



Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Email: recalls@accc.gov.au

Dear Sir/Madam

CHC Submission: A guide to the mandatory reporting law in relation to consumer goods, or product related services, associated with death or serious injury or illness – Consultation Draft August 2010.

Thank you for providing the complementary healthcare industry an opportunity to comment on the Consultation Draft for guides to mandatory reporting for consumer goods, dated August 2010.

The Complementary Healthcare Council (CHC) is the leading expert association exclusively committed to a vital and sustainable complementary healthcare products industry. The CHC is unique in representing all stakeholder groups in the complementary healthcare industry, including importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers.

The CHC strongly supports consumer safety with respect to complementary medicines and endorses appropriate reporting means relating to adverse events however, provides the following comments for consideration.

Reporting timeframe

The CHC notes that the reporting regime proposes that a supplier must, within two days of becoming aware, provide a written report (notice) to the Commonwealth Minister. Currently, any adverse events associated with a complementary medicine, must be reported to the Office of Medicines Safety Monitoring (within the Therapeutic Goods Administration).

The complementary healthcare industry complies with requirements outlined in the *Australian Pharmacovigilance Guideline* which states that any serious adverse event associated with a complementary medicine, must be reported within 72 hours of becoming aware of the matter. Given a timeframe for reporting events is already in place, and functions well, the CHC proposes that the Therapeutic Goods Administration continue to oversee the reporting for complementary medicines.

Circumstances for not reporting

The guidance document stipulates that '*where the supplier or another person is already required to report death, serious injury or illness: under a Commonwealth, State or Territory law specified in regulations established under the ACL, or under an industry code specified in regulations established under the ACL*'.

The CHC notes that the laws and codes to be specified in the ACL have yet to be finalised. The CHC suggests that therapeutic good legislation be captured in this list which would allow continuation of the current model for reporting adverse events.

Please do not hesitate in contacting me for further information about the comments within this submission.

Yours sincerely



Dr Wendy Morrow
Executive Director
Complementary Healthcare Council

20 September 2010