Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Ms Catherine Gwynne / Ms Jane Parker
Australian Self Medication Industry
PO Box 764
NORTH SYDNEY NSW 2059

Ms Kristy Thomas
Complementary Healthcare Council of Australia
PO Box 104
DEAKIN WEST ACT 2600

Dear Catherine, Jane and Kristy

I am writing further to our meeting on 13 October 2010 in which we discussed the TGA's adverse event reporting requirements for registered OTC and listed medicines; and related matters.

Specifically, you pointed out the proposed arrangements pre- and post-ANZTPA and noted these were never finalised. This in turn has lead to an ongoing inconsistency between the requirements for reporting non-serious adverse events for prescription and non-prescription medicines, as currently published on the TGA website.

For prescription medicines, "other reactions (non-serious unexpected reactions and non-serious expected reactions) occurring in Australia should not be notified immediately but should be reported on request or as line listings in a Periodic Safety Update Report". Whereas, for registered OTC and listed medicines, "other reactions, although not warranting the same urgency, should also be reported to the TGA ('regularly') using the "blue card" format, as the sponsor becomes aware of the report(s)".

These arrangements effectively impose more stringent reporting requirements upon non-prescription medicines than for prescription medicines. As discussed during our meeting, I now reaffirm my agreement with your proposal that the aforementioned reporting requirement for non-prescription medicines be aligned with that for prescription medicines. From our meeting, I also note that this would also ensure consistency with current industry practice.

Of course (and as I also mentioned during our meeting), this change to the currently published process should in no way diminish the TGA's capacity to be able to quickly respond to an emerging trend or concern. In this regard, sponsors should still be able to urgently provide information upon request about non-serious events involving non-prescription medicines where an unusual or unexpected situation arises which requires further investigation.

I will arrange for the relevant documents on the TGA website to be updated and trust this information will be of assistance to you.

Yours sincerely

Larry Kelly
Group Coordinator
Monitoring and Compliance Group
8 November 2010

cc. Mr Pio Cesarin – Head: Office of Medicines Authorisation
Mr Michael Smith – Head: Office of Complementary Medicines