Panel to Review the Transparency of the Therapeutic Goods Administration

21 JAN 2011

Dear Sir/Madam

As the Chair of the Panel to Review the Transparency of the Therapeutic Goods Administration (TGA), I am writing to invite you to make a submission to the Review.

The Review was announced by the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP on 16 November 2010. The purpose of the Review is to improve the TGA's transparency. In particular, it will focus on the way the TGA communicates its regulatory processes and decisions.

The purpose of the project is to improve public knowledge of the TGA's regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods so that the Australian community can understand how the TGA operates and the reasons for its key decisions.

The Review Panel includes consumer, health professional and therapeutic goods industry representatives and I have been asked to report by the end of April 2011.

The Panel has been asked to report on:

- opportunities to provide more information about products on the market;
- how the public can improve its understanding of the ways new products are assessed and products on the market are monitored;
- the timing for making information available about new products;
- the type of information and how it is made public by comparable overseas regulators;
- constraints (or barriers) to the release of further information, such as implications for public health and safety;
- how the material can be published – e.g. use of the internet and other publication methods; and
- opportunities for the public to access more information about the advertising of therapeutic goods.

For the full Terms of Reference, membership of the Panel and to read comments already provided to the Panel by some individuals and organisations please visit the TGA website at http://www.tga.gov.au/consult/tga-transparency-Review.htm.

In particular, the Panel would like to hear from consumers about:

- instances where it could have been useful for you to have had access to better information about your medicine, supplement or device;
- the type of information that could have helped you;
- the way you would like to access that information – e.g. on the internet or other electronic media; through your doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device;

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au

Telephone: 02 6232 8427 Facsimile: 02 6232 8239 ABN 40 939 406 804

- whether you have ever looked for information provided by the TGA and, if so, where did you find it and was it helpful; and
- what other information you use.

If you are a health professional the Panel would like your comments on:

- information provided by the TGA on the safety, quality and efficacy of medicines and the safety, quality and performance of medical devices included on the Australian Register of Therapeutic Goods (ARTG) including:
    - Australian Public Assessment Reports for prescription medicines;
    - Approved Product Information;
    - Consumer Medicine Information;
    - Public summary documents on the ARTG;
    - TGA Advisories and Medicines Safety Updates; and
- any problems that you have encountered in regard to the transparency of TGA processes and decision- making.

If you participate in the production or marketing of therapeutic goods, please provide comment on:

- what ways you think the TGA could provide greater assistance to you in the evaluation and registration, listing or marketing processes; and
- any issues that you have encountered in regard to the transparency of TGA processes and decision-making.

If you work in the media, we would appreciate your comments on the timeliness, quality and utility of information provided in response to enquiries and/or Freedom of Information requests.

You are invited to comment on any matters relevant to the Terms of Reference.

Please note that all submissions will be made available on the TGA website.

To make a comment or a submission you can either email it to the Review Secretariat at TransReviewPanel@tga.gov.au **OR** mail it to:

Transparency Review Secretariat
Therapeutic Goods Administration
P O Box 100
WODEN ACT 2606

Submissions must reach the Secretariat no later than **Friday 11 February 2011.**

The Panel will hold a limited number of public meetings in late February and March 2011 and details about these will be provided on the TGA website on Thursday 3 February 2011.

I look forward to receiving your views.

Yours sincerely

Dennis Pearce

Dennis Pearce AO
18 January 2011