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Health Canada's *Efforts to Strengthen Canada's Regulatory Framework for Veterinary Antimicrobials*

NFAHWC

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Purpose

- Provide an overview and update on collaborative efforts underway to address antimicrobial resistance (AMR) associated with veterinary drugs in food-producing animals and as it relates to deliverables under the Federal Action Plan
  - Regulatory amendments pre-published in Canada Gazette Part 1 July, 2016
  - Policy initiatives to enhance prudent use
- Discuss next steps in addressing this cross-cutting issue and implications for the different sectors involved

Managing AMR in Veterinary Drugs Context

- **Antimicrobial use** – including the inappropriate use/overuse in humans, **animals** and plants – is leading to increases in the emergence and spread of AMR

- **AMR risk from animals** is one side of a multi-faceted problem
  - In Canada, an estimated 70 % of all medically important antimicrobial drugs are sold for use in food-producing animals
  - Shared jurisdiction (F/P/T) over sale and use of veterinary medicines
  - Multiple stakeholders, including federal, P/T and municipal governments, industry and stakeholders all have a role to play to manage AMR risk

- **Current Activities to address AMR**
  - We are making important Regulatory and Policy changes to strengthen prudent use of Medically important antimicrobials (MIAs) in livestock production
  - Guiding Principles:
    - While protecting public health minimising impact on access to needed products
    - Minimizing disruptions to distribution channels
    - Aligning internationally to the extent feasible
    - Working collaboratively with all affected parties

Snapshot – Vet Drugs AMR Initiatives Underway

These regulatory and policy initiatives are interconnected and mutually supportive:

1) Increasing oversight on importation of veterinary drugs (Own Use Importation)

- *new regulatory proposal*

2) Increasing oversight on importation and quality of active pharmaceutical ingredients (APIs)

- *new regulatory proposal*

3) Mandatory reporting of sales volume from manufacturers and importers to support antimicrobial use surveillance

- *new regulatory proposal*

4) Facilitating access to low risk veterinary health products (VHPs), as additional tools for the maintenance of animal health and welfare

- *new regulatory proposal and existing policy tools*

5) Removing growth promotion claims from medically-important antimicrobials (MIAs)

- *policy under existing regulatory tools*

6) Increasing veterinary oversight over all MIAs (Prescription status switch)

- *policy under existing regulatory tools*

1) Oversight on Importation of vet drugs (OUI)

Current Situation

- Veterinary drugs, including over the counter antimicrobials, can be imported to Canada for own use purposes with limited regulatory oversight. In this context, own use importation refers to importation by an individual for use on animal(s) under their care or guardianship, and not for further sale.

Regulatory proposal

- Prohibits importation of unapproved drugs for own use, with an exemption for specified drug products that do not represent an unacceptable risk to food safety and public health
- Exempted product list to be *Incorporated by Reference* and established based on specified criteria established by Health Canada
- No MIAs will be allowed to be imported for own use purposes for use in food-producing animals

2) Oversight on Importation and Quality of APIs

Current Situation

- There is limited oversight on the importation of antimicrobials as APIs for veterinary use.
- Currently, manufacturers, importers and compounders of APIs for veterinary use are not required to have an Establishment Licence (EL) or to follow Good Manufacturing Practices (GMPs). In 2013, EL and GMP requirements came into force for APIs for human use.

Regulatory proposal

- Expand existing regulatory requirements of GMPs and EL requirements for APIs used in human drugs to all veterinary APIs
- Restrictions on who can import MIAs (e.g. Importation of MIA APIs by food animal producers for their direct use in food animals will not be allowed)
- Require an EL for veterinarians seeking to import APIs for MIA drugs

3) Mandatory Reporting of antimicrobial sales volume

Current Situation

- No Regulatory authority to collect sales volume for drugs

Regulatory proposal

- Require manufacturers or importers of veterinary drugs in dosage form that contain an API for medically important antimicrobial to provide on an annual basis, a report identifying for each drug the total quantity sold and an estimate of the quantity sold for each intended animal species; and
- Require persons, including pharmacists and practitioners, that import and compound and sell an API for medically important antimicrobial drugs (List A) for veterinary use to provide, on an annual basis the same report

Data gathered will support the surveillance pillar of the Federal Action Plan…

4) New Pathway for Veterinary Health Products (VHPs)

Current Situation

- No regulatory provisions for sale of low risk veterinary health products

Regulatory proposal

- Creating a risk-based regulatory pathway to allow importation and sale of low risk veterinary health products for use in animals, including food animals
- The proposal builds on the successes and lessons learned from the “Interim Notification Pilot Program (INPP)” for companion animal drugs, and would need continued support from Producer groups and on Farm Food Safety Programs

5) Removal of Growth Promotion Claims

- Phase out non-prudent uses of MIAs in animals for long-term non-therapeutic purposes i.e. growth promotion and weight gain
- No growth promotion claims approved for new MIAs post-2004
- There is lack of modern data to show that these products are still effective at the approved dosage (approved several decades ago)
- Positive responses from manufacturers of all implicated products; overall support from food animal producers, veterinary professionals and other stakeholders
- About 64 products are implicated
- Minimizing impact on availability of treatment options

6) Increasing Veterinary Oversight of all MIAs (Pr)

- Moving all existing over the counter MIAs to the Prescription Drug List (Pr status)
- All in-feed MIAs to be included in CMIB; and require a Prescription (Pr) prior to sale for on-label products
- About 300 products implicated in all dosage forms (with about 75 in-feed MIAs)

Challenges and Opportunities

- Shared F/P/T jurisdiction on sale and distribution of drugs
- P/T variability in approach to regulating veterinary drugs (e.g. distribution channels such as livestock medicine outlets)
- Overall support in principle for the Pr switch proposal, including pan-Canadian implementation approach to the extent possible

Update & Next Steps

- Formal 75 day Canada Gazette, Part I consultation – July 2 to September 14, 2016
- Comments received from stakeholders during CGI consultation indicate overall support for the regulatory proposal
- Analysis of comments received will inform subsequent changes to the regulatory proposal if needed
- Once approved by the Treasury Board, final regulations are published in the Canada Gazette, Part II
- Work underway on implementation details and guidance, incorporating feedback received
- Plan to synchronise implementation of policy initiatives with regulatory amendments to the extent possible

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