



Public Health Association
AUSTRALIA

**Submission from the Public Health Association of Australia on
the transparency of the TGA**

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Review the Transparency of the TGA
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Background

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles.

The PHAA is a national organisation comprising around 1800 individual members and representing over 40 professional groups concerned with the promotion of health at a population level. This includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the Association’s role.

Key roles of the organisation include capacity building, advocacy and the development of policy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. The PHAA has been a key proponent of a preventive approach for better population health outcomes championing such policies and providing strong support for the government and for the Preventative Health Taskforce and NHMRC in their efforts to develop and strengthen research and actions in this area across Australia.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the

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development of policies. In addition to these groups the Australian New Zealand Journal of Public Health draws on individuals from within the PHAA who provide editorial advice, review and who edit the Journal.

In recent years the PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all aspects of government and promoting key policies and advocacy goals through the media and other means.

The PHAA is grateful for the opportunity to comment on the issues and express our real concerns around the issue of transparency at the TGA.

Transparency: using international benchmarks

In 2009, the World Health Organization produced a manual of indicators “Measuring Transparency in the Public Pharmaceutical Sector”.¹ The PHAA suggests that it may be useful for the TGA to review its performance using relevant indicators from this document.

In addition, there is considerable activity going on to improve transparency by the European Medicines Agency (EMA)² and the U.S. Food and Drug Administration (FDA).³

The PHAA suggests that, at the very least, the transparency provisions of the TGA should be comparable with those being implemented by the EMA and the FDA.

Clarifying what is and is not “commercial-in-confidence” information

The TGA appears to interpret “commercial-in-confidence” considerations very broadly compared to **EMEU guidelines. In addition, Section 47 (b) of the Freedom of Information Amendment (Reform) Act 2010 states that a document is an exempt if its disclosure under this Act would disclose, “any other information having a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.** This provision has resulted in the TGA refusing to provide test results on the adulteration of herbal products and adverse effects of therapeutic goods as reported by sponsors to the TGA.

At the EMA, any information encompassing nonclinical and clinical development of the medicinal product and the subsequent assessment by the CHMP (Committee for Medicinal Products for Human Use) is recognised as not commercially confidential and, therefore, its deletion cannot be accepted as a general rule”.⁴

The PHAA believes that Section 47 (b) of the Freedom of Information Amendment (Reform) Act 2010 should be removed and the EMA guidelines used to clarify “commercial-in-confidence” considerations.

¹ <http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF>

² http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf

³ <http://www.nejm.org/doi/full/10.1056/NEJMp1005202>

⁴ http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC50004043.pdf

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Educating the public (and health professionals)

about limitations of the current “risk-based” TGA assessment procedures.

A number of submissions to the TGA consultation on improving advertising arrangements for therapeutic goods⁵ suggested that, by default, all therapeutic goods not assessed for efficacy by the TGA or a comparable national authority should contain an appropriate warning on their ARTG public summary document, the product label and all promotional material, for example, “The claims made for this product have not been assessed by Australian health authorities”.

In addition, the current Listing system has allowed the misconception that all complementary medicines containing the same ingredients are equally effective. The reality is that complementary medicines especially herbal medicines are complex products with numerous biologically active components. This means that evidence of benefits (and risks) are specific to the product tested and cannot necessarily be extrapolated.

The PHAA believes that the TGA should be more proactive and transparent in educating the public about these matters.

Making it easier

for health professionals and consumers to know which products have been added to, or removed, from the ARTG.

At the moment it is difficult (or impossible) to know that a product has been removed from the ARTG. This can occur when a TGA review finds that the sponsor cannot substantiate indications listed on the ARTG, or a sponsor de-lists a product themselves rather than face a review. The end result is that de-listed products continue to be used.

The PHAA believes that information about all products that have been added to, removed from, or who have had information changed on the ARTG, should be made publically available, either on the TGA web site or via subscription to a TGA email alert system.

ALL complaints

about the promotion of therapeutic goods referred to the TGA by Complaint Resolution Committee (CRP), the Complaint Resolution Committee (CRC) of the Complementary Health Care Council, or handled direct should be made publically available as should the action taken, the time line and the outcome.

The TGA's “new” policy⁶ on complaint investigations only concerns publishing the outcome of “certain” investigations into complaints about advertising which have been referred by the CRP.

The PHAA believes that ALL complaints referred to the TGA should be dealt with expeditiously and transparently. Alternatively, the CRP should handle all complaints and be given the power to enforce sanctions.

⁵ <http://www.tga.gov.au/regreform/cons-advertising.htm>

⁶ <http://www.tga.gov.au/advert/complaint-investigations.htm>

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Improving transparency about adverse events related to therapeutic goods

At least two recent examples from the response to febrile reactions in young children associated with influenza vaccine in 2010 indicate that the TGA's transparency has been sub-optimal.

The first example concerns untimely disclosure of data regarding adverse events following immunisation with H1N1 monovalent influenza vaccine (i.e. CSL Panvax). During a plenary session at the August 2010 at the PHAA Annual Immunisation Meeting a representative of the TGA presented data on convulsions following administration of Panvax vaccine. The data were said to be current as of 30 April 2010 and directly reflected information placed on the TGA website on 17 June 2010. The data provided to the PHAA meeting attendees indicated there had been 16 Panvax associated convulsions in children.

However, as subsequent review of data obtained by a state health department on 20 August 2010 directly from the TGA found that there had been 37 reports of convulsions for children < 5 years following PANVAX; the vast majority of the reports had been received at the TGA before the 17 June 2010 web posting and all were known to the TGA by the time of the PHAA presentation. So, while the TGA data presented on 18 August 2010 appears to have accurately reflected the number of reports received by 30 April, the failure to publically disclose that a substantial number of reports of convulsions following Panvax had been received in more recent months was misleading, and unfortunate as this information had potential importance for the well-publicized, then ongoing investigation of febrile convulsions following receipt of the CSL trivalent influenza vaccine (TIV).

The second example involves selective disclosure of information regarding TGA's response to AEFI following seasonal influenza vaccine. The following statement is posted on the TGA website <http://www.tga.gov.au/alerts/medicines/stokes-review-response.htm> (accessed 31 January 2011)

"Timeline of events:

- On 19 March 2010 the WA childhood influenza vaccine program commenced.
- Between 31 March and 13 April 2010 WA Health authorities were advised on several occasions by clinicians and public health officials of side effects, particularly febrile reactions, associated with the 2010 seasonal influenza vaccine. The TGA was not notified by the WA Department of Health at that time, nor were all the individual adverse reactions reported to the TGA."

However, documentation that PHAA has reviewed clearly indicate that at least one report of a febrile convulsion after TIV vaccination was sent from a General Practitioner in WA directly to the TGA on 18 March 2010; the TGA acknowledged this report in communication directly with the provider on 23 March 2010. In contrast, the Stokes Review documents that the first febrile convulsion reported to WA DOH occurred on 12 April 2010. In our assessment it seems disingenuous for the TGA to disseminate information suggesting others agencies delayed notifying the TGA about febrile convulsions following influenza vaccinations while omitting the fact that the TGA had been notified weeks earlier by directly by providers.

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The PHAA believes that more complete disclosure of the above sequence of events is clearly necessary if we are to accurately assess the TGA's response to influenza vaccine-associated AEFI in 2010 and in the future.

The PHAA would like to thank the Panel for the opportunity to make this submission and would be pleased to provide additional information to further assist the Panel should it be appropriate.



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