

Tighter Controls Lie Ahead in Canada to Ensure Appropriate Use of Medically Important Antimicrobials in Feed and Water

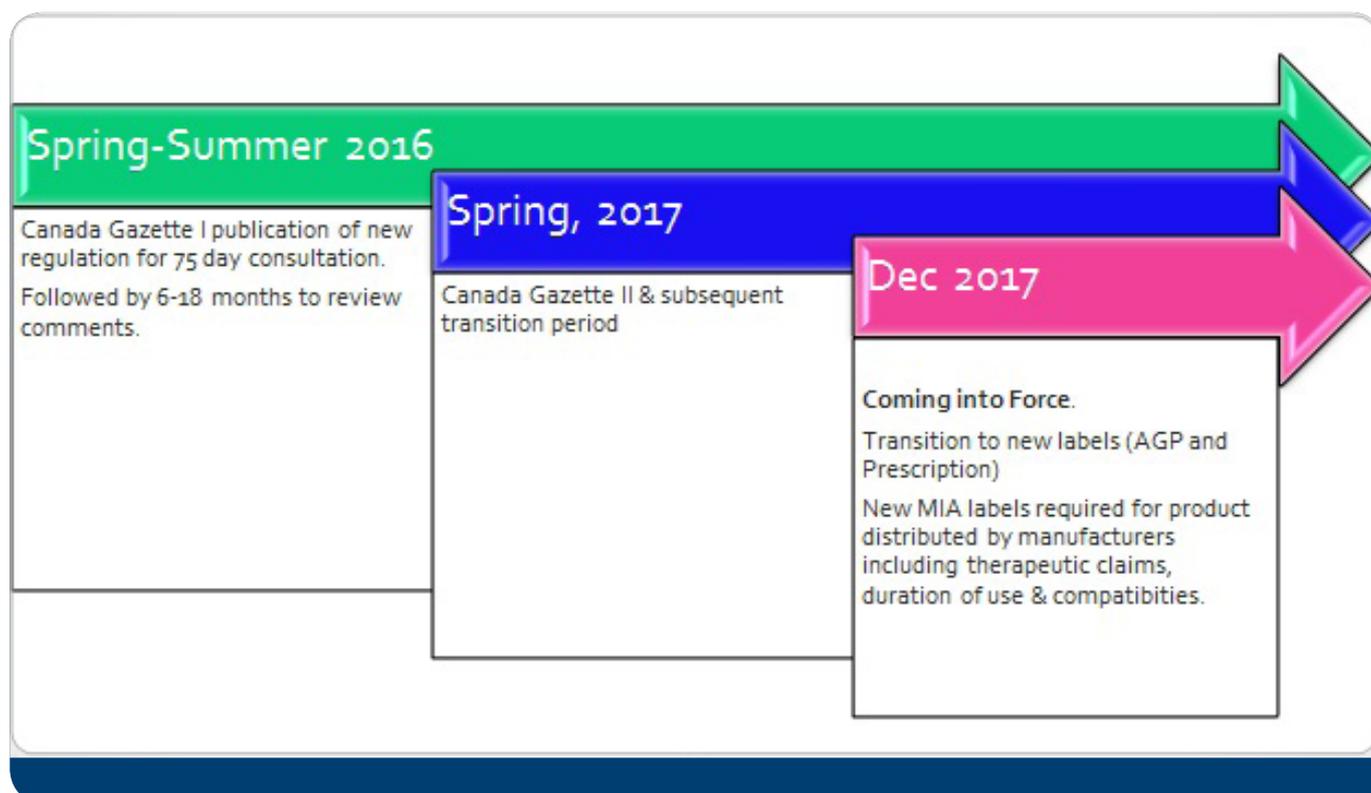
External and internal forces are driving change in Canada to ensure appropriate use of medically important antimicrobials in animals. In 2015 alone there were four key directives made by prominent international organisations around management of antimicrobial resistance. Canada is acting on these resolutions and is implementing initiatives under its own Federal Action Plan on Antimicrobial Resistance and Use.¹

In May 2015, the World Organization for Animal Health passed Resolution #26² which targets the prudent use of antimicrobials as a means of combating resistance. The document outlines the need for surveillance and need for quantitative data on antimicrobial use. Importantly, though, it also urges member countries to have veterinary statutory bodies implement and ensure compliance involving veterinary oversight of medications. Similarly, in June 2015, the Food and Agricultural Organization (FAO) passed a resolution asking countries to demonstrate political leadership in managing antimicrobial resistance and to take actions by preventing the unnecessary use of antimicrobials and by phasing out of growth promotants and by promoting good production practices along with biosecurity and biosafety.³ Political leaders then did take action with the passing of the Berlin Declaration, signed by the health ministers of G7 countries, on Antimicrobial Resistance⁴ in the fall of 2015. The Declaration calls for a 'One Health' approach to managing resistance. It notes that resistance is multi-sectoral in nature and requires the cooperation of nations around; 1) improving infection

prevention and controls 2) preserving the effectiveness of existing and new antimicrobials and 3) engaging in research to optimise approaches and to develop new antimicrobials and find alternatives to using antimicrobials. Canada's major trading partner and immediate neighbour, the United States, also saw its president announce a National Action Plan for Combating Antimicrobial Resistance.⁵ All this to say developed nations are acknowledging the concerns around antimicrobial resistance and taking actions to mitigate harmful outcomes from the use of antimicrobials in humans and animals.

In Canada, the Federal Action Plan on Antimicrobial Resistance and Use was announced in March 2015. It denotes the Public Health Agency of Canada as the lead on the topic with five other federal departments signing off on the initiative. Pillars of the plan revolve around surveillance, stewardship and innovation. From the perspective of animal use of antimicrobials, much is happening. The Canadian Animal Health Institute (CAHI) and Health Canada's Veterinary Drugs Directorate (VDD) are working in partnership to remove the growth promotion claims from medically important antimicrobials (MIA) used in feed and water. Removal of the growth promotion claims involves about 64 products.

MIA products used in feed and water will also come under prescription drug status, bringing them under the oversight





of veterinarians. No longer will over-the-counter sales be permitted for MIA used in feed and water. This means that there will be greater professional intervention of licensed veterinarians prior to the sale of the MIA products, while minimally impacting access to drugs when needed. Prescription status for the MIAs also brings with it the appropriate record-keeping requirements. About 140 products are implicated in the initiative around veterinary oversight.

Greater controls of the importation of veterinary drugs through Health Canada's own use (OUI) provision and on active pharmaceutical ingredient (API) will be happening in concert with removal of the growth promotion claims. In the future, animal owners will not be able to import MIA in finished form from other countries to use on their own animals. Veterinarians and pharmacists will be required to have an establishment licence (EL) with Health Canada when importing API for commercially licensed product. API will also have to meet GMP requirements. Veterinarians will also have to have an EL and meet GMP for API requirements if importing a non-commercially available product. Pharmacists will be exempt from EL and GMP for API requirements if importing an unlicensed product so that they can meet the needs of human medicine.

Controls over OUI and API importation will require regulatory changes. With these changes will also come a change in regulation to allow for a regulatory pathway for "veterinary health products" for both companion and food animals. The current Interim Low Risk Animal Health Product Notification Program for dogs, cats and horses not for slaughter is currently operating by policy only.

It is acknowledged that there will need to be alignment of the regulatory (OUI, API, veterinary drug products) initiatives with those of the non-regulatory aspects of the components of the aforementioned changes (OTC to prescription drug status).

The time frame for the regulatory changes to accommodate the above actions, while subject to some uncertainty, is expected to be as follows;

- Spring/Summer 2016: Canada Gazette I will provide official notice of regulatory amendments associated

with removal of the growth promotant claims from MIA used in feed and water. There will be a 75-day consultation period on the notice followed by a 6- to 18-month time period for government review of the comments.

- Spring 2017: Canada Gazette II provides notice of enactment of regulations as well as orders around enactment.
- December 2017: There will be a transition to the new labels for the MIA products. This will include some updating of therapeutic claims, and on duration of use and compatibility claims.

Canada is taking measures to meet international standards. Human resources are tight in Canada and there was and is much work to do on the initiatives, and a need to consult thoroughly on the changes that lie ahead. Consequently, removal of the growth promotion claims and veterinary oversight of the MIA used in feed and water will lag behind the US by one year. Controls over OUI and API will result in Canada being more closely aligned with other developed countries, inclusive of its trading partners. The changes outlined will contribute to improved knowledge around use of MIA and lead to further discussion around a Pan-Canadian strategy to manage antimicrobial resistance.

References

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Jean serves on a number of agricultural Boards and has a love for equine sports. She lives with her husband and son on a farm near Guelph, Ontario.

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