



Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Chlorhexidine, hydrocortisone, ibuprofen

Do you support the proposed conditions and wording of the advisory statements? If there are aspects you do not support, please explain why you do not support them? You may make suggestions for alternative wording or additional statements that you think are suitable. You may wish to include an assessment of how the proposed change will impact on you; that is, what do you see as the likely benefits or costs to you (these may be financial or non-financial).

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 chlorhexidine, hydrocortisone and ibuprofen. In preparing this submission, SHPA has consulted with our Medication Safety and Medicines Information Speciality Practice groups.

SHPA supports the proposed changes to the RASML for chlorhexidine, hydrocortisone and ibuprofen. SHPA believes these changes and the suggested wording is reasonable and makes the warnings now consistent with available safety evidence.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jjik@shpa.org.au.

Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Melatonin

Do you support the proposed conditions and wording of the advisory statements? If there are aspects you do not support, please explain why you do not support them? You may make suggestions for alternative wording or additional statements that you think are suitable. You may wish to include an assessment of how the proposed change will impact on you; that is, what do you see as the likely benefits or costs to you (these may be financial or non-financial).

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SHPA welcomes the opportunity to provide feedback to the TGA on the proposed changes to Required Advisory Statements for Medicine Labels (RASML) for melatonin. In preparing this submission, SHPA has consulted with our Medication Safety, Medicines Information Speciality Practice groups.

SHPA supports the proposed changes to the RASML melatonin. SHPA believes these changes and the suggested wording is reasonable and makes the warnings now consistent with TGA pregnancy categorisations, available safety evidence.

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Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Mometasone

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SHPA welcomes the opportunity to provide feedback to the TGA on the proposed changes to Required Advisory Statements for Medicine Labels (RASML) for mometasone. In preparing this submission, SHPA has consulted with our Medication Safety, Medicines Information Speciality Practice groups.

SHPA supports the proposed changes to the RASML for both the dermal and nasal spray preparations of mometasone. SHPA believes these changes and the suggested wording is reasonable and makes the warnings now consistent with TGA pregnancy categorisations, available safety evidence.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Triptans

Do you support the proposed conditions and wording of the advisory statements? If there are aspects you do not support, please explain why you do not support them? You may make suggestions for alternative wording or additional statements that you think are suitable. You may wish to include an assessment of how the proposed change will impact on you; that is, what do you see as the likely benefits or costs to you (these may be financial or non-financial).

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SHPA welcomes the opportunity to provide feedback to the TGA on the proposed changes to Required Advisory Statements for Medicine Labels (RASML) for triptans. In preparing this submission, SHPA has consulted with our Medication Safety, Medicines Information Speciality Practice groups.

SHPA provides in-principle support for the proposed changes to the RASML for triptans. SHPA however, has concerns around the use of technical language such as monoamine oxidase inhibitors (MAOIs) which will not be understood by the majority of consumers, and limiting its indications to depression given it can at times be used for anxiety too. We recommend simply stating *“do not use/consult your doctor or pharmacist before use: if you have taken a medication used to treat depression or anxiety...”*

SHPA also recommends that wording for the zolmitriptan RASML should stipulate the interval of time since using a MAOI. International sources such as Stockleys, DrugDex and Lexicomp Drug Interactions, state that there should be a 14-day gap between ceasing a MAOI and starting zolmitriptan due to the risk of serotonin syndrome. SHPA therefore proposes the following changes to the RASML for zolmitriptan, *“consult your doctor or pharmacist before use: if you are taking or have taken medications for depression or anxiety in the last 2 weeks.”* These changes and the suggested wording will ensure the warnings are consistent with available safety evidence.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.



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