Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Committee
25th Meeting (7 September 2004)

Information for Stakeholders – Report on Meeting

The 25th Meeting of the Therapeutic Goods Committee (TGC) was held by teleconference on 7 September 2004, commencing at 10.00 a.m. and closing at 12.00 p.m.

Participating:

TGC Members:	Professor Stella O'Donnell (Chair) Dr John Ballard Dr Mark Bowden Mr David Clayton Mr Philip Daffy Associate Professor Loraine Holley Associate Professor William Rawlinson (part meeting)
Apologies:	Mr Barry Evers-Buckland Professor Klaus Schindhelm
TGA officers:	Ms Julie Emery (part meeting) Mr Phil Harrison Dr Larry Kelly Ms Rita Maclachlan
Secretariat:	Ms Lyn Lewis (Secretary)

AGENDA AND COMMITTEE ADMINISTRATION

Opening of Meeting – Welcome and Apologies

The Chair opened the Meeting at 10.00 am and welcomed Members. Apologies were noted.

It was noted that the primary purpose of this teleconference was to provide Members with information relating to the trans-Tasman therapeutic products agency due to commence operation on 1 July 2005.

Terms of Reference and Members' Contact Details

Members noted the Committee's functions, composition and provisions relating to tenure of office as given in Regulation 34 of *The Therapeutic Goods Regulations 1990.*

Members were requested to check their contact details as currently held by the Secretariat and to advise of any errors or changes.

Adoption of Agenda

Members adopted the agenda as presented.

Conflict of Interest Declarations

Members were reminded to complete a Disclosure of Interest Declaration and mail this to the Secretary. Members also were reminded that any potential conflicts of interest should be drawn to the Chairman's attention prior to discussion of the relevant agenda item.

No conflicts of interest were declared.

Minutes of the 24th Meeting of the TGC

Members noted that, in accordance with agreed processes the Minutes of the 24th Meeting of the TGC, held on 4 May 2004, were ratified out-of-session on 13 July 2004, and the *Summary of Key Resolutions* and subsequent *Information for Stakeholders - Report on Meeting* had been published on the TGA website.

RESOLUTION

The Therapeutic Goods Committee NOTES that:

- **The Minutes of the 24th Meeting of the TGC, held on 4 May 2004, were ratified out-of-session on 13 July 2004;**
- **The key resolutions made by the TGC at the 24th Meeting were released on the TGA website on 31 May 2004; and**
- **The Information for Stakeholders - Report on Meeting was released on the TGA website on 30 July 2004.**

REPORT ON TGC SUBCOMMITTEES

Subcommittee on Blood and Tissues

As this Subcommittee had been established to consider the very specific issue of standards for haematopoietic stem cells, and had now finalised its recommendations, the TGC noted there did not appear to be an ongoing need for the Subcommittee on Blood and Tissues. The Committee agreed to consider disbanding this Subcommittee at its next meeting.

Subcommittee on Child-Resistant Packaging

The TGC noted that although some of the tasks to be undertaken by this Subcommittee were long-term projects, the rationalisation of current Australian and New Zealand requirements for child-resistant packaging needed to be undertaken before commencement of the joint agency. To assist in this, it was agreed that it would be essential that New Zealand representation was included in the membership.

SUMMARY AND STATUS OF THERAPEUTIC GOODS ORDERS

Members noted a summary giving the status of current Therapeutic Goods Orders. Since the Committee's last Meeting, TGO 65 *Child-Resistant Packaging for Therapeutic Goods* and TGO 69A *Amendment to Therapeutic Goods Order No. 69 – General requirements for labels for medicines* had been gazetted.

TRANS TASMAN TERMINOLOGY PROJECT

The Committee noted a report on the trans-Tasman Terminology project which would progress the harmonisation of ingredient names to International Non-proprietary Names (INN) within the broader context of agreed trans-Tasman terminology. The terminology under consideration related to listed and registered prescription and over-the-counter medicines (including complementary medicines).

Members recognised that, as a number of Therapeutic Goods Orders and Regulatory Guidelines included references to ingredients that may be the subject of a name change, consequential changes to these documents (or their trans-Tasman successor) would be needed once the list had been finalised. The Committee also noted the need for appropriate information to be provided to health professionals as well as public education strategies.

The TGC resolved that:

RESOLUTION

The Therapeutic Goods Committee NOTES:

- **the progress of the trans-Tasman terminology project to date; and**
- **the implementation plan for the continuation and finalisation of this project, including time frames.**

ESTABLISHMENT OF JOINT EXPERT COMMITTEE ON TRANS TASMAN LABELLING REQUIREMENTS FOR MEDICINES

The Committee recalled that at its last Meeting, Members had recommended the establishment of a new expert committee on medicine labelling to consider, and make recommendations on, standards for the labelling of medicines to be applied by the trans-Tasman joint therapeutic products agency. It was recommended that membership of this committee be expertise-based and drawn from both Australia and New Zealand.

It was now noted that this recommendation was considered by the Therapeutic Products Interim Ministerial Council (TPIMC) at its 4th meeting, held on 28 May 2004, and that establishment of this new joint expert committee was endorsed. The TGC noted the agreed membership and terms of reference for the joint expert committee on medicine labelling and that the first meeting of this committee was to be held on 1 October 2004. The TGC then resolved:

RESOLUTION

The Therapeutic Goods Committee NOTES the establishment of the Joint Expert Committee on Trans Tasman Labelling Requirements for Medicines, its Terms of Reference and Membership.

TRANS TASMAN - PROPOSAL FOR A JOINT EXPERT ADVISORY COMMITTEE ON STANDARDS AND AN INTERIM EXPERT ADVISORY COMMITTEE

The TGC noted advice that, in accordance with the Trans-Tasman Treaty under which the joint therapeutic products agency is to be established with New Zealand, standards for therapeutic products, including authoritative standards and principles, can be prescribed in the Rules of the agency. Furthermore, the Managing Director of the joint agency would be able to set standards in Orders. It was intended that a Joint Expert Advisory Committee on Standards would be established under the Rules to advise the Managing Director on matters concerning standards for therapeutic products, labelling and packaging of therapeutic products, manufacturing principles for therapeutic products and other matters referred to it by the Managing Director. Membership of this Expert Committee would be defined in terms of expertise rather than representational function.

The TGC was advised further that, in order to ensure that a single joint set of standards can be implemented on 1 July 2005, there was need for all standards for therapeutic products that currently apply separately in Australia and New Zealand to be reviewed, revised as necessary and brought into the trans-Tasman context. Importantly it would also be necessary to determine the principal (default) standard that would apply under the new agency arrangements. For this reason, establishment of a Joint Interim Expert Advisory Committee on Standards to review and develop as necessary joint standards for adoption had been proposed. This Interim Committee would have the same structure and composition, in terms of expertise, as the proposed Joint Expert Advisory Committee, and both TGA and Medsafe would provide Regulatory Advisors to the Committee. Nominations for appointment to the Interim Committee had been sought by the TGA / Medsafe, and these nominations would be considered by the TPIMC in due course.

In relation to the work to be undertaken by the Interim Committee, the TGC noted that it had an opportunity to assist through providing advice on standards appropriate for the Australian environment. In particular, the TGC could provide a view on the currency and adequacy of existing Therapeutic Goods Orders. The TGC therefore resolved:

RESOLUTION

The Therapeutic Goods Committee NOTES:

- **The functions and composition of the proposed Joint Expert Advisory Committee on Standards; and**
- **The proposal for formation of a Joint Interim Expert Advisory Committee on Standards to develop a single joint set of standards for implementation upon commencement of the trans-Tasman joint therapeutic products agency.**

CLOSE OF MEETING

There being no further business, the Chair closed the Meeting at 12.00 pm and thanked Members for their participation.