Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Committee
24th Meeting (4 May 2004)

Information for Stakeholders – Report on Meeting

The 24th Meeting of the Therapeutic Goods Committee (TGC) was held in Conference Room 1, Ground Floor, TGA Building, Narrabundah Lane, Symonston on 4 May 2004, commencing at 10.30 a.m. and closing at 4.00 p.m.

Present

TGC Members:	Professor Stella O'Donnell (Chair) Dr John Ballard Dr Mark Bowden Ms Amanda Cornwall Mr David Clayton Mr Philip Daffy Mr Barry Evers-Buckland Associate Professor Loraine Holley Professor Klaus Schindhelm
Apologies:	Associate Professor William Rawlinson
TGA officers:	Dr Christine Anantharajah (part meeting) Mr Paul Archer (part meeting) Ms Christine Bell (part meeting) Ms Christianna Cobbold (part meeting) Mr Phil Harrison (part meeting) Mr Peter Liehne
Medsafe officers:	Ms Susan Martindale (part meeting, by telecon)
Secretariat:	Ms Lyn Lewis (Secretary)

AGENDA AND COMMITTEE ADMINISTRATION

Opening of Meeting – Welcome and Apologies

The Chair opened to Meeting at 10.30 a.m. and welcomed Members. Apologies were noted.

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 noted the agenda and agreed to amend the order of discussion according to the availability of relevant TGA advisers.

Conflict of Interest Declarations

In accordance with the *Guidelines on Confidentiality and Conflict of Interest* adopted by the Therapeutic Goods Committee in November 2000, Members were reminded to complete the Disclosure of Interest Declaration included in the front of the agenda and provide this to the Chairman.

Members also were reminded that, prior to the commencement of any agenda item in relation to which a potential conflict of interest had been declared, the Chairman's attention should be drawn to this fact. Where a potential conflict of interest was declared, the remainder of the Committee would need to resolve the extent to which that Member could be allowed to participate in the consideration of the item.

Minutes of the 23rd Meeting of the TGC

Members noted that the Minutes of the 23rd Meeting of the TGC were ratified out-of-session on 26 March 2004 according to the process previously determined by the Committee, and that 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 23rd Meeting of the Committee were ratified out-of-session on 26 March 2004; and**

- **The *Summary of Key Resolutions* made by the TGC at the 23rd Meeting and the subsequent *Information for Stakeholders - Report on Meeting* has been included on the TGA website.**

REPORT ON TGC SUB-COMMITTEES

Sub-committee on Blood and Tissues

During the 21st TGC Meeting in February 2003, the TGC established an *ad hoc* Working Party to consider the adoption of appropriate international standards for haematopoietic progenitor cells (HPCs), both cord blood derived and non-cord blood derived. At the 22nd meeting (August 2003), the TGC established a sub-committee on blood and tissues, to be chaired by Associate Professor Rawlinson, to address the ongoing issue of standards for application in Australia for haematopoietic progenitor cells (HPCs). The membership was subsequently endorsed by the TGC and the sub-committee, held their first meeting (by teleconference) on 27 November 2003.

The TGC noted advice that a new Therapeutic Goods Order (TGO 72 *Standards for blood components*) had been gazetted. This TGO adopted the 9th edition of the Council of Europe *Guide for the preparation, use and quality assurance of blood components* as the standard in Australia for blood components including red cells, white cells, platelets and plasma for transfusion, as recommended by the TGC at it last Meeting.

It was also noted that the TGA was continuing to work towards adopting the standards for haematopoietic stem cells as recommended by the Sub-committee on Blood and Tissues and by TGC at its last Meeting.

The TGC therefore resolved:

RESOLUTION

The Therapeutic Goods Committee NOTES:

1. **The gazettal of Therapeutic Goods Order No. 72 *Standards for blood components;* and**

2. **Progress towards the development of the Therapeutic Goods Order:**
   - **(a) for manufacture of Haematopoietic Progenitor Stem Cells; and**
   - **(b) to prescribe the oversight of allogeneic, autologous and directed Haematopoietic Progenitor Cells.**

In relation to the Sub-committee on Blood and Tissues, the Committee noted comments from a Member regarding the Terms of Reference of this sub-committee and its function (as defined in Resolution No. 22/01), to provide a draft TGO specifying standards for haematopoietic stem cells. It was suggested that, as the TGC had previously decided that there should not be standing sub-committees of a general nature, disbanding of this sub-committee should be considered.

Sub-committee on Child-Resistant Packaging

At the 22nd Meeting (August 2003), the TGC agreed to re-establish the sub-committee on Child-Resistant Packaging to advise on forms of child-resistant packaging (CRP) not covered by the existing Therapeutic Goods Orders. It was agreed that the sub-committee would be Chaired by Associate Professor Holley and have an appropriate expert membership. At the 23rd meeting (December 2003), the general composition of the sub-committee was determined. It was noted that while nominations had been received against several positions, no formal appointments had been made to the sub-committee.

The TGC noted that a request had been received from the Injury Prevention Section (Population Health Division) of the Department of Health and Ageing for observer status on the sub-committee. The Injury Prevention Section oversaw the Strategic Injury Prevention Partnership and implementation of the National Injury Prevention Plan, one priority of which was the prevention of poisoning in children.

The TGC were advised that, in considering the work to be undertaken by this sub-committee, it had become evident that any outcomes from the sub-committee would coincide with the establishment of the trans Tasman joint therapeutic products agency on 1 July 2005. For this reason, any new standards proposed would need to be considered in the trans Tasman context for application in both Australia and New Zealand. In order to determine requirements for CRP to be applied by the joint agency on commencement, there was a need for comparison and gap analysis of current Australian and New Zealand requirements / legislation relating to CRP. This would provide the opportunity to review and update of the list of substances for which such packaging was justified on the basis of most recent poisoning data.

In order to address these issues, and as a step towards the establishment of the joint agency and the setting of appropriate standards, the TGC was requested to consider amending:

- the TOR of the sub-committee to include these additional roles; and
- the composition of the sub-committee to include appropriate expertise drawn from New Zealand as well as Australia.

It was agreed that membership appointments would continue to be based on relevant expertise. Although no change to the identified fields of expertise was proposed, it would be necessary to include additional members from NZ in some fields (such as poisons information services) as these would be specific to individual countries.

TGC was advised that both TGA and Medsafe were supportive of this initiative and both would provide appropriate technical advisers.

In amending the composition and TOR of the sub-committee, TGC agreed that the legislative requirements governing functioning of the TGC, as well as the needs of the joint agency, would be met by the sub-committee reporting to both the TGC and the Therapeutic Products Interim Ministerial Council.

The TGC therefore resolved:

RESOLUTION

1. **The Therapeutic Goods Committee AMENDS the Terms of Reference of its Sub-committee on Child-Resistant Packaging that were determined at the 22nd Meeting of the Committee in August 2003.**

2. **The sub-committee is to:**

   - **Undertake a comparison of requirements for child-resistant packaging and safety packaging of therapeutic goods currently applying in Australia and New Zealand;**
   - **Recommend requirements for child-resistant packaging and/or safety packaging to be applied upon commencement of the trans Tasman joint therapeutic products agency, including standards to apply to such forms of packaging and identification of substances to be packaged in this manner;**
   - **Consider new national and international standards for child-resistant packaging, including British Standard (BS 8404:2001*) Packaging – Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for pharmaceutical products* and their relevance and possible application in Australia and New Zealand; and**
   - **Consider issues of concern to injury prevention agencies and health departments related to the child-resistant packaging of therapeutic goods; and**
   - **advise the Therapeutic Goods Committee and the Therapeutic Products Interim Ministerial Council on the outcomes of its considerations.**

3. **The Therapeutic Goods Committee AMENDS the composition of its Sub-committee on Child-Resistant Packaging that was determined at the 23rd Meeting of the Committee in December 2003.**

4. **The Therapeutic Goods Committee RECOMMENDS the following composition for the expert Sub-committee on Child-Resistant Packaging:**

   - **A Chairperson who is a Member of the Therapeutic Goods Committee and is appointed by that Committee;**
   - **A Member with expertise in child-resistant packaging technologies;**
   - **One or two Members with expertise in the packaging of medicines;**
   - **One or two Members with expertise in poisons information services;**
   - **One or two Members with expertise in injury prevention and surveillance;**
   - **A Member with expertise in the regulation of poisons; and**
   - **A Member with expertise in the consumer use of medicines.**

5. **The sub-committee is to be Chaired by Associate Professor Holley. The expert membership will be drawn from both Australia and New Zealand.**

Sub-committee on Medicine Labelling

The Committee noted that there were two issues for consideration. These were to consider firstly whether there was any need to retain the TGC's current sub-committee on medicine labelling and secondly, the establishment of a new sub-committee to address the labelling of medicines under trans Tasman joint regulatory arrangements.

It was noted that the current sub-committee had been established out-of-session in October 2003 to provide advice on the issue of inclusion of manufacturer's details on medicine labels. Establishment of the sub-committee, membership appointments and Terms of Reference (TOR) were endorsed by the TGC at its 23rd Meeting in December 2003. A draft of the Discussion Paper referred to in the TOR had been considered by the TGC at its last Meeting, and was subsequently amended and released for stakeholder consultation. The stakeholder responses were considered by the TGC earlier in the meeting.

The TGC therefore considered whether there was any need to retain this sub-committee or whether the work described in the TOR was now, in effect, complete. Members concurred that, although the sub-committee's TOR had included the review of the stakeholder responses, this would not be necessary as the TGC itself had considered the responses and made its recommendation on the matter. It would be appropriate therefore for the sub-committee to be disbanded, giving the TGC the freedom to consider the establishment of a new sub-committee with different TOR.

The TGC therefore resolved:

RESOLUTION

The Therapeutic Goods Committee:

- **DISBANDS its Sub-committee on Medicine Labelling established in October 2003 to consider issues associated with the inclusion of manufacturer details on medicine labels; and**
- **RECORDS a vote of thanks to Members of the sub-committee for their efforts and advice in consideration of this matter.**

In relation to the formation of a new sub-committee, the TGC noted it had previously been advised of a number of labelling issues being progressed by the TGA. The Committee had recognised then that a new sub-committee on medicine labelling may be needed to consider these broader issues. It also was evident now that there was need for consideration of labelling requirements in the context of the trans Tasman joint therapeutic products agency, with appropriate involvement of both Australia and New Zealand, and the coordination and consolidation of all labelling actions being undertaken by the TGA and Medsafe.

The TGC considered a proposal to form a new expert committee on medicine labelling. Rather than acting as a sub-committee to the TGC, it was subsequently agreed that the new expert committee should instead, report to the TGC. This would allow the Minister and the Therapeutic Products Interim Ministerial Council the flexibility to decide how this expert committee would best operate, while still acknowledging the role of the TGC.

In conclusion the TGC resolved that:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS that:

1. **A new expert Committee on Medicine Labelling be established to consider, and make recommendations on, standards for the labelling of medicines to be applied by the Trans Tasman Joint Therapeutic Products Agency;**

2. **The Committee should to report to the Therapeutic Goods Committee and the Therapeutic Products Interim Ministerial Council on the outcomes of its considerations;**

3. **Membership of the Committee should be expertise-based and drawn from both Australia and New Zealand; and**

4. **In its considerations, the Committee should be mindful of:**

    - **The timeframe for commencement of the Trans Tasman Joint Therapeutic Products Agency;**
    - **Current labelling issues under consideration by the Therapeutic Goods Administration and/or Medsafe;**
    - **Lead times needed by the medicines industry to implement any required label changes and the desirability of consolidating all necessary changes into a single action; and**
    - **The needs of consumers and health professionals.**

SUMMARY AND STATUS OF THERAPEUTIC GOODS ORDERS

Members considered a summary of the status of Therapeutic Goods Orders. It was noted that a number of Orders were undergoing administrative processes for revocation, in accordance with earlier recommendations of the TGC. It was also noted that several new Orders or amendments were under development.

MEDICINE LABELLING – CONSIDERATION OF STAKEHOLDER RESPONSES TO THE DISCUSSION PAPER *MEDICINE LABEL IMPROVEMENTS TO ASSIST PRODUCT RECALL*

At its last Meeting, the TGC had received a report from its Sub-committee on Medicine Labelling and a draft Discussion Paper concerning a proposal for inclusion of manufacturers' details on the labels of medicines and other changes intended to facilitate the identification of medicines, and hence recall processes.

In accordance with the TGC discussion and recommendations made at that Meeting, the Discussion Paper for Stakeholder Consultation *Medicine Labelling – Medicine Label Improvements to Assist Product Recall* was released for broad stakeholder consultation in March 2004. The consultation period closed on 23 April 2004, and copies of the responses received from stakeholders had been provided to TGC Members for consideration.

At this Meeting, the TGC discussed the submissions from stakeholders received in response to the Discussion Paper and how to progress this issue further. It was noted that, in view of the establishment of the trans Tasman joint therapeutic products agency, this consultation had been of interest to Medsafe and the New Zealand medicines industry, and any recommended labelling changes would need to be considered in that context also.

Thirty nine responses to the consultation had been received and the TGC noted that the number and detail of these responses reflected the importance of the issue and the concerns held by stakeholders.

The majority of responses received supported the objective of the Discussion Paper but indicated opposition to including manufacturer's details on labels, based on multiple arguments. These are broadly categorised as:

- Potential for increased consumer confusion;
- Existing legal obligations and quality systems;
- Impact and costs;
- Practicality;
- Commercial issues; and
- Other.

In its discussion, the following general issues and remarks were noted by the TGC:

- Sound labelling is important for public safety;
- Labelling issues are complex;
- Different interest groups use labels differently and therefore have different needs;
- Labelling changes can have a long lead time for implementation and any changes recommended by the Committee in respect of this issue would have implications for the joint agency;
- Labelling changes are costly for industry and requiring multiple changes over a period of time should be avoided;
- The specific consideration addressed in the Discussion Paper was that of inclusion of the manufacturer on the label, as an aid to product recall; and
- Other aspects of medicine labelling were being considered by the TGA, and all such considerations should be coordinated with the focus being on the totality of the label.

The TGC noted that its Sub-committee on Medicine Labelling had concluded previously that adding the manufacturer's details to labels would not improve the recall processes.

In contrast to the lack of support for inclusion of manufacturer's details on labels, a number of the submissions did support other proposed actions that would have a positive benefit. These included educational campaigns around sponsors' responsibilities and the necessity for sponsors to have processes in place to retrieve the required information. A range of ideas about other aspects of labelling also had been provided, relating to matters such as the size and presentation of the AUST R and AUST L numbers. The TGC agreed it was important not to lose sight of these suggestions, when medicine labelling as a whole was reviewed in the trans Tasman context.

Having considered the responses received from stakeholders, and the issues involved, the TGC concluded that the addition of manufacturer's details to medicine labels would not assist in facilitating product recalls through improving consumer and/or retailer identification of affected products. For this reason, the TGC recommended that this proposed action not proceed.

Notwithstanding this, the TGC noted positive feedback on other proposals included in the Discussion Paper as well as a number of other suggestions for improvements in medicine labelling. These responses and suggestions should be collated and given careful consideration in the development of medicine labelling requirements under the trans Tasman joint therapeutic products agency.

In conclusion, the TGC resolved as follows:

RESOLUTION

1. **In relation to facilitating medicine recalls, and after careful consideration of submissions received from a very broad range of stakeholders, the Therapeutic Goods Committee RECOMMENDS that there be no mandatory requirement for details of the manufacturers of medicines to be included on product labels.**

2. **The Therapeutic Goods Committee concluded that the inclusion of manufacturers' details on the label would not improve the identification of medicines subject to recall. Reasons for reaching this conclusion included:**

    - **The complexity of manufacturing processes (involvement of multiple manufacturers) for most medicines;**
    - **The potential for increased consumer confusion and hindering of recall efforts if multiple manufacturers are included on labels (either by name or code number), or if a single manufacturer is included but this is not the manufacturer responsible for the recall;**
    - **Medicine labels already include sufficient information to uniquely identify products subject to recall (product name, AUST R or AUST L number, batch number, expiry date and sponsor's or supplier's name and address);**
    - **The impact and costs associated with amending labels for almost every medicine marketed in Australia;**
    - **The impracticality of batch specific labels and the potential for the inclusion of additional information to compromise existing labelling;**
    - **Commercial issues including risk of commercial damage to a named manufacturer if not responsible for the recall, disclosure of confidential information and potential impacts on market competition; and**
    - **The possibility of alternative, more effective mechanisms to achieve the objective.**

3. **The Therapeutic Goods Committee NOTED a number of suggestions from stakeholders for improvements in medicine labelling that should be given careful consideration in the development of requirements for medicine labelling under the new trans Tasman joint therapeutic products agency.**

4. **The Therapeutic Goods Committee RECOMMENDS that the Therapeutic Goods Administration take steps to ensure that all sponsors comply with their obligations under therapeutic goods legislation in relation to maintaining product records in a manner that will permit batches of medicines to be tracked easily, accurately and in a timely manner in the event of a recall.**

BRITISH PHARMACOPOEIA 2003

Out-of-Session recommendation for Adoption of British Pharmacopoeia 2003

The TGC recalled that at its December 2003 Meeting, the Committee agreed to consider out-of-session the adoption of British Pharmacopoeia 2003 (BP 2003) as the edition of the BP referenced under the *Therapeutic Goods Act 1989*. This out-of-session consideration was to follow the close of the stakeholder consultation period on 30 January 2004. Following close of the consultation period, copies of the responses received were circulated to TGC Members, who unanimously agreed to the following resolution:

> OOS RESOLUTION NO. OOS2004/01
>
> The Therapeutic Goods Committee RECOMMENDS the adoption of the British Pharmacopoeia 2003 on 1 April 2004 for the purposes of the edition of the British Pharmacopoeia defined under the *Therapeutic Goods Act 1989*.

This recommendation had been accepted by the Delegate of the Minister and the Notice adopting BP 2003 as the principle standard in Australia with effect 1 April 2004 was gazetted on 24 March 2004.

The TGC therefore resolved:

RESOLUTION

> **The Therapeutic Goods Committee NOTES its recommendation made out-of-session in February 2004 (RESOLUTION NO. OOS2004/01) that the British Pharmacopoeia 2003 be adopted in Australia on 1 April 2004 for the purposes of the edition of the British Pharmacopoeia defined under the *Therapeutic Goods Act 1989.***

Consequential amendment to Therapeutic Goods Order No. 70 S*tandards for Export Only Medicine*

The TGC noted that Therapeutic Goods Order No. 70 *Standards for Export Only Medicine* (TGO 70), as amended by Therapeutic Goods Order No. 70A, specifies British Pharmacopoeia 2002 as one of the alternative pharmacopoeial standards to which medicine manufactured in Australia, or imported into Australia, for export only may comply.

As the Committee had previously indicated that TGO 70 should be maintained to reflect the most recent editions of each of the referenced pharmacopoeias, consideration was now given to a consequential amendment to TGO 70 to update the reference to the British Pharmacopoeia to the 2003 edition. Members supported this amendment.

The TGC therefore resolved:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS that Therapeutic Goods Order No. 70 *Standards for Export Only Medicine*, as amended by Therapeutic Goods Order No. 70A, be amended to replace the reference to British Pharmacopoeia 2002 with reference to British Pharmacopoeia 2003.

Status of European Pharmacopoeia Supplements taken up into the British Pharmacopoeia

As the BP adopts monographs of the European Pharmacopoeia (EP) "as amended by any subsequent supplements and revisions", the TGC noted that legal advice had been sought on the status of Supplements to the EP taken up into the edition of the BP adopted under the *Therapeutic Goods Act 1989.*

In particular the question was whether adoption of the BP in Australia results in the automatic uptake of monographs and amendments contained in Supplements to the EP even if these are published after the particular edition of the BP which has effect in Australia.
It was noted that the published version of BP 2003 included Supplements up to and including Supplement 4.5, but Supplement 4.6 had an effective date in the BP of 1 January 2004 and Supplement 4.7 had an effective date in the BP of 1 April 2004. Further Supplements would be published and adopted into BP 2003 before the end of the year.

The TGC considered the legal advice provided and subsequently resolved:

RESOLUTION

The Therapeutic Goods Committee NOTES that the edition of the British Pharmacopoeia adopted under the *Therapeutic Goods Act 1989* (the Act) with effect 1 April 2004 is British Pharmacopoeia 2003 and, for the purposes of the Act, this edition incorporates those amendments to monographs published in Supplements to the European Pharmacopoeia up to and including Supplement 4.7.

OTHER MATTERS

Standing Report – Trans Tasman Joint Therapeutic Products Agency

The TGC noted a report from the Director of the Trans Tasman Group in the TGA on progress towards the establishment of a the trans Tasman joint therapeutic products agency, that had occurred since the Treaty between Australia and New Zealand had been signed.

Review of The Code of Good Wholesaling Practice for Therapeutic Goods for Human Use – Update For Information

The TGC noted a progress report on the review of the *Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* being undertaken by its Working Party. Work had been ongoing to revise several particular sections of the Code and to develop new provisions relating to secure storage and transport of controlled drugs and high illicit-value substances.

It was also noted that the draft revision of the Code has not yet been released for stakeholder consultation as it has been referred back to the NCCTG for further direction or clarification on a number of specific issues. It was acknowledged that more work was required in the section on recall provisions.

CLOSE OF MEETING

There being no further business, the Chair closed the Meeting at 4.00 pm and thanked Members for their attendance.

The Minutes of the 24th TGC Meeting were signed by the Chair on 13 July 2004 as a true and correct record of the Meeting.