



September 22, 2025

Veterinary Drugs Directorate  
Health Products and Food Branch  
Health Canada

***Sent via email: vdd.hsd-dih.dmv@hc-sc.gc.ca***

To whom it may concern,

Re: Categorization of antimicrobial drugs based on importance in human medicine

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On behalf of the 19,000 members that Beef Farmers of Ontario (BFO) represents, I would like to bring forward our concerns regarding the categorization of some of the antimicrobial drugs based on importance in human medicine.

BFO understands and promotes best management practices (BMPs) related to antimicrobial use (AMU) and antimicrobial resistance (AMR). Our farmers are committed to antimicrobial stewardship (AMS) and work closely with veterinarians, livestock producers, and other stakeholders to promote responsible animal health practices.

### **Executive Summary**

#### **BFO Concerns**

- **Lack of Transparency and Process Issues**
  - Limited clarity on which experts or stakeholders were involved in developing the proposed recategorization.
  - Uncertainty about decision-making criteria.
  - Stripping Category III of practically all medically relevant drugs for veterinary use.
- **Oversimplification of Categorization System**
  - Moving from a three-tier to an oversimplified structure contradicts the WHO scheme, which has six categories.
  - Misalignment with international standards makes it harder for veterinarians and industry to follow stewardship guidelines.
- **Impact on Stewardship Efforts**
  - With Category III nearly eliminated, there will be little distinction between Category II and III drugs.

- Reclassifying older, commonly used drugs (aminoglycosides, phenicols, pleuromutilins, tetracyclines) to Category II undermines stewardship guidelines encouraging lowest-tier use first.
- Could eliminate incentives to preserve Category II antimicrobials.
- **Industry Stewardship Track Record**
  - The proposed changes risk creating a perception that industry is moving backward on stewardship when the opposite is true.
  - As per the 2023 Veterinary Antimicrobial Sales Highlights Report:
    - Category III drugs accounted for 68 per cent of use.
    - Category II accounted for 29 per cent.
    - This is an improvement from 2015, where use was nearly 50/50.
  - Proposed recategorization would artificially inflate reported use of Category II (high-importance) drugs, even without changes in prescribing.
- **Specific Concerns with Tetracyclines**
  - Proposal to move first- and second-generation tetracyclines from Category III to II will significantly impact beef cattle production.
  - First-generation tetracyclines (chlortetracycline, oxytetracycline) are the most commonly used antimicrobials in beef, dairy, and pig production.
  - These drugs remain highly effective for managing liver abscesses despite resistance.
  - Recategorization would place all liver abscess therapy options (tetracyclines, tylosin, virginiamycin) in Category II, leaving no clear guidance on first-line use.

#### **BFO Questions**

- Why were certain experts or stakeholders chosen for input (or excluded) in developing the draft categorization?
- What transparent, science-based criteria are being used to recategorize antimicrobials?
- Has a formal risk assessment been conducted for antimicrobials shifting from Category III to II, especially considering generational differences within drug classes?
- How will reclassification affect veterinarians' ability to follow stewardship principles in practice?
- How will Health Canada ensure alignment with the WHO scheme, which has more categories and finer distinctions?

#### **Recommendations / Path Forward**

- **Immediately pause the proposed recategorization process.**
- Establish a credible One Health Committee with external stakeholders, including livestock veterinarians and academia.
- Adopt a transparent, science-based decision framework.
- Conduct a formal risk assessment for antimicrobials proposed to shift categories.
- Ensure future consultations are collaborative, practical, and aligned with international best practices.

#### **Full BFO Submission**

BFO has concerns about the lack of transparency in the process leading up to the proposed recategorization, the decision-making criteria used, and the stripping of Category III of any medically relevant drugs for veterinary use. BFO recommends:

- The immediate pause of the proposed recategorization process and the establishment of a credible One Health Committee that includes stakeholders external to Health Canada, with representation from livestock veterinarians and academia.
- Reviewing the decision framework for antimicrobial categorization to ensure it is transparent, science-based, replicable, and considers the potential impact on antimicrobial stewardship in livestock.
- Conducting a formal risk assessment for those antimicrobials that are proposed to transition from Category III (medium) to II (high), and that considers the relevant differences between different generations of drugs in the same category.

The consultation documents lack clarity on which experts or stakeholders were involved in developing the proposed recategorization, leading to uncertainty about the decision-making process. Considering the complex and diverse applications of the categorization scheme, we recommend a multidisciplinary advisory committee guide this work to ensure comprehensive representation of a One Health perspective. An example of an effective advisory committee is the World Health Organization, which established an Advisory Group on Critically Important Antimicrobials for Human Medicine that includes 17 experts from human, veterinary, agriculture, and environmental sectors. Such a committee would be able to capture a diverse viewpoint while also understanding how these changes will impact all stakeholders at a practical level.

BFO supports the antimicrobial drug classes proposed for Category I and Category IV and agrees with placing critical antimicrobials in Category I, as these drugs are vital for the protection of the health of Canadians. BFO supports the decision to retain Category IV, which designates antimicrobial classes not used in human medicine and preserves the ability to use ionophores as an antimicrobial-sparing tool to support cattle health.

BFO is concerned with the proposed recategorization, as the change strips Category III of practically all useful antimicrobials for veterinary medicine. The oversimplification of the three-tier system is in the opposite direction of the WHO prioritization scheme, which now has six categories, five of which include antimicrobials authorized for non-human use.

The distinction between Category II and III is critical to ensure stewardship efforts are taken in such a way as to ensure the lower-tier medically important antibiotics are used before the more important ones. With the new breakdown of Category II and III, few differences will be seen between antibiotics. The stewardship guidelines that encourage veterinarians to start with the lowest category drug that is expected to be effective will be eroded, as reclassifying older, commonly used drugs from Category III to II—including the aminoglycosides, phenicols, pleuromutilins, and all tetracyclines—will eliminate incentives and direction to preserve the current Category II drugs.

Our industry in Canada prides itself on ensuring we are responsible stewards of the environment and animal health, which includes the use of antibiotics, and with these proposed changes it will appear that the industry is trending in the wrong direction when in fact the industry is trending in the right direction. As per the 2023 Veterinary Antimicrobial Sales Highlights Report, Category III drugs accounted for 68 per cent of use, and 29 per cent of the use was under Category II. This is an improvement from 2015, where the split between these two categories was basically 50/50.

Overall, if the proposed categorization is accepted, the expanded scope of Category II will result in an artificial increase in the reported use of high-importance antimicrobials even in the absence of

any prescribing change. Conversely, if pressures rise for AMU reduction, prescribers may shift from current Category III products, such as chlortetracycline, to current Category II drugs, such as virginiamycin, which have lower label dosages, thereby appearing to use a lower quantity of antimicrobials, counter to current stewardship messaging.

BFO believes that the proposed recategorization misses the intended point by increasing the misalignment with the WHO and making it even harder for veterinarians and industry to make prudent use of stewardship guidelines.

Within these changes, Health Canada is proposing to recategorize first- and second-generation tetracyclines from Category III to Category II. This proposed change will have a significant impact on beef cattle production.

In Canada, only first-generation tetracyclines—specifically chlortetracycline and oxytetracycline—are used in livestock. These antimicrobials represent the most commonly used class in beef, dairy, and pig production. In beef cattle, their primary use is for the prevention, control, and treatment of liver abscesses, a critical application for maintaining animal health and welfare. Although resistance to first-generation tetracyclines is widespread among various veterinary pathogens, these drugs continue to be highly effective in managing liver abscesses. Recategorizing first-generation tetracyclines as Category II would result in all antimicrobial drugs appropriate for liver abscess therapy being Category II. The other antimicrobials used for this purpose are tylosin and virginiamycin. Without a clear distinction between true Category II antimicrobials and the proposed changes, such as first-generation tetracyclines, producers and veterinarians will have little direction on which one should be used first based on the new categorization of the antimicrobials.

A collaborative approach between the federal government and industry is outlined within the Stewardship pillar of the Pan-Canadian Action Plan on Antimicrobial Resistance (AMR), as it aims to promote responsible antimicrobial use and reduce resistance across human, animal, and environmental sectors. For this reason, we urge the federal government to continue engaging collaboratively with industry, rather than implementing changes unilaterally. Policies and decisions related to drug categorization are most effective when developed through joint efforts, as unilateral actions may inadvertently impact animal health, trade, and Canada's broader antimicrobial stewardship objectives.

BFO urges Health Canada to consult more with industry on how the changes they have outlined in *Proposed Categorization of Antimicrobial Drugs Based on Importance to Human Medicine (Third Version – June 2025 – Draft for Public Consultation)* will play out in a practical sense and undermine the overall goal and value of the Category system. The system also helps all stakeholders to understand which antimicrobials are most important to human health, so industry can follow the stewardship goal of using the lowest category drug that is expected to be effective for the illness they are treating.

Only through a balanced, evidence-based approach can we ensure the continued effectiveness of Canada's antimicrobial stewardship efforts. BFO appreciates the opportunity to comment on such an important topic, and we welcome any future engagement with the Veterinary Drugs Directorate on this issue.

Sincerely,

A handwritten signature in black ink that reads "Craig McLaughlin". The script is fluid and cursive, with the first name "Craig" and last name "McLaughlin" clearly legible.

Craig McLaughlin  
President