25 May 2014

Medsafe
PO Box 5013
**WELLINGTON**

**Email:** alyssa_currie@moh.govt.nz

**CONSULTATION RESPONSE**
**RE: Proposed changes to evaluation administrative processes**

Dear Alyssa,

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 document 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

**Proposed changes to format of correspondence**

NZSMI fully supports the move to electronic communication. We would however point out that if Medsafe receives notification that an email could not be delivered then Medsafe should still insist upon companies confirming receipt of each communication. It will be incumbent on sponsor companies to be vigilant about monitoring email accounts for all staff where staff changes have been made. It will also be a requirement for sponsors to notify Medsafe where email addresses may have been changed and we see this as good business practice.

With regard to the paragraph, ***"All correspondence will be emailed as PDF attachments with Medsafe letterhead and an electronic signature inserted into the letter***", NZSMI would point out that a number of sponsors have been receiving PDF attachments from Medsafe in varying formats, e.g. some with no letterhead or signature and some with letterhead but no signature. NZSMI's view is that this makes the letters look unofficial to sponsors and their respective clients. Medsafe needs to have an internal check process to ensure that all PDFs they issue have both letterhead and signature.

**Proposed changes to requirements for electronic submissions**

Under the paragraph, *"Applicants would continue to be required to submit applications and responses to RFIs in hardcopy*, *Medsafe does not have the facility to receive applications and responses to RFIs via email".*

Although NZSMI acknowledges that currently Medsafe do not have the capacity to receive applications and response to RFIs via email, we do not agree with the requirement that applicants are required to submit applications and response to RFIs in hardcopy. We suggest this be amended to electronic copy or hardcopy. This would seem to align with the move by TGA to a paperless system.

We note that *"Medsafe is proposing that electronic copies of SACNs and small CMNs would not be mandatory"*. As this particular statement was made in the paragraph relating to Over The Counter (OTC) applications, we would wish to seek clarification that the proposal that electronic copies of SACNs and small CMNs not be mandatory does not relate **specifically** to OTC applications.

Further, we would ask for specific clarification around the statement *"small CMN"*. There seems to be a lack of a consistent approach to submissions in this regard; the interpretation of small CMN varying from one evaluator to another.

It is also unclear whether any changes are proposed to the current requirement of "*Currently it is mandatory for all Over the Counter (OTC) applications to include two electronic copies of all submissions*", as the statement is not followed by any decision to retain or change the requirements.

For the avoidance of doubt, we suggest that Medsafe place a statement on their website stating that only electronic versions of communications will henceforth be issued and these constitute official Medsafe documents.

In summary, NZSMI is supportive of the move on the proposed changes to evaluation administrative processes with the proviso that the comments made above are taken into consideration and clarification is obtained where required.