17th March 2015

RASML Officer
OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
Woden
ACT 2606
AUSTRALIA

Email: rasml@tga.gov.au

Dear Sir / Madam

CONSULTATION: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs) FOR ORAL USE – PROPOSED ADVISORY STATEMENTS FOR MEDICINES

NZSMI (New Zealand Self Medication Industry Association) is pleased to be able to respond to the above consultation with our submission. We have taken cognisance of the TGA's report and also their options for consideration with our response below.

NZSMI is the premier body in New Zealand representing companies that are involved in the manufacture, distribution, marketing of consumer healthcare products. We represent approximately 85% of the companies who trade in over the counter medicines in New Zealand.
Executive Summary

- NZSMI supports the proposed warning statements as outlined in the consultation document released on 4 February 2015 and further states that the wording is acceptable from this industry association. To be precise we support:
  
  The labels of oral medicines containing flurbiprofen, ibuprofen, ketoprofen, mefenamic acid or naproxen to the effect that "excessive or prolonged use can increase the risk of heart attack or stroke"
  
  The labels of oral medicines containing diclofenac to the effect that "excessive or prolonged use can increase the risk of heart attack, stroke or liver damage"
  
  NZSMI believes these statements are succinct and can be easily understood by patients and consumers. In our view they will remove the risk of inappropriate use.
  
  Some of our sponsor companies already include "similar" wording and therefore it is important to provide clarity around what alternative statements will be acceptable to the regulator and could be included in RASML as alternative acceptable statements.
  
  • With regard to paediatric products there appears to be no direction on the need for inclusion of the proposed warning statements. NZSMI would respectfully suggest that the same requirement for warnings regarding CV factors in adults is much less of a factor in children under 12 years of age. We therefore suggest that there is no need to include these statements on equivalent paediatric products.

- Harmonisation with other jurisdictions with regard to warning statements, especially with the close proximity between Australia and New Zealand, should be encouraged. The warning statements as proposed by the TGA following the consultation and review process should in our view be applied both in Australia and New Zealand.

- NZSMI supports an 18 month transition period. This has increased from the 12 months in our earlier September 2014 submission due to the fact that most members have just completed updating labels as a result of RASML 2 of the Medicines Advisory Statement spec. 2014 (MASS 2014). These additional warning statements will therefore require a further update change.

- NZSMI would further comment on the critical importance of excellent communication and education of the changes to label statements and warnings. This communication will require information to both health practitioners and consumers alike. There is a real chance of consumers being unnecessarily frightened by label warning changes if the communication is handled poorly.

- NZSMI believes that all stakeholders need to agree both the level and the content of communication that is disseminated from the TGA.