



**CHC Submission to the Therapeutic Goods Administration on draft approach
to disclosure of commercially confidential information (CCI)**

To:

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From:

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Date:

29 August, 2013

Introduction

The Complementary Healthcare Council of Australia (CHC) thanks you for the opportunity to provide comment on the Therapeutic Goods Administration draft approach to disclosure of commercially confidential information (CCI), version 1.0 (draft) June 2013.

The CHC is the peak industry body representing companies involved in all facets of the complementary medicine industry from: sponsors, manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable complementary medicines industry. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality, contributing to improved population health outcomes.

1. The CHC notes that the approach outlined for what is meant by commercially confidential information is consistent with the definition used by the EMA and includes:

“Any information which is not in the public domain or publically available, and where disclosure may undermine the economic interest or competitive position of the owner of the information.”

2. Commercially confidential information held by the TGA may include ... “certain information about clinical trials,” including the “outcome of testing of a product or investigations into its performance.”
 - a. The CHC supports the intention of this statement that re-affirms that clinical data is considered CCI under established practices.
3. The CHC is concerned that there is other information that is generated by the TGA that could be considered equally confidential and its release could be damaging to sponsors/manufacturers. For example, TGA Inspection Reports of Licensed Manufacturers. Previously, these reports included “Commercial-in-Confidence” on the footer of each page. Because these reports contain information that is not specifically supplied to the TGA as “commercial-in-confidence”, but rather gathered by TGA inspectors in conducting TGA Inspections of Licensed Manufacturers, it would seem that this type of information may not be considered as confidential.
 - a. The CHC submits that the information contained in TGA Inspection Reports of Licensed Manufacturers is also of a very confidential nature. It could be used to the detriment of the manufacturer if it was obtained by competitive manufacturers. For example, this type of information could be used to influence the public to only use a particular manufacturer over another due to better equipment, quality systems, IT systems, or for any other reason.

4. The CHC supports that in addition commercial entities will have avenues to contest the release of any information they believe to be CCI. "Any decision to release information to the public on a regular or systematic basis about any aspect of its (the TGA) regulatory functions that could involve the release of commercially confidential information will be preceded by consultation with affected stakeholders and the release appropriately authorized under legislation."