Veterinary Drugs Directorate Update

2016 CAHI Annual Meeting
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Health Canada
Outline

• Mitigating the risks of Antimicrobial Resistance (AMR) – An update on VDD’s initiatives

• International Regulatory Cooperation – RCC, Joint Review

• Minor Use and Minor Species

• Management of Submissions

• Questions
Antimicrobial Resistance: The Context

• Multiple federal initiatives are underway on both the human and veterinary sides of AMR in a coordinated manner (“One Health” approach)


• Proposed policy and regulatory initiatives aimed at strengthening prudent use of Medically-Important Antimicrobials (MIAs) in animal health are under development at the federal level

• *Guiding principles*: Minimising any impact on access to needed products, aligning internationally, and working collaboratively with all affected parties are key guiding principles for this work
VDD’s AMR Initiatives Underway: A Snapshot

- Removing growth promotion claims from pre-2004 approved medically-important antimicrobials (MIAs)
  - policy approach

- Increasing veterinary oversight over all MIAs (pre-2004 approved)
  - policy and existing regulatory tools

- Increasing oversight on importation of veterinary drugs (Own Use Importation) and active pharmaceutical ingredients (APIs)
  - new regulatory proposal

- Facilitating access to low risk veterinary health products as additional tools for the maintenance of animal health and welfare
  - new regulatory proposal and existing policy tools

- Mandatory reporting of sales volume from manufacturers and importers to support antimicrobial use surveillance
  - new regulatory proposal
AMR – Next Steps

• Continue moving forward with the multipronged strategy to address AMR in veterinary drugs context

• Critical that all planned initiatives roll out concurrently

• Regulatory Package near completion

• Continue conversations with all stakeholders (P/T partners, producers, etc.)

• Work underway on implementation details and guidance, incorporating feedback received
International Regulatory Cooperation

 Regulatory Cooperation Council: Veterinary Drugs Initiative

• US FDA-CVM and VDD are coordinating submission and review processes to enable simultaneous product reviews with a view to simultaneous decisions and product availability

• 2015-2016: 2 drugs approved, including first food producing animal drug

• 10 drug submissions currently in review

 Joint Review

• VDD, Australian Pesticides and Veterinary Medicine Agency and New Zealand Ministry of Primary Industries leading to a drug approval for sheep
Drugs for Minor Use and Minor Species (MUMS)

- **Current MUMS Process**
  - Traditional – directly with the sponsor
    - Pre-requisite when formulation not already approved in a food animal in Canada
    - Can leverage international data
  - Partnership model with Pest Management Centre (PMC) – Agriculture and Agri Food Canada
    - Can leverage international data
    - Can use bridging studies to fill gaps if any
    - Use of expert opinions

- **Results**
  - 2016: 2 drugs approved for use in sheep (traditional)
  - 2015: 3 drugs for use in sheep; 1 drug for rabbits (T and PMC)
  - 2014: 1 drug for sheep, 2 drugs for rabbits (T and PMC)
Drugs for Minor Use and Minor Species (MUMS)

Facilitating safe and effective drugs are available for use in MUMS
Pre-submission consultations

- Fiscal Year 14/15 - 39 meetings
- Fiscal Year 15/16 – 49 meetings
- Timeliness and the type of advice sought is essential for effective discussions

Drug Submissions received

- Increase in overall number of major submission types: new drugs, supplements, generic drugs
- Performance as measured by total time to decision has stabilised for major submissions

Challenges and Opportunities
Management of Submissions

Number of Large Submission Types Received (NDS, SNDS, ANDS, SANDS)

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- Fiscal Year
Management of Submissions

Electronic Submissions for Pharmacovigilance

• CFIA / Health Canada are implementing a single PV – Works system providing a single window for CFIA (CCVB) and HC (VDD) pharmacovigilance reporting system

• Implementing Pilot Phase including accepting e-reports through the gateway (3 companies)

• From pilot to production environment with pilot companies (fall 2016) followed by further expansion
Thank you

VDD appreciates CAHI’s ongoing support and involvement on important public and animal health issues and looks forward to continued collaboration.