



11 February 2011

Professor Dennis Pearce AO
Chair
Panel to Review the Transparency of the TGA
Transparency Review Secretariat
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Professor Pearce

Review of the Transparency of the Therapeutic Goods Administration (TGA)

The Australian Nursing Federation (ANF) welcomes the decision by the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP to initiate a review of the transparency of the Therapeutic Goods Administration (TGA).

With a membership of over 196,000 the ANF is the largest professional and industrial organisation in Australia for nurses, midwives and assistants in nursing. Members of the ANF are employed in a wide range of settings in urban, rural and remote locations in both the public and private sectors.

The core business of the ANF is industrial and professional representation of our members and of the professions of nursing and midwifery.

The ANF participates in the development of policy relating to nurses and midwives on issues such as: practice, professionalism, regulation, health and aged care, community services, veterans' affairs, education, training, workforce, socio-economic welfare, occupational health and safety, industrial relations, social justice, human rights, immigration and migration, foreign affairs and law reform.

Given the numbers of ANF members across all areas of the health and aged care sectors, our organisation has an intense interest in medicines and all other therapeutic products used in treatment regimes. A concern for the well-being of the people for whom the nursing and midwifery professions provide care naturally extends to the regulatory processes for the approval and monitoring of these items. As members of regulated professions, nurses and midwives appreciate the importance of regulation in defining and maintaining standards in the interests of protection of the public. The ANF fully supports the need for this protective mechanism in the health and aged care environment.

The ANF is aware of problems encountered by nurses, midwives and other health professionals, as well as consumers of health and aged care services, due to inability in the past to have meaningful communication with the TGA. For this reason the ANF supports the preparedness of the Government to undertake a review regarding the transparency of information processes between the TGA and stakeholder individuals and groups.

The health and aged care sectors expose people to many occupational health and safety risks due to the complex technology, devices and substances that are used on a day to day basis in prevention, diagnosis, treatment and care. With an increasing focus on evidence-based health care and occupational health and safety, the ANF considers that the TGA, as the regulator of therapeutic goods, is obliged to respond when an identified risk in the use of such products is identified. In addition, the ANF takes the position that an interim warning may be a prudent step to alert the health industry and the community at large in the first instance, while the TGA conducts research and develops an appropriate regulatory response to protect the community: be they patients in the health or aged care systems, health professionals or other workers in the health or aged care industry. The Australian Government is vulnerable to severe criticism, censure and perhaps liability if its regulator of medicines and other therapeutic products is not seen to act on information about items which have the potential to harm its citizens.

The comments submitted to date by other organisations to the Review Panel have been reviewed by ANF. Many of the expressed sentiments are supported by the ANF. Particular points of concurrence are:

- Investment of time and funding by the TGA towards improving the profile of its functions and contribution to the safety and quality of medicines and other therapeutic products, both to health professionals and within the general public. The TGA performs a vital function in the safe and effective use of medicines and other therapeutic products in Australia, which is not currently well understood by the general public nor indeed by many health professionals. Strategies need to be employed to communicate the messages of regulation: evidence-base for initial approval and on-going monitoring, with formats to suit the broad range of stakeholder groups.
- Review of the TGA website for greater ease of access of information. The ANF, having been involved in the TGA website redevelopment, acknowledges that this work is underway. This is a vital component of the move to enhance transparency of TGA processes. Use of the website for retrieval of information is now common place in the community. This means that there is an expectation from health professionals and consumers of health and aged care that they will be able to locate all relevant information they require for decision making on therapeutic goods.
- Implementation of mechanisms to enable greater engagement with TGA of both health professionals and consumers of health and aged care services in order to create greatly improved information flow on issues relating to medicines and other therapeutic products (for example, adverse reactions to medicines or deficits in medical devices).

- Provision of evidence-based information on all therapeutic items regardless of perception as low or high risk products.
- Provision of information on post-market surveillance on newly introduced therapeutic items, especially recently developed medicines and vaccines which have undergone limited clinical trialing in Australia and/or overseas.
- Inclusion of the views of health professionals, industry groups and consumers of health and aged care services in the post-market monitoring processes of medicines and other therapeutic products.
- Prompt response from TGA to issues raised about medicines or other therapeutic products in the monitoring process. Publication of complaints and action instigated by the TGA.
- Regular publishing on the TGA website of the list of therapeutic items removed from the Australian Register of Therapeutic Goods (ARTG) as a result of a regulatory decision, along with an explanation as to the reasons for delisting of these items.

The ANF looks forward to learning of the progress of the Review and to disseminating information to our members as this becomes available.

Should you require any additional information or wish to discuss this matter further please contact Elizabeth Foley, Federal Professional Officer, on (03) 9602 8500 or elizabethf@anf.org.au.

Yours sincerely,



Lee Thomas
Federal Secretary

The industrial and professional organisation for nurses and midwives in Australia

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