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 JCPAA'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 reports on the establishment and operation of the Trans-Tasman Therapeutic Products Agency, now known as the Australia New Zealand Therapeutic Products Authority (ANZTPA). The first report was provided to the JCPAA in March 2006. The second report on this recommendation is below.

The remaining five recommendations were responded to in May 2006.

Response 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.

Report on the establishment and operation of the Australia New Zealand Therapeutic Products Authority (ANZTPA)

In March 2006, the JCPAA was advised that:

- the Australian and New Zealand Governments had 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);
- the joint regulatory scheme to be administered by the new Australia New Zealand Therapeutic Products Authority (ANZTPA) will be set out in a single set of Ministerial Council Rules, which will apply in both countries; and
- a Joint Agency Establishment Group (JAEG) was in place and that Mr Philip Davies had been appointed as the Transitional Director for the JAEG.

Under the direction of the Transitional Director, the JAEG has begun an extensive process of stakeholder consultation.

The *Stakeholder Consultation Programme 2006/07,* which was published on 27 March 2006, includes a schedule of consultation events to be held in both Australia and New Zealand in the lead up to the establishment of the ANZTPA. The consultation programme was issued to provide stakeholders with advance notice of the planned timing for consultation on key documents relating to the establishment of the Authority and the proposed regulatory scheme.

During 2006/07 there will be a phased release of draft Ministerial Council Rules and draft Managing Director's Orders relating to the joint regulatory scheme. Phase one of the consultation program is currently underway and focuses on the draft Rules for medicines and medical devices; key components of the draft Administration Rule; and, proposed arrangements for fees and charges. Phase two (planned for September 2006) will focus on the draft Rules for advertising, blood and blood components and scheduling. The final consultation phase (planned for March 2007) will include draft Managing Director's Orders on technical topics consulted on previously in relation to the development of standards through joint interim expert committees.

Phase one of the consultation programme began as scheduled, on 23 May 2006, with the release of the draft Rules for medicines and medical devices and other supporting documents. Following the release of the consultation documents, information / consultation sessions were held in Christchurch, Auckland, Adelaide, Melbourne, Brisbane and Sydney, during the month of June. The meetings were held to provide an opportunity for industry and other interested stakeholders to hear about the ANZTPA Establishment Project and for officials from both countries to outline the proposed regulatory scheme, answer questions and receive preliminary feedback.

Consultation on the proposed regulatory scheme is not intended to substitute for either country's formal consultation processes on the proposed implementing legislation. In addition to the draft Ministerial Council Rules and draft Managing Director's Orders, work has also been underway on the separate, but aligned Bills, for Australia and New Zealand.

The Therapeutic Products Bills are close to finalisation. The New Zealand Bill is expected to be introduced to the New Zealand Parliament in the next few months. Consultation with stakeholders on the New Zealand legislation will occur as part of the Parliamentary process, during Select Committee consideration of the Bill. An exposure draft of the Australian Bill is scheduled for release for stakeholder consultation, to coincide with the introduction to the New Zealand parliamentary system of the New Zealand Bill.

In May 2006, the Therapeutic Products Interim Ministerial Council (the Australian Parliamentary Secretary to the Minister for Health and Ageing, Christopher Pyne and New Zealand Minister of State Services, Annette King) announced that the proposed joint regulatory scheme is expected to begin in the second half of 2007. In announcing the date, the Interim Ministerial Council advised that before the final commencement date of the joint regulatory scheme can be decided, stakeholder consultations need to be completed and legislation introduced into the parliaments of both countries.

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19 July 2006