



17 May 2021

Sven Johanson
RASML Officer, OTC Medicines Evaluation Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: sven.johanson@health.gov.au

Dear Mr Johanson,

RE: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Lidocaine (lignocaine)

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

SHPA welcomes the opportunity to provide feedback to the TGA on the proposed changes to Required Advisory Statements for Medicine Labels (RASML) for Lidocaine (lignocaine). In preparing this submission, SHPA has consulted with our Medication Safety, Medicines Information, Women's and Newborn Health, and Paediatrics and Neonatology Speciality Practice groups.

SHPA members, in principle, support the proposed changes to the RASML for lidocaine in preparations for topical oral use. However, SHPA members believe the suggested draft wording, "*Do not use for teething pain in children*", could be altered to refer parents to their health professionals for advice.

SHPA is concerned that such a definitive warning statement as proposed by the TGA, may result in confusion and concern if parents were indeed advised by a health professional to utilise this product for their child.

SHPA members therefore recommend an alternative phrasing such as, "*Consult a doctor or pharmacist before using for teething pain in children*" to be included in the warning label for topical oral preparations containing more than 1.5% lidocaine base.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, A/g General Manager, Advocacy and Leadership on jyik@shpa.org.au.

Yours sincerely,

A handwritten signature in black ink that reads 'Kristin Michaels'.

Kristin Michaels
Chief Executive



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