Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Committee
26th Meeting (24 November 2004)

Information for Stakeholders – Report on Meeting

The 26th Meeting of the Therapeutic Goods Committee (TGC) was held in Meeting Room 6, First Floor, TGA Building, Narrabundah Lane, Symonston on 24 November 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 Mr David Clayton Mr Philip Daffy Mr Barry Evers-Buckland Associate Professor Loraine Holley Associate Professor William Rawlinson
Apologies:	Professor Klaus Schindhelm
TGA officers:	Dr Larry Kelly Ms Siepie Larkin Mr Peter Liehne Mr Andrew Muir
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 and TGA officers. 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

The Committee adopted the agenda as presented and agreed to amend the order of discussion according to the availability of relevant TGA advisers.

Conflict of Interest Declarations

Members submitted their completed Disclosure of Interest Declarations in accordance with Committee procedures.

No conflicts of interest were declared.

Minutes of the 25th Meeting of the TGC

Members considered the draft Minutes of the 25th Meeting of the Committee, which had been held by teleconference on 7 September 2004, and agreed they were a true and accurate record of that Meeting.

RESOLUTION

The Therapeutic Goods Committee RATIFIES the Minutes of the 25th Meeting of the Therapeutic Goods Committee, held on 7 September 2004, as a true and accurate record of that Meeting.

REPORT ON TGC SUBCOMMITTEES

Subcommittee on Blood and Tissues

The TGC noted that the role of this Subcommittee, as defined in its Terms of Reference, had been completed and therefore the Subcommittee could be disbanded. If the need arose, another Subcommittee could be established in the future to advise on any additional matters. The TGC therefore resolved:

RESOLUTION

The Therapeutic Goods Committee:

- **DISBANDS its Subcommittee on Blood and Tissues established in August 2003 to consider standards for haematopoietic stem cells harvested from placental cord blood, and haematopoietic stem cells harvested from sources other than placental cord blood, and provide a draft Therapeutic Goods Order for consideration by the Therapeutic Goods Committee; and**

- **RECORDS a vote of thanks to Members of the Subcommittee for their efforts and consideration of this matter.**

Subcommittee on Child-Resistant Packaging

At its 22nd Meeting in August 2003, the TGC had agreed to re-establish the Subcommittee on Child-Resistant Packaging and developed its Terms of Reference (TOR), which were to advise the TGC on a number of specified matters related to child-resistant packaging. The general composition of the Subcommittee was subsequently determined.

At its 24th Meeting in May 2004, the TGC noted that any outcomes from the Subcommittee would coincide with the establishment of the trans-Tasman joint therapeutic products agency and any new standards proposed would need to be considered in that context. The TGC therefore amended the Subcommittee's TOR to include additional roles, and its composition to include expertise drawn from New Zealand.

The TGC now noted that, for a number of reasons, establishment of this Subcommittee had not progressed. In considering whether the Subcommittee should now be convened, Members noted that it would be difficult for the Subcommittee to reach a useful outcome prior to commencement of the joint agency on 1 July 2005[1], and that once the joint agency commenced operation, there may be no legal basis for continuation of work by the Subcommittee. Any partially completed work may therefore be redundant. It also was noted that the outcomes from such a Subcommittee may not be acceptable to a trans-Tasman standards committee because of a perception that they were Australian-focussed.

The TGC recognised that there were significant differences between Australia and New Zealand in requirements for child-resistant packaging, and reaching a unified position may be difficult. Therefore there was considerable work to be undertaken on this issue before commencement of the joint agency.

Members concluded that it would be better at this time for progression of child-resistant packaging issues to be handled by the trans-Tasman standards committee which was expected to be established in the near future. The TGC therefore resolved:

RESOLUTION

The Therapeutic Goods Committee:

[1] Expected date at time of this TGC meeting

- **RECOMMENDS that the matters identified in Resolution No. 24/03 relating to standards for child-resistant packaging be referred to the proposed Joint Interim Expert Advisory Committee on Standards, as standards for such packaging must be resolved in the context of the trans-Tasman therapeutic products agency; and**

- **DECIDES not to proceed with the establishment of a Subcommittee on Child-Resistant Packaging as previously recommended in Resolution No. 24/03 of May 2004.**

MEDICINAL PRODUCTS

ADOPTION OF A NEW EDITION OF THE BRITISH PHARMACOPOEIA

The TGC noted that a new edition of the British Pharmacopoeia (British Pharmacopoeia 2004 - BP 2004) had been published and was to take effect in the United Kingdom on 1 December 2004. The BP was the principal standard applying under the *Therapeutic Goods Act 1989,* and adoption of a new edition required gazettal of a change to the definition for British Pharmacopoeia contained in the Act, following a recommendation to this effect from the Committee. Since 1 April 2004, the British Pharmacopoeia 2003 (BP 2003) had had effect in Australia.

In relation to adoption of BP 2004, the TGA had initiated consultation with peak industry organisations, with the aim of identifying any particular difficulties that would be associated with this action. It was noted that stakeholders had been advised that this consideration was independent of that to occur in relation to default pharmacopoeial standards for application by the joint trans-Tasman therapeutic products agency, and it was necessary in order to maintain the currency of the definition of British Pharmacopoeia in the existing Australian legislation until such time as this legislation was repealed.

As the consultation period did not close for some time, Members agreed to consider the consultation responses out-of-session. The TGC therefore resolved that:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS consideration of the consultation responses on adoption of the British Pharmacopoeia 2004 occur out-of-session, following close of the consultation period on 13 December 2004, with a view to adoption of the British Pharmacopoeia 2004 as the edition of that document defined under the *Therapeutic Goods Act 1989*.

UPDATE TO ANNEX I OF THE AUSTRALIAN CODE OF GOOD MANUFACTURING PRACTICE (GMP) FOR MEDICINAL PRODUCTS

The TGC considered an amendment to Annex I of the *Australian Code of Good Manufacturing Practice for Medicinal Products, 16 August 2002* and the adoption of this amended edition of the Australian Code as a Manufacturing Principle.

It was noted that the *Australian Code of GMP for Medicinal Products, 16 August 2002*, gazetted as a Manufacturing Principle in August 2002, was based entirely on the Pharmaceutical Inspection Cooperation Scheme (PIC/S) document *Guide to Good Manufacturing Practices for Medicinal*

Products. Revision to Annex I was undertaken to maintain consistency with the PIC/S document and addressed the minor differences between the relevant International Standards Organisation standard (EN/ISO 14644-1) and GMP requirements for particles in a Grade A clean area.

The TGC was advised that appropriate industry consultation had been undertaken by the TGA. The Office of Regulation Review had considered the changes to be minor and did not require a Regulation Impact Statement.

In relation to the previous adoption of the PIC/S Code as an Australian Code of GMP, the meeting discussed the inclusion of an interpretation section in which the words 'should' and 'shall' were given the meaning of 'must'. The original intention had been that the Code would be principles-based to allow flexibility for industry, but some Members considered that the addition of this interpretation had caused the Code to become mandatory requirements rather than principles.

While it was acknowledged that this interpretation had been necessary to give the Code legal force, the TGC cautioned that it was important that amendments made to standards for legal purposes did not unwittingly change the intent of such standards, or the adoption of guidelines did not automatically make compliance mandatory. The TGC resolved as follows:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS the adoption of the November 2004 edition of the *Australian Code of Good Manufacturing Practice for Medicinal Products* as a Manufacturing Principle.

MEDICINE LABELLING – REPORT FROM JOINT EXPERT COMMITTEE ON TRANS TASMAN LABELLING REQUIREMENTS FOR MEDICINES

Members were provided with a verbal report on progress by the Joint Expert Committee on Trans Tasman Labelling Requirements for Medicines in reviewing medicine labelling requirements in Australia and New Zealand and developing a joint labelling order for application by the trans-Tasman therapeutic products agency. Three TGC Members (including the Chairman) were members of the Joint Expert Committee.

It was noted that work in reviewing current requirements and developing a joint labelling order was ongoing, and it was expected that a draft order would be ready for stakeholder consultation in early 2005. Members noted that when the draft order was released for consultation, there would be an opportunity for the TGC to provide comment.

MEDICAL DEVICES

THERAPEUTIC GOODS ORDER NO. 34 *STANDARD FOR DIAGNOSTIC GOODS OF HUMAN ORIGIN*

The TGC received advice from the TGA that a proposal to revise Therapeutic Goods Order No. 34 *Standard for Diagnostic Goods of Human Origin* (TGO 34) would not proceed at this time.

The Committee noted that TGO 34 specified requirements for the quality and method of preparation for goods which contain materials of human origin which are intended as reagents for *in vitro* diagnostic kits (IVDs). It had been proposed to update technical requirements, practices and test methods and in addition, revise the scope of TGO 34 to include *ex vivo* diagnostics.

In view of the new regulatory frameworks for IVDs, and human tissues and cellular therapies (including *ex vivo* reagents), being developed by the TGA, it had been decided not to proceed with the proposed revision of TGO 34. This therefore would remain the applicable standard for *in vitro* diagnostic products of human origin until the end of the transition period for the introduction of the new IVD regulatory framework.

In consideration of this advice, the TGC resolved as follows:

RESOLUTION

The Therapeutic Goods Committee NOTES that, following consultation by the Therapeutic Goods Administration on a proposal to revise Therapeutic Goods Order No. 34 (TGO 34) *Standard for Diagnostic Goods of Human Origin*, TGO 34 is to remain the applicable standard for diagnostic goods of human origin until the end of the transition period for the introduction of the new regulatory framework for *in vitro* diagnostic medical devices (IVDs).

OTHER MATTERS

PROGRESS REPORT ON A REVIEW OF THE CODE OF GOOD WHOLESALING PRACTICE FOR THERAPEUTIC GOODS FOR HUMAN USE

The TGC noted a progress report on the review of the current *Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* (cGWP) that was being undertaken at the request of the National Coordinating Committee on Therapeutic Goods (NCCTG).

Following a meeting of the working party established to undertake this task, and out-of-session discussions, a draft revised Code was provided to the NCCTG at its April 2004 meeting for comment and advice prior to its finalisation for wider consultation. The NCCTG was provided with a further update at its special meeting held on 9 September 2004 in relation to implementation of the Galbally review recommendations. A specific issue on which advice was sought from the NCCTG was that of substances with high illicit-value for which additional security measures were being introduced. Stakeholder consultation on the draft cGWP could not occur until a list of such substances was available.

The NCCTG had provided several suggestions in relation to this list and recommended that comment should be sought from the major wholesalers in relation to the format and amount of detail to be included. There was concern that too large a list, or lack of specific detail, would make compliance by wholesalers difficult.

The TGC now noted that this comment had been received, and the wholesalers held the view that the most practical approach would be to include only the products of particular risk of diversion from warehouses. Trade names and pack size details were considered to be essential for compliance. The Committee agreed however that, because of the constant maintenance that would be required, it would not be appropriate for the cGWP to include the type of detailed list requested

by the wholesalers. It would be possible however for the TGA to provide assistance to wholesalers in this regard through providing printouts from the Australian Register of Therapeutic Goods.

Members commented on several other issues in relation to the draft document that may be considered controversial by stakeholders but agreed that it was important that the draft document be released for consultation. It would be important however for it to reach the relevant stakeholder groups. The Committee therefore resolved:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS that, subject to minor amendment, the draft document *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* (November 2004 revision) be released for appropriate stakeholder consultation.

THERAPEUTIC GOODS ORDERS – REVIEW FOR CURRENCY AND/OR NEED FOR REVISION

The TGC considered a summary document listing all current Therapeutic Goods Orders (TGOs) and their status, together with copies of these Orders. The Committee was requested to advise on the need for retention of these Orders by a trans-Tasman therapeutic products agency, and the need for, and priority of, any revision.

It was noted that a primary task of the Joint Interim Expert Advisory Committee on Standards, when established, would be to advise the Therapeutic Products Interim Ministerial Council on matters relating to standards for therapeutic goods, and in particular the need for Managing Director's Orders to specify standards for particular product types to apply under the new joint regulatory arrangements. At its last Meeting, the TGC had considered that it could help facilitate this action by providing preliminary advice on the currency of existing TGOs, and prioritising those in need of revision.

A systematic review of the TGOs indicated that these could be grouped into the following categories:

- Orders previously recommended by the Committee for revocation and awaiting administrative action;
- Orders revoking earlier TGOs, and which could lapse with the current Australian legislation;
- Orders already under review in the trans-Tasman context;
- Orders relating to medical devices which need only be retained under current Australian legislation for the duration of the transition period for the new medical device regulatory system;
- Orders relating to 'Other Therapeutic Goods' that will need to be retained as Australia-only standards, but may need consideration for adoption by the trans-Tasman agency; and
- Orders that will need consideration for adoption by the joint agency.

The TGC subsequently resolved:

RESOLUTION

1. The Therapeutic Goods Committee RECOMMENDS that:

- **TGO 9 *Standard for B. abortus. Rose-Bengal Antigen*;**
- **TGO 10 *Standard for B. abortus. Milk Ring Test Antigen*;**
- **TGO 12 *Standard for Sterility of Intramammary Injections*;**
- **TGO 21 *General Standard for Live Avian Viral Vaccines*;**
- **TGO 25 *Standard for Hydrocortisone Acetate Eye Ointment and Ear Ointment*; and**
- **TGO 30 *Standards Adopted from the British Pharmacopoeia (Veterinary) 1985, the British Pharmacopoeia (Veterinary) 1977 and the British Veterinary Codex 1965, supplement 1970*,**

should continue in the revocation process, as previously recommended.

2. The Therapeutic Goods Committee CONSIDERS that:

- **TGO 29 *Standard for Ethanol*;**
- **TGO 44 *Revocation*;**
- **TGO 46 *Revocation*; and**
- **TGO 60 *Revocation of Therapeutic Goods Order No. 14 – "General Standards for Metered Dose Aerosols for inhalation"*,**

are only relevant under the current therapeutic goods legislation and should not require consideration by the proposed Joint Interim Expert Advisory Committee on Standards.

3. The Therapeutic Goods Committee NOTES that:

- **TGO 69 *General requirements for labels for medicines*; and**
- **TGO 69A *Amendment to Therapeutic Goods Order No. 69 – General requirements for labels for medicines*,**

are already under consideration in the trans-Tasman context by the Joint Expert Committee on Trans Tasman Labelling Requirements for Medicines.

4. The Therapeutic Goods Committee NOTES that the following Therapeutic Goods Orders for medical devices are not relevant to the Therapeutic Goods Administration's new regulatory system for medical devices. These Orders need to be retained only until 4 October 2007, which marks the end of the transition period for the new regulatory system for medical devices:

- **TGO 28 *Standard for Contraceptive Devices – Diaphragms*;**
- **TGO 34 *Standard for Diagnostic Goods of Human Origin*;**
- **TGO 37 *General Requirements for Labels for Therapeutic Devices*;**
- **TGO 41 *Single-use Syringes for the Injection of 100 Units per millilitre Insulin (U-100)*;**
- **TGO 49 *General Standard for Sutures*;**
- **TGO 52 *Gloves for General Medical and Dental Use*;**
- **TGO 53 *Single-use Sterile Surgical Rubber Gloves*;**
- **TGO 59 *Polymer Urethral Catheters for General Medical Use*;**
- **TGO 61A *Replacement of TGO 61: Contraceptive Devices - Rubber Condoms*;**
- **TGO 67 *Standard for Dental Material*;**

- **TGO 67A *Amendment to Therapeutic Goods Order No. 67A - Standard for Dental Materials*; and**
- **TGO 68 *Standard for Plasticized Polyvinyl Chloride (PVC) Blood Bags.***

5. The Therapeutic Goods Committee RECOMMENDS that the following Therapeutic Goods Orders should be reviewed in the trans-Tasman context by the proposed Joint Interim Expert Advisory Committee on Standards:

- **TGO 8 *Standards Adopted from the British Pharmaceutical Codex 1973*;**
- **TGO 20 *Child Resistant Containers* (superseded by TGO 65, current only for transition period);**
- **TGO 33 *Amendment of Schedules to Therapeutic goods Order No. 20 Child Resistant Containers* (superseded by TGO 65, current only for transition period);**
- **TGO 45 *Amendments of the Schedule to Therapeutic Goods Order No.8 - Standards adopted from the British Pharmaceutical Codex 1973*;**
- **TGO 47 *Barium Lime*;**
- **TGO 50 *General Standard for Pyrogen and Endotoxin Content of Therapeutic Goods*;**
- **TGO 54 *Standard for Disinfectants and Sterilants*;**
- **TGO 54A *Amendment to the Standard for Disinfectants and Sterilants*;**
- **TGO 54B *Amendment to the Standard for Disinfectants and Sterilants*;**
- **TGO 56 *General standard for tablets, pills and capsules*;**
- **TGO 63 *Standard for Sterile Therapeutic Goods*;**
- **TGO 64 *Standard for Tampons – Menstrual*;**
- **TGO 64A *Amendment to TGO 64: Standard for Tampons – Menstrual*;**
- **TGO 65 *Child-resistant packaging*;**
- **TGO 70 *Standards for Export Only Medicines*;**
- **TGO 70A *Amendment to TGO 70 Standards for Export Only Medicines*;**
- **TGO 71 *Tamper-Evident Packaging of Therapeutic Goods* (not yet gazetted); and**
- **TGO 72 *Standards for Blood Components.***

Of these Therapeutic Goods Orders, the Therapeutic Goods Committee NOTES that:

- **TGO 56, TGO 65 and TGO 71 should be given high priority for review;**
- **TGO 50 and TGO 63 may no longer be relevant and hence may not be needed;**
- **TGO 54/54A/54B and TGO 64, whilst needing review, are outside the scope of the trans-Tasman regulatory framework and are likely to be Australia-only requirements.**

6. The Therapeutic Goods Committee REQUESTS that the Joint Interim Expert Advisory Committee on Standards provide advice to the Therapeutic Goods Committee on the outcome of its consideration of these Therapeutic Goods Orders.

DEFAULT STANDARD FOR THERAPEUTIC GOODS

The TGC had recognised previously that one of the roles of the Joint Interim Expert Advisory Committee on Standards, when established, would be to provide advice on appropriate default standard arrangements to apply under the new joint regulatory system. To assist the Joint Interim Committee in this, the TGC had considered that it would be useful to identify issues that should be taken into consideration in formulating this advice.

The TGC noted differences currently existing between Australian and New Zealand default standard arrangements, specifically that the *Therapeutic Goods Act 1989* (the Act) in Australia adopts the British Pharmacopoeia (BP) as the principle standard, whereas New Zealand legislation provides a list of 'specified publications' rather than defining a single authoritative standard. The history to the adoption of the BP in Australia as the primary source of pharmaceutical standards was noted.

The TGC agreed that the issue of default standards was contentious, and there were many factors to consider. The fundamental questions to be resolved under joint agency arrangements were whether there should be a single default standard, or a series of standards from which sponsors could chose; and if only a single default standard were to apply, then which of those available would be most appropriate. Members made a number of comments and identified many issues that would require consideration in resolving these questions.

In conclusion, the TGC requested that these comments be referred to the Joint Interim Expert Advisory Committee on Standards for consideration.

CLOSE OF MEETING

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