

8 January 2014

RASML Officer
OTC Medicines Evaluation
Office of Medicines Authorisation
Therapeutic Goods Administration (TGA)
PO Box 100
WODEN ACT 2606

Via email: rasml@tga.gov.au

Dear RASML Officer

Proposed advisory statements for chloramphenicol, propamidine, dibromopropamidine and sulfacetamide

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) has reviewed the TGA's proposed advisory statements for chloramphenicol, propamidine, dibromopropamidine and sulfacetamide.

RANZCO's mission is to drive improvements in eye health care in Australia, New Zealand and the Asia Pacific region through continuing exceptional training, education, research and advocacy. Underpinning all of RANZCO's work is a commitment to: best patient outcomes; providing contemporary education, training and continuing professional development; evidence based decision making; collaboration; and collegiality. RANZCO also seeks to educate the general public in all matters relating to vision and the health of the human eye and advocates for accessible ophthalmology services for patients.

RANZCO supports inclusion of the two statements '*Contact lens wearers should not use this product except on the advice of a doctor or optometrist*' and '*If your eye infection does not start to improve within 48 hours, seek immediate medical advice*' on labels for all four agents.

With respect to the statement '*Do not use in children under 2 years of age except on medical advice*', RANZCO remains concerned about medically unsupervised use of antibacterial agents in infants due to the risks associated with delayed diagnosis. The TGA has indicated that part of its



rationale for inclusion of this statement on labels for chloramphenicol is '*to exclude serious causes of red eye that can lead to permanent impairment of vision, particularly when the eyes of infants are developing*'. This rationale applies equally to propamidine, dibromopropamidine and sulfacetamide. As such, RANZCO recommends the statement be required on labels for all four agents.

Should you require any further information in relation to this submission, please contact RANZCO Policy Officer, Ritu Mohan at rmohan@ranzco.edu.

Yours sincerely



Gerhard Schlenther
General Manager, Policy and Development