



17 March 2005

Mr. Bob Baldwin MP Chairman: Joint Committee of Public Accounts and Audit Department of the House of Representatives Parliament House CANBERRA ACT 2600

Dear Mr. Chairman,

ANAO Audit Report No. 18 2004-2005 Regulation of Non-prescription Medicinal Products

The Australian therapeutics goods industries have taken a keen interest in the ANAO's performance audit of compliance procedures in the TGA. We note that the report has now been tabled in the Parliament and thus stands referred to your Committee for consideration and report to the Parliament.

Industry strives for a co-operative working relationship with the TGA but this is not always achieved. We have a high regard for the professionalism of the TGA staff. As the ANAO notes, however, there is a need for some procedures to be improved. The Dept of Health and Ageing has indicated support for all the recommendations and the Department's agreement to implement all recommendations is also positively noted.

In our view, however, the recommended improvements must not only be agreed, but must also be seen to have been put into effect. We would hope the Committee will take the lead in this. The public is entitled to know that the regulatory regime for therapeutic goods does indeed ensure the safety, quality and efficacy of products which go to market.

Finally, it is important that whatever is done to put the ANAO's recommendations into effect pays due regard to the regulatory arrangements being developed for the Trans Tasman Agency. We understand this is a complex matter, but we believe it is necessary to be sure any changes made now address the needs of the future.

We are very keen to discuss these matters with you or your staff, and to appear before your Committee, should there be an opportunity.

Yours sincerely

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c.c. Ms Jane Halton, Secretary of the Department of Health & Ageing Mr Terry Slater, National Manager, Therapeutic Goods Administration