

24 May 2024

Chemical Review

Australian Pesticides and Veterinary Medicines Authority

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Public consultation: Neomycin – proposed decisions on reconsideration

Australian Dairy Farmers (ADF) welcomes the opportunity to provide a submission on the proposed decisions on the reconsideration of neomycin product registrations and label approvals.

The ADF is the national industry representative body (IRB) for dairy farmers across Australia. The Australian dairy industry is the third largest rural industry in Australia and a key sector of the agricultural and Australian economy, generating close to A\$6.1 billion in farmgate value in the 2022/23 financial year¹.

As the recognized national representative body for dairy farmers across the six dairy producing States, ADF's mission is to improve the productivity and sustainability of dairy farmers in Australia. Critical to this mission is to maintain and improve Australia's animal health and welfare systems. ADF is comprised of State dairy farming representative organisations, and dairy farmers themselves, from all of the dairy producing States of Australia.

Mastalone® Intramammary Suspension For Lactating Cows (CRIS# 49851) is considered by ADF to be a vital tool for dairy farmers to treat clinical mastitis. Mastitis is a painful disease, causing significant animal welfare concerns and economic losses on every dairy farm. Timely and appropriate treatment is essential for the welfare of the affected animal(s).

Mastalone® contains antibiotic active constituents (Oxytetracycline, Oleandomycin and Neomycin) that are not available in other registered intramammary products, are of low importance to the development of antimicrobial resistance² and cover a broader spectrum of mastitis pathogens than alternative products. It provides an important alternative product to other intramammary lactating cow products, which contain only beta-lactam antibiotic active constituents.

ADF is aware of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) responsibility to assess the efficacy, safety and risks to trade of all products captured within the scope of the APVMA's review of neomycin.

¹ Australian Dairy Industry In Focus 2023 (2024) Dairy Australia, Level 3, HWT Tower, 40 City Rd., Southbank VIC 3006

² Australian Strategic and Technical Advisory Group on Antimicrobial Resistance. (2018, June). Importance Ratings and Summary of Antibacterial Uses in Human and Animal Health in Australia. Australain Government.

ADF is extremely concerned that the APVMA proposes to cancel the registration of Mastalone®, primarily due to a lack of data to enable the APVMA to assess risks to trade from chemical residues.

ADF considers there is a very real risk of an inappropriate and perverse regulatory outcome if Mastalone® were deregistered. By removing registration of a tried and tested, broad-spectrum, low risk product, the availability of a poorer selection of products covering a narrower spectrum of pathogens at arguably higher risk may result. This may lead to inferior animal-welfare outcomes in Australia's third largest agricultural sector.

In appealing for ongoing access to Mastalone as a vital tool for farmers, ADF makes the following points:

- Mastalone® has been used for over 50 years by dairy farmers in Australia when treating severe cases of mastitis or as a second-line treatment where others have failed.
- The industry has a long history of monitoring for, and successfully managing the risks of antimicrobial residues in milk and meat products traded domestically and around the world.
- Individual farmers place high importance on adhering to risk-management procedures, particularly when drug treatments are involved.
- Through industry's established chemical residue risk management procedures, ADF is unaware of Mastalone® being identified as posing a risk to the health of consumers of dairy products or to trade in such products.

Dairy Australia is providing a separate submission to provide more detail on the industry's risk management procedures for antibiotic residues, which are endorsed by ADF.

ADF and its representative member State dairy farmer organisations do not consider the ongoing label-compliant use of Mastalone® as posing a risk to the domestic or international trade of dairy products, and so support the on-going registration of this vital intramammary product.

Yours sincerely



Ben Bennett,

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