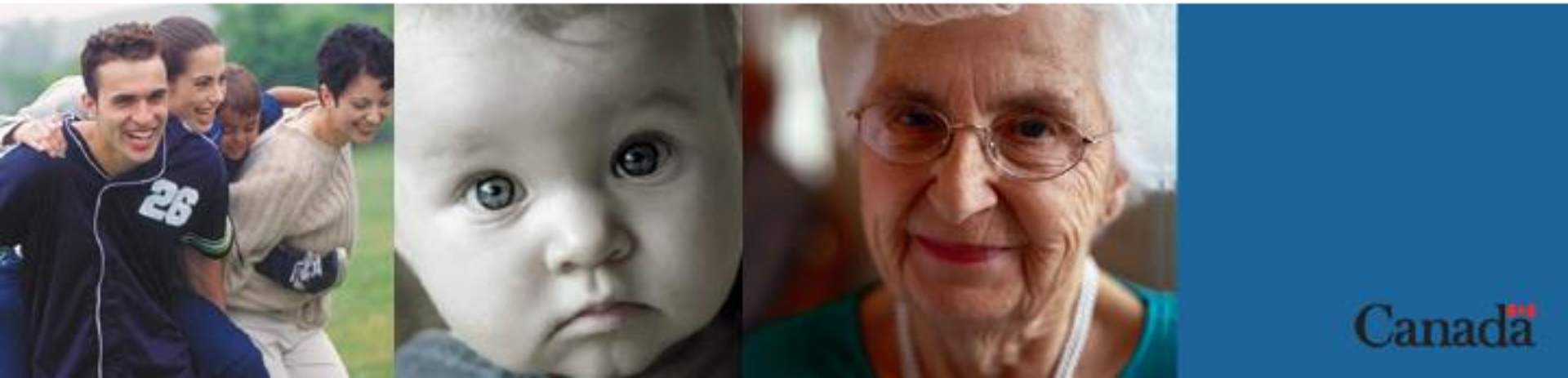
Federal Action Plan on Antimicrobial Resistance: Update on VDD's Initiatives

NFAHWC Meeting
November 24, 2015



International Context

- World Health Assembly resolution May 2014 called for global action to address antimicrobial resistance (AMR)
  - Global Action Plan released May 2015
- World Organization for Animal Health (OIE) Resolution No. 26 on Combatting AMR – May 2015
- Food and Agricultural Organization (FAO): passed a resolution on AMR- June 2015
- “Berlin Declaration on AMR” by the G7 health ministers – Oct 2015
- Everyone adopting “One health approach” to address AMR
- President Obama’s executive order to combat AMR – Sept 2014
- Need for alignment with US FDA on AMR initiatives given the integrated nature of North American agri-food and pharmaceutical industry

National Context

- Federal Framework on AMR– Oct 2014
- Federal Action Plan on AMR/AMU – March 2015
- Notice of Intent in CG1 to amend the *Food and Drug Regulations* to address AMR – April 2015
- Health Canada's commitments in response to the Spring 2015 OAG report
- Strong engagement of stakeholders with good support on goals and ongoing discussions on means – latest round of consultations March 2015
- Shared F/P/T jurisdiction with different approaches to regulating use of veterinary drugs amongst provinces

Policy Intent and Guiding Principles

- Strengthening stewardship of medically important antimicrobials (MIAs) in order to prolong their effectiveness while
  - Maintaining access to needed products for animal health and welfare
  - Aligning internationally in regulating MIAs (aiming at FDA target of Dec 2016)
  - Working collaboratively with multiple federal and provincial partners as well as external stakeholders

VDD's Initiatives to Strengthen Antimicrobial Stewardship

- Remove growth promotion claims from all MIAs (underway)
- Increase veterinary oversight over the sale of MIAs by moving away from Over The Counter sales
- Require sales volume from manufacturers to support AMU surveillance
- Increase oversight on importation of veterinary drugs and active pharmaceutical ingredients (API) for own use (OUI)
- Facilitate access to low risk veterinary health products as additional tools for maintenance of health and welfare of animals

Removal of Growth Promotion (GP) Claims

- **Issue**
  - Phasing out non-prudent uses of antimicrobial drugs in animals for non-therapeutic purposes i.e. growth promotion and weight gain
- **Proposal**
  - Initiative is already well underway with positive response from manufacturers of all the implicated products and overall strong support from food animal producers, veterinary professionals and other stakeholders
  - Aiming to align with US FDA timeline of a similar initiative (Dec 2016)
  - Label changes to be in sync with increasing vet oversight of MIAs
  - Several submissions to remove GP claims have been received
- **Considerations**
  - About 64 products are implicated. No anticipated loss of treatment options.
  - No GP claims approved for new MIAs since 2004
  - There is lack of modern data to show that these products are still effective at the approved dosage (approved several decades ago)

Increasing Veterinary Oversight (1 of 3)

- **Issue**
  - Need to strengthen veterinary oversight of AMU in food animal production
- **Key Objectives**
  - Professional intervention of licensed veterinarians prior to sale of MIA drugs with minimal impact on access to drugs when needed
  - Establishment of appropriate record keeping requirements
- **Options Considered**

1. Prescription status for all MIA drugs approved prior to 2004
   - Internationally aligned
   - Consultation indicated support in principle by stakeholders
   - Impact on access can be minimized by making certain amendments
2. For in-feed products an approach similar to the US Veterinary Feed Directive - VFD (in between Prescription and OTC)
   - Introduction of a new concept in Federal regulation and the impact on provincial rules
   - Consultation indicated risk of adding confusion / complexity to an already complex situation
   - Further analysis indicates no added benefits over prescription status (product access perspective) with amendments

Increasing Veterinary Oversight (2 of 3)

- **Proposal Under Consideration**
  - Move all MIAs approved prior to 2004 to the Prescription Drug List (PDL)
  - Include all in-feed MIAs in the CMIB so that proper instructions for feed mills to manufacture medicated feeds containing approved levels of these MIAs and required labelling information, including proper warnings and cautions for the end user, are provided.
  - No restriction on manufacturing and stockpiling of such MIA-medicated feeds if manufactured pursuant to Health Canada approvals (CMIB). A document signed by a veterinarian would be required before the sale of MIA-medicated feed.

Increasing Veterinary Oversight (3 of 3)

- **Considerations**
  - About 140 products implicated
  - Shared F/P/T jurisdiction on sale and distribution
  - Change in availability status of these old products would have an impact on distribution chain (access to products)
  - The economic aspect - producers
  - P/T variability in approach to regulating veterinary drugs
    - Variability in drug distribution channels (e.g. livestock medicine outlets)
    - P/T in different stages of readiness to embrace the change (e.g Quebec, New Foundland)
- **Next Steps**
  - Discussions underway with CFIA to identify specific changes to be made at operational level to accommodate changes to medicated feeds
  - Continue to work on the proposal with P/T partners

Increasing Oversight on Importation

- **Issue**
  - Unapproved veterinary drugs (finished products) as well as APIs are imported for direct administration to food-producing animals. Need additional controls in place

- **Proposal**
  - Prohibition of importation of unapproved products for own use coupled with an exemption for specified drug products that do not represent an unacceptable risk to food safety and public health
  - Rules for GMPs for Veterinary APIs
  - Veterinarians to require an EL if importing an API not licensed in Canada for use in animals.
  - Regulatory amendment will be necessary (NOI 2015)

- **Considerations**
  - Unique situation internationally
  - March 2015 technical discussion with stakeholders has brought us closer to a viable proposal for resolving this long standing issue

Low Risk Veterinary Health Products (LRVHPs)

- **Issue**
  - Many LRVHPs serve as additional tools to maintain health and welfare of animals
  - No viable approach within the current system for these products to be in compliance with the regulations
  - Producer groups and On Farm Food Safety programs discourage the use of products that are not legal for sale
- **Proposal**
  - Creating a regulatory pathway to allow importation and sale of such products for use in food animals
  - Regulatory amendment required
- **Considerations**
  - The proposal has been “tested” for companion animal drugs through the “Interim Notification Pilot Program (INPP)” with strong support from stakeholders
  - Implementation will require coordination with federal partners

Stakeholder Views on VDD's AMR Initiatives

- Overall strong support on the goal
- On-going discussion on implementation/operationalization
- Stakeholder support by sector
  - Public health officials (strong support)
  - Academia (strong support)
  - Pharmaceutical industry and association (strong support)
  - Producers (good support - interest in level playing field, minimal trade impacts)
  - Provincial/territorial authorities (support/alignment of overall goals – more discussion required on the approaches)
  - Veterinary professionals (good support, strong support from certain veterinary associations)

Challenges and Opportunities

- Diverse Regulations governing distribution and use of MIAs in provinces/territories
- Need a Pan-Canadian approach for implementing increased veterinary oversight
- Need to ensure alignment of the regulatory and non-regulatory aspects of ongoing initiatives to achieve effective implementation (initiatives are inter-linked)
- Need to align with efforts being undertaken in the US

Next Steps / Timelines

- Engagement with Federal partners – Fall 2015
- Additional round of stakeholder engagement with focus on changes further to feedback from March 2015 consultation – Nov / Dec 2015
- Drafting of Regulations – Q3/Q4 2015/16

VDD's initiatives roll up to just one piece of this multi-piece puzzle…