Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Committee

27TH MEETING (9 JUNE 2005)

INFORMATION FOR STAKEHOLDERS – REPORT ON MEETING

The 27th Meeting of the Therapeutic Goods Committee (TGC) was held in Meeting Room 6, TGA Building, Narrabundah Lane, Symonston ACT on 9 June 2005, commencing at 10:30am and closing at 3:00pm.

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
Apologies:	Associate Professor William Rawlinson Professor Klaus Schindhelm
TGA officers:	Dr Larry Kelly Ms Silvana Niutta Dr Richard Pembrey Dr Glenn Smith
Secretariat:	Ms Lyn Lewis (Secretary) Miss Margaret Joy

Agenda and committee administration

Opening of Meeting – Welcome and Apologies

The Chair opened to Meeting at 10:30am 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 26th Meeting of the TGC

Members considered the draft Minutes of the 26th Meeting of the Committee, which had been held on 24 November 2004, and agreed it was a true and accurate record of that Meeting. The TGC resolved that:

RESOLUTION

The Therapeutic Goods Committee RATIFIES the Minutes of the 26th Meeting of the Therapeutic Goods Committee, held on 24 November 2004, as a true and accurate record of that Meeting.

Actions arising from the 26th meeting of the TGC

The TGC were advised that progress with finalising the consultation draft of the revised Code of Good Wholesaling Practice for Therapeutic Goods for Human Use had been delayed due to changes requested by States and Territories. It was suggested that manufacturers, in order to overcome difficulties with the Code potentially applying to raw materials with common uses, should be permitted similar exemptions from the Code as apply to GMP licence requirements for manufacture. It was expected that the document should be ready for consultation in the near future.

Medicinal products

Adoption of British Pharmacopoeia 2004

At the time of the November 2004 meeting of the TGC, public consultation was underway on the adoption of the 2004 edition of the British Pharmacopoeia (BP 2004) as the edition of the BP defined under the *Therapeutic Goods Act 1989.* The TGC considered the responses out-of-session in early 2005. Stakeholder consultation had raised no objections and the TGC had recommended the adoption of the BP 2004 to take effect on 1 July 2005. The instrument was signed on 19 May 2005 and registered in the Federal Register of Legislative Instruments. The TGC therefore resolved that:

RESOLUTION

The Therapeutic Goods Committee NOTES:

- **its recommendation made out-of-session in April 2005 (RESOLUTION NO. OOS2005/01) that the British Pharmacopoeia 2004 be adopted in Australia on 1 July 2005 for the purposes of the edition of the British Pharmacopoeia defined under the *Therapeutic Goods Act 1989*; and**
- **that an order giving effect to this was signed by the Delegate of the Minister for Health and Ageing on 19 May 2005 and duly registered on the Federal Register of Legislative Instruments.**

Consequential consideration of TGO 70, Standards for Export Only medicines

Therapeutic Goods Order No. 70 *Standards for Export Only Medicine* (TGO 70) specified alternate pharmacopoeial standards to which medicines manufactured in Australia for export only, or imported into Australia for export only, may comply. The pharmacopoeias referenced were the British Pharmacopoeia (BP), the European Pharmacopoeia, the United States Pharmacopeia (USP) and the Japanese Pharmacopoeia.

The TGC was aware that current Australian legislation did not allow for the automatic updating of editions of pharmacopoeias or publications referenced in a TGO. The Committee had previously advised that TGO 70 should be maintained to reflect the most recent editions of each of the referenced pharmacopoeias. TGO 70 had previously been amended to accommodate publication of the then latest editions of the BP and USP, which had resulted in the issue of TGO 70A.

Since the gazettal of TGO 70A, new editions of, or supplements to, all four pharmacopoeias mentioned in TGO 70 and TGO 70A had been published. The peak industry associations for medicines had been advised of the proposal to update the editions of the pharmacopoeias referenced in TGO 70.

Members mentioned imminent changes in the regulation of therapeutic products in Japan; these changes could affect the Japanese Pharmacopoeia in future.

The TGC subsequently resolved that:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS that:

1. **Therapeutic Goods Order No. 70A *Amendment to Therapeutic Goods Order No. 70 – Standards for Export Only Medicine* be revoked; and**

2. **Therapeutic Goods Order No. 70 *Standards for Export Only Medicines* be amended to update the references to all four Pharmacopoeias in it as follows:**

   a. European Pharmacopoeia 4th Edition be amended to European Pharmacopoeia 5th Edition;

   b. United States Pharmacopoeia 26th Edition be amended to United States Pharmacopoeia 28th Edition;

   c. British Pharmacopoeia 2002 be amended to British Pharmacopoeia 2004; and

   d. Japanese Pharmacopoeia 14th Edition be amended to Japanese Pharmacopoeia 14th Edition including Supplement 1.

Labelling requirements for medicines under the proposed joint Australia New Zealand Therapeutic Products Agency – Stakeholder consultation

The TGC noted that the document *Draft Labelling Requirements for Medicines under a Joint Australia New Zealand Therapeutic Products Agency*, in the form of a draft Managing Director's Order, had been issued by the Joint Expert Committee on Trans Tasman Labelling Requirements for Medicines and was open for public consultation. The draft Order was accompanied by a *Draft Best Practice Guideline on Prescription Medicine Labelling*. The TGC was provided with a comparison of the major areas where the draft Order differed from TGO 69, Australia's current Order on labelling of medicines. The starting point for the draft Order for the new Agency was TGO 69, with changes to address deficiencies that have emerged with practical experience in Australia and to include issues relevant to New Zealand.

A Member reported on the Industry Symposium on Packaging, Labelling and Marketing of Medicines held in Melbourne on 27 May 2005. Attendees at that meeting had been encouraged to respond to the draft Order. Look-alike/sound-alike names, and corporate branding, had been raised as issues for both innovator and generic products. There had also been discussion on dispensary practices that could add to, or minimise, confusion between similarly labelled products; the need for adequate space for the dispensing pharmacist's label; and the importance of legibility and colour contrast in label design.

Child-resistant packaging requirements for products containing iron oxides

The TGC considered correspondence from an industry association seeking revision of the iron compounds entry in the First Schedule of TGO 65 *Child-resistant packaging for therapeutic goods* to align it with the provisions of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) for iron compounds. The industry association believed that the difference in wording could lead sponsors to unintentionally breach their legislative obligations.

Specifically, the SUSDP excluded up to 10 mg of iron oxides, when present as excipients, from the calculation of iron for the purpose of determination of the poisons schedule. For TGO 65 the calculation included all iron from iron oxides for the determination of the need for child-resistant packaging. These differences had been in place for several years.

Advice from the TGA's Office of Complementary Medicines was that medicines containing iron oxides that complied with the SUSDP Schedule 2 exemption were highly unlikely to cause gastrointestinal irritation in children and were not likely to lead to harmful absorption of iron. The TGC also noted advice from the Office that "no adverse effects attributable to the ingestion of iron oxides have been reported in humans".

Amendment of this single aspect of TGO 65 would require consultation with other stakeholders and time for legislative processes. Conversely it was suggested that a single change to the TGO would be more efficient than repeated requests for exemptions from sponsors.

The preferred resolution was for the TGC to publish a clarification statement on the exclusion of iron oxides from the calculation of iron compounds for the purpose of determining the requirement for child-resistant packaging. The same calculation method could be applied, although with different cut-off points, for SUSDP purposes and for TGO 65 purposes. It was noted, however, that TGO 65 was not intended to merely reflect the SUSDP by requiring child-resistant packaging for scheduled medicines but not for non-scheduled medicines. .

The TGC also sought to draw the clarification to the attention of the Expert Committee that is to consider child-resistant packaging requirements under Trans-Tasman arrangements. The TGC agreed to clarify the method of calculation of iron content and resolved that:

RESOLUTION

The Therapeutic Goods Committee:

1. **CLARIFIES the entry for iron oxides included in the First Schedule of Therapeutic Goods Order No. 65 *Child-Resistant Packaging for Therapeutic Goods* (TGO 65), in that the calculation of elemental iron content should exclude iron oxides, when these are present as an excipient in:**

    - **divided preparations containing 10 mg or less of total iron oxides per dosage unit; or**
    - **undivided preparations containing 1 per cent or less of total iron oxides,**

    for the purposes of determining whether a requirement for child-resistant packaging exists under TGO 65; and

2. **RECOMMENDS that this clarification be drawn to the attention of the Joint Interim Expert Advisory Committee on Standards for consideration in the context of requirements for child-resistant packaging under joint regulatory arrangements.**

Medicine labelling – Correspondence prompted by Austpharmlist posting

The TGC considered a small number of near-identical letters received in relation to medicine labelling and specifically the need for adequate free space on labels of prescription medicines to allow attachment of the pharmacist's label. The correspondence appeared to be in response to a suggestion on the AusPharmList website encouraging pharmacists to lobby the TGC, erroneously believed to be the Committee responsible for current medicine labelling consultation. The TGC noted that the current stakeholder consultation on the document *Draft Best Practice Guideline on Prescription Medicine Labelling* addressed this particular concern. No action by the TGC was considered necessary.

Blood and tissues

Standards for blood components

The current standards for blood components were prescribed in Therapeutic Goods Order No. 72 *Standards for Blood Components* (TGO 72), which referred to the 9th edition of the Council of Europe *Guide to the Preparation, Use and Quality Assurance of Blood Components* (the Guide).

The TGC was advised that the 11th edition of the Guide was ratified by the relevant committee in Europe, and the TGC was requested to consider a revision to TGO 72 to update the edition of the Guide and to formalise current donor deferral practice in regard to variant Creutzfeld-Jakob Disease (vCJD).

The TGA had liaised extensively with the Australian Red Cross Blood Service (ARCBS) on the requirements of the 11th edition. The 11th edition of the Guide required that blood donors be deferred for "6 months following return from tropical areas and then only if they have not suffered an unexplained fever or illness". Its strict adoption would halt blood donations from residents and visitors to northern Australia. Both the TGA and ARCBS supported non-adoption of this clause. The ARCBS had provided the TGA with a risk analysis on mosquito-vectored viruses in Australia - dengue fever was identified as the major threat. From this analysis, a strategy had been proposed for the selective deferral of donors or the discard of fresh blood components in areas and in periods in which an epidemic of an infectious disease could be transmitted by blood transfusion. The strategy had been reviewed and agreed by the TGA. The TGC gave in-principle support for the further development of the strategy.

The TGC agreed to adopt the 11th edition of the Guide, excepting the clause on donors from tropical areas. This approach would be transparent for all interested parties, including the Council of Europe. The excepted clause could be dealt with as a condition of approval of the technical master file to include compliance with the strategy for monitoring donors from tropical areas.

The TGC therefore resolved that:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS:

1. **the adoption of the 11th 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;**

2. **that reference to tropical areas under the heading "Tropical Diseases" on page 39 of the 11th edition of the Council of Europe *Guide for the preparation, use and quality assurance of blood components* should not be taken to include areas within Australia; and**

3. **that, in relation to blood components, the Therapeutic Goods Administration negotiate a strategy with the Australian Red Cross Blood Service for managing donors and donations from tropical Australia during any outbreaks of tropical diseases.**

In relation to vCJD the Committee recalled that, in September 2000, Australian Health Ministers agreed to place a temporary ban on blood donations from persons who had lived in the UK for six months or more between 1980 and 1996. The vCJD deferral criteria had been extended in July 2003 to include persons who had received a blood transfusion in the UK from 1980 onwards. These deferral criteria had been implemented by the ARCBS but were without legal standing for the enforcement of compliance. The TGC was advised that incorporation of these deferral requirements into a TGO would ensure that blood sourced within and outside of Australia meets the requirements to minimise vCJD transmission risk.

The TGC therefore also resolved that:

RESOLUTION

The Therapeutic Goods Committee RECOMMENDS that blood and blood components must not be manufactured from blood donors who:

- **have lived in the United Kingdom for a cumulative period of six months or more between 1 January 1980 and 31 December 1996; or**
- **have had a transfusion of blood or blood products in the United Kingdom from 1980 onwards.**

Other matters

Matters referred from the Joint Interim Expert Advisory Committee on Standards

The TGC was advised of the creation and membership of the Joint Interim Expert Advisory Committee on Standards (JIEACS), including the appointment of the Chairperson of TGC (Professor O'Donnell) as the Chairperson of JIEACS.

The first meeting of the JIEACS had been held on 7 June 2005. The JIEACS had been briefed on the establishment processes for the new agency and on the current situation relating to standards for therapeutic products in Australia and New Zealand. This had included the TGC's resolution from November 2004 that had referred a number of TGOs to the JIEACS for its consideration.

The JIEACS had discussed a range of issues relating to standards. The JIEACS had agreed on the priorities for further actions and a workplan had been developed that involved specialist subcommittees to address key issues such as the default standard to be applied to medicines under the new agency.

For information

Trans-Tasman Therapeutic Products Agency – Deferral of start-up date

The TGC noted the advice that the commencement date of the Trans-Tasman Therapeutic Products Agency had been deferred from 1 July 2005 to 1 July 2006.

Federal Register of Legislative Instruments

The Meeting was provided with a brief overview of the Federal Register of Legislative Instruments (FRLI). This was a whole-of-government initiative to create a comprehensive and authoritative repository of Australian Government legislative instruments in electronic form. Therapeutic Goods Orders were included within the scope of FRLI. The Committee noted that: departments and agencies were now required to appropriately consult prior to making a legislative instrument; most legislative instruments would sunset after ten years, on either 1 April or 1 October; for non-controversial matters, revocation and replacement of old Orders was a cleaner approach than amendment and compilation of several Orders; and inclusion in FRLI now replaced the requirement for publication in the Gazette.

Close of Meeting

There being no further business, the Chair closed the Meeting at 3:00pm and thanked Members for their attendance.