THE HON TONY ABBOTT MP
MINISTER FOR HEALTH AND AGEING
Leader of the House of Representatives

Mr Tony Smith MP
Chair
Joint Committee of Public Accounts and Audit
Parliament House
CANBERRA ACT 2600

Dear Mr Smith Tony

I am writing to you in relation to Report No. 404 of the Joint Committee of Public Accounts and Audit (JCPAA).

The JCPAA report made six recommendations (Recommendations 37 to 42 inclusive) to the Therapeutic Goods Administration (TGA), a part of my Department, relating to the regulation of non-prescription medicinal products.

Recommendation 42 required a report on the establishment and operation of the Trans-Tasman Therapeutic Products Agency (now referred to as the Australia New Zealand Therapeutic Products Authority – ANZTPA) by February 2006, with a further report on progress to be provided in June 2006.

The report responding to Recommendation 42, in the *Executive Minute* format required by the JCPAA and signed by the Secretary of my Department, is attached.

The responses to the remaining five recommendations will be provided by the due date of 7 May 2006.

Yours sincerely

TONY ABBOTT

09 MAR 2006

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EXECUTIVE MINUTE

on
JOINT COMMITTEE OF PUBLIC ACCOUNTS AND AUDIT
REPORT NO. 404
Review of Auditor-General's Reports: Report No.18 of 2004-2005 - Regulation of Non-prescription Medicinal Products - Department of Health and Ageing and Therapeutic Goods Administration

General Comments

The Committee's Report made six recommendations to the Therapeutic Goods Administration (TGA), a part of the Department of Health and Ageing. One of the recommendations (Recommendation 42) required responses in February and June 2006, in the form of a report on the establishment and operation of the Trans-Tasman Therapeutic Products Agency. The report on this recommendation is below.

The remaining five recommendations will be responded to in May 2006.

Responses to the Recommendation

Recommendation No. 42 paragraph 12.86

The Committee recommends that the Therapeutic Goods Administration report to the Committee on the establishment and operation of the Trans-Tasman Therapeutic Products Agency, with regard to how the new agency will continue to regulate non-prescription medicinal products in accordance with the 26 ANAO recommendations. The TGA should also report on any changes to its governance and reporting arrangements. These reports should be forwarded to the Committee in February and June 2006.

Progress report on the establishment and operation of the Trans-Tasman Therapeutic Products Agency

The Australian and New Zealand Governments have agreed to establish a single agency to administer a joint regulatory scheme for therapeutic products (including prescription and over-the-counter medicines, complementary medicines, medical devices, blood products and tissues). This inter-Governmental agreement is entitled *The Agreement for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products* – referred to as The Treaty.

The *Australia New Zealand Therapeutic Products Authority* (ANZTPA) will replace Australia's Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

The Treaty provides for the establishment of a Ministerial Council to oversee the operation of the scheme and the ANZTPA. The Treaty does not come into force until the two countries

have exchanged diplomatic notes confirming the completion of their respective domestic procedures for the entry into force of The Treaty, including passage of implementing legislation. The Australian and New Zealand Governments agreed to establish a Therapeutic Products Interim Ministerial Council (TPIMC) with similar functions to those of the Ministerial Council, to apply until the Ministerial Council is created. The TPIMC has a particular focus on facilitating decision making on matters such as establishment issues, infrastructure development, regulatory arrangements, and appointment of the Board.

The joint regulatory scheme is being developed with a number of essential features in mind: no lessening of accountability to the Australian Government than is currently the case; no lessening of responsiveness to the Government; and, no lessening of the standards that currently protect public health and safety in Australia.

The joint regulatory scheme will be set out in a single set of Ministerial Council Rules which will apply in both countries. These Rules are currently being drafted and are well-advanced. It is expected that the first package of the draft Ministerial Council Rules for the new scheme will be released for consultation in the forthcoming months.

After this time it is proposed that the legislation will be introduced to the New Zealand parliamentary system and released as an exposure draft for stakeholder consultation in Australia. In both countries this will signal the beginning of formal consultations with interested parties on the legislation.

The TPIMC has agreed that in order to allow stakeholders time to prepare for this extensive period of review of the draft legislation, a consultation plan will be provided shortly with indicative consultation periods for a phased release of the draft implementing Bills, draft Ministerial Council Rules and a consultation paper on fees and charges.

The Treaty provides for the ANZTPA to have a Managing Director. However, the Managing Director cannot be appointed until the Treaty comes into force. The TPIMC identified the need for a role of Transitional Director to cover the period leading up to the establishment of the ANZTPA and to oversee the process of development until then.

A Joint Agency Establishment Group is also in place to provide support to the establishment of the ANZTPA.

In December 2005, the TPIMC announced the appointment of Mr Philip Davies as the Transitional Director for the Joint Agency Establishment Group. Mr Davies has held senior positions in both the New Zealand Ministry of Health and the Australian Department of Health and Ageing and will report to these organizations in his new role. As noted above, Mr Davies' role will be for the period up to the establishment of the ANZTPA. In the lead-up to the commencement of the ANZTPA, an international recruitment firm will be engaged to assist in the recruitment of a Managing Director to lead the ANZTPA once it becomes operational.

The regulation of non-prescription medicines in the joint regulatory scheme

As the joint regulatory scheme will substantially reflect the current arrangements in Australia, all of the changes resulting from implementation of the 26 recommendations of the Australian National Audit Office will transfer into the new scheme and be given legal underpinning through the new legislation, where necessary. It is of note that these changes and improvements have been implemented for regulation of all therapeutic products, not just for the regulation of non-prescription medicinal products as recommended by ANAO. These improvements and processes will be maintained in the context of ANZTPA.

Changes to TGA Governance and reporting arrangements

The governance committee structure has been reviewed and adjusted to make it consistent with the committee structure proposed to operate under ANZTPA, including establishing a TGA Executive Committee to assist the National Manager on strategic and leadership matters. An audit and risk management committee is being established which will be supported by a TGA risk manager. The business planning cycle has been reviewed to strengthen and align business planning with the TGA priorities and the monitoring of progress against the business plan.

In addition, a Post-Market Monitoring and Compliance Coordination Group has been established to:

- enhance the operational interface between key post-market activities;
- provide a forum for information sharing and review of the relevant post-market monitoring and compliance activities;
- provide guidance in order to improve the effectiveness and efficiency of post-market operational activities; and
- develop optimal strategies for improving post-market operations.

Jane Halton
Secretary
Department of Health and Ageing

March 2006