CANADIAN CATTLEMEN'S ASSOCIATION

National Voice Of Cattle Producers

Backgrounder

Important changes to how producers can access antimicrobials

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Antimicrobial Resistance (AMR) is a global issue that impacts the ability of medicines to treat infections and disease in both animals and humans. Action is being taken around the world on reducing the risk of AMR. Canada has its own pan-Canadian framework to address AMR including some changes to how livestock producers can access antimicrobials. Of note to beef producers is a change to the own use importation (OUI) process, effective November 13, 2017. Additional changes will see claims for growth promotion dropped from labels of medically important antimicrobials used in livestock production, and access to these products restricted to prescription only effective December 1, 2018.

Canada's beef industry has a proven track record of prudent and judicious use of veterinary antimicrobials, however we recognize that all stakeholders in Canada's human and animal health systems must play a role in minimizing AMR development. These changes ensure that the antimicrobial products we have now continue to be effective into the future. Additionally, the enhanced tracking associated with these changes should help improve consumer confidence in how the beef industry accesses and uses antimicrobials.

The laying of the groundwork for these changes began last year with drug manufacturers (voluntarily) rescinding the label claim for growth promotion from medically important antimicrobials used in livestock production. These included all products in Categories I, II, and III deemed very high importance, high importance and medium importance to human medicine respectively. (There are very few medically important (Class I, II or III) antibiotics that have a growth promotion claim for cattle.) This change will affect a total of eight in-feed products. Four of these will have the label modified to remove references to growth and feed efficiency, while leaving the health-related claims intact. The other four in-feed products only have a feed efficiency label claim and may be taken off the market, unless a health-related label claim is approved. Ionophores (monensin, etc.) are Category IV, and will keep their growth promotion claims. The target date for this policy to be fully effective is December 1, 2018. No new medically-important products approved for livestock have been permitted a growth promotion claim since 2004.

More recently, Health Canada consulted upon, and then published in *Canada Gazette II,* regulatory amendments to the Food and Drugs Regulations for Veterinary Drugs. These amendments included:

- veterinary Active Pharmaceutical Ingredients (APIs) imported or sold in Canada must be manufactured in accordance with Good Manufacturing Practices (GMPs);
- persons who fabricate, package/label, import or test an API for veterinary use must to do so in accordance with an Establishment Licence (EL);

- own use importation (OUI) of certain unauthorized drugs (including APIs) is restricted;
- manufacturers and importers must provide sales volume information by species for veterinary antimicrobials; and
- the introduction of an alternative, more appropriate pathway for manufacturers to legally import and sell low-risk Veterinary Health Products (VHPs).

Additionally, a policy set by Health Canada effective December 1, 2018 will require that all Category I, II, and III antimicrobials may only be sold pursuant to the presentation of a valid prescription. Prescriptions from a veterinarian will be required regardless of route of administration, so injectables, in-water and in-feed formulations are all affected. This will mean all livestock producers will require a valid Veterinary-Client-Patient Relationship (VCPR) in order to obtain the necessary prescription to access these antimicrobials. These products will only be available from a veterinary drug dispensary or pharmacy, subject to provincial regulations on veterinary drug dispensing. This is an important change. For instance, antimicrobials that many producers commonly use to treat calf scours or footrot will no longer be available over the counter at farm supply stores or feedmills.

Of particular interest to beef producers are the changes to the own use importation process. The established CCA policy has always been that only products already approved for use in Canada should be imported for own use and limited to over the counter products including parasiticides. The objective for this policy has always been about price control and competitiveness for our industry, not about accessing new products not available in Canada.

One option was to shut down OUI completely. However, through the consultation process, industry prevailed in maintaining a process for OUI that will continue to allow specified products to be imported for own use by a livestock producer. Effective November 13, 2017, only those products registered on "List B," published on the Health Canada website will be permitted for OUI. These will not include any Category I, II, or III antimicrobials, biologics (vaccines) or pesticides regulated under the Pest Management Regulatory Agency (PMRA).

The need for a valid VCPR will likely help some producers who could benefit from interacting with their veterinarian more frequently. That will help elevate the overall herd health and welfare management of industry.

However, these changes come with some significant challenges, particularly as the feed and livestock industries adapt to the new rules. Antibiotic prices may rise, because fewer businesses will be able to sell them. Not all provinces legally allow veterinary pharmacies to be established. Large operations that do on-farm feed mixing may have fewer options regarding where they are allowed to purchase certain types of medicated products. Feedmills are not pharmacies, so they won't be allowed to sell bags of tetracycline or tylosin for on-farm mixing.

Similarly, it is unclear at this time whether wholesaler distributors will be allowed to sell prescription product directly to producers, even with a valid prescription. Producers in remote areas will be particularly affected. They will need to do much more careful pre-planning of their animal health program, in collaboration with their veterinarian, to ensure that they maintain an adequate inventory of antimicrobials to respond to animal health emergencies that occur outside of normal working hours, or when timely on-call veterinary service is particularly difficult to access.

The Canadian beef industry's stellar history of responsible use of veterinary antimicrobials is a matter of public record, as evidenced by random residual drug testing at processors and the surveillance program conducted by

the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), under the Public Health Agency of Canada.

Since 2002 CIPARS has collected and tested samples from abattoirs and retail beef. The surveillance shows that resistance to antimicrobials of the highest importance in human health is very low and not increasing in Canada. The same holds for multi-drug antimicrobial resistance. Similar results have been seen in a series of collaborative studies conducted by industry and government research teams in commercial Canadian feedlots since the late 1990's.

The very low level of antimicrobial resistance observed in Canadian cattle and beef indicate that Canada's cattle producers use antimicrobials prudently. Research confirms this; over 90 per cent of the antimicrobials used in feedlot production are ionophores – a class of antimicrobial not used in human medicine.

Still, there is always room for improvement from all stakeholders. These include doctors, hospitals, and patients on the human side; veterinarians, producers and animal care givers on the livestock side. Our mutual goal is to ensure that the medicines we currently have, and new ones in the future, will be effective when used properly.

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