



17 May 2021

Sven Johanson  
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Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606

Email: [sven.johanson@health.gov.au](mailto:sven.johanson@health.gov.au)

Dear Mr Johanson,

**RE: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Sedating antihistamines**

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 sedating antihistamines. 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 supports the proposed changes to the RASML for non-prescription medications containing sedating antihistamines.** SHPA believes these changes and the suggested wording is reasonable and makes the warnings now consistent with TGA pregnancy categorisations, available safety evidence, Therapeutic Guidelines and the Australian Medicines handbook. This reduce confusion and concerns amongst pregnant and breastfeeding women who are prescribed or advised to these medicines by healthcare professionals.

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](mailto:jyik@shpa.org.au).

Yours sincerely,

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

Kristin Michaels  
Chief Executive



**The Society of Hospital Pharmacists of Australia**

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