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CONSULTATION RESPONSE

THE TRANS-TASMAN EARLY WARNING SYSTEM –
"HOW THE PROCESS WILL WORK IN AUSTRALIA AND NEW ZEALAND"

Introduction

The New Zealand Self Medication Industry (NZSMI) is the representative trade organisation for the major *"over the counter"* (OTC) medicine sponsor companies within New Zealand.

We appreciate the opportunity to make comment on the consultation paper and hope our comments are taken in a constructive manner to assist in developing the final document.

We are willing to support our comments verbally if required and meet with representatives of Medsafe if appropriate.

Yours faithfully

Tim Roper
Executive Director
New Zealand Self-Medication Industry

EXECUTIVE SUMMARY

NZSMI appreciates the opportunity to respond to this consultation document. Further, involvement in the workshop process in April 2012 was helpful in bringing about the changes that are now proposed in this Early Warning System consultation. As an organisation NZSMI is supportive of the concept of a trans-Tasman Early Warning System which would indeed provide timely communication on safety issues to consumers and health professionals. Nevertheless the way the process is implemented will be critical to its success in meeting stated objectives and the principles of the Early Warning System.

NZSMI represents the OTC medicine sponsors and recognise that prescription medicines are more likely to be the focus of a monitoring communication or alert. The products that we are involved with are inherently low risk products which generally have a favourable safety profile and a long history of use. Notwithstanding there may be occasions in the future when an OTC medicine becomes the subject of a monitoring communication or an alert and therefore our thoughts on this subject should be given appropriate recognition.

NZSMI highlights its concerns by way of the bullet system below.

- ***International best practice***
  NZSMI is concerned that in developing any new system that regulators in other jurisdictions across the globe, particularly USA, Canada and Europe are considered when developing a new Early Warning System. In particular we highlight the effectiveness of the M2 programme developed in New Zealand and believe there are good reasons why this should be applied across both countries. Further, procedures in the European Union (EU) should also be given close consideration and embraced in the development and implementation of the Early Warning System. We are of the view that international best practice is the way forward in the development of ANZTPA schemes and systems, rather than those that are Australia and New Zealand specific.

- ***Sponsor engagement***
  In our view it is critical that sponsor engagement responses should be an inherent part of the Early Warning System. Following the publication of a monitoring communication or an alert about a product, it is inevitable that sponsors will receive an increased number of consumer and healthcare professional enquiries. We are concerned that the consultation document does not specifically involve sponsor engagement to the level that we would expect. NZSMI believes that sponsors are key stakeholders in the process and will inevitably be affected commercially by the publication of an alert of a communication. NZSMI therefore believes Medsafe and the TGA have a responsibility to engage with sponsors during the assessment process when decisions are being made about a possible communication or alert. We would respectfully suggest that the section on sponsor engagement should be amended to reflect the importance of the TGA/Medsafe and sponsor communication at all of the critical steps – detection of safety signals, assessments, decisions on possible communications or alerts as well as requests to check for factual inaccuracies.

- ***Timeline predictability***
  The trans-Tasman Early Warning System needs to include a commitment for clear timeframes based on the complexity of the safety issue, any associated risk communications, applications and workload required. NZSMI cannot detect any estimates of timelines in the management of potential safety issues in the consultation document released.

A lack of clarity on timelines associated with safety reviews impacts the sponsor's ability to update relevant information for patients and healthcare professionals.

- ***Decision criteria***
  NZSMI are concerned about some aspects of the decision criteria for initial assessment / risk analysis as well as signal investigation / assessment step. Decisions on whether or not to proceed with a monitoring communication or an alert should be based on objective criteria and scientific evidence. NZSMI agree that a potential safety concern should meet the definition of a serious adverse event or it should follow advice from an expert advisory committee.

  TGA/Medsafe should consider developing additional tools or criteria to enable decision makers to make accurate, consistent and appropriate decisions, based on the number of reports, the robustness of the information contained in the reports and their seriousness.

- ***Initial safety communications***
  NZSMI believes that all consumer information should be carefully worded and in keeping with sound communication principles. Consumers, many of whom have low levels of literacy and understanding of health and regulatory issues, will be expected to read, understand and act upon and follow the monitoring communications and alerts. Consumer communications therefore should be carefully worded and structured so that they are easy to comprehend and not alarmist.

- ***Mechanisms for appeal***
  Consideration should be given to mechanisms for review of decisions and appeals – what avenues will be made available for decisions to be challenged or appealed? This is an important consideration given the potential commercial impact on a sponsor, as well as the impact on a sponsor's or manufacturer's reputation following a possible alert.

- ***Review of the Early Warning System after implementation***
  NZSMI encourages TGA/Medsafe to consider a review of the Early Warning System after a suitable period of operation, for example, 18 months to 2 years. This will allow examination of its strengths and weaknesses and provide an avenue for further refinement of the system.

- ***Costs***
  NZSMI notes that the cost for the Early Warning System has not been discussed in any depth. It would be helpful to have some discussion prior to implementation

CONCLUSION

NZSMI appreciates the opportunity to provide input into the Early Warning System through this consultation- in addition to participation in the workshops held in April 2012. We are supportive of an Early Warning System that has the potential to affect all who have an interest in healthcare, whether they be healthcare professionals, consumers, sponsors, manufacturers as well as overseas regulators.

Our concerns have been expressed in the Executive Summary in bullet form. Nevertheless despite these concerns, NZSMI is a strong advocate for increased TGA/Medsafe transparency and we remain committed to work with TGA/Medsafe and other stakeholders to bring about meaningful reform in this area.

The trans-Tasman Early Warning System has the potential to provide improved patient outcomes, avoidance of adverse effects through timely communications of safety issues,

increase transparency and the benefits that his may have by improving confidence in the health system as well as the role of the regulator.

Hopefully our comments above have been helpful in further developing the trans-Tasman Early Warning System.